AMERICAN ACADEMY OF PEDIATRICS

Policy of the American Academy of Pediatrics

Pediatric Clinical Practice Guidelines & Policies

A Compendium of Evidence-based Research for Pediatric Practice

21st Edition

eBook access included!

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Pediatric Clinical Practice Guidelines & Policies

A Compendium of Evidence-based Research for Pediatric Practice

21st Edition

American Academy of Pediatrics
345 Park Blvd
Itasca, IL 60143
www.aap.org

AMERICAN ACADEMY OF PEDIATRICS
PUBLISHING STAFF

Mary Lou White
Chief Product and Services Officer/SVP, Membership, Marketing, and Publishing

Mark Grimes
Vice President, Publishing

Jennifer McDonald
Senior Editor, Digital Publishing

Sean Rogers
Digital Content Specialist

Leesa Levin-Doroba
Production Manager, Practice Management

Peg Mulcahy
Manager, Art Direction and Production

Linda Smessaert, MSIMC
Director, Marketing

Mary Louise Carr
Marketing Manager, Clinical Publications

The American Academy of Pediatrics is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children, adolescents, and young adults.

The recommendations in this publication do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

Products are mentioned for informational purposes only. Inclusion in this publication does not imply endorsement by the American Academy of Pediatrics.

Every effort has been made to ensure that the drug selection and dosage set forth in this publication are in accordance with the current recommendations and practice at the time of publication. It is the responsibility of the health care professional to check the package insert of each drug for any change in indications and dosage and for added warnings and precautions.

This publication has been developed by the American Academy of Pediatrics. The authors, editors, and contributors are expert authorities in the field of pediatrics. No commercial involvement of any kind has been solicited or accepted in the development of the content of this publication.

First edition published 2001; 21st, 2021.

Printed in the United States of America

9-5/0920
MA1016
ISBN: 978-1-61002-502-7
eBook: 978-1-61002-503-4
ISSN: 1942-2024

INTRODUCTION TO *PEDIATRIC CLINICAL PRACTICE GUIDELINES & POLICIES: A COMPENDIUM OF EVIDENCE-BASED RESEARCH FOR PEDIATRIC PRACTICE*

Clinical practice guidelines have long provided physicians with evidence-based decision-making tools for managing common pediatric conditions. Policy statements issued and endorsed by the American Academy of Pediatrics (AAP) are developed to provide physicians with a quick reference guide to the AAP position on child health care issues. We have combined these 2 authoritative resources into 1 comprehensive manual/eBook resource to provide easy access to important clinical and policy information.

This manual contains

- Clinical practice guidelines from the AAP, plus related recommendation summaries, *ICD-10-CM* coding information, and AAP patient education handouts
- Clinical practice guidelines endorsed by the AAP, including abstracts where applicable
- Full text of all 2020 AAP policy statements, clinical reports, and technical reports
- Policy statements, clinical reports, and technical reports issued or endorsed through December 2020, including abstracts where applicable

The eBook, which is available via the code on the inside cover of this manual, builds on content of the manual and points to the full text of all AAP

- Clinical practice guidelines
- Policy statements
- Clinical reports
- Technical reports
- Endorsed clinical practice guidelines and policies

For easy reference within this publication, dates when AAP clinical practice guidelines, policy statements, clinical reports, and technical reports first appeared in the AAP journal *Pediatrics* are provided. In 2009, the online version of *Pediatrics* at http://pediatrics.aappublications.org became the official journal of record; therefore, date of online publication is given for policies from 2010 to present.

Additional information about AAP policy can be found in a variety of professional publications such as

Red Book®, 32nd Edition, and *Red Book® Online* (http://redbook.solutions.aap.org)

Pediatric Nutrition, 8th Edition

Medications in Pediatrics: A Compendium of AAP Clinical Practice Guidelines and Policies

Injury and Violence Prevention: A Compendium of AAP Clinical Practice Guidelines and Policies

Adolescent Health: A Compendium of AAP Clinical Practice Guidelines and Policies

Pediatric Mental Health: A Compendium of AAP Clinical Practice Guidelines and Policies

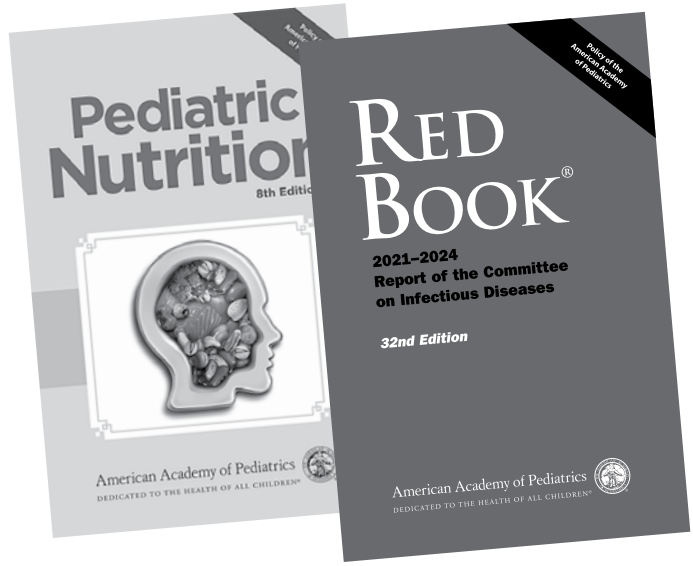
Neonatal Care: A Compendium of AAP Clinical Practice Guidelines and Policies

Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients, 4th Edition

Guidelines for Perinatal Care, 8th Edition

Pediatric Environmental Health, 4th Edition

To order these and other pediatric resources, please call 866/843-2271 or visit http://shop.aap.org/books.



All policy statements, clinical reports, and technical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time. Please check the American Academy of Pediatrics website at www.aap.org for up-to-date reaffirmations, revisions, and retirements.

AMERICAN ACADEMY OF PEDIATRICS

The American Academy of Pediatrics (AAP) and its member pediatricians dedicate their efforts and resources to the health, safety, and well-being of infants, children, adolescents, and young adults. The AAP has approximately 67,000 members in the United States, Canada, and Latin America. Members include pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

Core Values. ***We believe***

- In the inherent worth of all children; they are our most enduring and vulnerable legacy.
- Children deserve optimal health and the highest quality health care.
- Pediatricians, pediatric medical subspecialists, and pediatric surgical specialists are the best qualified to provide child health care.
- Multidisciplinary teams including patients and families are integral to delivering the highest quality health care.

The AAP is the organization to advance child health and well-being and the profession of pediatrics.

Vision. Children have optimal health and well-being and are valued by society. American Academy of Pediatrics members practice the highest quality health care and experience professional satisfaction and personal well-being.

Mission. The mission of the AAP is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. To accomplish this mission, the AAP shall support the professional needs of its members.

Table of Contents

SECTION 4

CURRENT POLICIES FROM THE AMERICAN ACADEMY OF PEDIATRICS

SECTION 5

ENDORSED POLICIES

SECTION 1

Clinical Practice Guidelines

From the American Academy of Pediatrics

- *Clinical Practice Guidelines*
  EVIDENCE-BASED DECISION-MAKING TOOLS FOR MANAGING COMMON PEDIATRIC CONDITIONS

- *Quick Reference Tools*
  TOOLS FOR IMPLEMENTING AMERICAN ACADEMY OF PEDIATRICS GUIDELINES IN YOUR PRACTICE AND AT THE POINT OF CARE

FOREWORD

To promote the practice of evidence-based medicine and to improve the health outcomes of children, the American Academy of Pediatrics (AAP) provides physicians with evidence-based guidelines for managing common pediatric conditions. The AAP has established an organizational process and methodology for the development, implementation, and improvement of these clinical practice guidelines.

The evidence-based approach to developing clinical practice guidelines begins by systematically reviewing and synthesizing the literature to provide the scientific basis for guideline recommendations. Clinical practice guideline teams with stakeholder representation systematically develop recommendations by carefully considering the evidence, risk, benefits, patient and caregiver preferences, and effect on equity, diversity, and inclusion. Each clinical practice guideline undergoes a thorough peer-review process before publication. The AAP supports efforts to implement the recommendations into practice and to evaluate whether they are leading to improved outcomes. Every 5 years, each clinical practice guideline and the scientific literature are reevaluated by the subcommittee to ensure that the recommendations are based on the most up-to-date science.

American Academy of Pediatrics clinical practice guidelines are designed to provide physicians with an analytic framework for evaluating and treating common pediatric conditions and are not intended as an exclusive course of treatment or standard of care. The AAP recognizes circumstances in which there is a lack of definitive data and relies on expert consensus in cases in which data do not exist. American Academy of Pediatrics clinical practice guidelines allow for flexibility and adaptability at the local and patient levels to address unique circumstances and should not replace sound clinical judgment.

If you have any questions about current or future clinical practice guidelines, please contact Kymika Okechukwu, senior manager of evidence-based medicine initiatives at the AAP, at 630/626-6317 or via email at kokechukwu@aap.org.

To order copies of patient education resources that accompany each guideline, please call the AAP at 866/843-2271 or visit http://shop.aap.org/books.

Joel Tieder, MD, MPH, FAAP
Chairperson, Council on Quality Improvement and Patient Safety

Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/ Hyperactivity Disorder in Children and Adolescents

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents

Mark L. Wolraich, MD, FAAP,[a] Joseph F. Hagan, Jr, MD, FAAP,[b,c] Carla Allan, PhD,[d,e] Eugenia Chan, MD, MPH, FAAP,[f,g] Dale Davison, MSpEd, PCC,[h,i] Marian Earls, MD, MTS, FAAP,[j,k] Steven W. Evans, PhD,[l,m] Susan K. Flinn, MA,[n] Tanya Froehlich, MD, MS, FAAP,[o,p] Jennifer Frost, MD, FAAFP,[q,r] Joseph R. Holbrook, PhD, MPH,[s] Christoph Ulrich Lehmann, MD, FAAP,[t] Herschel Robert Lessin, MD, FAAP,[u] Kymika Okechukwu, MPA,[v] Karen L. Pierce, MD, DFAACAP,[w,x] Jonathan D. Winner, MD, FAAP,[y] William Zurhellen, MD, FAAP,[z] SUBCOMMITTEE ON CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVE DISORDER

Attention-deficit/hyperactivity disorder (ADHD) is 1 of the most common neurobehavioral disorders of childhood and can profoundly affect children's academic achievement, well-being, and social interactions. The American Academy of Pediatrics first published clinical recommendations for evaluation and diagnosis of pediatric ADHD in 2000; recommendations for treatment followed in 2001. The guidelines were revised in 2011 and published with an accompanying process of care algorithm (PoCA) providing discrete and manageable steps by which clinicians could fulfill the clinical guideline's recommendations. Since the release of the 2011 guideline, the *Diagnostic and Statistical Manual of Mental Disorders* has been revised to the fifth edition, and new ADHD-related research has been published. These publications do not support dramatic changes to the previous recommendations. Therefore, only incremental updates have been made in this guideline revision, including the addition of a key action statement related to diagnosis and treatment of comorbid conditions in children and adolescents with ADHD. The accompanying process of care algorithm has also been updated to assist in implementing the guideline recommendations. Throughout the process of revising the guideline and algorithm, numerous systemic barriers were identified that restrict and/or hamper pediatric clinicians' ability to adopt their recommendations. Therefore, the subcommittee created a companion article (available in the Supplemental Information) on systemic barriers to the care of children and adolescents with ADHD, which identifies the major systemic-level barriers and presents recommendations to address those barriers; in this article, we support the recommendations of the clinical practice guideline and accompanying process of care algorithm.

abstract

[a]*Section of Developmental and Behavioral Pediatrics, University of Oklahoma, Oklahoma City, Oklahoma;* [b]*Department of Pediatrics, The Robert Larner, MD, College of Medicine, The University of Vermont, Burlington, Vermont;* [c]*Hagan, Rinehart, and Connolly Pediatricians, PLLC, Burlington, Vermont;* [d]*Division of Developmental and Behavioral Health, Department of Pediatrics, Children's Mercy Kansas City, Kansas City, Missouri;* [e]*School of Medicine, University of Missouri-Kansas City, Kansas City, Missouri;* [f]*Division of Developmental Medicine, Boston Children's Hospital, Boston, Massachusetts;* [g]*Harvard Medical School, Harvard University, Boston, Massachusetts;* [h]*Children and Adults with Attention-Deficit/Hyperactivity Disorder, Lanham, Maryland;* [i]*Dale Davison, LLC, Skokie, Illinois;* [j]*Community Care of North Carolina, Raleigh, North Carolina;* [k]*School of Medicine, University of North Carolina, Chapel Hill, North Carolina;* [l]*Department of Psychology, Ohio University, Athens, Ohio;* [m]*Center for Intervention Research in Schools, Ohio University, Athens, Ohio;* [n]*American Academy of Pediatrics, Alexandria, Virginia;* [o]*Department of Pediatrics, University of Cincinnati, Cincinnati, Ohio;* [p]*Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio;* [q]*Swope Health Services, Kansas City, Kansas;* [r]*American Academy of Family Physicians, Leawood, Kansas;* [s]*National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, Atlanta, Georgia;* [t]*Departments of Biomedical Informatics and Pediatrics, Vanderbilt University, Nashville, Tennessee;* [u]*The Children's Medical Group, Poughkeepsie, New York;*

To cite: Wolraich ML, Hagan JF, Allan C, et al. AAP SUBCOMMITTEE ON CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVE DISORDER. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics.* 2019;144(4):e20192528

INTRODUCTION

This article updates and replaces the 2011 clinical practice guideline revision published by the American Academy of Pediatrics (AAP), "Clinical Practice Guideline: Diagnosis and Evaluation of the Child with Attention-Deficit/Hyperactivity Disorder."[1] This guideline, like the previous document, addresses the evaluation, diagnosis, and treatment of attention-deficit/hyperactivity disorder (ADHD) in children from age 4 years to their 18th birthday, with special guidance provided for ADHD care for preschool-aged children and adolescents. (Note that for the purposes of this document, "preschool-aged" refers to children from age 4 years to the sixth birthday.) Pediatricians and other primary care clinicians (PCCs) may continue to provide care after 18 years of age, but care beyond this age was not studied for this guideline.

Since 2011, much research has occurred, and the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)*, has been released. The new research and *DSM-5* do not, however, support dramatic changes to the previous recommendations. Hence, this new guideline includes only incremental updates to the previous guideline. One such update is the addition of a key action statement (KAS) about the diagnosis and treatment of coexisting or comorbid conditions in children and adolescents with ADHD. The subcommittee uses the term "comorbid," to be consistent with the *DSM-5*.

Since 2011, the release of new research reflects an increased understanding and recognition of ADHD's prevalence and epidemiology; the challenges it raises for children and families; the need for a comprehensive clinical resource for the evaluation, diagnosis, and treatment of pediatric ADHD; and the barriers that impede the implementation of such a resource. In response, this guideline is supported by 2 accompanying documents, available in the Supplemental Information: (1) a process of care algorithm (PoCA) for the diagnosis and treatment of children and adolescents with ADHD and (2) an article on systemic barriers to the care of children and adolescents with ADHD. These supplemental documents are designed to aid PCCs in implementing the formal recommendations for the evaluation, diagnosis, and treatment of children and adolescents with ADHD. Although this document is specific to children and adolescents in the United States in some of its recommendations, international stakeholders can modify specific content (ie, educational laws about accommodations, etc) as needed. (Prevention is addressed in the Mental Health Task Force recommendations.[2])

PoCA for the Diagnosis and Treatment of Children and Adolescents With ADHD

In this revised guideline and accompanying PoCA, we recognize that evaluation, diagnosis, and treatment are a continuous process. The PoCA provides recommendations for implementing the guideline steps, although there is less evidence for the PoCA than for the guidelines. The section on evaluating and treating comorbidities has also been expanded in the PoCA document.

Systems Barriers to the Care of Children and Adolescents With ADHD

There are many system-level barriers that hamper the adoption of the best-practice recommendations contained in the clinical practice guideline and the PoCA. The procedures recommended in this guideline necessitate spending more time with patients and their families, developing a care management system of contacts with school and other community stakeholders, and providing continuous, coordinated care to the patient and his or her family. There is some evidence that African American and Latino children are less likely to have ADHD diagnosed and are less likely to be treated for ADHD. Special attention should be given to these populations when assessing comorbidities as they relate to ADHD and when treating for ADHD symptoms.[3] Given the nationwide problem of limited access to mental health clinicians,[4] pediatricians and other PCCs are increasingly called on to provide services to patients with ADHD and to their families. In addition, the AAP holds that primary care pediatricians should be prepared to diagnose and manage mild-to-moderate ADHD, anxiety, depression, and problematic substance use, as well as co-manage patients who have more severe conditions with mental health professionals. Unfortunately, third-party payers seldom pay appropriately for these time-consuming services.[5,6]

To assist pediatricians and other PCCs in overcoming such obstacles, the companion article on systemic barriers to the care of children and adolescents with ADHD reviews the barriers and makes recommendations to address them to enhance care for children and adolescents with ADHD.

ADHD EPIDEMIOLOGY AND SCOPE

Prevalence estimates of ADHD vary on the basis of differences in research methodologies, the various age groups being described, and changes in diagnostic criteria over time.[7] Authors of a recent meta-analysis calculated a pooled worldwide ADHD prevalence of 7.2% among children[8]; estimates from some community-based samples are somewhat higher, at 8.7% to 15.5%.[9,10] National survey data from 2016 indicate that 9.4% of children in the United States 2 to 17 years of age have ever had an ADHD diagnosis, including 2.4% of children 2 to 5 years of age.[11] In that

national survey, 8.4% of children 2 to 17 years of age currently had ADHD, representing 5.4 million children.[11] Among children and adolescents with current ADHD, almost two-thirds were taking medication, and approximately half had received behavioral treatment of ADHD in the past year. Nearly one quarter had received neither type of treatment of ADHD.[11]

Symptoms of ADHD occur in childhood, and most children with ADHD will continue to have symptoms and impairment through adolescence and into adulthood. According to a 2014 national survey, the median age of diagnosis was 7 years; approximately one-third of children were diagnosed before 6 years of age.[12] More than half of these children were first diagnosed by a PCC, often a pediatrician.[12] As individuals with ADHD enter adolescence, their overt hyperactive and impulsive symptoms tend to decline, whereas their inattentive symptoms tend to persist.[13,14] Learning and language problems are common comorbid conditions with ADHD.[15]

Boys are more than twice as likely as girls to receive a diagnosis of ADHD,[9,11,16] possibly because hyperactive behaviors, which are easily observable and potentially disruptive, are seen more frequently in boys. The majority of both boys and girls with ADHD also meet diagnostic criteria for another mental disorder.[17,18] Boys are more likely to exhibit externalizing conditions like oppositional defiant disorder or conduct disorder.[17,19,20] Recent research has established that girls with ADHD are more likely than boys to have a comorbid internalizing condition like anxiety or depression.[21]

Although there is a greater risk of receiving a diagnosis of ADHD for children who are the youngest in their class (who are therefore less developmentally capable of compensating for their weaknesses), for most children, retention is not beneficial.[22]

METHODOLOGY

As with the original 2000 clinical practice guideline and the 2011 revision, the AAP collaborated with several organizations to form a subcommittee on ADHD (the subcommittee) under the oversight of the AAP Council on Quality Improvement and Patient Safety.

The subcommittee's membership included representation of a wide range of primary care and subspecialty groups, including primary care pediatricians, developmental-behavioral pediatricians, an epidemiologist from the Centers for Disease Control and Prevention; and representatives from the American Academy of Child and Adolescent Psychiatry, the Society for Pediatric Psychology, the National Association of School Psychologists, the Society for Developmental and Behavioral Pediatrics (SDBP), the American Academy of Family Physicians, and Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) to provide feedback on the patient/parent perspective.

This subcommittee met over a 3.5-year period from 2015 to 2018 to review practice changes and newly identified issues that have arisen since the publication of the 2011 guidelines. The subcommittee members' potential conflicts were identified and taken into consideration in the group's deliberations. No conflicts prevented subcommittee member participation on the guidelines.

Research Questions

The subcommittee developed a series of research questions to direct an evidence-based review sponsored by 1 of the Evidence-based Practice Centers of the US Agency for Healthcare Research and Quality (AHRQ).[23] These questions assessed 4 diagnostic areas and 3 treatment areas on the basis of research published in 2011 through 2016.

The AHRQ's framework was guided by key clinical questions addressing diagnosis as well as treatment interventions for children and adolescents 4 to 18 years of age.

The first clinical questions pertaining to ADHD diagnosis were as follows:

1. What is the comparative diagnostic accuracy of approaches that can be used in the primary care practice setting or by specialists to diagnose ADHD among children younger than 7 years of age?
2. What is the comparative diagnostic accuracy of EEG, imaging, or executive function approaches that can be used in the primary care practice setting or by specialists to diagnose ADHD among individuals aged 7 to their 18th birthday?
3. What are the adverse effects associated with being labeled correctly or incorrectly as having ADHD?
4. Are there more formal neuropsychological, imaging, or genetic tests that improve the diagnostic process?

The treatment questions were as follows:

1. What are the comparative safety and effectiveness of pharmacologic and/or nonpharmacologic treatments of ADHD in improving outcomes associated with ADHD?
2. What is the risk of diversion of pharmacologic treatment?
3. What are the comparative safety and effectiveness of different monitoring strategies to evaluate the effectiveness of treatment or changes in ADHD status (eg, worsening or resolving symptoms)?

In addition to this review of the research questions, the subcommittee considered information from a review of evidence-based psychosocial treatments for children and adolescents with ADHD[24] (which, in some cases, affected the evidence grade) as well as updated information on prevalence from the Centers for Disease Control and Prevention.

Evidence Review

This article followed the latest version of the evidence base update format used to develop the previous 3 clinical practice guidelines.[24–26] Under this format, studies were only included in the review when they met a variety of criteria designed to ensure the research was based on a strong methodology that yielded confidence in its conclusions.

The level of efficacy for each treatment was defined on the basis of child-focused outcomes related to both symptoms and impairment. Hence, improvements in behaviors on the part of parents or teachers, such as the use of communication or praise, were not considered in the review. Although these outcomes are important, they address how treatment reaches the child or adolescent with ADHD and are, therefore, secondary to changes in the child's behavior. Focusing on improvements in the child or adolescent's symptoms and impairment emphasizes the disorder's characteristics and manifestations that affect children and their families.

The treatment-related evidence relied on a recent review of literature from 2011 through 2016 by the AHRQ of citations from Medline, Embase, PsycINFO, and the Cochrane Database of Systematic Reviews.

The original methodology and report, including the evidence search and review, are available in their entirety and as an executive summary at https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-203-adhd-final_0.pdf.

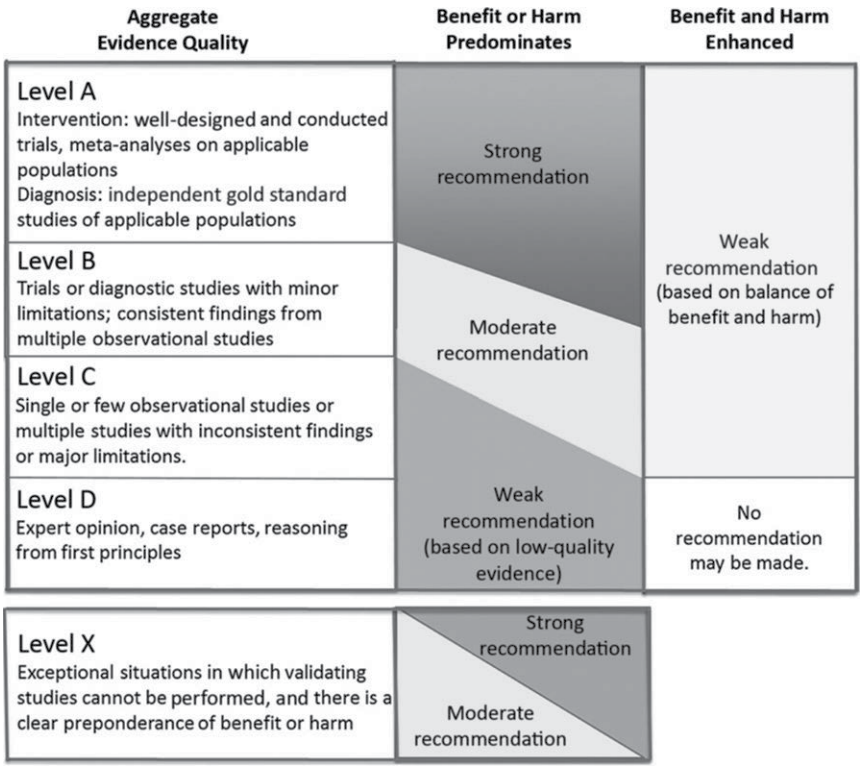


FIGURE 1
AAP rating of evidence and recommendations.

The evidence is discussed in more detail in published reports and articles.[25]

Guideline Recommendations and Key Action Statements

The AAP policy statement, "Classifying Recommendations for Clinical Practice Guidelines," was followed in designating aggregate evidence quality levels for the available evidence (see Fig 1).[27] The AAP policy statement is consistent with the grading recommendations advanced by the University of Oxford Centre for Evidence Based Medicine.

The subcommittee reached consensus on the evidence, which was then used to develop the clinical practice guideline's KASs.

When the scientific evidence was at least "good" in quality and demonstrated a preponderance of benefits over harms, the KAS provides a "strong recommendation" or "recommendation."[27] Clinicians should follow a "strong recommendation" unless a clear and compelling rationale for an alternative approach is present; clinicians are prudent to follow a "recommendation" but are advised to remain alert to new information and be sensitive to patient preferences[27] (see Fig 1).

When the scientific evidence comprised lower-quality or limited data and expert consensus or high-quality evidence with a balance between benefits and harms, the KAS provides an "option" level of recommendation. Options are clinical interventions that a reasonable health care provider might or might not wish to implement in the practice.[27] Where the evidence was lacking, a combination of evidence and expert consensus

would be used, although this did not occur in these guidelines, and all KASs achieved a "strong recommendation" level except for KAS 7, on comorbidities, which received a recommendation level (see Fig 1).

As shown in Fig 1, integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms leads to a designation of a strong recommendation, recommendation, option, or no recommendation.

Once the evidence level was determined, an evidence grade was assigned. AAP policy stipulates that the evidence supporting each KAS be prospectively identified, appraised, and summarized, and an explicit link between quality levels and the grade of recommendation must be defined. Possible grades of recommendations range from "A" to "D," with "A" being the highest:

- grade A: consistent level A studies;
- grade B: consistent level B or extrapolations from level A studies;
- grade C: level C studies or extrapolations from level B or level C studies;
- grade D: level D evidence or troublingly inconsistent or inconclusive studies of any level; and
- level X: not an explicit level of evidence as outlined by the Centre for Evidence-Based Medicine. This level is reserved for interventions that are unethical or impossible to test in a controlled or scientific fashion and for which the preponderance of benefit or harm is overwhelming, precluding rigorous investigation.

Guided by the evidence quality and grade, the subcommittee developed 7 KASs for the evaluation, diagnosis, and treatment of ADHD in children and adolescents (see Table 1). These KASs provide for consistent and high-quality care for children and adolescents who may have symptoms suggesting attention disorders or problems as well as for their families. In developing the 7 KASs, the subcommittee considered the requirements for establishing the diagnosis; the prevalence of ADHD; the effect of untreated ADHD; the efficacy and adverse effects of treatment; various long-term outcomes; the importance of coordination between pediatric and mental health service providers; the value of the medical home; and the common occurrence of comorbid conditions, the importance of addressing them, and the effects of not treating them.

The subcommittee members with the most epidemiological experience assessed the strength of each recommendation and the quality of evidence supporting each draft KAS.

Peer Review

The guidelines and PoCA underwent extensive peer review by more than 30 internal stakeholders (eg, AAP committees, sections, councils, and task forces) and external stakeholder groups identified by the subcommittee. The resulting comments were compiled and reviewed by the chair and vice chair; relevant changes were incorporated into the draft, which was then reviewed by the full subcommittee.

KASS FOR THE EVALUATION, DIAGNOSIS, TREATMENT, AND MONITORING OF CHILDREN AND ADOLESCENTS WITH ADHD

KAS 1

The pediatrician or other PCC should initiate an evaluation for ADHD for any child or adolescent age 4 years to the 18th birthday who presents with academic or behavioral problems and symptoms of inattention, hyperactivity, or impulsivity (Table 2). (Grade B: strong recommendation.)

The basis for this recommendation is essentially unchanged from the previous guideline. As noted, ADHD is the most common neurobehavioral disorder of childhood, occurring in approximately 7% to 8% of children and youth.[8,18,28,29] Hence, the number of children with this condition is far greater than can be managed by the mental health system.[4] There is evidence that appropriate diagnosis can be accomplished in the primary care setting for children and adolescents.[30,31] Note that there is insufficient evidence to recommend diagnosis or treatment for children younger than 4 years (other than parent training in behavior management [PTBM], which does not require a diagnosis to be applied); in instances in which ADHD-like symptoms in children younger than 4 years bring substantial impairment, PCCs can consider making a referral for PTBM.

KAS 2

To make a diagnosis of ADHD, the PCC should determine that *DSM-5* criteria have been met, including documentation of symptoms and impairment in more than 1 major setting (ie, social, academic, or occupational), with information obtained primarily from reports from parents or guardians, teachers, other school personnel, and mental health clinicians who are involved in the child or adolescent's care. The PCC should also rule out any alternative cause (Table 3). (Grade B: strong recommendation.)

The American Psychiatric Association developed the *DSM-5* using expert consensus and an expanding research foundation.[32] The *DSM-5* system is used by professionals in psychiatry, psychology, health care systems, and primary care; it is also well established with third-party payers.

TABLE 1 Summary of KASs for Diagnosing, Evaluating, and Treating ADHD in Children and Adolescents

KASs	Evidence Quality, Strength of Recommendation
KAS 1: The pediatrician or other PCC should initiate an evaluation for ADHD for any child or adolescent age 4 years to the 18th birthday who presents with academic or behavioral problems and symptoms of inattention, hyperactivity, or impulsivity.	Grade B, strong recommendation
KAS 2: To make a diagnosis of ADHD, the PCC should determine that *DSM-5* criteria have been met, including documentation of symptoms and impairment in more than 1 major setting (ie, social, academic, or occupational), with information obtained primarily from reports from parents or guardians, teachers, other school personnel, and mental health clinicians who are involved in the child or adolescent's care. The PCC should also rule out any alternative cause.	Grade B, strong recommendation
KAS 3: In the evaluation of a child or adolescent for ADHD, the PCC should include a process to at least screen for comorbid conditions, including emotional or behavioral conditions (eg, anxiety, depression, oppositional defiant disorder, conduct disorders, substance use), developmental conditions (eg, learning and language disorders, autism spectrum disorders), and physical conditions (eg, tics, sleep apnea).	Grade B, strong recommendation
KAS 4: ADHD is a chronic condition; therefore, the PCC should manage children and adolescents with ADHD in the same manner that they would children and youth with special health care needs, following the principles of the chronic care model and the medical home.	Grade B, strong recommendation
KAS 5a: For preschool-aged children (age 4 years to the sixth birthday) with ADHD, the PCC should prescribe evidence-based PTBM and/or behavioral classroom interventions as the first line of treatment, if available.	Grade A, strong recommendation for PTBM
Methylphenidate may be considered if these behavioral interventions do not provide significant improvement and there is moderate-to-severe continued disturbance in the 4- through 5-year-old child's functioning. In areas in which evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication before the age of 6 years against the harm of delaying treatment.	Grade B, strong recommendation for methylphenidate
KAS 5b. For elementary and middle school-aged children (age 6 years to the 12th birthday) with ADHD, the PCC should prescribe FDA-approved medications for ADHD, along with PTBM and/or behavioral classroom intervention (preferably both PTBM and behavioral classroom interventions). Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an IEP or a rehabilitation plan (504 plan).	Grade A, strong recommendation for medications Grade A, strong recommendation for training and behavioral treatments for ADHD with family and school
KAS 5c. For adolescents (age 12 years to the 18th birthday) with ADHD, the PCC should prescribe FDA-approved medications for ADHD with the adolescent's assent. The PCC is encouraged to prescribe evidence-based training interventions and/or behavioral interventions as treatment of ADHD, if available. Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an IEP or a rehabilitation plan (504 plan).	Grade A, strong recommendation for medications Grade A, strong recommendation for training and behavioral treatments for ADHD with the family and school
KAS 6. The PCC should titrate doses of medication for ADHD to achieve maximum benefit with tolerable side effects.	Grade B, strong recommendation
KAS 7. The PCC, if trained or experienced in diagnosing comorbid conditions, may initiate treatment of such conditions or make a referral to an appropriate subspecialist for treatment. After detecting possible comorbid conditions, if the PCC is not trained or experienced in making the diagnosis or initiating treatment, the patient should be referred to an appropriate subspecialist to make the diagnosis and initiate treatment.	Grade C, recommendation

The *DSM-5* criteria define 4 dimensions of ADHD:

1. attention-deficit/hyperactivity disorder primarily of the inattentive presentation (ADHD/I) (314.00 [F90.0]);
2. attention-deficit/hyperactivity disorder primarily of the hyperactive-impulsive presentation (ADHD/HI) (314.01 [F90.1]);
3. attention-deficit/hyperactivity disorder combined presentation (ADHD/C) (314.01 [F90.2]); and
4. ADHD other specified and unspecified ADHD (314.01 [F90.8]).

As with the previous guideline recommendations, the *DSM-5* classification criteria are based on the best available evidence for ADHD diagnosis and are the standard most frequently used by clinicians and researchers to render the diagnosis and document its appropriateness for a given child. The use of neuropsychological testing has not been found to improve diagnostic accuracy in most cases, although it may have benefit in clarifying the child or adolescent's learning strengths and weaknesses. (See the

TABLE 2 KAS 1: The pediatrician or other PCC should initiate an evaluation for ADHD for any child or adolescent age 4 years to the 18th birthday who presents with academic or behavioral problems and symptoms of inattention, hyperactivity, or impulsivity. (Grade B: strong recommendation.)

Aggregate evidence quality	Grade B
Benefits	ADHD goes undiagnosed in a considerable number of children and adolescents. Primary care clinicians' more-rigorous identification of children with these problems is likely to decrease the rate of undiagnosed and untreated ADHD in children and adolescents.
Risks, harm, cost	Children and adolescents in whom ADHD is inappropriately diagnosed may be labeled inappropriately, or another condition may be missed, and they may receive treatments that will not benefit them.
Benefit-harm assessment	The high prevalence of ADHD and limited mental health resources require primary care pediatricians and other PCCs to play a significant role in the care of patients with ADHD and assist them to receive appropriate diagnosis and treatment. Treatments available have good evidence of efficacy, and a lack of treatment has the risk of impaired outcomes.
Intentional vagueness	There are limits between what a PCC can address and what should be referred to a subspecialist because of varying degrees of skills and comfort levels present among the former.
Role of patient preferences	Success with treatment is dependent on patient and family preference, which need to be taken into account.
Exclusions	None.
Strength	Strong recommendation.
Key references	Wolraich et al[31]; Visser et al[28]; Thomas et al[8]; Egger et al[30]

PoCA for more information on implementing this KAS.)

Special Circumstances: Preschool-Aged Children (Age 4 Years to the Sixth Birthday)

There is evidence that the diagnostic criteria for ADHD can be applied to preschool-aged children.[33–39] A review of the literature, including the multisite study of the efficacy of methylphenidate in preschool-aged children, found that the *DSM-5* criteria could appropriately identify children with ADHD.[25]

To make a diagnosis of ADHD in preschool-aged children, clinicians should conduct a clinical interview with parents, examine and observe the child, and obtain information from parents and teachers through *DSM*-based ADHD rating scales.[40] Normative data are available for the *DSM-5*–based rating scales for ages 5 years to the 18th birthday.[41] There are, however, minimal changes in the specific behaviors from the *DSM-IV*, on which all the other *DSM*-based ADHD rating scales obtained normative data. Both the ADHD Rating Scale-IV and the Conners Rating Scale have preschool-age normative data based on the *DSM-IV*. The specific behaviors in the *DSM-5* criteria for ADHD are the same for all children younger than 18 years (ie, preschool-aged children, elementary and middle school–aged children, and adolescents) and are only minimally different from the *DSM-IV*. Hence, if clinicians do not have the ADHD Rating Scale-5 or the ADHD Rating Scale-IV Preschool Version,[42] any other *DSM*-based scale can be used to provide a systematic method for collecting information from parents and teachers, even in the absence of normative data.

Pediatricians and other PCCs should be aware that determining the presence of key symptoms in this age group has its challenges, such as

TABLE 3 KAS 2: To make a diagnosis of ADHD, the PCC should determine that *DSM-5* criteria have been met, including documentation of symptoms and impairment in more than 1 major setting (ie, social, academic, or occupational), with information obtained primarily from reports from parents or guardians, teachers, other school personnel, and mental health clinicians who are involved in the child or adolescent's care. The PCC should also rule out any alternative cause. (Grade B: strong recommendation.)

Aggregate evidence quality	Grade B
Benefits	Use of the *DSM-5* criteria has led to more uniform categorization of the condition across professional disciplines. The criteria are essentially unchanged from the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)*, for children up to their 18th birthday, except that *DSM-IV* required onset prior to age 7 for a diagnosis, while *DSM-5* requires onset prior to age 12.
Risks, harm, cost	The *DSM-5* does not specifically state that symptoms must be beyond expected levels for developmental (rather than chronologic) age to qualify for an ADHD diagnosis, which may lead to some misdiagnoses in children with developmental disorders.
Benefit-harm assessment	The benefits far outweigh the harm.
Intentional vagueness	None.
Role of patient preferences	Although there is some stigma associated with mental disorder diagnoses, resulting in some families preferring other diagnoses, the need for better clarity in diagnoses outweighs this preference.
Exclusions	None.
Strength	Strong recommendation.
Key references	Evans et al[25]; McGoey et al[42]; Young[43]; Sibley et al[46]

observing symptoms across multiple settings as required by the *DSM-5*, particularly among children who do not attend a preschool or child care program. Here, too, focused checklists can be used to aid in the diagnostic evaluation.

PTBM is the recommended primary intervention for preschool-aged children with ADHD as well as children with ADHD-like behaviors whose diagnosis is not yet verified. This type of training helps parents learn age-appropriate developmental expectations, behaviors that strengthen the parent-child relationship, and specific management skills for problem behaviors. Clinicians do not need to have made an ADHD diagnosis before recommending PTBM because PTBM has documented effectiveness with a wide variety of problem behaviors, regardless of etiology. In addition, the intervention's results may inform the subsequent diagnostic evaluation. Clinicians are encouraged to recommend that parents complete PTBM, if available, before assigning an ADHD diagnosis.

After behavioral parent training is implemented, the clinician can obtain information from parents and teachers through *DSM-5*–based ADHD rating scales. The clinician may obtain reports about the parents' ability to manage their children and about the child's core symptoms and impairments. Referral to an early intervention program or enrolling in a PTBM program can help provide information about the child's behavior in other settings or with other observers. The evaluators for these programs and/or early childhood special education teachers may be useful observers, as well.

Special Circumstances: Adolescents (Age 12 Years to the 18th Birthday)

Obtaining teacher reports for adolescents is often more challenging than for younger children because many adolescents have multiple teachers. Likewise, an adolescent's parents may have less opportunity to observe their child's behaviors than they did when the child was younger. Furthermore, some problems experienced by children with ADHD are less obvious in adolescents than in younger children because adolescents are less likely to exhibit overt hyperactive behavior. Of note, adolescents' reports of their own behaviors often differ from other observers because they tend to minimize their own problematic behaviors.[43–45]

Despite these difficulties, clinicians need to try to obtain information from at least 2 teachers or other sources, such as coaches, school guidance counselors, or leaders of community activities in which the adolescent participates.[46] For the evaluation to be successful, it is essential that adolescents agree with and participate in the evaluation. Variability in ratings is to be expected because adolescents' behavior often varies between different classrooms and with different teachers. Identifying reasons for any variability can provide valuable clinical insight into the adolescent's problems.

Note that, unless they previously received a diagnosis, to meet *DSM-5* criteria for ADHD, adolescents must have some reported or documented manifestations of inattention or hyperactivity/impulsivity before age 12. Therefore, clinicians must establish that an adolescent had manifestations of ADHD before age 12 and strongly consider whether a mimicking or comorbid condition, such as substance use, depression, and/or anxiety, is present.[46]

In addition, the risks of mood and anxiety disorders and risky sexual behaviors increase during adolescence, as do the risks of intentional self-harm and suicidal behaviors.[31] Clinicians should also be aware that adolescents are at greater risk for substance use than are younger children.[44,45,47] Certain substances, such as marijuana, can have effects that mimic ADHD; adolescent patients may also attempt to obtain stimulant medication to enhance performance (ie, academic, athletic, etc) by feigning symptoms.[48]

Trauma experiences, posttraumatic stress disorder, and toxic stress are additional comorbidities and risk factors of concern.

Special Circumstances: Inattention or Hyperactivity/Impulsivity (Problem Level)

Teachers, parents, and child health professionals typically encounter children who demonstrate behaviors relating to activity level, impulsivity, and inattention but who do not fully meet *DSM-5* criteria. When assessing these children, diagnostic criteria should be closely reviewed, which may require obtaining more information from other settings and sources. Also consider that these symptoms may suggest other problems that mimic ADHD.

Behavioral interventions, such as PTBM, are often beneficial for children with hyperactive/impulsive behaviors who do not meet full diagnostic criteria for ADHD. As noted previously, these programs do not require a specific diagnosis to be beneficial to the family. The previous guideline discussed the diagnosis of problem-level concerns on the basis of the *Diagnostic and Statistical Manual for Primary Care (DSM-PC), Child and Adolescent Version*,[49] and made suggestions for treatment and care. The *DSM-PC* was published in 1995, however, and it has not been revised to be compatible with the *DSM-5*. Therefore, the *DSM-PC* cannot be used as a definitive source for diagnostic codes related to ADHD and comorbid conditions, although it can be used conceptually as a resource for

enriching the understanding of problem-level manifestations.

KAS 3

In the evaluation of a child or adolescent for ADHD, the PCC should include a process to at least screen for comorbid conditions, including emotional or behavioral conditions (eg, anxiety, depression, oppositional defiant disorder, conduct disorders, substance use), developmental conditions (eg, learning and language disorders, autism spectrum disorders), and physical conditions (eg, tics, sleep apnea) (Table 4). (Grade B: strong recommendation.)

The majority of both boys and girls with ADHD also meet diagnostic criteria for another mental disorder.[17,18] A variety of other behavioral, developmental, and physical conditions can be comorbid in children and adolescents who are evaluated for ADHD, including emotional or behavioral conditions or a history of these problems. These include but are not limited to learning disabilities, language disorder, disruptive behavior, anxiety, mood disorders, tic disorders, seizures, autism spectrum disorder, developmental coordination disorder, and sleep disorders.[50–66] In some cases, the presence of a comorbid condition will alter the treatment of ADHD.

The SDBP is developing a clinical practice guideline to support clinicians in the diagnosis of treatment of "complex ADHD," which includes ADHD with comorbid developmental and/or mental health conditions.[67]

Special Circumstances: Adolescents (Age 12 Years to the 18th Birthday)

At a minimum, clinicians should assess adolescent patients with newly diagnosed ADHD for symptoms and signs of substance use, anxiety, depression, and learning disabilities. As noted, all 4 are common comorbid conditions that affect the treatment approach. These comorbidities make it important for the clinician to consider sequencing psychosocial and medication treatments to maximize the impact on areas of greatest risk and impairment while monitoring for possible risks such as stimulant abuse or suicidal ideation.

KAS 4

ADHD is a chronic condition; therefore, the PCC should manage children and adolescents with ADHD in the same manner that they would children and youth with special health care needs, following the principles of the chronic care model and the medical home (Table 5). (Grade B: strong recommendation.)

As in the 2 previous guidelines, this recommendation is based on the evidence that for many individuals, ADHD causes symptoms and dysfunction over long periods of time, even into adulthood. Available treatments address symptoms and function but are usually not curative. Although the chronic illness model has not been specifically studied in children and adolescents with ADHD, it has been effective for other chronic conditions, such as asthma.[68] In addition, the medical home model has been accepted as the preferred standard of care for children with chronic conditions.[69]

The medical home and chronic illness approach may be particularly beneficial for parents who also have ADHD themselves. These parents can benefit from extra support to help them follow a consistent schedule for medication and behavioral programs.

Authors of longitudinal studies have found that ADHD treatments are frequently not maintained over time[13] and impairments persist into adulthood.[70] It is indicated in prospective studies that patients with ADHD, whether treated or not, are at increased risk for early death, suicide, and increased psychiatric

TABLE 4 KAS 3: In the evaluation of a child or adolescent for ADHD, the PCC should include a process to at least screen for comorbid conditions, including emotional or behavioral conditions (eg, anxiety, depression, oppositional defiant disorder, conduct disorders, substance use), developmental conditions (eg, learning and language disorders, autism spectrum disorders), and physical conditions (eg, tics, sleep apnea). (Grade B: strong recommendation.)

Aggregate evidence quality	Grade B
Benefits	Identifying comorbid conditions is important in developing the most appropriate treatment plan for the child or adolescent with ADHD.
Risks, harm, cost	The major risk is misdiagnosing the comorbid condition(s) and providing inappropriate care.
Benefit-harm assessment	There is a preponderance of benefits over harm.
Intentional vagueness	None.
Role of patient preferences	None.
Exclusions	None.
Strength	Strong recommendation.
Key references	Cuffe et al[51]; Pastor and Reuben[52]; Bieiderman et al[53]; Bieiderman et al[54]; Bieiderman et al[72]; Crabtree et al[57]; LeBourgeois et al[58]; Chan[115]; Newcorn et al[60]; Sung et al[61]; Larson et al[66]; Mahajan et al[65]; Antshel et al[64]; Rothenberger and Roessner[63]; Froehlich et al[62]

TABLE 5 KAS 4: ADHD is a chronic condition; therefore, the PCC should manage children and adolescents with ADHD in the same manner that they would children and youth with special health care needs, following the principles of the chronic care model and the medical home. (Grade B: strong recommendation.)

Aggregate evidence quality	Grade B
Benefits	The recommendation describes the coordinated services that are most appropriate to manage the condition.
Risks, harm, cost	Providing these services may be more costly.
Benefit-harm assessment	There is a preponderance of benefits over harm.
Intentional vagueness	None.
Role of patient preferences	Family preference in how these services are provided is an important consideration, because it can increase adherence.
Exclusions	None
Strength	Strong recommendation.
Key references	Brito et al[69]; Biederman et al[72]; Scheffler et al[74]; Barbaresi et al[75]; Chang et al[71]; Chang et al[78]; Lichtenstein et al[77]; Harstad and Levy[80]

comorbidity, particularly substance use disorders.[71,72] They also have lower educational achievement than those without ADHD[73,74] and increased rates of incarceration.[75–77] Treatment discontinuation also places individuals with ADHD at higher risk for catastrophic outcomes, such as motor vehicle crashes[78,79]; criminality, including drug-related crimes[77] and violent reoffending[76]; depression[71]; interpersonal issues[80]; and other injuries.[81,82]

To continue providing the best care, it is important for a treating pediatrician or other PCC to engage in bidirectional communication with teachers and other school personnel as well as mental health clinicians involved in the child or adolescent's care. This communication can be difficult to achieve and is discussed in both the PoCA and the section on systemic barriers to the care of children and adolescents with ADHD in the Supplemental Information, as is the medical home model.[69]

Special Circumstances: Inattention or Hyperactivity/Impulsivity (Problem Level)

Children with inattention or hyperactivity/impulsivity at the problem level, as well as their families, may also benefit from the chronic illness and medical home principles.

Recommendations for the Treatment of Children and Adolescents With ADHD: KAS 5a, 5b, and 5c

Recommendations vary depending on the patient's age and are presented for the following age ranges:

a. preschool-aged children: age 4 years to the sixth birthday;
b. elementary and middle school–aged children: age 6 years to the 12th birthday; and
c. adolescents: age 12 years to the 18th birthday.

The KASs are presented, followed by information on medication, psychosocial treatments, and special circumstances.

KAS 5a

For preschool-aged children (age 4 years to the sixth birthday) with ADHD, the PCC should prescribe evidence-based behavioral PTBM and/or behavioral classroom interventions as the first line of treatment, if available (grade A: strong recommendation). Methylphenidate may be considered if these behavioral interventions do not provide significant improvement and there is moderate-to-severe continued disturbance in the 4- through 5-year-old child's functioning. In areas in which evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication before the age of 6 years against the harm of delaying treatment (Table 6). (Grade B: strong recommendation.)

A number of special circumstances support the recommendation to initiate PTBM as the first treatment of preschool-aged children (age 4 years to the sixth birthday) with ADHD.[25,83] Although it was limited to children who had moderate-to-severe dysfunction, the largest multisite study of methylphenidate use in preschool-aged children revealed symptom improvements after PTBM alone.[83] The overall evidence for PTBM among preschoolers is strong.

PTBM programs for preschool-aged children are typically group programs and, although they are not always paid for by health insurance, they may be relatively low cost. One evidence-based PTBM, parent-child interaction therapy, is a dyadic therapy for parent and child. The PoCA contains criteria for the clinician's use to assess the quality of PTBM programs. If the child attends preschool, behavioral classroom interventions are also recommended. In addition, preschool programs (such as Head Start) and ADHD-focused organizations (such as CHADD[84]) can also provide behavioral supports. The issues related to referral, payment, and communication are discussed in the section on systemic barriers in the Supplemental Information.

TABLE 6 KAS 5a: For preschool-aged children (age 4 years to the sixth birthday) with ADHD, the PCC should prescribe evidence-based behavioral PTBM and/or behavioral classroom interventions as the first line of treatment, if available (grade A: strong recommendation). Methylphenidate may be considered if these behavioral interventions do not provide significant improvement and there is moderate-to-severe continued disturbance in the 4- through 5-year-old child's functioning. In areas in which evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication before the age of 6 years against the harm of delaying treatment (grade B: strong recommendation).

Aggregate evidence quality	Grade A for PTBM; Grade B for methylphenidate
Benefits	Given the risks of untreated ADHD, the benefits outweigh the risks.
Risks, harm, cost	Both therapies increase the cost of care; PTBM requires a high level of family involvement, whereas methylphenidate has some potential adverse effects.
Benefit-harm assessment	Both PTBM and methylphenidate have relatively low risks; initiating treatment at an early age, before children experience repeated failure, has additional benefits. Thus, the benefits outweigh the risks.
Intentional vagueness	None.
Role of patient preferences	Family preference is essential in determining the treatment plan.
Exclusions	None.
Strength	Strong recommendation.
Key references	Greenhill et al[83]; Evans et al[25]

In areas in which evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting methylphenidate before the age of 6 years against the harm of delaying diagnosis and treatment. Other stimulant or nonstimulant medications have not been adequately studied in children in this age group with ADHD.

KAS 5b

For elementary and middle school–aged children (age 6 years to the 12th birthday) with ADHD, the PCC should prescribe US Food and Drug Administration (FDA)–approved medications for ADHD, along with PTBM and/or behavioral classroom intervention (preferably both PTBM and behavioral classroom interventions). Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an Individualized Education Program (IEP) or a rehabilitation plan (504 plan) (Table 7). (Grade A: strong recommendation for medications; grade A: strong recommendation for PTBM training and behavioral treatments for ADHD implemented with the family and school.)

The evidence is particularly strong for stimulant medications; it is sufficient, but not as strong, for atomoxetine, extended-release guanfacine, and extended-release clonidine, in that order (see the Treatment section, and see the PoCA for more information on implementation).

KAS 5c

For adolescents (age 12 years to the 18th birthday) with ADHD, the PCC should prescribe FDA-approved medications for ADHD with the adolescent's assent (grade A: strong recommendation). The PCC is encouraged to prescribe evidence-based training interventions and/or behavioral interventions as treatment of ADHD, if available. Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an IEP or a rehabilitation plan (504 plan) (Table 8). (Grade A: strong recommendation.)

Transition to adult care is an important component of the chronic care model for ADHD. Planning for the transition to adult care is an ongoing process that may culminate after high school or, perhaps, after college. To foster a smooth transition, it is best to introduce components at the start of high school, at about 14 years of age, and specifically focus during the 2 years preceding high school completion.

Psychosocial Treatments

Some psychosocial treatments for children and adolescents with ADHD have been demonstrated to be effective for the treatment of ADHD, including behavioral therapy and training interventions.[24–26,85] The diversity of interventions and outcome measures makes it challenging to assess a meta-analysis of psychosocial treatment's effects alone or in association with medication treatment. As with medication treatment, the long-term positive effects of psychosocial treatments have yet to be determined. Nonetheless, ongoing adherence to psychosocial treatment is a key contributor to its beneficial effects, making implementation of a chronic care model for child health important to ensure sustained adherence.[86]

Behavioral therapy involves training adults to influence the contingencies in an environment to improve the behavior of a child or adolescent in that setting. It can help parents and school personnel learn how to effectively prevent and respond to adolescent behaviors such as

TABLE 7 KAS 5b: For elementary and middle school–aged children (age 6 years to the 12th birthday) with ADHD, the PCC should prescribe US Food and Drug Administration (FDA)–approved medications for ADHD, along with PTBM and/or behavioral classroom intervention (preferably both PTBM and behavioral classroom interventions). Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an Individualized Education Program (IEP) or a rehabilitation plan (504 plan). (Grade A: strong recommendation for medications; grade A: strong recommendation for PTBM training and behavioral treatments for ADHD implemented with the family and school.)

Aggregate evidence quality	Grade A for Treatment with FDA-Approved Medications; Grade A for Training and Behavioral Treatments for ADHD With the Family and School.
Benefits	Both behavioral therapy and FDA-approved medications have been shown to reduce behaviors associated with ADHD and to improve function.
Risks, harm, cost	Both therapies increase the cost of care. Psychosocial therapy requires a high level of family and/or school involvement and may lead to increased family conflict, especially if treatment is not successfully completed. FDA-approved medications may have some adverse effects and discontinuation of medication is common among adolescents.
Benefit-harm assessment	Given the risks of untreated ADHD, the benefits outweigh the risks.
Intentional vagueness	None.
Role of patient preferences	Family preference, including patient preference, is essential in determining the treatment plan and enhancing adherence.
Exclusions	None.
Strength	Strong recommendation.
Key references	Evans et al[25]; Barbaresi et al[73]; Jain et al[103]; Brown and Bishop[104]; Kambeitz et al[105]; Bruxel et al[106]; Kieling et al[107]; Froehlich et al[108]; Joensen et al[109]

interrupting, aggression, not completing tasks, and not complying with requests. Behavioral parent and classroom training are well-established treatments with preadolescent children.[25,87,88] Most studies comparing behavior therapy to stimulants indicate that stimulants have a stronger immediate effect on the 18 core symptoms of ADHD. Parents, however, were more satisfied with the effect of behavioral therapy, which addresses symptoms and functions in addition to ADHD's core symptoms. The positive effects of behavioral therapies tend to persist, but the positive effects of medication cease when medication stops. Optimal care is likely to occur when both therapies are used, but the decision about therapies is heavily dependent on acceptability by, and feasibility for, the family.

Training interventions target skill development and involve repeated practice with performance feedback over time, rather than modifying behavioral contingencies in a specific setting. Less research has been conducted on training interventions compared to behavioral treatments; nonetheless, training interventions are well-established treatments to target disorganization of materials and time that are exhibited by most youth with ADHD; it is likely that they will benefit younger children, as well.[25,89] Some training interventions, including social skills training, have not been shown to be effective for children with ADHD.[25]

TABLE 8 KAS 5c: For adolescents (age 12 years to the 18th birthday) with ADHD, the PCC should prescribe FDA-approved medications for ADHD with the adolescent's assent (grade A: strong recommendation). The PCC is encouraged to prescribe evidence-based training interventions and/or behavioral interventions as treatment of ADHD, if available. Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an IEP or a rehabilitation plan (504 plan). (Grade A: strong recommendation.)

Aggregate evidence quality	Grade A for Medications; Grade A for Training and Behavioral Therapy
Benefits	Training interventions, behavioral therapy, and FDA-approved medications have been demonstrated to reduce behaviors associated with ADHD and to improve function.
Risks, harm, cost	Both therapies increase the cost of care. Psychosocial therapy requires a high level of family and/or school involvement and may lead to unintended increased family conflict, especially if treatment is not successfully completed. FDA-approved medications may have some adverse effects, and discontinuation of medication is common among adolescents.
Benefit-harm assessment	Given the risks of untreated ADHD, the benefits outweigh the risks.
Intentional vagueness	None.
Role of patient preferences	Family preference, including patient preference, is likely to predict engagement and persistence with a treatment.
Exclusions	None.
Strength	Strong recommendation.
Key references	Evans et al[25]; Webster-Stratton et al[87]; Evans et al[95]; Fabiano et al[93]; Sibley and Graziano et al[94]; Langberg et al[96]; Schultz et al[97]; Brown and Bishop[104]; Kambeitz et al[105]; Bruxel et al[106]; Froehlich et al[108]; Joensen et al[109]

Some nonmedication treatments for ADHD-related problems have either too little evidence to recommend them or have been found to have little or no benefit. These include mindfulness, cognitive training, diet modification, EEG biofeedback, and supportive counseling. The suggestion that cannabidiol oil has any effect on ADHD is anecdotal and has not been subjected to rigorous study. Although it is FDA approved, the efficacy for external trigeminal nerve stimulation (eTNS) is documented by one 5-week randomized controlled trial with just 30 participants receiving eTNS.[90] To date, there is no long-term safety and efficacy evidence for eTNS. Overall, the current evidence supporting treatment of ADHD with eTNS is sparse and in no way approaches the robust strength of evidence documented for established medication and behavioral treatments for ADHD; therefore, it cannot be recommended as a treatment of ADHD without considerably more extensive study on its efficacy and safety.

Special Circumstances: Adolescents

Much less research has been published on psychosocial treatments with adolescents than with younger children. PTBM has been modified to include the parents and adolescents in sessions together to develop a behavioral contract and improve parent-adolescent communication and problem-solving (see above).[91] Some training programs also include motivational interviewing approaches. The evidence for this behavioral family approach is mixed and less strong than PTBM with pre-adolescent children.[92–94] Adolescents' responses to behavioral contingencies are more varied than those of younger children because they can often effectively obstruct behavioral contracts, increasing parent-adolescent conflict.

Training approaches that are focused on school functioning skills have consistently revealed benefits for adolescents.[95–97] The greatest benefits from training interventions occur when treatment is continued over an extended period of time, performance feedback is constructive and frequent, and the target behaviors are directly applicable to the adolescent's daily functioning.

Overall, behavioral family approaches may be helpful to some adolescents and their families, and school-based training interventions are well established.[25,94] Meaningful improvements in functioning have not been reported from cognitive behavioral approaches.

Medication for ADHD

Preschool-aged children may experience increased mood lability and dysphoria with stimulant medications.[83] None of the nonstimulants have FDA approval for use in preschool-aged children. For elementary school–aged students, the evidence is particularly strong for stimulant medications and is sufficient, but less strong, for atomoxetine, extended-release guanfacine, and extended-release clonidine (in that order). The effect size for stimulants is 1.0 and for nonstimulants is 0.7. An individual's response to methylphenidate verses amphetamine is idiosyncratic, with approximately 40% responding to both and about 40% responding to only 1. The subtype of ADHD does not appear to be a predictor of response to a specific agent. For most adolescents, stimulant medications are highly effective in reducing ADHD's core symptoms.[73]

Stimulant medications have an effect size of around 1.0 (effect size = [treatment M − control M)/control SD]) for the treatment of ADHD.[98] Among nonstimulant medications, 1 selective norepinephrine reuptake inhibitor, atomoxetine,[99,100] and 2 selective α-2 adrenergic agonists, extended-release guanfacine[101,102] and extended-release clonidine,[103] have also demonstrated efficacy in reducing core symptoms among school-aged children and adolescents, although their effect sizes, —around 0.7 for all 3, are less robust than that of stimulant medications. Norepinephrine reuptake inhibitors and α-2 adrenergic agonists are newer medications, so, in general, the evidence base supporting them is considerably less than that for stimulants, although it was adequate for FDA approval.

A free list of the currently available, FDA-approved medications for ADHD is available online at www.ADHDMedicationGuide.com. Each medication's characteristics are provided to help guide the clinician's prescription choice. With the expanded list of medications, it is less likely that PCCs need to consider the off-label use of other medications. The section on systemic barriers in the Supplemental Information provides suggestions for fostering more realistic and effective payment and communication systems.

Because of the large variability in patients' response to ADHD medication, there is great interest in pharmacogenetic tools that can help clinicians predict the best medication and dose for each child or adolescent. At this time, however, the available scientific literature does not provide sufficient evidence to support their clinical utility given that the genetic variants assayed by these tools have generally not been fully studied with respect to medication effects on ADHD-related symptoms and/or impairment, study findings are inconsistent, or effect sizes are not of sufficient size to ensure clinical utility.[104–109] For that reason, these pharmacogenetics tools are not recommended. In addition, these tests may cost thousands of dollars and are typically not covered by insurance. For a pharmacogenetics tool to be recommended for clinical use, studies would need to reveal (1) the genetic variants assayed have consistent, replicated associations with

medication response; (2) knowledge about a patient's genetic profile would change clinical decision-making, improve outcomes and/or reduce costs or burden; and (3) the acceptability of the test's operating characteristics has been demonstrated (eg, sensitivity, specificity, and reliability).

Side Effects

Stimulants' most common short-term adverse effects are appetite loss, abdominal pain, headaches, and sleep disturbance. The Multimodal Treatment of Attention Deficit Hyperactivity Disorder (MTA) study results identified stimulants as having a more persistent effect on decreasing growth velocity compared to most previous studies.[110] Diminished growth was in the range of 1 to 2 cm from predicted adult height. The results of the MTA study were particularly noted among children who were on higher and more consistently administered doses of stimulants.[110] The effects diminished by the third year of treatment, but no compensatory rebound growth was observed.[110] An uncommon significant adverse effect of stimulants is the occurrence of hallucinations and other psychotic symptoms.[111]

Stimulant medications, on average, increase patient heart rate (HR) and blood pressure (BP) to a mild and clinically insignificant degree (average increases: 1–2 beats per minute for HR and 1–4 mm Hg for systolic and diastolic BP).[112] However, because stimulants have been linked to more substantial increases in HR and BP in a subset of individuals (5%–15%), clinicians are encouraged to monitor these vital signs in patients receiving stimulant treatment.[112] Although concerns have been raised about sudden cardiac death among children and adolescents using stimulant and medications,[113] it is an extremely rare occurrence. In fact, stimulant medications have not been shown to increase the risk of sudden death beyond that observed in children who are not receiving stimulants.[114–118] Nevertheless, before initiating therapy with stimulant medications, it is important to obtain the child or adolescent's history of specific cardiac symptoms in addition to the family history of sudden death, cardiovascular symptoms, Wolff-Parkinson-White syndrome, hypertrophic cardiomyopathy, and long QT syndrome. If any of these risk factors are present, clinicians should obtain additional evaluation to ascertain and address potential safety concerns of stimulant medication use by the child or adolescent.[112,114]

Among nonstimulants, the risk of serious cardiovascular events is extremely low, as it is for stimulants. The 3 nonstimulant medications that are FDA approved to treat ADHD (ie, atomoxetine, guanfacine, and clonidine) may be associated with changes in cardiovascular parameters or other serious cardiovascular events. These events could include increased HR and BP for atomoxetine and decreased HR and BP for guanfacine and clonidine. Clinicians are recommended to not only obtain the personal and family cardiac history, as detailed above, but also to perform additional evaluation if risk factors are present before starting nonstimulant medications (ie, perform an electrocardiogram [ECG] and possibly refer to a pediatric cardiologist if the ECG is not normal).[112]

Additional adverse effects of atomoxetine include initial somnolence and gastrointestinal tract symptoms, particularly if the dosage is increased too rapidly, and decreased appetite.[119–122] Less commonly, an increase in suicidal thoughts has been found; this is noted by an FDA black box warning. Extremely rarely, hepatitis has been associated with atomoxetine. Atomoxetine has also been linked to growth delays compared to expected trajectories in the first 1 to 2 years of treatment, with a return to expected measurements after 2 to 3 years of treatment, on average. Decreases were observed among those who were taller or heavier than average before treatment.[123]

For extended-release guanfacine and extended-release clonidine, adverse effects include somnolence, dry mouth, dizziness, irritability, headache, bradycardia, hypotension, and abdominal pain.[30,124,125] Because rebound hypertension after abrupt guanfacine and clonidine discontinuation has been observed,[126] these medications should be tapered off rather than suddenly discontinued.

Adjunctive Therapy

Adjunctive therapies may be considered if stimulant therapy is not fully effective or limited by side effects. Only extended-release guanfacine and extended-release clonidine have evidence supporting their use as adjunctive therapy with stimulant medications sufficient to have achieved FDA approval.[127] Other medications have been used in combination on an off-label basis, with some limited evidence available to support the efficacy and safety of using atomoxetine in combination with stimulant medications to augment treatment of ADHD.[128]

Special Circumstances: Preschool-Aged Children (Age 4 Years to the Sixth Birthday)

If children do not experience adequate symptom improvement with PTBM, medication can be prescribed for those with moderate-to-severe ADHD. Many young children with ADHD may require medication to achieve maximum improvement; methylphenidate is the recommended first-line pharmacologic treatment of preschool children because of the lack of sufficient rigorous study in the preschool-aged population for nonstimulant ADHD medications and dextroamphetamine. Although amphetamine is the only medication

with FDA approval for use in children younger than 6 years, this authorization was issued at a time when approval criteria were less stringent than current requirements. Hence, the available evidence regarding dextroamphetamine's use in preschool-aged children with ADHD is not adequate to recommend it as an initial ADHD medication treatment at this time.[80]

No nonstimulant medication has received sufficient rigorous study in the preschool-aged population to be recommended for treatment of ADHD of children 4 through 5 years of age.

Although methylphenidate is the ADHD medication with the strongest evidence for safety and efficacy in preschool-aged children, it should be noted that the evidence has not yet met the level needed for FDA approval. Evidence for the use of methylphenidate consists of 1 multisite study of 165 children[83] and 10 other smaller, single-site studies ranging from 11 to 59 children, for a total of 269 children.[129] Seven of the 10 single-site studies revealed efficacy for methylphenidate in preschoolers. Therefore, although there is moderate evidence that methylphenidate is safe and effective in preschool-aged children, its use in this age group remains on an "off-label" basis.

With these caveats in mind, before initiating treatment with medication, the clinician should assess the severity of the child's ADHD. Given current data, only preschool-aged children with ADHD and moderate-to-severe dysfunction should be considered for medication. Severity criteria are symptoms that have persisted for at least 9 months; dysfunction that is manifested in both home and other settings, such as preschool or child care; and dysfunction that has not responded adequately to PTBM.[83]

The decision to consider initiating medication at this age depends, in part, on the clinician's assessment of the estimated developmental impairment, safety risks, and potential consequences if medications are not initiated. Other considerations affecting the treatment of preschool-aged children with stimulant medications include the lack of information and experience about their longer-term effects on growth and brain development, as well as the potential for other adverse effects in this population. It may be helpful to obtain consultation from a mental health specialist with specific experience with preschool-aged children, if possible.

Evidence suggests that the rate of metabolizing methylphenidate is slower in children 4 through 5 years of age, so they should be given a low dose to start; the dose can be increased in smaller increments. Maximum doses have not been adequately studied in preschool-aged children.[83]

Special Circumstances: Adolescents (Age 12 Years to the 18th Birthday)

As noted, before beginning medication treatment of adolescents with newly diagnosed ADHD, clinicians should assess the patient for symptoms of substance use. If active substance use is identified, the clinician should refer the patient to a subspecialist for consultative support and guidance.[2,130–134]

In addition, diversion of ADHD medication (ie, its use for something other than its intended medical purposes) is a special concern among adolescents.[135] Clinicians should monitor the adolescent's symptoms and prescription refill requests for signs of misuse or diversion of ADHD medication, including by parents, classmates, or other acquaintances of the adolescent. The majority of states now require prescriber participation in prescription drug monitoring programs, which can be helpful in identifying and preventing diversion activities. They may consider prescribing nonstimulant medications that minimize abuse potential, such as atomoxetine and extended-release guanfacine or extended-release clonidine.

Given the risks of driving for adolescents with ADHD, including crashes and motor vehicle violations, special concern should be taken to provide medication coverage for symptom control while driving.[79,136,137] Longer-acting or late-afternoon, short-acting medications may be helpful in this regard.[138]

Special Circumstances: Inattention or Hyperactivity/Impulsivity (Problem Level)

Medication is not appropriate for children whose symptoms do not meet *DSM-5* criteria for ADHD. Psychosocial treatments may be appropriate for these children and adolescents. As noted, psychosocial treatments do not require a specific diagnosis of ADHD, and many of the studies on the efficacy of PTBM included children who did not have a specific psychiatric or ADHD diagnosis.

Combination Treatments

Studies indicate that behavioral therapy has positive effects when it is combined with medication for pre-adolescent children.[139] (The combined effects of training interventions and medication have not been studied.)

In the MTA study, researchers found that although the combination of behavioral therapy and stimulant medication was not significantly more effective than treatment with medication alone for ADHD's core symptoms, after correcting for multiple tests in the primary analysis,[139] a secondary analysis of a combined measure of parent and teacher ratings of ADHD symptoms did find a significant advantage for the combination, with a small effect of $d = 0.28$.[140] The combined treatment also offered greater improvements on academic and conduct measures, compared to medication alone, when the ADHD was comorbid with anxiety and the child or adolescent lived in a lower socioeconomic environment.

In addition, parents and teachers of children who received combined therapy reported that they were significantly more satisfied with the treatment plan. Finally, the combination of medication management and behavioral therapy allowed for the use of lower stimulant dosages, possibly reducing the risk of adverse effects.[141]

School Programming and Supports

Encouraging strong family-school partnerships helps the ADHD management process.[142] Psychosocial treatments that include coordinating efforts at school and home may enhance the effects.

Children and adolescents with ADHD may be eligible for services as part of a 504 Rehabilitation Act Plan (504 plan) or special education IEP under the "other health impairment" designation in the Individuals with Disability Education Act (IDEA).[143] (ADHD qualifies as a disability under a 504 plan. It does not qualify under an IEP unless its severity impairs the child's ability to learn. See the PoCA for more details.) It is helpful for clinicians to be aware of the eligibility criteria in their states and school districts to advise families of their options. Eligibility decisions can vary considerably between school districts, and school professionals' independent determinations might not agree with the recommendations of outside clinicians.

There are essentially 2 categories of school-based services for students with ADHD. The first category includes interventions that are intended to help the student independently meet age-appropriate academic and behavioral expectations. Examples of these interventions include daily report cards, training interventions, point systems, and academic remediation of skills. If successful, the student's impairment will resolve, and the student will no longer need services.

The second category is intended to provide changes in the student's program so his or her ADHD-related problems no longer result in failure and cause distress to parents, teachers, and the student.[144] These services are referred to as "accommodations" and include extended time to complete tests and assignments, reduced homework demands, the ability to keep study materials in class, and provision of the teacher's notes to the student. These services are intended to allow the student to accomplish his work successfully and communicate that the student's impairment is acceptable. Accommodations make the student's impairment acceptable and are separate from interventions aimed at improving the students' skills or behaviors. In the absence of such interventions, long-term accommodations may lead to reduced expectations and can lead to the need for accommodations to be maintained throughout the student's education.

Encouraging strong family-school partnerships helps the ADHD management process, and addressing social determinants of health is essential to these partnerships.[145,146] Psychosocial treatments that include coordinating efforts at school and home may enhance the effects.

KAS 6

The PCC should titrate doses of medication for ADHD to achieve maximum benefit with tolerable side effects (Table 9). (Grade B: strong recommendation.)

The MTA study is the landmark study comparing effects of methylphenidate and behavioral treatments in children with ADHD. Investigators compared treatment effects in 4 groups of children who received optimal medication management, optimal behavioral management, combined medication and behavioral management, or community treatment. Children in the optimal medication management and combined medication and behavioral management groups underwent a systematic trial with 4 different doses of methylphenidate, with results suggesting that when this full range of doses is administered, more than 70% of children and adolescents with ADHD are methylphenidate responders.[140]

Authors of other reports suggest that more than 90% of patients will have a beneficial response to 1 of the psychostimulants if a range of medications from both the methylphenidate and amphetamine and/or dextroamphetamine classes

TABLE 9 KAS 6: The PCC should titrate doses of medication for ADHD to achieve maximum benefit with tolerable side effects. (Grade B: strong recommendation.)

Aggregate evidence quality	Grade B
Benefits	The optimal dose of medication is required to reduce core symptoms to, or close to, the levels of children without ADHD.
Risks, harm, cost	Higher levels of medication increase the chances of side effects.
Benefit-harm assessment	The importance of adequately treating ADHD outweighs the risk of adverse effects.
Intentional vagueness	None.
Role of patient preferences	The families' preferences and comfort need to be taken into consideration in developing a titration plan, as they are likely to predict engagement and persistence with a treatment.
Exclusions	None
Strength	Strong recommendation
Key references	Jensen et al[140]; Solanto[147]; Brinkman et al[149]

are tried.[147] Of note, children in the MTA study who received care in the community as usual, either from a clinician they chose or to whom their family had access, showed less beneficial results compared with children who received optimal medication management. The explanation offered by the study investigators was that the community treatment group received lower medication doses and less frequent monitoring than the optimal medication management group.

A child's response to stimulants is variable and unpredictable. For this reason, it is recommended to titrate from a low dose to one that achieves a maximum, optimal effect in controlling symptoms without adverse effects. Calculating the dose on the basis of milligrams per kilogram has not usually been helpful because variations in dose have not been found to be related to height or weight. In addition, because stimulant medication effects are seen rapidly, titration can be accomplished in a relatively short time period. Stimulant medications can be effectively titrated on a 7-day basis, but in urgent situations, they may be effectively titrated in as few as 3 days.[140]

Parent and child and adolescent education is an important component in the chronic illness model to ensure cooperation in efforts to achieve appropriate titration, remembering that the parents themselves may be significantly challenged by ADHD.[148,149] The PCC should alert parents and children that changing medication dose and occasionally changing a medication may be necessary for optimal medication management, may require a few months to achieve optimal success, and that medication efficacy should be monitored at regular intervals.

By the 3-year (ie, 36-month) follow-up to the MTA interventions, there were no differences among the 4 groups (ie, optimal medications management, optimal behavioral management, a combination of medication and behavioral management, and community treatment). This equivalence in poststudy outcomes may, however, have been attributable to convergence in ongoing treatments received for the 4 groups. After the initial 14-month intervention, the children no longer received the careful monthly monitoring provided by the study and went back to receiving care from their community providers; therefore, they all effectively received a level of ongoing care consistent with the "community treatment" study arm of the study. After leaving the MTA trial, medications and doses varied for the children who had been in the optimal medication management or combined medication and behavioral management groups, and a number stopped taking ADHD medication. On the other hand, some children who had been in the optimal behavioral management group started taking medication after leaving the trial. The results further emphasize the need to treat ADHD as a chronic illness and provide continuity of care and, where possible, provide a medical home.[140]

See the PoCA for more on implementation of this KAS.

KAS 7

The PCC, if trained or experienced in diagnosing comorbid conditions, may initiate treatment of such conditions or make a referral to an appropriate subspecialist for treatment. After detecting possible comorbid conditions, if the PCC is not trained or experienced in making the diagnosis or initiating treatment, the patient should be referred to an appropriate subspecialist to make the diagnosis and initiate treatment (Table 10). (Grade C: recommendation.)

The effect of comorbid conditions on ADHD treatment is variable. In some cases, treatment of the ADHD may resolve the comorbid condition. For example, treatment of ADHD may lead to improvement in coexisting aggression and/or oppositional defiant, depressive, or anxiety symptoms.[150,151]

Sometimes, however, the comorbid condition may require treatment in addition to the ADHD treatment. If the PCC is confident of his or her ability to diagnose and treat certain comorbid conditions, the PCC may do so. The PCC may benefit from additional consultative support and guidance from a mental health subspecialist or may need to refer a child with ADHD and comorbid conditions, such as severe mood or anxiety disorders, to subspecialists for assessment and management. The subspecialists could include child and adolescent psychiatrists, clinical child psychologists, developmental-behavioral pediatricians, neurodevelopmental disability physicians, child neurologists, or child- or school-based evaluation teams.

IMPLEMENTATION: PREPARING THE PRACTICE

It is generally the role of the primary care pediatrician to manage mild-to-moderate ADHD, anxiety, depression, and substance use. The AAP statement "The Future of Pediatrics: Mental Health Competencies for Pediatric Primary Care" describes the competencies needed in both pediatric primary and specialty care to address the social-emotional and mental health needs of children and families.[152] Broadly, these include incorporating mental health content and tools into health promotion, prevention, and primary care intervention, becoming knowledgeable about use of evidence-based treatments, and participating as a team member and comanaging with pediatric and mental health specialists.

The recommendations made in this guideline are intended to be integrated with the broader mental health algorithm developed as part of the AAP Mental Health Initiatives.[2,133,153] Pediatricians have unique opportunities

TABLE 10 KAS 7: The PCC, if trained or experienced in diagnosing comorbid conditions, may initiate treatment of such conditions or make a referral to an appropriate subspecialist for treatment. After detecting possible comorbid conditions, if the PCC is not trained or experienced in making the diagnosis or initiating treatment, the patient should be referred to an appropriate subspecialist to make the diagnosis and initiate treatment. (Grade C: recommendation.)

Aggregate evidence quality	Grade C
Benefits	Clinicians are most effective when they know the limits of their practice to diagnose comorbid conditions and are aware of resources in their community.
Risks, harm, cost	Under-identification or inappropriate identification of comorbidities can lead to inadequate or inappropriate treatments.
Benefit-harm assessment	The importance of adequately identifying and addressing comorbidities outweighs the risk of inappropriate referrals or treatments.
Intentional vagueness	None.
Role of patient preferences	The families' preferences and comfort need to be taken into consideration in identifying and treating or referring their patients with comorbidities, as they are likely to predict engagement and persistence with a treatment.
Exclusions	None.
Strength	Recommendation.
Key references	Pliszka et al[150]; Pringsheim et al[151]

to identify conditions, including ADHD, intervene early, and partner with both families and specialists for the benefit of children's health. A wealth of useful information is available at the AAP Mental Health Initiatives Web site (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Mental-Health/Pages/Tips-For-Pediatricians.aspx).

It is also important for PCCs to be aware of health disparities and social determinants that may impact patient outcomes and strive to provide culturally appropriate care to all children and adolescents in their practice.[145,146,154,155]

The accompanying PoCA provides supplemental information to support PCCs as they implement this guideline's recommendations. In particular, the PoCA describes steps for preparing the practice that provide useful recommendations to clinicians. For example, the PoCA includes information about using standardized rating scales to diagnose ADHD, assessing for comorbid conditions, documenting all aspects of the diagnostic and treatment procedures in the patient's records, monitoring the patient's treatment and outcomes, and providing families with written management plans.

The AAP acknowledges that some PCCs may not have the training, experience, or resources to diagnose and treat children and adolescents with ADHD, especially if severity or comorbid conditions make these patients complex to manage. In these situations, comanagement with specialty clinicians is recommended. The SDBP is developing a guideline to address such complex cases and aid pediatricians and other PCCs to manage these cases; the SDBP currently expects to publish this document in 2019.[67]

AREAS FOR FUTURE RESEARCH

There is a need to conduct research on topics pertinent to the diagnosis and treatment of ADHD, developmental variations, and problems in children and adolescents in primary care. These research opportunities include the following:

- assessment of ADHD and its common comorbidities: anxiety, depression, learning disabilities, and autism spectrum disorder;
- identification and/or development of reliable instruments suitable for use in primary care to assess the nature or degree of functional impairment in children and adolescents with ADHD and to monitor improvement over time;
- refinement of developmentally informed assessment procedures for evaluating ADHD in preschoolers;
- study of medications and other therapies used clinically but not FDA approved for ADHD;
- determination of the optimal schedule for monitoring children and adolescents with ADHD, including factors for adjusting that schedule according to age, symptom severity, and progress reports;
- evaluation of the effectiveness and adverse effects of medications used in combination, such as a stimulant with an α-adrenergic agent, selective serotonin reuptake inhibitor, or atomoxetine;
- evaluation of processes of care to assist PCCs to identify and treat comorbid conditions;
- evaluation of the effectiveness of various school-based interventions;
- comparisons of medication use and effectiveness in different ages, including both harms and benefits;
- development of methods to involve parents, children, and adolescents in their own care and improve adherence to both psychosocial and medication treatments;
- conducting research into psychosocial treatments, such as cognitive behavioral therapy and cognitive training, among others;

- development of standardized and documented tools to help primary care providers identify comorbid conditions;
- development of effective electronic and Web-based systems to help gather information to diagnose and monitor children and adolescents with ADHD;
- improvements to systems for communicating with schools, mental health professionals, and other community agencies to provide effective collaborative care;
- development of more objective measures of performance to more objectively monitor aspects of severity, disability, or impairment;
- assessment of long-term outcomes for children in whom ADHD was first diagnosed at preschool ages; and
- identification and implementation of ideas to address the barriers that hamper the implementation of these guidelines and the PoCA.

CONCLUSIONS

Evidence is clear with regard to the legitimacy of the diagnosis of ADHD and the appropriate diagnostic criteria and procedures required to establish a diagnosis, identify comorbid conditions, and effectively treat with both psychosocial and pharmacologic interventions. The steps required to sustain appropriate treatments and achieve successful long-term outcomes remain challenging, however.

As noted, this clinical practice guideline is supported by 2 accompanying documents available in the Supplemental Information: the PoCA and the article on systemic barriers to the car of children and adolescents with ADHD. Full implementation of the guideline's KASs, the PoCA, and the recommendations to address barriers to care may require changes in office procedures and the identification of community resources. Fully addressing systemic barriers requires identifying local, state, and national entities with which to partner to advance solutions and manifest change.[156]

SUBCOMMITTEE ON CHILDREN AND ADOLESCENTS WITH ADHD (OVERSIGHT BY THE COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY)

Mark L. Wolraich, MD, FAAP, Chairperson, Section on Developmental Behavioral Pediatrics
Joseph F. Hagan Jr, MD, FAAP, Vice Chairperson, Section on Developmental Behavioral Pediatrics
Carla Allan, PhD, Society of Pediatric Psychology
Eugenia Chan, MD, MPH, FAAP, Implementation Scientist
Dale Davison, MSpEd, PCC, Parent Advocate, Children and Adolescents with Attention-Deficit/Hyperactivity Disorder
Marian Earls, MD, MTS, FAAP, Mental Health Leadership Work Group
Steven W. Evans, PhD, Clinical Psychologist
Tanya Froehlich, MD, FAAP, Section on Developmental Behavioral Pediatrics/Society for Developmental and Behavioral Pediatrics
Jennifer Frost, MD, FAAFP, American Academy of Family Physicians
Joseph R. Holbrook, PhD, MPH, Epidemiologist, Centers for Disease Control and Prevention
Herschel Robert Lessin, MD, FAAP, Section on Administration and Practice Management
Karen L. Pierce, MD, DFAACAP, American Academy of Child and Adolescent Psychiatry
Christoph Ulrich Lehmann, MD, FAAP, Partnership for Policy Implementation
Jonathan D. Winner, MD, FAAP, Committee on Practice and Ambulatory Medicine
William Zurhellen, MD, FAAP, Section on Administration and Practice Management

STAFF

Kymika Okechukwu, MPA, Senior Manager, Evidence-Based Medicine Initiatives
Jeremiah Salmon, MPH, Program Manager, Policy Dissemination and Implementation

CONSULTANT

Susan K. Flinn, MA, Medical Editor

ABBREVIATIONS

AAP: American Academy of Pediatrics
ADHD: attention-deficit/hyperactivity disorder
ADHD/C: attention-deficit/hyperactivity disorder combined presentation
ADHD/HI: attention-deficit/hyperactivity disorder primarily of the hyperactive-impulsive presentation
ADHD/I: attention-deficit/hyperactivity disorder primarily of the inattentive presentation
AHRQ: Agency for Healthcare Research and Quality
BP: blood pressure
CHADD: Children and Adults with Attention-Deficit/Hyperactivity Disorder
DSM-5: *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*
DSM-IV: *Diagnostic and Statistical Manual of Mental Disorders Fourth Edition*
DSM-PC: *Diagnostic and Statistical Manual for Primary Care*
ECG: electrocardiogram
eTNS: external trigeminal nerve stimulation
FDA: US Food and Drug Administration
HR: heart rate
IDEA: Individuals with Disability Education Act
IEP: Individualized Education Program
KAS: key action statement
MTA: The Multimodal Treatment of Attention Deficit Hyperactivity Disorder
PCC: primary care clinician
PoCA: process of care algorithm
PTBM: parent training in behavior management
SDBP: Society for Developmental and Behavioral Pediatrics

[v]American Academy of Pediatrics, Itasca, Illinois; [w]American Academy of Child and Adolescent Psychiatry, Washington, District of Columbia; [x]Feinberg School of Medicine, Northwestern University, Chicago, Illinois; [y]Atlanta, Georgia; and [z]Holderness, New Hampshire

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention. Dr Holbrook was not an author of the accompanying supplemental section on barriers to care.

DOI: https://doi.org/10.1542/peds.2019-2528

Address correspondence to Mark L. Wolraich, MD, FAAP. Email: mark-wolraich@ouhsc.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the American Academy of Pediatrics board of directors. Dr Allan reports a relationship with ADDitude Magazine; Dr Chan reports relationships with TriVox Health and Wolters Kluwer; Dr Lehmann reports relationships with International Medical Informatics Association, Springer Publishing, and Thieme Publishing Group; Dr Wolraich reports a Continuing Medical Education trainings relationship with the Resource for Advancing Children's Health Institute; the other authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. American Academy of Pediatrics. Subcommittee on Attention-Deficit/Hyperactivity Disorder, Steering Committee on Quality Improvement and Management. ADHD: Clinical guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. *Pediatrics*. 2011;128(5):1007–1022
2. American Academy of Pediatrics Task Force on Mental Health. *Addressing Mental Health Concerns in Primary Care: A Clinician's Toolkit [CD-ROM]*. Elk Grove Village, IL: American Academy of Pediatrics; 2010
3. Pastor PN, Reuben CA. Racial and ethnic differences in ADHD and LD in young school-age children: parental reports in the National Health Interview Survey. *Public Health Rep*. 2005;120(4):383–392
4. US Department of Health and Human Services; Health Resources and Services Administration. Designated health professional shortage areas statistics: designated HPSA quarterly summary. Rockville, MD: Health Resources and Services Administration; 2018
5. Pelech D, Hayford T. Medicare advantage and commercial prices for mental health services. *Health Aff (Millwood)*. 2019;38(2):262–267
6. Melek SP, Perlman D, Davenport S. *Differential Reimbursement of Psychiatric Services by Psychiatrists and Other Medical Providers*. Seattle, WA: Milliman;2017
7. Holbrook JR, Bitsko RH, Danielson ML, Visser SN. Interpreting the prevalence of mental disorders in children: tribulation and triangulation. *Health Promot Pract*. 2017;18(1):5–7
8. Thomas R, Sanders S, Doust J, Beller E, Glasziou P. Prevalence of attention-deficit/hyperactivity disorder: a systematic review and meta-analysis. *Pediatrics*. 2015;135(4). Available at: www.pediatrics.org/cgi/content/full/135/4/e994
9. Wolraich ML, McKeown RE, Visser SN, et al. The prevalence of ADHD: its diagnosis and treatment in four school districts across two states. *J Atten Disord*. 2014;18(7):563–575
10. Rowland AS, Skipper BJ, Umbach DM, et al. The prevalence of ADHD in a population-based sample. *J Atten Disord*. 2015;19(9):741–754
11. Danielson ML, Bitsko RH, Ghandour RM, Holbrook JR, Kogan MD, Blumberg SJ. Prevalence of parent-reported ADHD diagnosis and associated treatment among U.S. children and adolescents, 2016. *J Clin Child Adolesc Psychol*. 2018; 47(2):199–212
12. Visser SN, Zablotsky B, Holbrook JR, et al. *National Health Statistics Reports, No 81: Diagnostic Experiences of Children with Attention-Deficit/Hyperactivity Disorder*. Hyattsville, MD: National Center for Health Statistics; 2015
13. Molina BS, Hinshaw SP, Swanson JM, et al; MTA Cooperative Group. The MTA at 8 years: prospective follow-up of children treated for combined-type ADHD in a multisite study. *J Am Acad Child Adolesc Psychiatry*. 2009;48(5):484–500
14. Holbrook JR, Cuffe SP, Cai B, et al. Persistence of parent-reported ADHD symptoms from childhood through adolescence in a community sample. *J Atten Disord*. 2016;20(1):11–20

15. Mueller KL, Tomblin JB. Examining the comorbidity of language disorders and ADHD. *Top Lang Disord*. 2012;32(3): 228–246

16. Pastor PN, Reuben CA, Duran CR, Hawkins LD. *Association Between Diagnosed ADHD and Selected Characteristics Among Children Aged 4–17 Years: United States, 2011–2013. NCHS Data Brief, No. 201*. Hyattsville, MD: National Center for Health Statistics; 2015

17. Elia J, Ambrosini P, Berrettini W. ADHD characteristics: I. Concurrent co-morbidity patterns in children & adolescents. *Child Adolesc Psychiatry Ment Health*. 2008;2(1):15

18. Centers for Disease Control and Prevention (CDC). Mental health in the United States. Prevalence of diagnosis and medication treatment for attention-deficit/hyperactivity disorder--United States, 2003. *MMWR Morb Mortal Wkly Rep*. 2005;54(34):842–847

19. Cuffe SP, Visser SN, Holbrook JR, et al. ADHD and psychiatric comorbidity: functional outcomes in a school-based sample of children [published online ahead of print November 25, 2015]. *J Atten Disord*. doi:10.1177/1087054715613437

20. Gaub M, Carlson CL. Gender differences in ADHD: a meta-analysis and critical review. *J Am Acad Child Adolesc Psychiatry*. 1997;36(8):1036–1045

21. Tung I, Li JJ, Meza JI, et al. Patterns of comorbidity among girls with ADHD: a meta-analysis. *Pediatrics*. 2016;138(4): e20160430

22. Layton TJ, Barnett ML, Hicks TR, Jena AB. Attention deficit-hyperactivity disorder and month of school enrollment. *N Engl J Med*. 2018;379(22): 2122–2130

23. Kemper AR, Maslow GR, Hill S, et al. *Attention Deficit Hyperactivity Disorder: Diagnosis and Treatment in Children and Adolescents. Comparative Effectiveness Reviews, No. 203*. Rockville, MD: Agency for Healthcare Research and Quality; 2018

24. Pelham WE Jr, Wheeler T, Chronis A. Empirically supported psychosocial treatments for attention deficit hyperactivity disorder. *J Clin Child Psychol*. 1998;27(2):190–205

25. Evans SW, Owens JS, Wymbs BT, Ray AR. Evidence-based psychosocial treatments for children and adolescents with attention deficit/hyperactivity disorder. *J Clin Child Adolesc Psychol*. 2018;47(2):157–198

26. Pelham WE Jr, Fabiano GA. Evidence-based psychosocial treatments for attention-deficit/hyperactivity disorder. *J Clin Child Adolesc Psychol*. 2008;37(1): 184–214

27. American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877

28. Visser SN, Lesesne CA, Perou R. National estimates and factors associated with medication treatment for childhood attention-deficit/hyperactivity disorder. *Pediatrics*. 2007;119(suppl 1):S99–S106

29. Centers for Disease Control and Prevention (CDC). Increasing prevalence of parent-reported attention-deficit/hyperactivity disorder among children–United States, 2003 and 2007. *MMWR Morb Mortal Wkly Rep*. 2010;59(44):1439–1443

30. Egger HL, Kondo D, Angold A. The epidemiology and diagnostic issues in preschool attention-deficit/hyperactivity disorder: a review. *Infants Young Child*. 2006;19(2):109–122

31. Wolraich ML, Wibbelsman CJ, Brown TE, et al. Attention-deficit/hyperactivity disorder among adolescents: a review of the diagnosis, treatment, and clinical implications. *Pediatrics*. 2005;115(6): 1734–1746

32. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*. 5th ed. Arlington, VA: American Psychiatric Association; 2013

33. Lahey BB, Pelham WE, Stein MA, et al. Validity of DSM-IV attention-deficit/hyperactivity disorder for younger children. *J Am Acad Child Adolesc Psychiatry*. 1998;37(7):695–702

34. Pavuluri MN, Luk SL, McGee R. Parent reported preschool attention deficit hyperactivity: measurement and validity. *Eur Child Adolesc Psychiatry*. 1999;8(2):126–133

35. Harvey EA, Youngwirth SD, Thakar DA, Errazuriz PA. Predicting attention-deficit/hyperactivity disorder and oppositional defiant disorder from preschool diagnostic assessments. *J Consult Clin Psychol*. 2009;77(2): 349–354

36. Keenan K, Wakschlag LS. More than the terrible twos: the nature and severity of behavior problems in clinic-referred preschool children. *J Abnorm Child Psychol*. 2000;28(1):33–46

37. Gadow KD, Nolan EE, Litcher L, et al. Comparison of attention-deficit/hyperactivity disorder symptom subtypes in Ukrainian schoolchildren. *J Am Acad Child Adolesc Psychiatry*. 2000;39(12):1520–1527

38. Sprafkin J, Volpe RJ, Gadow KD, Nolan EE, Kelly K. A DSM-IV-referenced screening instrument for preschool children: the Early Childhood Inventory-4. *J Am Acad Child Adolesc Psychiatry*. 2002;41(5):604–612

39. Poblano A, Romero E. ECI-4 screening of attention deficit-hyperactivity disorder and co-morbidity in Mexican preschool children: preliminary results. *Arq Neuropsiquiatr*. 2006;64(4):932–936

40. American Academy of Pediatrics. *Mental Health Screening and Assessment Tools for Primary Care*. Elk Grove Village, IL: American Academy of Pediatrics; 2012. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Mental-Health/Documents/MH_ScreeningChart.pdf. Accessed September 8, 2019

41. DuPaul GJ, Power TJ, Anastopoulos AD, Reid R. *ADHD Rating Scale – 5 for Children and Adolescents: Checklists, Norms, and Clinical Interpretation*. 2nd ed. New York, NY: Guilford Press; 2016

42. McGoey KE, DuPaul GJ, Haley E, Shelton TL. Parent and teacher ratings of attention-deficit/hyperactivity disorder in preschool: the ADHD rating scale-IV preschool version. *J Psychopathol Behav Assess*. 2007;29(4):269–276

43. Young J. Common comorbidities seen in adolescents with attention-deficit/hyperactivity disorder. *Adolesc Med State Art Rev*. 2008;19(2):216–228, vii

44. Freeman RD; Tourette Syndrome International Database Consortium. Tic disorders and ADHD: answers from

a world-wide clinical dataset on Tourette syndrome. *Eur Child Adolesc Psychiatry*. 2007;16(suppl 1):15–23

45. Riggs PD. Clinical approach to treatment of ADHD in adolescents with substance use disorders and conduct disorder. *J Am Acad Child Adolesc Psychiatry*. 1998;37(3):331–332
46. Sibley MH, Pelham WE, Molina BSG, et al. Diagnosing ADHD in adolescence. *J Consult Clin Psychol*. 2012;80(1): 139–150
47. Kratochvil CJ, Vaughan BS, Stoner JA, et al. A double-blind, placebo-controlled study of atomoxetine in young children with ADHD. *Pediatrics*. 2011;127(4). Available at: www.pediatrics.org/cgi/content/full/127/4/e862
48. Harrison AG, Edwards MJ, Parker KC. Identifying students faking ADHD: preliminary findings and strategies for detection. *Arch Clin Neuropsychol*. 2007; 22(5):577–588
49. Wolraich ML, Felice ME, Drotar DD. *The Classification of Child and Adolescent Mental Conditions in Primary Care: Diagnostic and Statistical Manual for Primary Care (DSM-PC), Child and Adolescent Version*. Elk Grove Village, IL: American Academy of Pediatrics; 1996
50. Rowland AS, Lesesne CA, Abramowitz AJ. The epidemiology of attention-deficit/hyperactivity disorder (ADHD): a public health view. *Ment Retard Dev Disabil Res Rev*. 2002;8(3):162–170
51. Cuffe SP, Moore CG, McKeown RE. Prevalence and correlates of ADHD symptoms in the national health interview survey. *J Atten Disord*. 2005; 9(2):392–401
52. Pastor PN, Reuben CA. Diagnosed attention deficit hyperactivity disorder and learning disability: United States, 2004-2006. *Vital Health Stat 10*. 2008; 10(237):1–14
53. Biederman J, Faraone SV, Wozniak J, Mick E, Kwon A, Aleardi M. Further evidence of unique developmental phenotypic correlates of pediatric bipolar disorder: findings from a large sample of clinically referred preadolescent children assessed over the last 7 years. *J Affect Disord*. 2004; 82(suppl 1):S45–S58
54. Biederman J, Kwon A, Aleardi M, et al. Absence of gender effects on attention deficit hyperactivity disorder: findings in nonreferred subjects. *Am J Psychiatry*. 2005;162(6):1083–1089
55. Biederman J, Ball SW, Monuteaux MC, et al. New insights into the comorbidity between ADHD and major depression in adolescent and young adult females. *J Am Acad Child Adolesc Psychiatry*. 2008;47(4):426–434
56. Biederman J, Melmed RD, Patel A, McBurnett K, Donahue J, Lyne A. Long-term, open-label extension study of guanfacine extended release in children and adolescents with ADHD. *CNS Spectr*. 2008;13(12):1047–1055
57. Crabtree VM, Ivanenko A, Gozal D. Clinical and parental assessment of sleep in children with attention-deficit/hyperactivity disorder referred to a pediatric sleep medicine center. *Clin Pediatr (Phila)*. 2003;42(9):807–813
58. LeBourgeois MK, Avis K, Mixon M, Olmi J, Harsh J. Snoring, sleep quality, and sleepiness across attention-deficit/hyperactivity disorder subtypes. *Sleep*. 2004;27(3):520–525
59. Chan E, Zhan C, Homer CJ. Health care use and costs for children with attention-deficit/hyperactivity disorder: national estimates from the Medical Expenditure Panel Survey. *Arch Pediatr Adolesc Med*. 2002;156(5):504–511
60. Newcorn JH, Miller SR, Ivanova I, et al. Adolescent outcome of ADHD: impact of childhood conduct and anxiety disorders. *CNS Spectr*. 2004;9(9): 668–678
61. Sung V, Hiscock H, Sciberras E, Efron D. Sleep problems in children with attention-deficit/hyperactivity disorder: prevalence and the effect on the child and family. *Arch Pediatr Adolesc Med*. 2008;162(4):336–342
62. Froehlich TE, Fogler J, Barbaresi WJ, Elsayed NA, Evans SW, Chan E. Using ADHD medications to treat coexisting ADHD and reading disorders: a systematic review. *Clin Pharmacol Ther*. 2018;104(4):619–637
63. Rothenberger A, Roessner V. The phenomenology of attention-deficit/hyperactivity disorder in tourette syndrome. In: Martino D, Leckman JF, eds. *Tourette Syndrome*. New York, NY: Oxford University Press; 2013:26–49
64. Antshel KM, Zhang-James Y, Faraone SV. The comorbidity of ADHD and autism spectrum disorder. *Expert Rev Neurother*. 2013;13(10):1117–1128
65. Mahajan R, Bernal MP, Panzer R, et al; Autism Speaks Autism Treatment Network Psychopharmacology Committee. Clinical practice pathways for evaluation and medication choice for attention-deficit/hyperactivity disorder symptoms in autism spectrum disorders. *Pediatrics*. 2012;130(suppl 2):S125–S138
66. Larson K, Russ SA, Kahn RS, Halfon N. Patterns of comorbidity, functioning, and service use for US children with ADHD, 2007. *Pediatrics*. 2011;127(3): 462–470
67. Society for Developmental and Behavioral Pediatrics. ADHD special interest group. Available at: www.sdbp.org/committees/sig-adhd.cfm. Accessed September 8, 2019
68. Medical Home Initiatives for Children With Special Needs Project Advisory Committee. American Academy of Pediatrics. The medical home. *Pediatrics*. 2002;110(1 pt 1):184–186
69. Brito A, Grant R, Overholt S, et al. The enhanced medical home: the pediatric standard of care for medically underserved children. *Adv Pediatr*. 2008;55:9–28
70. Sibley MH, Swanson JM, Arnold LE, et al; MTA Cooperative Group. Defining ADHD symptom persistence in adulthood: optimizing sensitivity and specificity. *J Child Psychol Psychiatry*. 2017;58(6): 655–662
71. Chang Z, D'Onofrio BM, Quinn PD, Lichtenstein P, Larsson H. Medication for attention-deficit/hyperactivity disorder and risk for depression: a nationwide longitudinal cohort study. *Biol Psychiatry*. 2016;80(12):916–922
72. Biederman J, Monuteaux MC, Spencer T, Wilens TE, Faraone SV. Do stimulants protect against psychiatric disorders in youth with ADHD? A 10-year follow-up study. *Pediatrics*. 2009;124(1):71–78
73. Barbaresi WJ, Katusic SK, Colligan RC, Weaver AL, Jacobsen SJ. Modifiers of long-term school outcomes for children with attention-deficit/hyperactivity disorder: does treatment with

stimulant medication make a difference? Results from a population-based study. *J Dev Behav Pediatr*. 2007; 28(4):274–287

74. Scheffler RM, Brown TT, Fulton BD, Hinshaw SP, Levine P, Stone S. Positive association between attention-deficit/hyperactivity disorder medication use and academic achievement during elementary school. *Pediatrics*. 2009; 123(5):1273–1279
75. Barbaresi WJ, Colligan RC, Weaver AL, Voigt RG, Killian JM, Katusic SK. Mortality, ADHD, and psychosocial adversity in adults with childhood ADHD: a prospective study. *Pediatrics*. 2013;131(4):637–644
76. Chang Z, Lichtenstein P, Långström N, Larsson H, Fazel S. Association between prescription of major psychotropic medications and violent reoffending after prison release. *JAMA*. 2016; 316(17):1798–1807
77. Lichtenstein P, Halldner L, Zetterqvist J, et al. Medication for attention deficit-hyperactivity disorder and criminality. *N Engl J Med*. 2012;367(21):2006–2014
78. Chang Z, Quinn PD, Hur K, et al. Association between medication use for attention-deficit/hyperactivity disorder and risk of motor vehicle crashes. *JAMA Psychiatry*. 2017;74(6):597–603
79. Chang Z, Lichtenstein P, D'Onofrio BM, Sjölander A, Larsson H. Serious transport accidents in adults with attention-deficit/hyperactivity disorder and the effect of medication: a population-based study. *JAMA Psychiatry*. 2014;71(3):319–325
80. Harstad E, Levy S; Committee on Substance Abuse. Attention-deficit/hyperactivity disorder and substance abuse. *Pediatrics*. 2014;134(1). Available at: www.pediatrics.org/cgi/content/full/134/1/e293
81. Dalsgaard S, Leckman JF, Mortensen PB, Nielsen HS, Simonsen M. Effect of drugs on the risk of injuries in children with attention deficit hyperactivity disorder: a prospective cohort study. *Lancet Psychiatry*. 2015;2(8):702–709
82. Raman SR, Marshall SW, Haynes K, Gaynes BN, Naftel AJ, Stürmer T. Stimulant treatment and injury among children with attention deficit hyperactivity disorder: an application of the self-controlled case series study design. *Inj Prev*. 2013;19(3):164–170
83. Greenhill L, Kollins S, Abikoff H, et al. Efficacy and safety of immediate-release methylphenidate treatment for preschoolers with ADHD. *J Am Acad Child Adolesc Psychiatry*. 2006;45(11): 1284–1293
84. Children and Adults with Attention-Deficit/Hyperactivity Disorder. CHADD. Available at: www.chadd.org. Accessed September 8, 2019
85. Sonuga-Barke EJ, Daley D, Thompson M, Laver-Bradbury C, Weeks A. Parent-based therapies for preschool attention-deficit/hyperactivity disorder: a randomized, controlled trial with a community sample. *J Am Acad Child Adolesc Psychiatry*. 2001;40(4):402–408
86. Van Cleave J, Leslie LK. Approaching ADHD as a chronic condition: implications for long-term adherence. *J Psychosoc Nurs Ment Health Serv*. 2008;46(8):28–37
87. Webster-Stratton CH, Reid MJ, Beauchaine T. Combining parent and child training for young children with ADHD. *J Clin Child Adolesc Psychol*. 2011;40(2):191–203
88. Shepard SA, Dickstein S. Preventive intervention for early childhood behavioral problems: an ecological perspective. *Child Adolesc Psychiatr Clin N Am*. 2009;18(3):687–706
89. Evans SW, Langberg JM, Egan T, Molitor SJ. Middle school-based and high school-based interventions for adolescents with ADHD. *Child Adolesc Psychiatr Clin N Am*. 2014;23(4):699–715
90. McGough JJ, Sturm A, Cowen J, et al. Double-blind, sham-controlled, pilot study of trigeminal nerve stimulation for attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2019;58(4):403–411.e3
91. Robin AL, Foster SL. *The Guilford Family Therapy Series. Negotiating Parent–Adolescent Conflict: A Behavioral–Family Systems Approach*. New York, NY: Guilford Press; 1989
92. Barkley RA, Guevremont DC, Anastopoulos AD, Fletcher KE. A comparison of three family therapy programs for treating family conflicts in adolescents with attention-deficit hyperactivity disorder. *J Consult Clin Psychol*. 1992;60(3):450–462
93. Fabiano GA, Schatz NK, Morris KL, et al. Efficacy of a family-focused intervention for young drivers with attention-deficit hyperactivity disorder. *J Consult Clin Psychol*. 2016;84(12):1078–1093
94. Sibley MH, Graziano PA, Kuriyan AB, et al. Parent-teen behavior therapy + motivational interviewing for adolescents with ADHD. *J Consult Clin Psychol*. 2016;84(8):699–712
95. Evans SW, Langberg JM, Schultz BK, et al. Evaluation of a school-based treatment program for young adolescents with ADHD. *J Consult Clin Psychol*. 2016;84(1):15–30
96. Langberg JM, Dvorsky MR, Molitor SJ, et al. Overcoming the research-to-practice gap: a randomized trial with two brief homework and organization interventions for students with ADHD as implemented by school mental health providers. *J Consult Clin Psychol*. 2018; 86(1):39–55
97. Schultz BK, Evans SW, Langberg JM, Schoemann AM. Outcomes for adolescents who comply with long-term psychosocial treatment for ADHD. *J Consult Clin Psychol*. 2017;85(3): 250–261
98. Newcorn JH, Kratochvil CJ, Allen AJ, et al; Atomoxetine/Methylphenidate Comparative Study Group. Atomoxetine and osmotically released methylphenidate for the treatment of attention deficit hyperactivity disorder: acute comparison and differential response. *Am J Psychiatry*. 2008;165(6): 721–730
99. Cheng JY, Chen RY, Ko JS, Ng EM. Efficacy and safety of atomoxetine for attention-deficit/hyperactivity disorder in children and adolescents-meta-analysis and meta-regression analysis. *Psychopharmacology (Berl)*. 2007; 194(2):197–209
100. Michelson D, Allen AJ, Busner J, et al. Once-daily atomoxetine treatment for children and adolescents with attention deficit hyperactivity disorder: a randomized, placebo-controlled study. *Am J Psychiatry*. 2002;159(11): 1896–1901
101. Biederman J, Melmed RD, Patel A, et al; SPD503 Study Group. A randomized,

double-blind, placebo-controlled study of guanfacine extended release in children and adolescents with attention-deficit/hyperactivity disorder. *Pediatrics*. 2008;121(1). Available at: www.pediatrics.org/cgi/content/full/121/1/e73

102. Sallee FR, Lyne A, Wigal T, McGough JJ. Long-term safety and efficacy of guanfacine extended release in children and adolescents with attention-deficit/hyperactivity disorder. *J Child Adolesc Psychopharmacol*. 2009; 19(3):215–226

103. Jain R, Segal S, Kollins SH, Khayrallah M. Clonidine extended-release tablets for pediatric patients with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2011; 50(2):171–179

104. Brown JT, Bishop JR. Atomoxetine pharmacogenetics: associations with pharmacokinetics, treatment response and tolerability. *Pharmacogenomics*. 2015;16(13):1513–1520

105. Kambeitz J, Romanos M, Ettinger U. Meta-analysis of the association between dopamine transporter genotype and response to methylphenidate treatment in ADHD. *Pharmacogenomics J*. 2014;14(1):77–84

106. Bruxel EM, Akutagava-Martins GC, Salatino-Oliveira A, et al. ADHD pharmacogenetics across the life cycle: new findings and perspectives. *Am J Med Genet B Neuropsychiatr Genet*. 2014;165B(4):263–282

107. Kieling C, Genro JP, Hutz MH, Rohde LA. A current update on ADHD pharmacogenomics. *Pharmacogenomics*. 2010;11(3): 407–419

108. Froehlich TE, McGough JJ, Stein MA. Progress and promise of attention-deficit hyperactivity disorder pharmacogenetics. *CNS Drugs*. 2010; 24(2):99–117

109. Joensen B, Meyer M, Aagaard L. Specific genes associated with adverse events of methylphenidate use in the pediatric population: a systematic literature review. *J Res Pharm Pract*. 2017;6(2): 65–72

110. Swanson JM, Elliott GR, Greenhill LL, et al. Effects of stimulant medication on growth rates across 3 years in the MTA follow-up. *J Am Acad Child Adolesc Psychiatry*. 2007;46(8):1015–1027

111. Mosholder AD, Gelperin K, Hammad TA, Phelan K, Johann-Liang R. Hallucinations and other psychotic symptoms associated with the use of attention-deficit/hyperactivity disorder drugs in children. *Pediatrics*. 2009; 123(2):611–616

112. Cortese S, Holtmann M, Banaschewski T, et al; European ADHD Guidelines Group. Practitioner review: current best practice in the management of adverse events during treatment with ADHD medications in children and adolescents. *J Child Psychol Psychiatry*. 2013;54(3):227–246

113. Avigan M. *Review of AERS Data From Marketed Safety Experience During Stimulant Therapy: Death, Sudden Death, Cardiovascular SAEs (Including Stroke). Report No. D030403*. Silver Spring, MD: Food and Drug Administration, Center for Drug Evaluation and Research; 2004

114. Perrin JM, Friedman RA, Knilans TK; Black Box Working Group; Section on Cardiology and Cardiac Surgery. Cardiovascular monitoring and stimulant drugs for attention-deficit/hyperactivity disorder. *Pediatrics*. 2008; 122(2):451–453

115. McCarthy S, Cranswick N, Potts L, Taylor E, Wong IC. Mortality associated with attention-deficit hyperactivity disorder (ADHD) drug treatment: a retrospective cohort study of children, adolescents and young adults using the general practice research database. *Drug Saf*. 2009;32(11):1089–1096

116. Gould MS, Walsh BT, Munfakh JL, et al. Sudden death and use of stimulant medications in youths. *Am J Psychiatry*. 2009;166(9):992–1001

117. Cooper WO, Habel LA, Sox CM, et al. ADHD drugs and serious cardiovascular events in children and young adults. *N Engl J Med*. 2011;365(20):1896–1904

118. Schelleman H, Bilker WB, Strom BL, et al. Cardiovascular events and death in children exposed and unexposed to ADHD agents. *Pediatrics*. 2011;127(6): 1102–1110

119. Garnock-Jones KP, Keating GM. Atomoxetine: a review of its use in attention-deficit hyperactivity disorder in children and adolescents. *Paediatr Drugs*. 2009;11(3):203–226

120. Reed VA, Buitelaar JK, Anand E, et al. The safety of atomoxetine for the treatment of children and adolescents with attention-deficit/hyperactivity disorder: a comprehensive review of over a decade of research. *CNS Drugs*. 2016;30(7):603–628

121. Bangs ME, Tauscher-Wisniewski S, Polzer J, et al. Meta-analysis of suicide-related behavior events in patients treated with atomoxetine. *J Am Acad Child Adolesc Psychiatry*. 2008;47(2): 209–218

122. Bangs ME, Jin L, Zhang S, et al. Hepatic events associated with atomoxetine treatment for attention-deficit hyperactivity disorder. *Drug Saf*. 2008; 31(4):345–354

123. Spencer TJ, Kratochvil CJ, Sangal RB, et al. Effects of atomoxetine on growth in children with attention-deficit/hyperactivity disorder following up to five years of treatment. *J Child Adolesc Psychopharmacol*. 2007;17(5):689–700

124. Elbe D, Reddy D. Focus on guanfacine extended-release: a review of its use in child and adolescent psychiatry. *J Can Acad Child Adolesc Psychiatry*. 2014; 23(1):48–60

125. Croxtall JD. Clonidine extended-release: in attention-deficit hyperactivity disorder. *Paediatr Drugs*. 2011;13(5): 329–336

126. Vaughan B, Kratochvil CJ. Pharmacotherapy of pediatric attention-deficit/hyperactivity disorder. *Child Adolesc Psychiatr Clin N Am*. 2012; 21(4):941–955

127. Hirota T, Schwartz S, Correll CU. Alpha-2 agonists for attention-deficit/hyperactivity disorder in youth: a systematic review and meta-analysis of monotherapy and add-on trials to stimulant therapy. *J Am Acad Child Adolesc Psychiatry*. 2014;53(2):153–173

128. Treuer T, Gau SS, Méndez L, et al. A systematic review of combination therapy with stimulants and atomoxetine for attention-deficit/hyperactivity disorder, including patient characteristics, treatment strategies, effectiveness, and tolerability. *J Child Adolesc Psychopharmacol*. 2013;23(3): 179–193

129. Greenhill LL, Posner K, Vaughan BS, Kratochvil CJ. Attention deficit hyperactivity disorder in preschool children. *Child Adolesc Psychiatr Clin N Am*. 2008;17(2):347–366, ix

130. Wilens TE, Spencer TJ. Understanding attention-deficit/hyperactivity disorder from childhood to adulthood. *Postgrad Med*. 2010;122(5):97–109

131. Foy JM, ed. Psychotropic medications in primary care. In: *Mental Health Care of Children and Adolescents: A Guide for Primary Care Clinicians*. Itasca, IL: American Academy of Pediatrics; 2018: 315–374

132. Wilens TE, Adler LA, Adams J, et al. Misuse and diversion of stimulants prescribed for ADHD: a systematic review of the literature. *J Am Acad Child Adolesc Psychiatry*. 2008;47(1): 21–31

133. American Academy of Pediatrics. Mental health initiatives. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Mental-Health/Pages/default.aspx. Accessed September 8, 2019

134. Levy S, Campbell MD, Shea CL, DuPont R. Trends in abstaining from substance use in adolescents: 1975-2014. *Pediatrics*. 2018;142(2):e20173498

135. Graff Low K, Gendaszek AE. Illicit use of psychostimulants among college students: a preliminary study. *Psychol Health Med*. 2002;7(3):283–287

136. Barkley RA, Cox D. A review of driving risks and impairments associated with attention-deficit/hyperactivity disorder and the effects of stimulant medication on driving performance. *J Safety Res*. 2007;38(1):113–128

137. Jerome L, Habinski L, Segal A. Attention-deficit/hyperactivity disorder (ADHD) and driving risk: a review of the literature and a methodological critique. *Curr Psychiatry Rep*. 2006;8(5): 416–426

138. Cox DJ, Merkel RL, Moore M, Thorndike F, Muller C, Kovatchev B. Relative benefits of stimulant therapy with OROS methylphenidate versus mixed amphetamine salts extended release in improving the driving performance of adolescent drivers with attention-deficit/hyperactivity disorder. *Pediatrics*. 2006;118(3). Available at: www.pediatrics.org/cgi/content/full/118/3/e704

139. The MTA Cooperative Group; Multimodal Treatment Study of Children with ADHD. A 14-month randomized clinical trial of treatment strategies for attention-deficit/hyperactivity disorder. *Arch Gen Psychiatry*. 1999;56(12):1073–1086

140. Jensen PS, Hinshaw SP, Swanson JM, et al. Findings from the NIMH Multimodal Treatment Study of ADHD (MTA): implications and applications for primary care providers. *J Dev Behav Pediatr*. 2001;22(1):60–73

141. Pelham WE Jr, Gnagy EM. Psychosocial and combined treatments for ADHD. *Ment Retard Dev Disabil Res Rev*. 1999; 5(3):225–236

142. Homer CJ, Klatka K, Romm D, et al. A review of the evidence for the medical home for children with special health care needs. *Pediatrics*. 2008;122(4). Available at: www.pediatrics.org/cgi/content/full/122/4/e922

143. Davila RR, Williams ML, MacDonald JT. Memorandum on clarification of policy to address the needs of children with attention deficit disorders within general and/or special education. In: Parker HC, ed. *The ADD Hyperactivity Handbook for Schools*. Plantation, FL: Impact Publications Inc; 1991:261–268

144. Harrison JR, Bunford N, Evans SW, Owens JS. Educational accommodations for students with behavioral challenges: a systematic review of the literature. *Rev Educ Res*. 2013;83(4): 551–597

145. Committee on Pediatric Workforce. Enhancing pediatric workforce diversity and providing culturally effective pediatric care: implications for practice, education, and policy making. *Pediatrics*. 2013;132(4). Available at: www.pediatrics.org/cgi/content/full/132/4/e1105

146. Berman RS, Patel MR, Belamarich PF, Gross RS. Screening for poverty and poverty-related social determinants of health. *Pediatr Rev*. 2018;39(5):235–246

147. Solanto MV. Neuropsychopharmacological mechanisms of stimulant drug action in attention-deficit hyperactivity disorder: a review and integration. *Behav Brain Res*. 1998;94(1):127–152

148. Wagner E. Chronic disease management: what will it take to improve care for chronic illness? *Effect Clin Pract*. 1998;1(1):2–4

149. Brinkman WB, Sucharew H, Majcher JH, Epstein JN. Predictors of medication continuity in children with ADHD. *Pediatrics*. 2018;141(6):e20172580

150. Pliszka SR, Crismon ML, Hughes CW, et al; Texas Consensus Conference Panel on Pharmacotherapy of Childhood Attention Deficit Hyperactivity Disorder. The Texas Children's Medication Algorithm Project: revision of the algorithm for pharmacotherapy of attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2006;45(6):642–657

151. Pringsheim T, Hirsch L, Gardner D, Gorman DA. The pharmacological management of oppositional behaviour, conduct problems, and aggression in children and adolescents with attention-deficit hyperactivity disorder, oppositional defiant disorder, and conduct disorder: a systematic review and meta-analysis. Part 1: psychostimulants, alpha-2 agonists, and atomoxetine. *Can J Psychiatry*. 2015; 60(2):42–51

152. Committee on Psychosocial Aspects of Child and Family Health and Task Force on Mental Health. Policy statement--The future of pediatrics: mental health competencies for pediatric primary care. *Pediatrics*. 2009;124(1):410–421

153. Foy JM, ed. Algorithm: a process for integrating mental health care into pediatric practice. In: *Mental Health Care of Children and Adolescents: A Guide for Primary Care Clinicians*. Itasca, IL: American Academy of Pediatrics; 2018:815

154. Cheng TL, Emmanuel MA, Levy DJ, Jenkins RR. Child health disparities: what can a clinician do? *Pediatrics*. 2015;136(5):961–968

155. Stein F, Remley K, Laraque-Arena D, Pursley DM. New resources and strategies to advance the AAP's values of diversity, inclusion, and health equity. *Pediatrics*. 2018;141(4):e20180177

156. American Academy of Pediatrics, Committee on Child Health Financing. Scope of health care benefits for children from birth through age 26. *Pediatrics*. 2012;129(1):185–189

Supplemental Information

ALGORITHM

IMPLEMENTING THE KEY ACTION STATEMENTS OF THE AAP ADHD CLINICAL PRACTICE GUIDELINES: AN ALGORITHM AND EXPLANATION FOR PROCESS OF CARE FOR THE EVALUATION, DIAGNOSIS, TREATMENT, AND MONITORING OF ADHD IN CHILDREN AND ADOLESCENTS

I. INTRODUCTION

Practice guidelines provide a broad outline of the requirements for high-quality, evidence-based care. The AAP "Clinical Practice Guideline: Diagnosis and Evaluation of the Child With Attention-Deficit/Hyperactivity Disorder" provides the evidence-based processes for caring for children and adolescents with ADHD symptoms or diagnosis. This document supplements that guideline. It provides a PoCA that details processes to implement the guidelines; describes procedures for the evaluation, treatment, and monitoring of children and adolescents with ADHD; and addresses practical issues related to the provision of ADHD-related care within a typical, busy pediatric practice. The algorithm is entirely congruent with the guidelines and is based on the practical experience and expert advice of clinicians who are experienced in the diagnosis and management of children and adolescents with ADHD. Unlike the guidelines, this algorithm is based primarily on expert opinion and has a less robust evidence base because of the lack of clinical studies specifically addressing this approach. Understanding that providing appropriate care to children with ADHD in a primary care setting faces a number of challenges and barriers, the subcommittee has also provided an additional article describing needed changes to address barriers to care (found in the Supplemental Information).

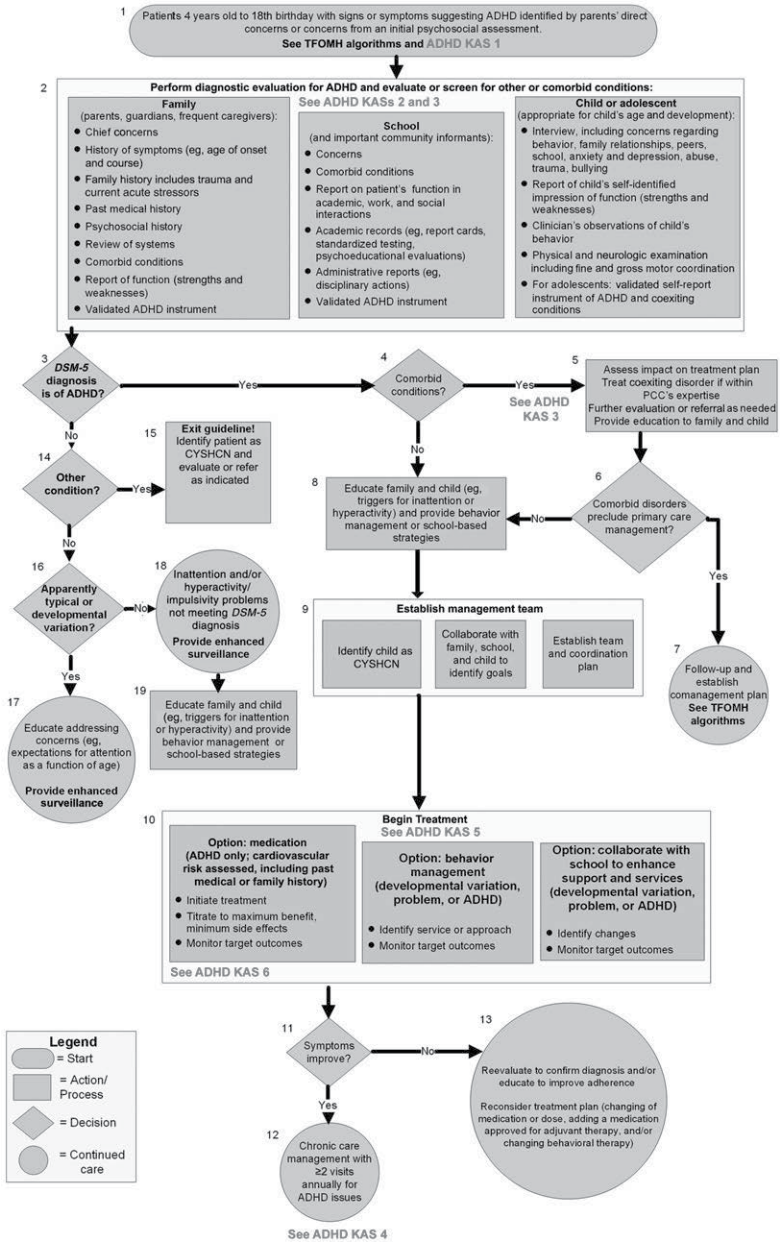
In this algorithm, we describe a continuous process; as such, its constituent steps are not intended to be completed in a single office visit or in a specific number of visits. Evaluation, treatment, and monitoring are ongoing processes to be addressed throughout the child's and adolescent's care within the practice and in transition planning as the adolescent moves into the adult care system. Many factors will influence the pace of the process, including the experience of the PCC, the practice's volume, the longevity of the relationship between the PCC and family, the severity of concerns, the availability of academic records and school input, the family's schedule, and the payment structure.

An awareness of the AAP "Primary Care Approach to Mental Health Care Algorithm," which is available on the AAP Mental Health Initiatives Web site, will enhance the integration of the procedures described in this document (http://www.aap.org/mentalhealth). That algorithm describes the process to integrate an initial psychosocial assessment at well visits and a brief mental health update at acute and chronic care visits. Mental health concerns, including symptoms of inattention and impulsivity, may present when (1) elicited during the initial psychosocial assessment at a routine well visit, (2) elicited during a brief mental health update at an acute or chronic visit, or (3) presented during a visit triggered by a family or school concern.

When concerns are identified, the algorithm describes the process of conducting a brief primary care intervention, secondary screening, diagnostic assessment, treatment, and follow-up. Like this document, the mental health algorithm is intended to present a process that may involve more than 1 visit and may be completed over time.

This algorithm assumes that the primary care practice has adopted the initial psychosocial assessment and mental health update, as described by the AAP Mental Health Initiatives.[153] It begins with steps paralleling the secondary assessment of the general mental health algorithm. Both algorithms focus on the care team and include the family as a part of that team.

In light of the prevalence of ADHD, the severe consequences of untreated ADHD, and the availability of effective ADHD treatments, the AAP recommends that every child and adolescent identified with signs or symptoms suggestive of ADHD be evaluated for ADHD or other conditions that may share its symptomatology. Documenting all aspects of the diagnostic and treatment procedures in the patient's records will improve the ability of the



SUPPLEMENTAL FIGURE 2
ADHD care algorithm. CYSHCN, children and youth with special health care needs; TFOMH, Task Force on Mental Health.

pediatrician to best treat children with ADHD.

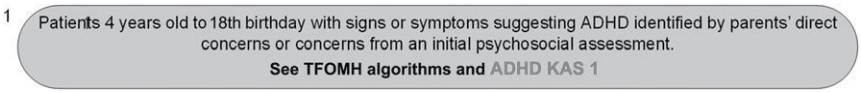
II. EVALUATION FOR ADHD

II a. A Child or Adolescent Presents With Signs and Symptoms Suggesting ADHD

The algorithm's steps can be implemented when a child or adolescent presents to a PCC for an assessment for ADHD. This may occur in a variety of ways.

Pediatricians and other PCCs traditionally have long-standing relationships with the child and family, which foster the opportunity to identify concerns early on. The young child may have a history of known ADHD risks, such as having parents who have been diagnosed with ADHD or having extremely low birth weight. In those instances, the PCC would monitor for emerging issues.

Many parents bring their child or adolescent to the PCC with specific concerns about the child's or adolescent's ability to sustain attention, curb activity levels, and/or inhibit impulsivity at home, school, or in the community. In many instances, the parents may express concerns about behaviors and characteristics



SUPPLEMENTAL FIGURE 3
Evaluate for ADHD. TFOMH, Task Force on Mental Health.

that are associated with ADHD but may not mention the core ADHD symptoms. For example, parents may report that their child is getting poor grades, does not perform well in team sports (despite being athletic), has few friends, or is moody and quick to anger. These children and adolescents may have difficulty remaining organized; planning activities; or inhibiting their initial thoughts, actions, or emotions, which are behaviors that fall under the umbrella of executive functioning (ie, planning, prioritizing, and producing) or cognitive control. Problems with executive functions may be correlated with ADHD and are common among children and adolescents with ADHD. As recommended by Bright Futures (a national health promotion and prevention initiative led by the AAP[157]), routine psychosocial screening at preventive visits may identify concerns on the part of parent or another clinician (see below for more information on co-occurring conditions.)

Finally, parents may bring a child to a PCC for ADHD evaluation on the basis of the recommendation of a teacher, tutor, coach, etc.

(See the ADHD guideline's KAS 1.)

II b. Perform a Diagnostic Evaluation for ADHD and Evaluate or Screen for Comorbid Disorders

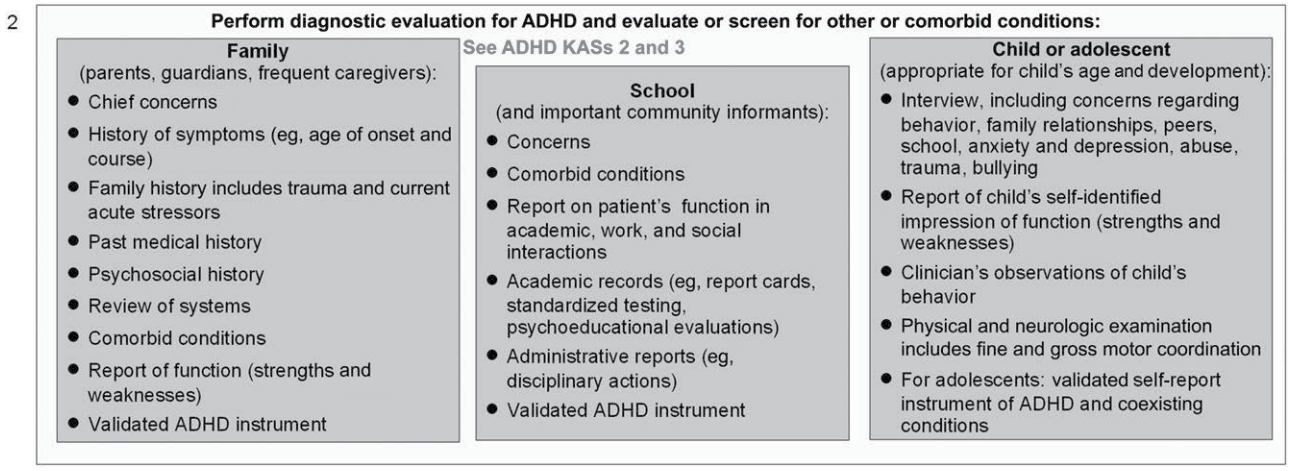
When a child or adolescent presents with concerns about ADHD, as described above, the clinician should initiate an evaluation for ADHD. (See the ADHD guideline's KASs 2 and 3.)

II c. Gather Information From the Family

As noted previously, the recommendations in the accompanying guideline are intended to be integrated with the broader mental health algorithm developed as part of the AAP Mental Health Initiatives.[2,133,153] It is also important for pediatricians and other PCCs to be aware of health disparities and social determinants that may affect patient outcomes and to provide culturally appropriate care to all children and adolescents in their practice, including during the initial evaluation and assessment of the patient's condition.[145,146,154,155,158]

Ideally, the PCC's office staff obtains information from the family about the visit's purpose at scheduling so that an extended visit or multiple visits can be made available for the initial ADHD evaluation. This also increases the efficiency of an initial evaluation. Data on the child's or adolescent's symptoms and functioning can be gathered from parents, school personnel, and other sources before the visit. Parents can be given rating scales that are to be completed before the visit by teachers, coaches, and others who interact with the child. This strategy allows the PCC to focus on the most pertinent issues for that child or adolescent and family at the time of the visit. (See later discussion for more information on rating scales.) Note that schools will not release data to pediatric providers without written parental consent.

During the office evaluation session, the PCC reviews the patient's medical, family, and psychosocial history. Developmental history is presumed to be part of the patient's medical



SUPPLEMENTAL FIGURE 4
Perform a diagnostic evaluation for ADHD and evaluate or screen for comorbid disorders

history. Family members (including parents, guardians, and other frequent caregivers) are asked to identify their chief concerns and provide a history of the onset, frequency, and duration of problem behaviors, situations that increase or decrease the problems, previous treatments and their results, and the caregivers' understanding of the issues. It is important to assess behaviors and conditions that are frequent side effects of stimulant medication (ie, sleep difficulties, tics, nail-biting, skin-picking, headaches, stomachaches, or afternoon irritability) and preexisting conditions, so they are not confused with the frequent side effects of stimulants. This enables the PCC to compare changes if medication is initiated later.

A sound assessment of symptoms and functioning in major areas can be used to construct an educational and behavioral profile that includes the child's strengths and talents. Many children with ADHD exhibit enthusiasm, exuberance, creativity, flexibility, the ability to detect and quickly respond to subtle changes in the environment, a sense of humor, a desire to please, etc. The most common areas of functioning affected by ADHD include academic achievement; relationships with peers, parents, siblings, and adult authority figures; participation in recreational activities, such as sports; and behavior and emotional regulation, including risky behavior.

The child's and family's histories can provide information about the status of symptoms and functioning and help determine age of onset and other factors that may be associated with the presenting problems. It also identifies any potential traumatic events that the child may have experienced, such as a family death, separation from the family, or physical or mental abuse.

The child or adolescent's medical history can help identify factors associated with ADHD, such as prenatal and perinatal complications and exposures (eg, preterm delivery, maternal hypertension, prenatal alcohol exposure), childhood exposures, and head trauma.

The family history includes any medical syndromes, developmental delays, cognitive limitations, learning disabilities, trauma or toxic stress, or mental illness in the patient and family members, including ADHD, mood, anxiety, and bipolar disorders. Ask what the family has already tried, what works, and what does not work to avoid wasting time on interventions that have already been attempted unsuccessfully. Parental tobacco and substance use, including their use prenatally, are relevant risk factors for, and correlate with, ADHD.[159] ADHD is highly heritable and is often seen in other family members who may or may not have been formally diagnosed with ADHD. For this reason, asking about family members' school experience, including time and task management, grades, and highest grade level achieved, can aid in treatment decisions.

The psychosocial history is important in any ADHD evaluation and usually includes queries about environmental factors, such as family stress and problematic relationships, which sometime contribute to the child or adolescent's overall functioning. The caregivers' current and past approaches to parenting and the child's misbehavior can provide important information that may explain discrepancies between reporters. For example, parents may reduce their expectations for their child with ADHD as a means to relieve parenting stress. When these expectations are reduced (eg, eliminating chores, not monitoring homework completion, etc), parents may experience far fewer problems with the child than do teachers who may have maintained expectations for the child to complete tasks and follow rules. Knowing the parents' approach to parenting may help the PCC understand differences in ratings completed by parents versus teachers.

Further evidence for an ADHD diagnosis includes an inability to independently complete daily routines in an age-appropriate manner as well as multiple and short-lasting friendships, trouble keeping and/or making friends, staying up late to complete assignments, and late, incomplete, and/or lost assignments. Somatic symptoms and school avoidance are more common among girls and may mask an ADHD diagnosis. With information obtained from the parents and school personnel, the PCC can make a clinical judgment about the effect of the core and associated ADHD symptoms on academic achievement, classroom performance, family and social relationships, independent functioning, and safety and/or unintentional injuries.

If other issues exist, such as self-injuries, comorbid mental health issues also need to be evaluated. Possible areas of functional impairment that require evaluation include domains such as self-perception, leisure activities, and self-care (ie, bathing, toileting, dressing, and eating). Additional guidance regarding functional assessment is available through the AAP ADHD Toolkit[2] and the AAP Mental Health Initiatives.[133,160] The ADHD Toolkit[2] is being revised concurrently with the development of these updated guidelines. After publication, the toolkit may be accessed at https://www.aap.org/en-us/professional-resources/quality-improvement/Pages/Quality-Improvement-Implementation-Guide.aspx. Additionally, a new Education in Quality Improvement for Pediatric Practice Module was developed on the basis of the new clinical recommendations and can also be accessed by using the same link above.

The patient needs to be screened for hearing and/or visual problems because these can mimic inattention. A full review of systems may reveal other symptoms or disorders, such as sleep disturbances, absence seizures, or tic disorders, which may assist in formulating a differential diagnosis and/or developing management plans. Internal feelings such as anxiety and depression can occur but may not be noticeable to parents and teachers, so it is important to elicit feedback about them from the patient as well.

The information gathered from this diagnostic interview, combined with the data from the rating scales (see below), provides an excellent foundation for determining the presence of symptoms and impairment criteria needed to diagnose ADHD.

II d. Use Parent Rating Scales and Other Tools

Rating scales that use the *DSM-5* criteria for ADHD can help obtain the information that will contribute to making a diagnosis. Rating scales for parents that use *DSM-5* criteria for ADHD are helpful in obtaining the core symptoms required to make a diagnosis on the basis of the *DSM-5*.[161] Because changes in the 18 core symptoms are essentially unchanged from *DSM-IV* criteria, *DSM-IV*–based rating scales can be used if *DSM-5* rating scales are not readily available. Some of these symptom rating scales include symptoms of commonly comorbid conditions and measures of impairment in a variety of domains that are also required for a diagnosis.[41,162] Some available measures are limited because they provide only a global rating.[163,164]

Caregiver and teacher endorsement of the requisite number of ADHD symptoms on the rating scales is not sufficient for diagnosis. A rating scale documents the presence of inattention, hyperactivity, and impulsivity symptoms but not whether these symptoms are actually attributable to ADHD versus a mimicking condition. Caregivers may misread or misunderstand some of the behaviors. Furthermore, rating scales do not inform the PCC about contextual influences that may account for the symptoms and impairment. Likewise, broadband rating scales that assess general mental health functioning do not provide reliable and valid indications of ADHD diagnoses, although they can help to screen for concurrent behavioral conditions.[165]

Nevertheless, parent ratings provide valuable information on their perspective of the child's symptoms and impairment and add information about normative levels of the parents' perspectives, which help the PCC determine the degree with which the problems are or are not in the typical range for the child's age and sex. Finally, broad rating scales that assess general mental health functioning do not provide sufficient information about all the ADHD core symptoms but may help screen for the concurrent behavioral conditions.[165]

To address the rating scales' limitations, pediatricians and other PCCs need to interview parents and may need to review documents such as report cards and standardized test results and historical records of detentions, suspensions, and/or expulsions from school, which can serve as evidence of functional impairment. Further evidence may include difficulty developing and maintaining lasting friendships. This information is discussed below.

II e. Gather Information From School and Community Informants

Information from parents is not the only source that informs diagnostic decisions for children and adolescents because a key criterion for an ADHD diagnosis is the display of symptoms and impairments in multiple settings. Gathering data from other adults who regularly interact with the child or adolescent being evaluated provides rich additional information for the evaluation.

The information from various sources may be inconsistent because parents and teachers observe the children at different times and under different circumstances, as described previously.[166] Disagreement may result from differences in students' behavior and performance in different classrooms, their relationship with the teachers, or variations in teachers' expectations, as well as training in or experience with behavior management. Classes with high homework demands or classes with less structure are often the most problematic for students with ADHD. Investigating these inconsistencies can lead to hypotheses about the child that help inform the eventual clinical diagnoses and treatment decisions.[167]

Teachers and Other School Personnel

Teachers and other school personnel can provide critically important information because they develop a rich sense of the typical range of behaviors within a specific age group over time. School and classrooms settings provide the greatest social and performance expectations that potentially tax children and adolescents with ADHD. Parents and older children may be the best sources for identifying the school personnel who can best complete rating scales for an ADHD evaluation.

The value of school ratings increases as children age because parents often have less detailed information about their child's behavior and performance at school as the student moves into the higher grades. With elementary and middle school children, the classroom teacher is usually the best source; he or she may be the only source necessary. Other school staff, such as a special education teacher or school counselor, may be valuable sources of information. Direct communication

with a school psychologist and/or school counselor may provide additional information on the child's functioning within the context of the classroom and school.

In secondary schools, students interact with many teachers who often instruct >100 students daily. As a result, high school teachers may not know the students as well as elementary and middle school teachers do. Parents and students may be encouraged to choose the 2 or 3 teachers who they believe know the student best and solicit their input (eg, math and English teachers or, for children or adolescents with learning disabilities, a teacher in an area of strong function and a teacher in an area of weak function). Regardless of the presence of a learning disability, it is helpful to obtain feedback from the teacher of the class in which the child or adolescent is having the most difficulty. The ADHD Toolkit provides materials relevant to school data collection.

Teachers may communicate their major concerns using questionnaires or verbally in person, via secure e-mail (if available), or over the telephone. It is important to ask an appropriate school representative to complete a validated ADHD instrument or behavior scale based on the *DSM-5* criteria for ADHD. A school representative's report might include information about any comorbid or alternative conditions, including disruptive behavior disorders, depression and anxiety disorders, tics, or learning disabilities. As noted, some parent rating scales have a version for teachers and assess symptoms and impairment in multiple domains.[41] Teacher rating scales exist that specifically target behavior and performance at school,[168] which provide a comprehensive and detailed description of a student's school functioning relative to normative data.

In addition to the academic information, it is important to request information characterizing the child or adolescent's level of functioning with regard to peer, teacher, and other authority figure relationships, ability to follow directions, organizational skills, history of classroom disruption, and assignment completion.

Academic Records

In addition to ratings from teachers and other school staff, academic records are sometimes available to inform a PCC's evaluation. These records include report cards; results from reading, math, and written expression standardized tests; and other assessments of academic competencies. If a child were referred for an evaluation for special education services, his or her file is likely to contain a report on the evaluation, which can be useful during an ADHD evaluation. School records pertaining to office discipline referrals, suspensions, absences, and detentions can provide valuable information about social function and behavioral regulation. Parents often keep report cards from early grades, which can provide valuable information about age of onset for children older than 12 years. Teachers in primary grades often provide information pertaining to important information about the history of the presenting problems.

Other Community Sources

It can be helpful to obtain information not only from school professionals but also from additional sources, such as grandparents, faith-based organization group leaders, scouting leaders, sports coaches, and others. Depending on the areas in which the child or adolescent exhibits impairment, these adults may be able to provide a valuable perspective on the nature of the presenting problems, although the accuracy of their reporting has not been studied.

II f. Gather Information From the Child or Adolescent

Another source of information is from the child or adolescent. This information is often collected but carries less weight than information from other sources because of children's and adolescents' limited ability to accurately report their strengths and weaknesses, including those associated with ADHD.[169] As a result, information gathered from the child about specific ADHD behaviors may do little to inform the presence or absence of symptoms and impairments because evidence suggests that children tend to minimize their problems and blame others for concerns.[170]

Nevertheless, self-report may provide other values. First, self-report is the primary means by which one can screen for internalizing conditions such as depression and anxiety. The AAP Mental Health Initiatives[133] and the *Guidelines for Adolescent Depression in Primary Care*[171–173] recommend the use of validated diagnostic rating scales for adolescent mood and anxiety disorders for clinicians who wish to use this format.[174–178] As measures of internal mental disorders, these data are likely to be more valid than the reports of adults about their children's behaviors.

Second, youth with ADHD are prone to talk impulsively and excessively when adults show an interest in them. They may share useful information about the home or classroom that parents and teachers do not know or impart. In addition, many share their experience with risky and dangerous behaviors that may be unknown to the adults in their lives. This information can be critical in both determining a diagnosis and designing treatment.

Third, even if little information of value is obtained, the fact that the PCC takes the time to meet alone and ask questions of the child or adolescents demonstrates respect and lays the foundation for

collaboration in the decision-making and treatment process to follow. This relationship building is particularly important for adolescents.

Fourth, by gaining an understanding of the child's perspective, the PCC can anticipate the likely acceptance or resistance to treatment.

Interviewing the child or adolescent provides many important benefits beyond the possibility of informing the diagnosis and warrants its inclusion in the evaluation. For example, part of this interview includes asking the child or adolescent to identify personal goals (eg, What do you want to be when you grow up? What do you think that requires? How can we help you get there?). It is helpful when children perceive the pediatrician and other PCCs as seeking to help them achieve their goals rather than arbitrarily labeling them as deficient, defective, or needing to be fixed in some way.

II g. Clinical Observations and Physical Examination of the Child or Adolescent

The physical and neurologic examination needs to be comprehensive to determine if further medical or developmental assessments are indicated. Baseline height, weight, BP, and pulse measurements are required to be recorded in the medical record. It is important to look for behaviors that are consistent with ADHD's symptoms, including the child's level of attention, activity, and impulsivity during the encounter. Yet, ADHD is context dependent, and for this reason, behaviors and core symptoms that are seen in other settings are often not observed during an office visit.[179] Although the presence of hyperactivity and inattention during an office visit may provide supporting evidence of ADHD symptoms, their absence is not considered evidence that the child does not have ADHD.

Observations of a broad range of behaviors can be important for considering their contribution to the presenting problems and the potential diagnosis of other conditions. Careful attention to these various behaviors can provide useful information when beginning the next step involving making diagnostic decisions. For example, hearing and visual acuity problems can often lead to inattention and overactivity at school. Attending to concerns about anxiety is also important given that young children may become overactive when they are in anxiety-provoking situations like a clinic visit.

In addition, observing the child's language skills is important because difficulties with language can be a symptom of a language disorder and predictor of subsequent reading problems. This observation is particularly important with young children given that language disorders may present as problems with sustaining attention and impulsivity. A language disorder may also involve pragmatic usage or the social use of language, which can contribute to social impairment. If the PCC, family, and/or school have concerns about receptive, expressive, or pragmatic language, it is important to make a referral for a formal speech and language evaluation. Dysmorphic features also need to be noted because symptoms of ADHD are similar to characteristics of children with some prenatal exposures and genetic syndromes (eg, fetal alcohol exposure,[180,181] fragile X syndrome).

Many children with ADHD have poor coordination, which may be severe enough to warrant a diagnosis of developmental coordination disorder and referral to occupational and/or physical therapy. Findings of poor coordination can affect how well the child performs in competitive sports, a frequent source of social interactions for children, and can adversely affect the child's writing skills. Detecting any motor or verbal tics is important as well, particularly because the use of stimulant medications may cause or exacerbate tics.

Finally, it is important to evaluate the child's cardiovascular status because cardiovascular health must be considered if ADHD medication becomes an option. Cardiac illness is rare, and more evidence is required to determine if children or adolescents with ADHD are at increased risk when taking ADHD medications. Nevertheless, before initiating therapy with stimulant medications, it is important to obtain the child or adolescent's history of specific cardiac symptoms, as well as the family history of sudden death, cardiovascular symptoms, Wolff-Parkinson-White syndrome, hypertrophic cardiomyopathy, and long QT syndrome. If any of these risk factors are present, clinicians should obtain additional evaluation with an ECG and possibly consult with a pediatric cardiologist.

II h. Gather Information About Conditions That Mimic or Are Comorbid With ADHD

It is important for the PCC to obtain information about the status and history of conditions that may mimic or are comorbid with ADHD, such as depression, anxiety disorders, and posttraumatic stress disorder. Several validated rating scales are within the public domain and can help identify comorbid conditions. Examples include the Pediatric Symptom Checklist-17 as a screen for depression and anxiety[182]; the Screen for Child Anxiety Related Emotional Disorders, more specifically for anxiety disorders[176]; the Patient Health Questionnaire modified for adolescents; the Screening to Brief Intervention tool[183,184]; and the Child and Adolescent Trauma Screen for exposure to trauma.[185] All include questionnaire forms for both parents and patients.[2] The results help the PCC assess the extent to which reported impairment and/or distress are associated with ADHD versus

comorbid conditions. These conditions are described in greater detail later.

Safety and Serious Mental Illness Concerns

PCCs may be asked to complete mental health or safety assessments, particularly for adolescents. Assessment requests may come from schools or other settings after a behavioral crisis, aggressive behavior, or destructive behaviors have occurred. With patient or guardian consent, information may be shared regarding diagnosis and current treatment strategies. Pediatricians and other PCCs are encouraged to exercise caution when asked to predict the likelihood of future behaviors in the absence of detailed understanding of the environment in which the behaviors occurred. Self-injurious behaviors or threats of self-harm are serious concerns that, when possible, should immediately be referred to community mental health crisis services or experienced child mental health professionals. PCCs are encouraged to provide further monitoring of the child or adolescent with these comorbidities.

III. MAKING DIAGNOSTIC DECISIONS

After gathering all of the relevant available information, the PCC will consider an ADHD diagnosis as well as a diagnosis of other related and/or comorbid disorders. The primary decision-making process involves comparing the information obtained to the *DSM-5* criteria for ADHD. Although this assessment is straightforward, there are some issues the PCC needs to consider, including development, sex, and other disorders that may fit the presenting problems better than ADHD (see below for more on these issues).

SUPPLEMENTAL FIGURE 5
Making diagnostic decisions.

III a. DSM-5 Criteria for ADHD

The *DSM-5* criteria define 4 dimensions of ADHD:

1. ADHD/I (314.00 [F90.0]);
2. ADHD/HI (314.01 [F90.1]);
3. ADHD/C (314.01 [F90.2]); and
4. ADHD other specified and unspecified ADHD (314.01 [F90.8]).

To make a diagnosis of ADHD, the PCC needs to establish that 6 or more (5 or more if the adolescent is 17 years or older) core symptoms are present in either or both of the inattention dimension and/or the hyperactivity-impulsivity dimension and occur inappropriately often. The core symptoms and dimensions are presented in Supplemental Table 2.

- ADHD/I: having at least 6 of 9 inattention behaviors and less than 6 hyperactive-impulsive behaviors;
- ADHD/HI: having at least 6 of 9 hyperactive-impulsive behaviors and less than 6 inattention behaviors;
- ADHD/C: having at least 6 of 9 behaviors in both the inattention and hyperactive-impulsive dimensions; and
- ADHD other specified and unspecified ADHD: These categories are meant for children who meet many of the criteria for ADHD, but not the full criteria, and who have significant impairment. "ADHD other specified" is used if the PCC specifies those criteria that have not been met; "unspecified ADHD" is used if the PCC does not specify these criteria.

In school-aged children and adolescents, diagnostic criteria for ADHD include documentation of the following criteria:

- At least 6 of the 9 behaviors described in the inattentive domain occur often, and to a degree, that is inconsistent with the child's developmental age. (For adolescents 17 years and older, documentation of at least 5 of the 9 behaviors is required.)
- At least 6 of the 9 behaviors described in the hyperactive-impulsive domain occur often, and to a degree, that is inconsistent with the child's developmental age. (For adolescents 17 years and older, documentation of at least 5 of the 9 behaviors is required.)
- Several inattentive or hyperactive-impulsive symptoms were present before age 12 years.
- There is clear evidence that the child's symptoms interfere with or reduce the quality of his or her social, academic, and/or occupational functioning.
- The symptoms have persisted for at least 6 months.
- The symptoms are not attributable to another physical, situational, or mental health condition.

Clear evidence exists that these criteria are appropriate for preschool-aged children (ie, age 4 years to the sixth birthday), elementary and middle school-aged children (ie, age 6 years to the 12th birthday), and adolescents (ie, age 12 years to the 18th birthday).[30,31] *DSM-5* criteria have also been updated to better describe how inattentive and hyperactive-impulsive symptoms present in older adolescents and adults.

DSM-5 criteria require evidence of symptoms before age 12 years. In some cases, however, parents and teachers may not recognize ADHD symptoms until the child is older than 12 years, when school tasks and

responsibilities become more challenging and exceed the child's ability to perform effectively in school. For these children, history can often identify an earlier age of onset of some ADHD symptoms. Delayed recognition may also be seen more often in ADHD/I, which is more commonly diagnosed in girls.

If symptoms arise suddenly without previous history, the PCC needs to consider other conditions, including mood or anxiety disorders, substance use, head trauma, physical or sexual abuse, neurodegenerative disorders, sleep disorders (including sleep apnea), or a major psychological stress in the family or school (such as bullying). In adolescents and young adults, PCCs are encouraged to consider the potential for false reporting and misrepresentation of symptoms to obtain medications for other than appropriate medicinal use (ie, diversion, secondary gain). The majority of states now require prescriber participation in prescription drug monitoring programs, which can be helpful in identifying and preventing diversion activities. Pediatricians and other PCCs may consider prescribing nonstimulant medications that minimize abuse potential, such as atomoxetine and extended-release guanfacine or extended-release clonidine.

In the absence of other concerns and findings on prenatal or medical history, further diagnostic testing will not help to reach an ADHD diagnosis. Compared to clinical interviews, standardized psychological tests, such as computerized attention tests, have not been found to reliably differentiate between youth with and without ADHD.[187,188] Appropriate further assessment is indicated if an underlying etiology is suspected. Imaging studies or screening for high lead levels and abnormal thyroid hormone levels can be pursued if they are suggested by other historic or physical information, such as history or symptoms of a tumor or significant brain injury. When children experience trauma, their evaluation needs to include the consideration of both the trauma and ADHD because they can co-occur and can exacerbate ADHD symptoms. Toxic stress has shown to be associated with the incidence of pediatric ADHD, but the conclusion that ADHD is a manifestation of this stress has not been demonstrated.[188]

Patients with ADHD commonly have comorbid conditions, such as oppositional defiant disorder, anxiety, depression, and language and learning disabilities. These conditions may present with ADHD symptoms and need evaluation because their treatment may relieve symptoms. Additionally, some conditions may present with ADHD symptoms and respond to treatment of the primary condition, such as sleep disorders, absence seizures, and hyperthyroidism. (Comorbid conditions are discussed later in this document.)

In addition, the behavioral characteristics specified in the *DSM-5* remain subjective and may be interpreted differently by various observers. Rates of ADHD and its treatment have been found to be different for different racial and/or ethnic groups.[50,189] Cultural norms and the expectations of parents or teachers may influence reporting of symptoms. Hence, the clinician benefits from being sensitive to cultural differences about the appropriateness of behaviors and perceptions of mental health conditions.[145,155]

After the diagnostic evaluation, a PCC will be able to answer the following questions:

- How many inattentive and hyperactive/impulsive behavior criteria for ADHD does the child or adolescent manifest across major settings of his or her life?
- Have these criteria been present for 6 months or longer?
- Was the onset of these or similar behaviors present before the child's 12th birthday?
- What functional impairments are caused by these behaviors?
- Could any other condition be a better explanation for the behaviors?
- Is there evidence of comorbid problems or disorders?

On the basis of this information, the clinician is usually able to arrive at a preliminary diagnosis of whether the child or adolescents has ADHD or not. (For children and adolescents who do not receive an ADHD diagnosis, see below.)

III b. Developmental Considerations

Considerations About the Child or Adolescent's Age

Although the diagnostic criteria for ADHD are the same for children up to age 17 years, developmental considerations affect the interpretation of whether a symptom is present. Before school age, the primary set of distinguishing symptoms involve hyperactivity, although this can be difficult to identify as outside of the normal range given the large variability in this young age group. Similarly, difficulties sustaining attention are difficult to determine with young children because of considerable variability in presentation and the limited demands for children in this age group to sustain attention over time. (See below for more information on developmental delays.)

Some children demonstrate hyperactivity and inattention that are clearly beyond the normal range. They may experience substantial impairment to an extent that baby-sitters or child care agencies refuse to care for them, parents are unable to take them shopping or to restaurants, or they routinely engage in dangerous or risky behaviors. In these extreme cases, the PCC may be able to make

the decision for an ADHD diagnosis more quickly than other scenarios that require a thorough assessment. For other young children, the diagnosis will be less obvious, and developmental and environmental issues may lead the PCC to be cautious in making an ADHD diagnosis. In these situations, monitoring for the emergence or clarification of ADHD symptoms and/or providing a diagnosis of other specified *ADHD* or unspecified *ADHD* are appropriate options.

Adolescence is another developmental period when developmental considerations are warranted. Beginning at age 17 years, there are only 5 symptoms of inattention and/or 5 symptoms of hyperactivity/impulsivity required for an ADHD diagnosis. Hyperactivity typically diminishes for most children during adolescence, but problems associated with impulsivity can be dangerous and can include impaired driving, substance use, risky sexual behavior, and suicide. Disorganization of time and resources can be associated with substantial academic problems at school. Parent-child conflict and disengagement from school can provide a context that contributes toward poor long-term outcomes. Comorbid depression and conduct disorder are common but do not negate the importance of diagnosing ADHD when the developmental path warrants it and the ADHD symptoms exacerbate problems associated with the comorbid conditions.

Adolescence is the first developmental period for which age of onset of symptoms must be documented before 12 years. School records and parent reports are often the richest source for making this determination. It is important to try to identify adolescents (or their parents) who are pursuing a diagnosis of ADHD for secondary gains such as school accommodations, standardized testing accommodations, and/or stimulant prescriptions. In addition, impairment sometimes emerges when expectations for the adolescent markedly increase or when accommodations are removed. The teenager's level of functioning may stay the same, but when faced with the expectations of advanced placement courses or a part-time job, failure to keep pace with increasing expectations may lead to concerns that warrant an evaluation for ADHD. These examples emphasize the importance of determining an early age of onset.

Considerations About the Child or Adolescent's Sex

ADHD is diagnosed in boys about twice as often as it is diagnosed in girls. There are many hypotheses about reasons for this difference; the primary reason appears to simply be that the disorder is more common in boys than girls. Some have raised concerns that the difference may be attributable to variances in society's expectations for boys versus girls or underdiagnosis in girls, but these reasons are unlikely to account for the large difference in diagnoses. Hence, no adjustment is needed in terms of the standards for girls to meet the criteria for an ADHD diagnosis compared with boys.

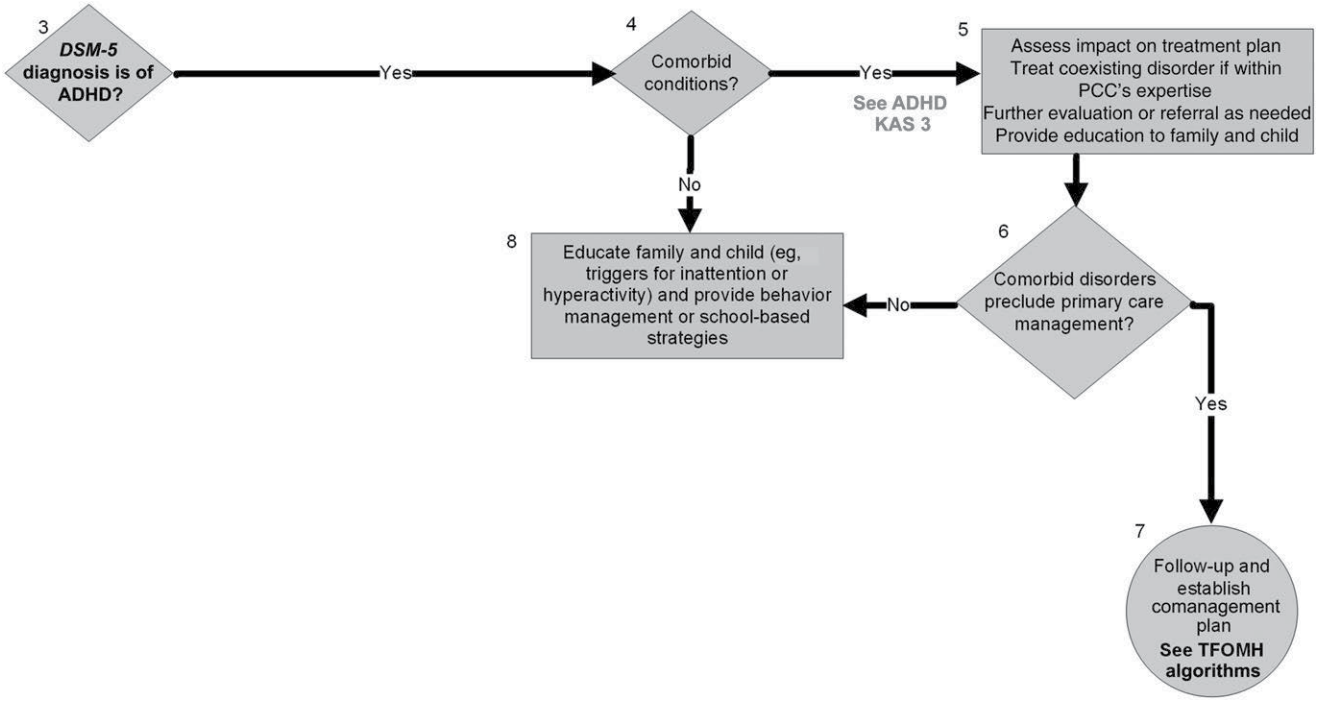
Girls are less likely to exhibit hyperactivity symptoms, which are the most easily observable of all ADHD symptoms, particularly in younger patients. This fact may account for a portion of the difference in diagnosis between girls and boys. As a result, it is important to fully consider a diagnosis of ADHD, predominantly inattentive presentation, when evaluating girls.

Symptoms of inattention alone can complicate the diagnosis because inattention is 1 of the most common symptoms across all disorders in the *DSM-5*. After puberty, it is more common for depression and anxiety to be diagnosed in girls than in boys, and symptoms of inattention may be a result of these disorders as well as ADHD. Examining the age of onset and considering other distinguishing features, such as avoidance and anhedonia, can help the PCC clarify this challenging differential when evaluating girls for ADHD. For example, does the inattention occur primarily in anxiety-provoking situations or when the child or adolescent is experiencing periods of low mood and then remit when the anxiety or mood improves?

III c. Consideration of Comorbid Conditions

If other disorders are suspected or detected during the diagnostic evaluation, an assessment of the urgency of these conditions and their impact on the ADHD treatment plan should be made. Comorbid conditions provide unique challenges for treatment planning. Urgent conditions need to be addressed immediately with services capable of handling crisis situations. These conditions include suicidal thoughts or acts and other behaviors with the potential to severely injure the child, adolescent, and/or other people, including severe temper outbursts or child abuse. Note that adolescents are potentially more likely to provide honest answers if the PCC asks sensitive questions in the absence of the parents and may respond more readily to rating scales that assess mood or anxiety. In addition, substance use disorders require immediate attention and may precede or coincide with beginning treatment of ADHD. Additional information is available in the complex ADHD guideline published by the SDBP.[67]

Evidence shows that comorbid conditions may improve with treatment of ADHD, including oppositional behaviors and anxiety.[140] For example, children with ADHD and comorbid anxiety disorders may find that addressing the ADHD symptoms with



SUPPLEMENTAL FIGURE 6
Consideration of comorbid conditions. TFOMH, Task Force on Mental Health.

medications also decreases anxiety or mood symptoms. Other children may require additional therapeutic treatments to treat the ADHD adequately and treat comorbid conditions, including cognitive behavioral therapy (CBT), academic interventions, or different and/or additional medications.

The PCC may evaluate and treat the comorbid disorder if it is within his or her training and expertise. In addition, the PCC can provide education to the family and child or adolescent about triggers for inattention and/or hyperactivity. If the PCC requires the advice of a subspecialist, the clinician is encouraged to consider carefully when to initiate treatment of ADHD. In some cases, it may be advisable to delay the start of medication until the role of each member of the treatment team is established (see below). Integrated care models can be helpful (see www.integratedcareforkids.org).

The following are brief discussions of sleep disorders, psychiatric disorders, emotion dysregulation, exposure to trauma, and learning disabilities, all of which can manifest in manners similar to ADHD and can complicate making a diagnosis.

(See the ADHD guideline's KAS 3.)

Sleep Disorders

Sleepiness impairs most people's ability to sustain attention and often leads to caffeine consumption to counter these effects. In the same way, sleep disturbance can lead to symptoms and impairment that mimic or exacerbate ADHD symptoms. A child with ADHD may have difficulty falling asleep because of the busy thoughts caused by ADHD. Some sleep disorders are frequently associated with ADHD or present as symptoms of inattention, hyperactivity, and impulsivity, such as obstructive sleep apnea syndrome and restless legs syndrome and/or periodic limb movement disorder (RLS/PLMD).[190–193]

The differential diagnosis of insomnia in children and adolescents with ADHD includes the following:

- inadequate sleep hygiene (eg, inconsistent bedtimes and wake times, absence of a bedtime routine, electronics in the bedroom, caffeine use)[194];
- ADHD medication (stimulant and nonstimulant) effects:
  - o direct effects on sleep architecture: prolonged sleep onset, latency, and decreased sleep duration, increased night wakings[195–197]; and
  - o indirect effects: inadequate control of ADHD symptoms in the evening and medication withdrawal or rebound symptoms[198,199];
- sleep problems associated with comorbid psychiatric conditions (eg, anxiety and mood disorders, disruptive behavior disorders)[200];
- circadian-based phase delay in sleep-wake patterns, which have been shown to occur in some children with ADHD, resulting in both prolonged sleep onset and difficulty waking in the morning[201]; and

- intrinsic deficit associated with ADHD. Authors of numerous studies have reported that nonmedicated children with ADHD without comorbid mood or anxiety disorders have significantly greater bedtime resistance, more sleep onset difficulties, and more frequent night awakenings when compared with typically developing children in control groups.[202] In addition, some children with ADHD appear to have evidence of increased daytime sleepiness, even in the absence of a primary sleep disorder.[202–204]

For this reason, all children and adolescents who are evaluated for ADHD need to be systematically screened for symptoms of primary sleep disorders, such as frequent snoring, observed breathing pauses, restless sleep, urge to move one's legs at night, and excessive daytime sleepiness. (Issues of access to these services are discussed in the accompanying section, Systemic Barriers to the Care of Children and Adolescents with ADHD.) In addition, screenings generally include primary sleep disorders' risk factors, such as adenotonsillar hypertrophy, asthma and allergies, obesity, a family history of RLS/PLMD, and iron deficiency.[199] Sleep assessment measures that have been shown to be useful in the pediatric primary care practice setting include brief screening tools[205] and parent-report surveys.[206,207] Overnight polysomnography is generally required for children who have symptoms suggestive of and/or risk factors for obstructive sleep apnea syndrome and RLS/PLMD.[208,209]

If the results suggest the presence of a sleep disorder, the PCC needs to obtain a comprehensive sleep history, including assessment of the environment in which the child sleeps; the cohabitants in the room; the bedtime routine, including its initiation, how long it takes for the child fall asleep, sleep duration, and any night-time awakenings; and what time the child wakes up in the morning and his or her state when awakening. It is important to determine sleep interventions attempted and their results. Even when no primary sleep disorders occur, modest reductions in sleep duration or increases in sleep disruption may be associated with increased, detectable problems with attention in children and adolescents with ADHD.[210] Although fully disentangling sleep disruption from ADHD may not be possible because significant sleep problems and their associated impairment are often comorbid with ADHD, sleep disruptions often warrant consideration as an additional target for treatment. In addition, some children with ADHD appear to show evidence of increased daytime sleepiness, even in the absence of a primary sleep disorder.[203,204] Significant sleep problems and their associated impairment are often comorbid with ADHD and, for many children, are considered as an additional target for treatment.

A variety of issues need to be considered when determining if sleep problems constitute an additional diagnosis of insomnia disorder or are linked to ADHD-related treatment issues. First, a child's sleep can be affected if he or she is already taking stimulant medication or regularly consuming caffeine. The dosage and timing of this consumption needs to be tracked and manipulated to examine its effects; simple modifications of timing and dosage of stimulant consumption can improve sleep onset, duration, and quality. Second, sleep problems can occur from inadequate sleep health and/or hygiene[194] or from other disorders, such as anxiety and mood disorders, when the rumination and worry associated with them impairs or disrupts the child's sleep. Restructuring behavior preceding and at bedtime can dramatically improve sleep and diminish associated impairments. These potential causes of sleep disturbance and the related impairments that mimic or exacerbate ADHD symptoms need to be considered before diagnosing ADHD, related problems, or insomnia disorder.

Trauma

Children with ADHD are at higher-than-normal risk of experiencing some forms of trauma, including corporal punishment and accidents (often because of their risk-taking behaviors). In addition, posttraumatic stress disorder may manifest some similar symptoms. Depending on the child, the trauma may have been a one-time event or one to which they are consistently exposed. Exposure to trauma may exacerbate or lead to symptoms shared by trauma disorders and ADHD (eg, inattention). As a result, when evaluating a child for ADHD, obtaining a brief trauma history and screening for indicators of impairing responses to trauma can be helpful. Although a trauma history does not inform the diagnosis of ADHD, it may identify an alternative diagnosis and inform treatment and other interventions, including referral for trauma-focused therapy and reporting suspected abuse.

Mental Health Conditions

In children or adolescents who have coexisting mild depression, anxiety, or obsessive-compulsive disorder, the PCC may undertake the treatment of all disorders if doing so is within his or her abilities. Another option is to collaborate with a mental health clinician to treat the coexisting condition while the PCC oversees the ADHD treatment. As a third option, the consulting specialists may advise about the treatment of the coexisting condition to the extent that the PCC is comfortable treating both ADHD and the coexisting problems. With some coexisting psychiatric disorders, such as severe anxiety, depression, autism, schizophrenia, obsessive-compulsive

disorder, oppositional defiant disorder, conduct disorder, and bipolar disorder, a comanaging developmental-behavioral pediatrician or child and adolescent psychiatrist might take responsibility for treatment of both ADHD and the coexisting illness.

Many children with ADHD exhibit emotion dysregulation, which is considered to be a common feature of the disorder and one that is potentially related to other executive functioning deficits.[211] A child exhibiting emotion dysregulation with either or both positive (eg, exuberance) or negative (eg, anger) emotions along with symptoms of ADHD can be considered as a good candidate for an ADHD diagnosis. Sometimes behavior related to emotion dysregulation can lead the PCC to consider other diagnoses such as disruptive mood dysregulation disorder, intermittent explosive disorder, and bipolar disorder. All 3 may be diagnosed with ADHD. Intermittent explosive disorder and bipolar disorder are rare in children, and data are currently inadequate to know the prevalence of disruptive mood dysregulation disorder. Given the base rates, these other diagnoses are unlikely, although they do occur in childhood. If the PCC has any uncertainty about making these distinctions, referring the child to a clinical child psychologist or child mental health professionals may be warranted.

Learning Disabilities

Learning disabilities frequently co-occur with ADHD and can lead to symptoms and impairment that are similar to those in children with ADHD. As a result, screening for learning disabilities' presence, such as via the Vanderbilt ADHD Rating Scale,[212] is important given that treatment of ADHD and learning disabilities differ markedly.

Learning disabilities involve impairment related to learning specific academic content, usually reading or math, although there is increased awareness about disorders of written expression. The impairment is not attributable to difficulties with sustaining attention; however, some children with learning disabilities have trouble sustaining attention in class because they cannot keep up and then disengage. A careful evaluation for learning disabilities includes achievement testing, cognitive ability testing, and measures of the child's learning in response to evidence-based instruction. Such thorough evaluations are typically not available in a PCC practice. If screening suggests the possibility of learning disabilities, the PCC can help advise parents on how to obtain school psychoeducational evaluations or refer the child to a psychologist or other specialist trained in conducting these evaluations.

The PCC's attention is directed to language skills in preschool-aged and young school-aged children because difficulties in language skills can be a symptom of a language disorder and predictor of subsequent reading problems. Language disorders may present as problems with attention and impulsivity. Likewise, social interactions need to be noted during the examination because they may be impaired when the child or adolescent's language skills are delayed or disordered.

Children who have intellectual or other developmental disabilities may have ADHD, but assessment of these patients is more difficult because a diagnosis of ADHD would only be appropriate if the child or adolescent's level of inattention or hyperactivity/impulsivity is disproportionate to his or her developmental rather than chronological age. Therefore, assessment of ADHD in individuals with intellectual disabilities requires input from the child or adolescent's education specialists, school psychologists, and/or independent psychologists. Although it is important to attempt to differentiate whether the presenting problems are associated with learning disabilities, ADHD, or something else, it is important to consider the possibility that a child has multiple disorders. Pediatricians and other PCCs who are involved in assessing ADHD in children with intellectual disabilities will need to collaborate closely with school or independent psychologists.

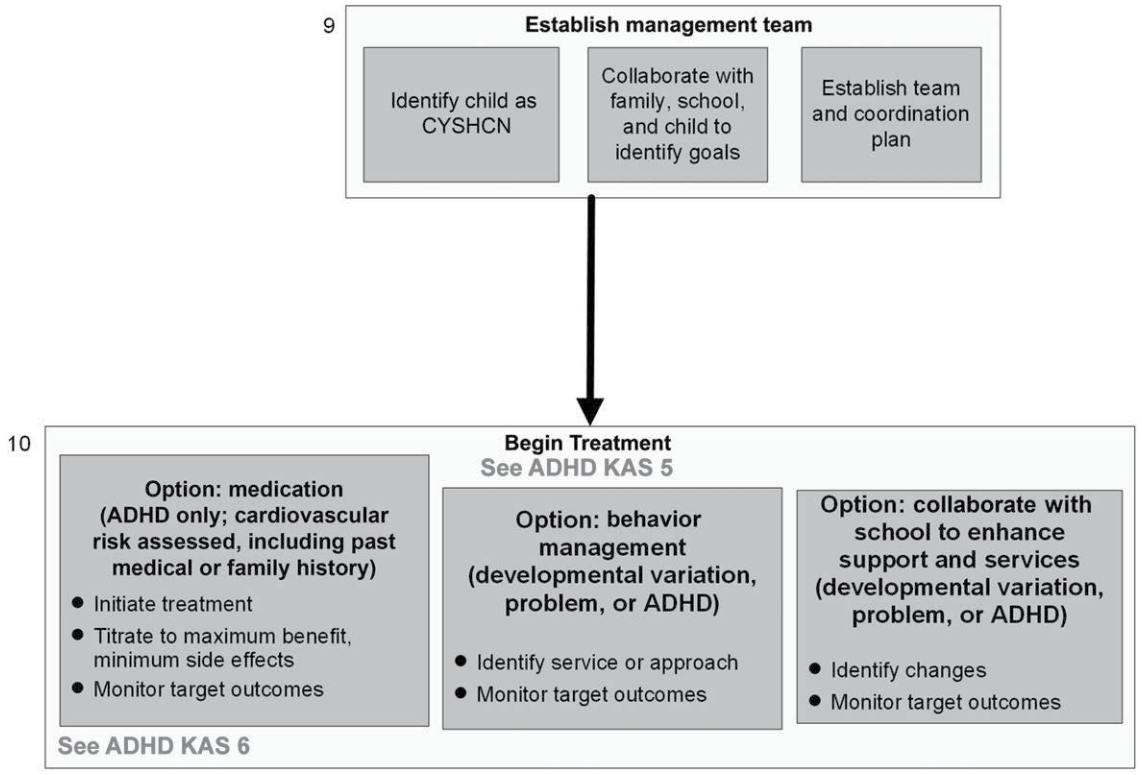
Summary

Overall, there are many factors that influence a diagnostic decision. Frequently, these decisions must be made without the benefit of all of the relevant information described. Family and cultural issues that affect parents' expectations for their child and perceptions about mental health can further complicate this process. Poverty, family history, access to care, and many other factors that a PCC will probably not know when making the diagnosis can also be formative in the child's presenting problems.[145,146,154,155,158] The PCC will wisely remain sensitive to individual variations in parents' beliefs, values, and perception of their culture and community when completing the assessment and determining a diagnosis. These factors add complexities to the assessment and diagnostic process and make a good evaluation and diagnosis a function of clinical experience, judgment, and a foundation in science.

IV. TREATMENT

If the child meets the *DSM-5* criteria for ADHD, including commensurate functional disabilities, progress through the PoCA.

(See the AHDH guideline's KASs 5 and 6.)



SUPPLEMENTAL FIGURE 7
Treatment. CYSHCN, children and youth with special health care needs.

IV a. Establish Management Team: Identify the Patient as a Child With Special Health Care Needs

Any child who meets the criteria for ADHD is considered a "child or youth with special health care needs"; these children are best managed in a medical home.[213–217] In addition, the AAP encourages clinicians to develop systems to allow the medical home to meet all needs of children with chronic illnesses. These needs and strategies for meeting them are discussed in further detail in AAP resources such as the Building Your Medical Home toolkit and Addressing Concerns in Primary Care: A Clinician's Toolkit. Care in the medical home is reviewed in the AAP publication *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition*. Pediatricians and other PCCs who provide effective medical homes identify family strengths and recognize the importance of parents in the care team.[218–221] The PCC may provide education about the disorder and treatment options, medication, and/or psychosocial treatment and monitor response to treatments over time as well as the child's development.

IV b. Establish Management Team: Collaborate With Family, School, and Child to Identify Target Goals

ADHD is a chronic illness; hence, education for both the child or adolescent and other family members is a critical element in the care plan. Family education involves all members of the family, including the provision of developmentally age-appropriate information for the affected child or adolescent and any siblings. Topics may include the disorder's potential causes and typical symptoms, the assessment process; common coexisting disorders; ADHD's effect on school performance and social participation; long-term sequelae; and treatment options and their potential benefits, adverse effects, and long-term outcomes. It is important to address the patient's self-concept and clarify that having ADHD does not mean that the child is less smart than others. At every stage, education must continue in a manner consistent with the child or adolescent's level of understanding.

The emphasis for parental education is on helping parents understand the disorder, how to obtain additional accurate information about ADHD and treatments, and how to effectively advocate for their child. This may include addressing parental concerns about labeling the child or adolescent with a disorder by providing information

on the benefits of diagnosis and treatment.

Some guidance about effective parenting strategies may be helpful, but PTBM is likely to be most beneficial for most parents (see the section on Psychosocial Treatments). Pediatricians and other PCCs are encouraged to be cognizant of the challenges families may face to attend such training, including taking time off from work and covering the costs associated with the intervention.

Parents may benefit from learning about optimal ways to partner with schools, particularly their child's teachers, and become part of the educational and intervention teams. Educating parents about special education and other services can be helpful, but school interventions and advocacy may be best aided by partnering closely with an advocate or clinician experienced in working with schools (see the Psychosocial Treatment section). With the parent's permission, the clinician may provide educators at the school with information from the evaluation that will help the school determine eligibility for special education services or accommodations and/or develop appropriate services.

In addition, it is helpful to provide assistance to the parent or other caregiver in understanding and using any relevant electronic health record (EHR) system. Sometimes, the health literacy gap around EHRs can lead to confusion and frustration on the family's side. Also, providing information on community resources, such as other health care providers or specialists, can be beneficial in addressing fragmentation and communication barriers.

Family education continues throughout the course of treatment and includes anticipatory guidance in areas such as transitions (eg, from elementary to middle school, middle to high school, and high school to college or employment); working with schools; and developmental challenges that may be affected by ADHD, including driving, sexual activity, and substance use and abuse. For parents who are interested in understanding the developmental aspects of children's understanding about ADHD (ie, causes, manifestations, treatments), several AAP publications may be useful.[222–224]

Although having a child diagnosed with ADHD can sometimes provide relief for families, it is important to check on the parents' well-being. Having a disruptive child who has trouble interacting with others can be stressful for parents, and learning that their child has a disorder sometimes gives them something to blame other than themselves. Helping families cope with parenting challenges or making referrals for services to address their stress or depression can be an important part of care. These concerns are particularly relevant when a parent has ADHD or associated conditions. Parents may require support balancing the needs of their child with ADHD and their other children's needs. Advocacy and support groups such as the National Resource on ADHD (a program of CHADD: https://chadd.org/about/about-nrc/) and the Attention Deficit Disorder Association (www.add.org) can provide information and support for families. There also may be local support organizations. The ADHD Toolkit provides lists of educational resources including Internet-based resources, organizations, and books that may be useful to parents and children.

IV c. Establish Management Team: Establish Team and Coordination Plan

Treatment Team

The optimal treatment team includes everyone involved in the care of the child: the child, parents, teachers, PCC, therapists, subspecialists, and other adults (such as coaches or faith leaders) who will be actively engaged in supporting and monitoring the treatment of ADHD.[218–221] It is helpful for the PCC or another assigned care coordinator to make each team member aware of his or her role, the process and timing of routine and as-needed communication strategies, and expectations for reports (ie, frequency, scope). Collaboration with school personnel goes beyond the initial report of diagnosis and is best facilitated by agreement on a standardized, reliable communication system. Although there are obstacles to achieving this level of coordination, if successful, it enhances care and improves outcomes for the child. (See Systemic Barriers to the Care of Children and Adolescents With ADHD section in the Supplemental Information for a discussion of systemic challenges.)

Treatment Goals

Management plans include the establishment of treatment goals for the areas of concern, such as those most commonly affected by ADHD: academic performance; relationships with peers, parents, and siblings; and safety. It is not necessary to develop goals in every area at once. Families might be encouraged to identify up to 3 of the most impairing areas to address initially. Parents and the child or adolescent can add other targets as indicated by their relative importance. Other goals may be identified using the International Classification of Function, Disability, and Health analysis conducted in the diagnostic phase of the clinical pathway. This process increases the understanding of ADHD's effects on each family member and may lead to improved collaboration in developing a few specific and measurable outcomes. It is helpful to incorporate a child's strengths and resilience when considering target goals and generating the treatment plan. Academic or school goals require the input of teachers and other personnel

for both identification and measurement.

Establishing measurable goals in interpersonal domains and improving behavior in unstructured settings may be particularly important. Wherever possible, progress should be quantifiable to monitor the frequency of behaviors. The number of achieved and missed goals per day can be recorded by the parent, child, and/or teacher. Charts may be suggested as strategies to record events so that parents, teachers, children, and PCCs can agree on how much progress has been made building success in a systematic and measurable way. Keeping the focus on progress toward the identified goals can keep all family members engaged, provide a rubric for measuring response to various treatments, and offer a vehicle for rewarding success. Such strategies can help a family accurately assess and see progress of behavior changes. A single-page daily report card can be used to identify and monitor 4 or 5 behaviors that affect function at school and the card can be shared with parents. Other strategies and tools are available to clinicians in the AAP *ADHD Provider Toolkit, Third Edition*,[225] and for parents, *ADHD: What Every Parent Needs to Know.*[226]

As treatment proceeds, in addition to using a *DSM-5*–based ADHD rating scale to monitor core symptom changes, formal and informal queries can be made in the areas affected by ADHD. At every visit, it is helpful for the PCC to gradually further empower children and adolescents so they are able to be full partners in the treatment plan by adolescence. Data from school are helpful at these visits, including rating scales completed by the child or adolescent's teacher, grades, daily behavior ratings (when available), and formal test results.

Management Plan

In addition to educating the family, the PCC can consider developing a management plan that, over time, addresses the following questions:

- Does the family need further assistance in understanding the core symptoms of ADHD and the child or adolescent's target symptoms and coexisting conditions?
- Does the family need support in learning how to establish, measure, and monitor target goals?
- Have the family's goals been identified and addressed in the care plan?
- Does the family have an understanding of effective behavior management techniques for responding to tantrums, oppositional behavior, and/or poor compliance with requests or commands?
- Does the family need help on normalizing peer and family relationships?
- Does the child need help in academic areas? If so, has a formal evaluation been performed and reviewed to distinguish work production problems secondary to ADHD or attributable to coexisting learning or language disabilities?
- Does the child or adolescent need assistance in achieving independence in self-help or schoolwork?
- Does the child or adolescent or family require help with optimizing, organizing, planning, or managing schoolwork?
- Does the family need help in recognizing, understanding, or managing coexisting conditions?
- Does the family have a plan to educate the child or adolescent systematically about ADHD and its treatment, as well as the child's own strengths and weaknesses?
- Does the family have a plan to empower the child or adolescent with the knowledge and understanding that will increase their adherence to treatments? Has that plan been initiated, and is it pitched at the child or adolescent's developmental level?
- Does the family have a copy of a care plan that summarizes the evaluation findings and treatment recommendations?
- Does the follow-up plan provide comprehensive, coordinated, family-centered, and culturally competent ongoing care?
- Does the family have any needed referrals to specialists to provide additional evaluations, treatments, and support?
- Does the family have a plan for the transition from pediatric to adult care that provides the transitioning youth with the necessary ADHD self-management skills, understanding of health care and educational privacy laws, identified adult clinician to continue his or her ADHD care, and health insurance coverage?

IV d. Treatment: Medication, Psychosocial Treatment, and Collaboration With the School to Enhance Support Services

The decision about the most acceptable treatment of the child rests with the family and its decisions about treatment. The PCC needs to encourage that this decision is based on accurate and adequate information, which often involves correcting misinformation or unwarranted concerns about medication. If the family still declines medication treatment, the PCC can encourage all other types of effective treatment and provide appropriate monitoring (families who decline medication are discussed in more detail below).

Pediatricians and other PCCs need to educate families about the benefits and characteristics of evidence-based ADHD psychosocial treatment and explicitly communicate that play therapy and sensory-related therapies have not been

demonstrated to be effective. Likewise, for children younger than 7 years, individual CBT lacks demonstrated effectiveness; CBT has some, but not strong, evidence for children 7 to 17 years of age. Families should be made aware that for psychosocial treatments to be effective, the therapist needs to work with the family (not just the child or adolescent) on setting and maintaining routines, discipline and reward-related procedures, training programs, and creating a home environment that will bring out the best in the child and minimize ADHD-related dysfunction.

(See the ADHD guideline KASs 5 and 6.)

Treatment: Medication

This treatment option is restricted to children and adolescents who meet diagnostic criteria for ADHD.

The FDA has approved stimulant medications (ie, methylphenidate and amphetamines) and several nonstimulant medications for the treatment of ADHD in children and adolescents. New brands of methylphenidate and amphetamines continue to be introduced, including longer-acting products, various isomeric products, and delayed-release products. Hence, it is increasingly unlikely that pediatricians and other PCCs need to consider the off-label use of other medications. A free and continually updated list of medications is available at www.adhdmedicationguide.com. (See the ADHD guideline for information on off-label use.)

With the expanded choices and considerations of the clinical effects comes the reality that clinical choices are often heavily restricted by insurance coverage. Some, but not all, of the problems include changes in insurance and formulary that preclude the use of certain medications or force a stable patient to change medications, step therapy requirements that may delay effective treatment, and financial barriers that preclude a patient's use of newer drugs or those not preferred by the payer. (See Systemic Barriers to the Care of Children and Adolescents with ADHD section in the Supplemental Information for a discussion of this issue.)

The choice of stimulant medication formulation depends on such factors as the efficacy of each agent for a given child, the preferred length of coverage, whether a child can swallow pills or capsules, and out-of-pocket costs. The extended-release formulations are generally more expensive than the immediate-release formulations. Families and children may prefer them, however, because of the benefits of consistent and sustained coverage with fewer daily administrations. Long-acting formulations usually avoid the need for school-based administration of ADHD medication. Better coverage with fewer daily administrations leads to greater convenience to the family and is linked with increased adherence to the medication management plan.[227]

Some patients, particularly adolescents, may require more than 12 hours of coverage daily to ensure adequate focus and concentration during the evening, when they are more likely to be studying and/or driving. In these cases, a nonstimulant medication or short-acting preparation of stimulant medication may be used in the evening in addition to a long-acting preparation in the morning. Of note, stimulant medication treatment of individuals with ADHD has been linked to better driving performance and a significant reduced risk of motor vehicle crashes.[78]

The ease with which preparations can be administered and the minimization of adverse effects are key quality-of-life factors and are important concerns for children, adolescents, and their parents. When making medication recommendations, PCCs have to consider the time of day when the targeted symptoms occur, when homework is usually done, whether medication remains active when teenagers are driving, whether medication alters sleep initiation, and risk status for substance use or stimulant misuse or diversion.

All FDA-approved stimulant medications are methylphenidate or amphetamine compounds and have similar desired and adverse effects. Given the extensive evidence of efficacy and safety, these drugs remain the first choice in medication treatment. The decision about what compound a PCC prescribes first should be made on the basis of individual clinician and family preferences and the child's age. Some children will respond better to, or experience more adverse effects with, 1 of the 2 stimulants groups (ie, methylphenidate or amphetamine) over another. Because this cannot be determined in advance, medication trials are appropriate. If a trial with 1 group is unsuccessful because of poor efficacy or significant adverse effects, a medication trial with medication from the other group should be undertaken. At least half of children who fail to respond to 1 stimulant medication have a positive response to the alternative medication.[228]

Of note, recent meta-analyses have documented some subtle group-level differences in amphetamine and/or dextroamphetamine and methylphenidate response. Authors of 1 such analysis found that, on average, youth with ADHD who were treated with either amphetamine- or methylphenidate-based medications showed improvement in ADHD symptoms.[229] There was a marginally larger improvement in clinicians' ADHD symptom ratings for amphetamine-based versus methylphenidate-based

preparations.[229] This meta-analysis indicated that overall adverse effects (including sleep problems and emotional side effects) were more prominent among those using amphetamine-based preparations. The findings were corroborated by a 2018 meta-analysis in which authors found that amphetamine and/or dextroamphetamine worsened emotional lability compared to the premedication baseline. Authors of the meta-analysis found there was a tendency for methylphenidate to reduce irritability and anxiety compared to the patients' premedication ratings.[230] Among individual patients, medication's efficacy and adverse effects can vary from these averages.

Families who are concerned about the use of stimulants or the potential for their abuse and/or diversion may choose to start with atomoxetine, extended-release guanfacine, or extended-release clonidine. In addition, those not responding to either stimulant group may still respond to atomoxetine, extended-release guanfacine, or extended-release clonidine.

There is a black box warning on atomoxetine about the possibility of suicidal ideation when initiating medication management. Early symptoms of suicidal ideation may include thinking about self-harm and increasing agitation. If there are any concerns about suicidal ideation in children prescribed atomoxetine, further evaluation (ie, using the Patient Health Questionnaire-9 rating scale, asking about suicidal ideation, reviewing presence of firearms in the home, determining if there is good communication between the patient and parents or trusted adults, etc), reconsideration about the use of atomoxetine, and more frequent monitoring should be considered; referral to a mental health clinician may be necessary.

Atomoxetine is a selective norepinephrine reuptake inhibitor that may demonstrate maximum response after approximately 4 to 6 weeks of use, although some patients experience modest benefits after 1 week of atomoxetine treatment. Extended-release guanfacine and extended-release clonidine are α-2A adrenergic agonists that may demonstrate maximum response in about 2 to 4 weeks. It is worth making families aware that symptom change is more gradual with atomoxetine and α-2A adrenergic agonists than the rapid effect seen with stimulant medications. Atomoxetine may cause gastrointestinal tract symptoms and sedation early on, so it is recommended to prescribe half the treatment dose (0.5 mg/kg) for the first week. Appetite suppression can also occur. Both α-2A agonists can cause the adverse effect of somnolence. It is recommended that α-2A agonists be tapered when discontinued to prevent possible rebound hypertension.

In patients who only respond partially to stimulant medications, it is possible to combine stimulant and nonstimulant α-2 agonist medications to obtain better efficacy (see Medication for ADHD section in the clinical practice guideline). It is helpful to ask the family if they have any previous experience with any of the medications because a previous good or bad experience in other family members may indicate a willingness or reluctance to use 1 type or a specific stimulant medication. When there is concern about possible use or diversion of the medication or a strong family preference against stimulant medication, an FDA-approved nonstimulant medication may be considered as the first choice of medication.

Medications that use a microbead technology can be opened and sprinkled on food and are, therefore, suitable for children who have difficulty swallowing tablets or capsules. For patients who are unable to swallow pills, alternative options include immediate- and extended-release methylphenidate and amphetamine in a liquid and chewable form, a methylphenidate transdermal patch, and an orally disintegrating tablet.

It is often helpful to inform families that the initial medication titration process may take several weeks to complete, medication changes can be made on a weekly basis, and subsequent changes in medication may be necessary. Completion of ADHD rating scales before dose adjustment helps promote measurement-based treatment. The usual procedure is to begin with a low dose of medication and titrate to the dose that provides maximum benefit and minimal adverse effects. Core symptom reduction can be seen immediately with stimulant medication initiation, but improvements in function require more time to manifest. Stimulant medications can be effectively titrated with changes occurring in a 3- to 7-day period. During the first month of treatment, the medication dose may be titrated with a weekly or biweekly follow-up. The increasing doses can be provided either by prescriptions that allow dose adjustments upward or, for some of medications, by 1 prescription of tablets or capsules of the same strength with instructions to administer progressively higher amounts by doubling or tripling the initial dose.

Another approach, similar to the one used in the MTA study,[228] is for parents to be directed to administer different doses of the same preparation, each for 1 week at a time (eg, Saturday through Friday). At the end of each week, feedback from parents and teachers and/or *DSM-5*–based ADHD rating scales can be obtained through a phone interview, fax, or a secure electronic system. In addition to the ADHD rating scale, parents and teachers can be asked to

review adverse effects and progress on target goals.

Follow-up Visits

A face-to face follow-up visit is recommended at about the fourth week after starting the medication. At this visit, the PCC reviews the child or adolescent's responses to the varying doses and monitors adverse effects, pulse, BP, and weight. To promote progress in controlling symptoms is maintained, PCCs will continue to monitor levels of core symptoms and improvement in specified target goals. ADHD rating scales should be completed at each visit, particularly before any changes in medication and/or dose.

In the first year of treatment, face-to-face visits to the PCC are recommended to occur on a monthly basis until consistent and optimal response has been achieved, then they should occur every 3 months. Subsequent face-to-face visits will be dependent on the response; they typically occur quarterly but need to occur at least twice annually until it is clear that target goals are progressing and that symptoms have stabilized. Thereafter, visits occur periodically as determined by the family and the PCC. After several years, if the child or adolescent is doing well and wants to attempt a trial off of the medication, this can be initiated.

Results from the MTA study suggest that there are some children who, after 3 years of medication treatment, continue to improve even if the medication is discontinued.[13] These findings suggest that children who are stable in their improvement of ADHD symptoms may be given a trial off medication after extended periods of use to determine if medication is still needed. This process is best undertaken with close monitoring of the child's core symptoms and function at home, in school, and in the community. If pharmacologic interventions do not improve the child or adolescent's symptoms, the diagnosis needs to be reassessed (see Treatment Failure section).

Whenever possible, improvements in core symptoms and target goals should be monitored in an objective way (eg, an increase from 40% goal attainment to 80% per week; see the ADHD Toolkit for more information). Core symptoms can be monitored with 1 of the *DSM-5*–based ADHD rating scales.

Pediatricians and other PCCs are encouraged to educate parents that although medications can be effective in facilitating schoolwork, they have not been shown to be effective in addressing learning disabilities or a child's level of motivation. A child or adolescent who continues to experience academic underachievement after attaining some control of his or her ADHD behavioral symptoms needs to be assessed for a coexisting condition. Such coexisting conditions include learning and language disabilities, other mental health disorders, and other psychosocial stressors. This assessment is part of the initial assessment in children who present with difficulties in keeping up with their schoolwork and grades and who are rated as having problems in the 3 academic areas (ie, reading, writing, and math).

Treatment: Psychosocial Treatment

Two types of psychosocial treatments are well established for children and adolescents with ADHD, including some behavioral treatments and training.[25]

Behavioral Treatments

There is a great deal of evidence supporting the use of behavioral treatments for preschool-aged and elementary and middle school–aged children, including several types of PTBM and classroom interventions (see the clinical practice guideline for more information). There are multiple PTBM programs available, which are reviewed in the ADHD Toolkit.[225]

Evidence-based PTBM training typically begins with 7 to 12 weekly group or individual sessions with a trained or certified therapist. Although PTBM treatments differ, the primary focus is on helping parents improve the methods they use to reward and motivate their child to reduce the behavioral difficulties posed by ADHD and improve their child's behavior. Therapists help parents establish consistent relationships or contingencies between the child's specific behaviors and the parents' use of rewards or logical consequences for misbehavior. These treatments typically use specific directed praise, point systems, time-outs, and privileges to shape behavior. Parents learn how to effectively communicate expectations and responses to desirable and undesirable behaviors.

PTBM programs offer specific techniques for reinforcing adaptive and positive behaviors and decreasing or eliminating inappropriate behaviors, which alter the motivation of the child or adolescent to control attention, activity, and impulsivity. These programs emphasize establishing positive interactions between parents and children, shaping children's behaviors through praising and strengths spotting, giving successful commands, and reinforcing positive behaviors. They help parents to extinguish inappropriate behaviors through ignoring, to identify behaviors that are most appropriately handled through natural consequences, and to use natural consequences in in a responsible way.

These programs all emphasize teaching self-control and building positive family relationships. If parents strongly disagree about behavior management or have contentious relationships, parenting programs will likely be unsuccessful.

Depending on the severity of the child or adolescent's behaviors and the capabilities of the parents, group or individual training programs will be required. Programs may also include support for maintenance and relapse prevention.

Although all effective parenting uses behavioral techniques, applying these strategies to children or adolescents with ADHD requires additional rigor, adherence, and persistence, compared with children without the disorder. Some PTBM programs include additional components such as education about ADHD, development and other related issues, motivational interviewing, and support for parents coping with a child with ADHD.

PTBM training has been modified for use with adolescents to incorporate a family therapy approach that includes communication, problem-solving, and negotiation. Initially developed for adolescents with a wide range of problems,[94,231] this approach has been modified for adolescents with ADHD.[94,233] The approach's effects are not as large as with PTBM training with children, but clear benefits have been reported; this is a feasible clinic-based approach that warrants a referral, if available.

Although PTBM training is typically effective, such programs may not be available in many areas (see Systemic Barriers to the Care of Children and Adolescents with ADHD section in the Supplemental Information for further discussion of this issue[153]). Factors that may diminish PTBM's effects and/or render them ineffective include the time commitment required to attend sessions and practice the recommendations at home, particularly given other competing demands for the family's time. Parental disagreements about implementing the PTBM program, conflicts between parents, and separated parents who share caretaking responsibilities can adversely affect the results. Careful monitoring of progress and follow-up by the therapist or PCC can reduce the likelihood of these risks. PTBM training may not be covered by health insurance (insurance issues are discussed in the Systemic Barriers to the Care of Children and Adolescents With ADHD section).

Training Interventions

Training interventions are likely to be effective with children and adolescents with ADHD. These interventions involve targeting specific deficiencies in skills such as study, organization, and interpersonal skills. Effective training approaches involve targeting a set of behaviors that are useful to the child in daily life and providing extensive training, practice, and coaching over an extended period of time. For some children, the combination of behavioral treatments and training may be most effective. Psychosocial treatments are applicable for children who have problems with inattentive or hyperactive/impulsive behaviors but do not meet the *DSM-5* criteria for a diagnosis of ADHD.

Many of the behavioral and training treatments described above can be provided at school. Coaching, which has emerged as a treatment modality over the last decade, can be a useful alternative to clinic- or school-based treatments. There has yet to be rigorous studies to support its benefits, although it has good face validity. Currently, there is no standardized training or certification for coaches.

Other Considerations

PCCs can make recommendations about treatments that are most likely to help a child or adolescent with ADHD and discourage the use of nonmedication treatments that are unlikely to be effective. Pediatricians and other PCCs are encouraged to discuss what parents have tried in the past and what has been beneficial for the child and his or her family.

Treatments for which there is insufficient evidence include large doses of vitamins and other dietary alterations, vision and/or visual training, chelation, EEG biofeedback, and working memory (ie, cognitive training) programs.[25] To date, there is insufficient evidence to determine that these therapies lead to changes in ADHD's core symptoms or functioning. There is a lack of information about the safety of many of these alternative therapies. Although there is some minimal information that significant doses of essential fatty acids may help with ADHD symptoms, further study on effectiveness, negative impacts, and adverse effects is needed before it can be considered a recommended treatment.[233]

As noted, some therapies that are effective for other disorders are not supported for use with children or adolescents with ADHD. These include CBT (which has documented effectiveness for the treatment of anxiety and depressive disorders), play therapy, social skills training, and interpersonal talk therapy. Although it is possible that these treatments may improve ADHD symptoms in a specific child or adolescent, they are less likely to do so compared to evidence-based treatments. As a result, the PCC should discourage use of these approaches. If these ineffective treatments are attempted before evidence-based modalities, parents may erroneously conclude that all mental health treatments are ineffective. For example, if CBT or play therapy does not help their child's ADHD, parents may dismiss other treatments, like PTBM, which could be helpful. Parents also may discount CBT if it subsequently is recommended for an emerging anxiety disorder.

Pediatricians and other PCCs are unlikely to be effective in providing

psychosocial treatment unless they are specifically trained, have trained staff, are colocated with a therapist, or dedicate multiple visits to providing this treatment. Clinicians may have difficulty determining if the therapists listed in the patient's health insurance plan have the requisite skills to provide evidence-based, psychosocial ADHD-related treatment. This determination is important because many therapists focus on a play therapy or interpersonal talk therapy, which have not been shown to be effective in treating the impairments associated with ADHD.

Pediatricians and other PCCs may want to develop a resource list of local therapists, agencies, and other mental health clinicians who can treat these impairments. Clinicians might request references from other parents of children with ADHD, professional organizations (eg, the Association for Behavioral and Cognitive Therapies), and ADHD advocacy organizations (eg, CHADD). Parents who have read authoritatively written books about psychosocial treatment may be in a better position to know what they are looking for in a therapist. Some of these resources are available in the ADHD Toolkit[225] and in *ADHD: What Every Parent Needs to Know*[226] as well as other online sources.[226,234–236] Unfortunately, lack of insurance coverage, availability, and accessibility of effective services may limit the implementation of this process (see Systemic Barriers to the Care of Children and Adolescents with ADHD section in the Supplemental Information for further discussion).

Treatment: Collaborate With School to Enhance Support and Services

School-based approaches have demonstrated both short- and long-term benefits for at least 1 year beyond treatment.[95,97] Schools can implement behavioral or training interventions that directly target ADHD symptoms and interventions to enhance academic and social functioning. Schools may use strategies to enhance communication with families, such as daily behavior report cards. All schools should have specialists (eg, school psychologists, counselors, special educators) who can observe the child or adolescent, identify triggers and reinforcers, and support teachers in improving the classroom environment. School specialists can recommend accommodations to address ADHD symptoms, such as untimed testing, testing in less distracting environments, and routine reminders. As children and adolescents get older, their executive functioning skills continue developing. Thus, their delays may decrease, and they may no longer need the accommodations. Alternatively, further intervention may be indicated to facilitate the development of these independent skills.

It is helpful for PCCs to be aware of the eligibility criteria for 504 Rehabilitation Act and the IDEA support in their state and local school districts.[143] It is helpful to understand the process for referral and the specific individuals to contact about these issues. Providing this information to parents will support their efforts to secure classroom adaptations for their child or adolescent, including the use of empirically supported academic interventions to address the achievement difficulties that are often associated with ADHD symptoms.

Educate Parents About School Services

School is often the place where many problems of a child or adolescent with ADHD occur. Although services are available through special education, IDEA, and Section 504 plans, classroom teachers can help students with ADHD. Students with ADHD are most likely to succeed in effectively managed classrooms in which teachers provide engaging instruction, support their students, and implement rules consistently. School staff can sometimes consult with classroom teachers to help them improve their skills in these areas. In many schools, parents can ask the principal for a specific teacher for their child the following academic year.

In some schools, teachers may implement activities to help a student before he or she is considered for special services, including a daily report card, organization interventions, behavioral point systems, and coordinating with the parents, such as using Web sites or portal systems for communication. Individualized behavioral interventions, if implemented well and consistently, are some of the most effective interventions for children with ADHD. In addition to individualized interventions, encouraging parents to increase communication with the teacher can help parents reinforce desirable behavior at school.

If these approaches are not adequate or teachers are unwilling to provide them, parents can be encouraged to write to the principal or the director of special education requesting an evaluation for special education services. An evaluation from a PCC can help this evaluation process but is unlikely to replace it. A child who has an ADHD diagnosis may be eligible for special education services in the category of "other health impaired." Depending on the specific nature of a child's impairment at school, he or she may be eligible for the categories of "emotional and behavioral disorders" or "specific learning disability." The category of eligibility does not affect the services available to the child but usually reflect the nature of the problems that resulted in his or her eligibility for special education services.

Although a PCC may recommend that a child is eligible for special education

and specific services, these are only recommendations, as specific evaluation procedures and criteria for eligibility are determined by each school district within federal guidelines. If the ADHD is severe and interfering with school performance, services are usually provided under the other health impaired category. It is important for PCCs to avoid using language in the report that could alienate people in the school or create conflict between the parents and school staff. After school staff complete the evaluation, a meeting will be held to review the results of all evaluation information (including the PCC report) and determine the student's eligibility for an IEP or a 504 plan. If they wish, the parents may invite others to attend the meeting. Some communities have individuals who are trained to help parents effectively advocate for services; being aware of existing resources, if they exist, can help the PCC refer parents to them. Additional details about eligibility are usually available on the Web sites of the school district and the state department of education.

A PCC can help educate the parents about the types of services they can request at the meeting. There are generally 2 categories of services. Some of the most common services are often referred to as accommodations, including extending time on tests, reducing homework, or providing a child with class notes from the teacher or a peer. These services reduce the expectations for a child and can quickly eliminate school problems. For example, if a child is failing classes because he or she is not completing homework and the teacher stops assigning the child homework, then the child's grade in the class is likely to improve quickly. Similarly, parent-child conflict regarding homework will quickly cease. Although these outcomes are desirable, if discontinuing the expectation for completing homework results does not help improve the student's ability to independently complete tasks outside school, which is an important life skill, it may not be beneficial. Although appealing, these services may not improve and in some cases may decrease the child's long-term competencies. They need to be considered with this in mind.

The second set of services consists of interventions that enhance the student's competencies. These take much more work to implement than the services described above and do not solve the problem nearly as quickly. Although appealing, these services may decrease the child's long-term competencies if they are not combined with interventions that are aimed at improving the student's skills and behaviors. Accommodations need to be considered with this broader context in mind. The advantage of interventions is that many students improve their competencies and become able to independently meet age-appropriate expectations over time (for more information on this approach, see information on the Life Course Model[237]).[238] Interventions include organization interventions, daily report cards, and training study skills. The following school-based interventions have been found to be effective in improving academic and interpersonal skills for students with ADHD: Challenging Horizons Program,[95] Child Life and Attention Skills Program,[239] and Homework and Organization Planning Skills.[96] If these are available in area schools, it is important to encourage their use.

V. AGE-RELATED ISSUES

V a. Preschool-Aged Children (Age 4 Years to the Sixth Birthday)

Clinicians can initiate treatment of preschool-aged children with ADHD (ie, children age 4 years to the sixth birthday) with PTBM training and assess for other developmental problems, especially with language. If children continue to have moderate-to-severe dysfunction, the PCC needs to reevaluate the extent to which the parents can implement the therapy; the PCC can also consider prescribing methylphenidate, as described previously. Titration should start with a small dose of immediate-release methylphenidate because preschool-aged children metabolize medication at a slower rate. They have shown lower optimal milligrams-per-kilogram daily doses than older children and may be more sensitive to emotional side effects such as irritability and crying.[83,98]

Currently, dextroamphetamine is the only FDA-approved ADHD medication to treat preschool-aged children. However, when dextroamphetamine received FDA approval, the criteria were less stringent than they are now, so there is only sparse evidence to support its safety and efficacy in this age group. There is more abundant evidence that methylphenidate is safe and efficacious for preschool-aged children with ADHD. For this reason, methylphenidate is the first-line recommended ADHD medication treatment of this age group despite not having FDA approval.[28]

The Preschool ADHD Treatment Study,[83] the landmark trial documenting methylphenidate's safety and efficacy in this age group, included children with moderate-to-severe dysfunction. Therefore, the recommendation for methylphenidate treatment is reserved for children with significant, rather than mild, ADHD-related impairment. In the Preschool ADHD Treatment Study trial, moderate-to-severe impairment was defined as having symptoms present for at least 9 months and clear impairment in both the home and child care and/or preschool settings that did not respond to an appropriate intervention.

There is limited published evidence of the safety and efficacy for the preschool-aged group of atomoxetine,

extended-release guanfacine, or extended-release clonidine. None of these nonstimulant medications have FDA approval for this age group.[47]

V b. Adolescents (Age 12 Years to the 18th Birthday)

Pediatricians and other PCCs may increase medication adherence and engagement in the treatment process by closely involving adolescents (age 12 years to the 18th birthday) in medication treatment decisions. Collaborating with the adolescent to determine if the medication is beneficial can help align outcome measures with the adolescent's own goals. Special attention ought to be paid to provide medication coverage at times when the adolescent may exhibit risky behaviors, such as when he or she is driving or spending unsupervised time with friends. Longer-acting or late-afternoon administration of nonstimulant medications or short-acting medications may be helpful.

If pediatricians and other PCCs begin transitioning children to be increasingly responsible for treatment decisions during early adolescence, then transitioning to a primary care physician who specializes in care for adults will be a natural continuation of that process when the adolescent reaches the highest grades in high school. Preparation for the transition to adulthood is an important step that includes planning for transferring care, adapting treatment to new activities and schedules, and educating the patient about effective ways to obtain insurance and engage in services.

Counseling for adolescents around medication issues needs to include dealing with resistance to treatment and empowering the patient to take charge of and own his or her medication management as much as possible. Techniques of motivational interviewing may be useful in improving adherence.[240]

In addition to the numerous developmental changes encountered when working with adolescents, PCCs should assess adolescent patients with ADHD for symptoms of substance use or abuse before beginning medication treatment. If substance use is revealed, the patient should stop the use. Referral for treatment of substance use must be provided before beginning treatment of ADHD (see the clinical practice guideline). Pediatricians and other PCCs should pay careful attention to potential substance use and misuse and diversion of medications. Screening for signs of substance use is important in the care of all adolescents and, depending on the amount of use, may lead a PCC to recommend treatment of substance use. Extensive use or abuse may result in concerns about continuing medication treatment of ADHD until the abuse is resolved. Similar concerns and consideration of discontinuing medication treatment of ADHD could emerge if there is evidence that the adolescent is misusing or diverting medications for other than its intended medical purposes. Pediatricians and other PCCs are encouraged to monitor symptoms and prescription refills for signs of misuse or diversion of ADHD medication. Diversion of ADHD medication is a special concern among adolescents.[132]

When misuse or diversion is a concern, the PCC might consider prescribing nonstimulant medications with much less abuse potential, such as atomoxetine, extended-release guanfacine, or extended-release clonidine. It is more difficult but not impossible to extract the methylphenidate or amphetamine for abuse from the stimulant medications lisdexamfetamine, dermal methylphenidate, and osmotic-release oral system methylphenidate, although these preparations still have some potential for abuse or misuse.

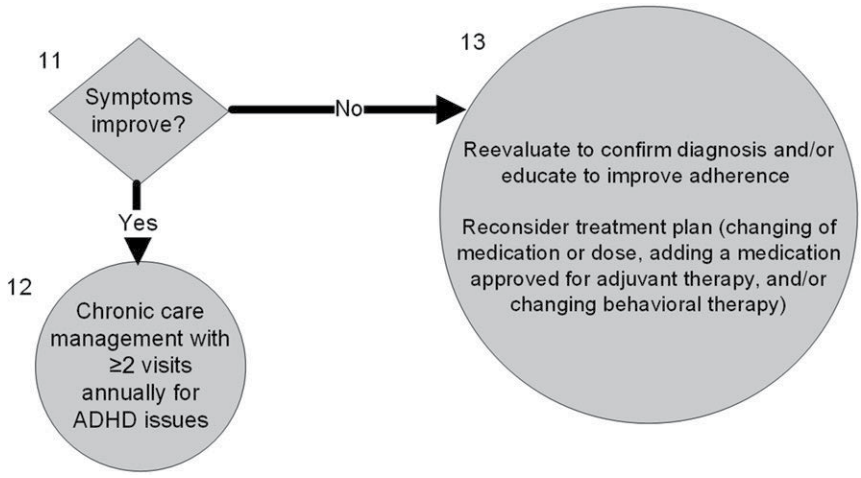
PCCs should be aware that short-acting, mixed amphetamine salts are the most commonly misused or diverted ADHD medication. It is important to note that diversion and misuse of ADHD medications may be committed by individuals who have close contact with or live in the same house as the adolescent, not necessarily by the adolescent him- or herself; this is especially true for college-aged adolescents. Pediatricians and other PCCs are encouraged to discuss safe storage practices, such as lockboxes for controlled substances, when used by college-aged adolescents.

VI. MONITORING

Pediatricians and other PCCs should regularly monitor all aspects of ADHD treatment, including the following:

- systematic reassessment of core symptoms and function;
- regular reassessment of target goals;
- family satisfaction with the care it is receiving from other clinicians and therapists, if applicable;
- provision of anticipatory guidance, further child or adolescent and family education, and transition planning as needed and appropriate;
- occurrence and quality of care coordination to meet the needs of the child or adolescent and family;
- confirmation of adherence to any prescribed medication regimen, with adjustments made as needed;
- HR, BP, height, and weight monitoring; and
- furthering the therapeutic relationship with the child or adolescent and empowering families and children or adolescents to be strong, informed advocates.

Some treatment monitoring can occur during general health care visits if the PCC inquires about the child or adolescent's progress toward target goals, adherence to medication and behavior therapy, concerns, and



SUPPLEMENTAL FIGURE 8
Monitoring.

changes. This extra time and evaluation effort may generate an evaluate and management (E/M) code along with the well-child care code and may result in an additional cost to the family (see the section on barriers, specifically the compensation section[153]). Monitoring of a child or adolescent with inattention or hyperactivity/impulsivity problems can help to ensure prompt treatment should symptoms worsen to the extent that a diagnosis of ADHD is warranted.

As treatment proceeds, in addition to using a *DSM-5*–based ADHD rating scale to monitor core symptom changes, the PCC can make formal and informal queries in the areas of function most commonly affected by ADHD: academic achievement; peer, parent, or sibling relationships; and risk-taking behavior. Progress can be measured by monitoring the target goals established in collaboration with the child and family. Checklists completed by the school can facilitate medication monitoring. Data from the school, including ADHD symptom ratings completed by the teacher as well as grades and any other formal testing, are helpful at these visits. Screening for substance use and sleep problems is best continued throughout treatment because these problems can emerge at any time. At every visit, it is helpful to gradually further empower children to become full partners in their treatment plan by adolescence.

In the early stages of treatment, after a successful titration period, the frequency of follow-up visits will depend on adherence, coexisting conditions, family willingness, and persistence of symptoms. As noted, a general guide for visits to the PCC is for these visits to occur initially on a monthly basis, then at least quarterly for the first year of treatment. More frequent visits may be necessary if comorbid conditions are present. Visits then need be held preferably quarterly but at least twice each year, with additional phone contact monitoring at the time of medication refill requests. Ongoing communication with the school regarding medication and services is needed.

There is little evidence establishing the optimal, practical follow-up regimen. It is likely that the regimen will need to be tailored to the individual child or adolescent and family needs on the basis of clinical judgment. Follow-up may incorporate electronic collection of rating scales, telehealth, or use of remote monitoring of symptoms and impairment. The time-intensive nature of this process, insurance restrictions, and lack of payment may be significant barriers to adoption (see Systemic Barriers to the Care of Children and Adolescents with ADHD section in the Supplemental Information for more information on this issue).

(See the ADHD guideline's KAS 4.)

VI A. TREATMENT FAILURE

ADHD treatment failure may be a sign of inadequate dosing, lack of patient or family information or compliance, and/or incorrect or incomplete diagnosis. Family conflict and parental psychopathology can also contribute to treatment failure.

In the event of treatment failure, the PCC is advised to repeat the full diagnostic evaluation with increased attention to the possibility of another condition or comorbid conditions that mimic or are associated with ADHD, such as sleep disorders, autism spectrum disorders, or epilepsy (eg, absence epilepsy or partial seizures). Treatment failure may also arise from a new acute stressor or from an unrecognized or underappreciated traumatic event. A coexisting learning disability may cause an apparent treatment failure. In the case of a child or adolescent previously

diagnosed with problem-level inattention or hyperactivity, repeating the diagnostic evaluation may result in a diagnosis of ADHD, which would allow for increased school support and the inclusion of medication in the treatment plan. A forthcoming complex ADHD guideline from the SDBP will provide additional information on diagnostic evaluation and treatment of children and adolescents with ADHD treatment failure and/or ADHD that is complicated by coexisting developmental or mental health conditions.

Treatment failure could result from poor adherence to the treatment plan. Increased monitoring and education, especially by including the patient, may increase adherence. It is helpful to try to identify the issues restricting adherence, including lack of information about or understanding of the treatment plan. It is also important to recognize that cultural factors may impact the patient's treatment and outcomes.

If the child continues to struggle despite the school's interventions and treatment of ADHD, further psychoeducational, neuropsychological, and/or language assessments are necessary to evaluate for a learning, language, or processing disorder. The clinician may recommend evaluation by an independent psychologist or neuropsychologist.

VII. CHILDREN AND ADOLESCENTS FOR WHOM AN ADHD DIAGNOSIS IS NOT MADE

If the evaluation identifies or suggests another disorder is the cause of the concerning signs and symptoms, it is appropriate to exit this algorithm.

VII a. Other Condition

The subsequent approach is dictated by the evaluation's results. If the PCC has the expertise and ability to evaluate and treat the other or comorbid condition, he or she may do so. Many collaborative care models exist to help facilitate a pediatrician's comfort with comorbidity, as well as programs that teach pediatricians to manage comorbidities. It is important for the PCC to frame the referral questions clearly if a referral is made. A comanagement plan must be established that addresses the family's and child or adolescent's ongoing needs for education and general and specialty health care. Resources from the AAP Mental Health Initiatives and the forthcoming complex ADHD clinical practice guideline from the SDBP may be helpful.[67,133,241]

VII b. Apparently Typical or Developmental Variation

Evaluation may reveal that the child or adolescent's inattention, activity level, and impulsivity are within the typical range of development, mildly or inconsistently elevated in comparison with his or her peers, or is not associated with any functional impairment in behavior, academics, social skills, or other domains. The clinician can probe further to determine if the parents' concerns are attributable to other issues in the family, such as parental tension or drug use by a family member; whether they are caused by other issues in school, such as social pressures or bullying; or whether they are within the spectrum of typical development.

In talking with parents, it may help to explain that ADHD differs from a condition like pregnancy, which is a "yes" or "no" condition. With ADHD, behaviors follow a spectrum from variations on typical behavior, to atypical behaviors that cause problems but are not severe enough to be considered a disorder, to consistent behaviors that are severe enough to be considered a disorder. With problematic behaviors, it is helpful for the PCC to provide education about both the range of typical development and strategies to improve the child or adolescent's behaviors. A schedule of enhanced surveillance absolves the family of the need to reinitiate contact if the situation deteriorates. If a recommendation for continued routine systematic surveillance is made by the PCC, it is important to provide reassurance that ongoing concerns can be revisited at future primary care visits.

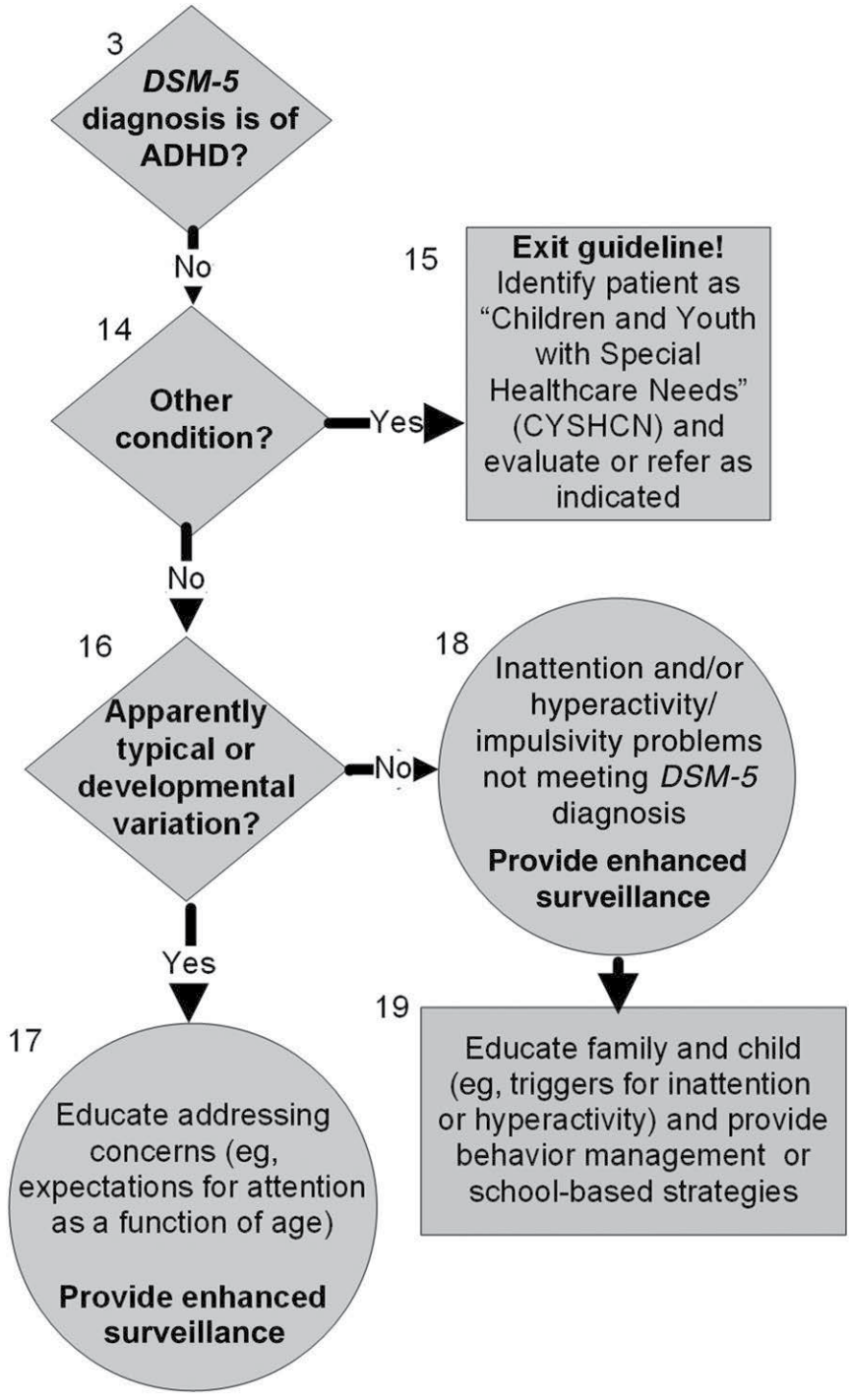
VII c. Children and Adolescents With Inattention or Hyperactivity/Impulsivity (Problem Level)

Children and adolescents whose symptoms do not meet the criteria for diagnosis of ADHD may still encounter some difficulties or mild impairment in some settings, as described in the *DSM-PC*, *Child and Adolescent Version*.[49] For these patients, enhanced surveillance is recommended. PCCs are encouraged to provide education for both the patient and his or her family, specifically about triggers for inattention and/or hyperactivity as well as behavior management strategies.

Medication is not appropriate for children and adolescents whose symptoms do not meet *DSM-5* criteria for diagnosis of ADHD, but PTBM does not require a diagnosis of ADHD to be recommended.

VIII. COMPLEMENTARY AND ALTERNATIVE THERAPIES AND/OR INTEGRATIVE MEDICINE

Families of children and adolescents with ADHD increasingly ask their pediatrician and other PCCs about complementary and alternative therapies. These include megavitamins and other dietary alterations, vision and/or visual training, chelation, EEG biofeedback, and working memory (eg, cognitive training) programs.[242] As noted, there is insufficient evidence to suggest that these therapies lead to changes in ADHD's core symptoms or function.



SUPPLEMENTAL FIGURE 9
Children and adolescents for whom an ADHD diagnosis is not made. CYSHCN, children and youth with special health care needs.

For many complementary and alternative therapies, limited information is available about their safety. Both chelation and megavitamins have been proven to cause adverse effects and are contraindicated.[243,244] For these reasons, complementary and alternative therapies are not recommended.

Pediatricians and other PCCs can play a constructive role in helping families make thoughtful treatment choices by reviewing the goals and/or effects claimed for a given treatment, the state of evidence to support or discourage use of the treatment, and known or potential adverse effects. If families are interested in trying complementary and alternative treatments, it is helpful to have them

define specific measurable goals to monitor the treatment's impact. Families also need to be strongly encouraged to use evidence-based interventions while they explore complementary and alternative treatments. PCCs have to respect families' interests and preferences while they address and answer questions about complementary and alternative therapies.

Pediatricians and other PCCs should ask about additional therapies that families may be administering to adequately monitor for drug interactions. Parents and children or adolescents who do not feel that their choices in health care are respected by their PCCs may be less likely to communicate about complementary or alternative therapies and/or integrative medicine.

IX. IMPLEMENTATION ISSUES: PREPARING THE PRACTICE

Implementation of the process described in this algorithm can be enhanced with preparation of the practice to meet the needs of children and adolescents with ADHD. This preparation includes both internal practice characteristics and relationships within the community. (More detail can be found in the AAP Mental Health Initiatives' resources.[133,245])

The following office procedures and resources will help practices facilitate the steps in this algorithm:

- developing a packet of ADHD questionnaires and rating scales for parents and teachers to complete before a scheduled visit;
- allotting adequate time for ADHD-related visits;
- determining billing and documentation procedures and monitoring insurance payments to appropriately capture the services rendered to the extent possible;
- implementing methods to track and follow patients (see Systemic Barriers to the Care of Children and Adolescents with ADHD section in the Supplemental Information for more information on this issue);
- asking questions during all clinical encounters and promoting patient education materials (ie, brochures and posters) that alert parents and patients that appropriate issues to discuss with the PCC include problem behaviors, school problems, and concerns about attention and hyperactivity;
- developing an office system for monitoring and titrating medication, including communication with parents and teachers. For stimulant medications, which are controlled substances requiring new, monthly prescriptions, it is necessary to develop a monitoring and refill process including periodic review of the state's database of controlled substance prescriptions (any such system is based on the PCC's assessment of family organization, phone access, and parent-teacher communication effectiveness); and
- using the ADHD Toolkit resources.

Establishing relations with schools and other agencies can facilitate communication and establish clear expectations when collaborating on care for a child. A community-level system that reflects consensus among district school staff and local PCCs for key elements of diagnosis, interventions, and ongoing communication can help to provide consistent, well-coordinated, and cost-effective care. A community-based system with schools relieves the individual PCC from negotiating with each school about care and communication regarding each patient. Offices that have incorporated medical home principles are ideal for establishing this kind of community-level system. Although achieving the level of coordination described below is ideal and takes consistent effort over the years, especially in areas with multiple separate school systems, some aspects may be achieved relatively quickly and will enhance services for children.

The key elements for a community-based collaborative system include consensus on the following:

- a clear and organized process by which an evaluation can be initiated when concerns are identified either by parents or school personnel;
- a packet of information completed by parents and teachers about each child and/or adolescent referred to the PCC;
- a contact person at the practice to receive information from parents and teachers at the time of evaluation and during follow-up;
- an assessment process to investigate coexisting conditions;
- a directory of evidence-based interventions available in the community;
- an ongoing process for follow-up visits, phone calls, teacher reports, and medication refills;
- availability of forms for collecting and exchanging information;
- a plan for keeping school staff and PCCs up to date on the process; and
- awareness of the network of mental health providers in your area and establishments of collaborative relationships with them.

The PCC may face challenges to developing such a collaborative process. For example, a PCC is typically caring for children from more than 1 school system, a school system may be large and not easily accessed, schools may have limited staff and resources to complete assessments, or scheduling may make it difficult for the PCC to communicate with school personnel. Further complicating these efforts is

the fact that many providers encounter a lack of recognition and payment for the time involved in coordinating care. These barriers may hamper efforts to provide the internal resources within a practice and coordination across schools and other providers that are described above; nevertheless, some pediatricians and other PCCs have found ways to lessen some of these obstacles (see Systemic Barriers to the Care of Children and Adolescents with ADHD section in the Supplemental Information for more information on overcoming challenges).

In the case of multiple or large school systems in a community, the PCC may want to begin with 1 school psychologist or principal, or several practices can initiate contact collectively with a community school system. Agreement among the clinicians on the components of a good evaluation process facilitates cooperation and communication with the school toward common goals. Agreement on behavior rating scales used can facilitate completion by school personnel. Standard communication forms that monitor progress and specific interventions can be exchanged among the school and the pediatric office to share information. Collaborative systems can extend to other providers who may comanage care with a PCC. Such providers may include a mental health professional who sees the child or adolescent for psychosocial interventions or a specialist to address difficult cases, such as a developmental-behavioral pediatrician, child and adolescent psychiatrist, child neurologist, neurodevelopmental disability physician, or psychologist. The AAP Mental Health Initiatives provide a full discussion of collaborative relationships with mental health professionals, including colocation and integrated models, in its Chapter Action Kit and PediaLink Module.[133,241]

Achieving this infrastructure in the practice and the coordination across schools and other providers will enhance the PCC's ability to implement the treatment guidelines and this algorithm. Achieving these ideals is not necessary for providing care consistent with these practices, however.

X. CONCLUSIONS

ADHD is the most common neurobiological disorder of children and adolescents. Untreated or undertreated ADHD can have far-reaching and serious consequences for the child or adolescent's health and well-being. Fortunately, effective treatments are available, as are methods for assessing and diagnosing ADHD in children and adolescents. The AAP is committed to supporting primary care physicians in providing quality care to children and adolescents with ADHD and their families. This algorithm represents a portion of that commitment and an effort to assist pediatricians and other PCCs to deliver care that meets the quality goals of the practice guideline. This PoCA, in combination with the guideline and Systemic Barriers to the Care of Children and Adolescents With ADHD section below, is intended to provide support and guidance in what is currently the best evidence-based care for their patients with ADHD. Additional support and guidance can be obtained through the work and publications of the AAP Mental Health Initiatives.[133,241]

BARRIERS

SYSTEMIC BARRIERS TO THE CARE OF CHILDREN AND ADOLESCENTS WITH ADHD

INTRODUCTION

The AAP strives to improve the quality of care provided by PCCs through quality improvement initiatives including developing, promulgating, and regularly revising evidence-based clinical practice guidelines. The AAP has published a revision to its 2011 guideline on evaluating, diagnosing, and treating ADHD on the basis of the latest scientific evidence (see main article). This latest revision of the clinical practice guideline is accompanied by a PoCA (also found in the Supplemental Information), which outlines the applicable diagnostic and treatment processes needed to implement the guidelines. This section, which is a companion to the clinical guideline and PoCA, outlines common barriers that impede ADHD care and provides suggested strategies for clinicians seeking to improve care for children and adolescents with ADHD and work with other concerned public and private organizations, health care payers, government entities, state insurance regulators, and other stakeholders.

ADHD is the most common childhood neurobehavioral disorder in the United States and the second most commonly diagnosed childhood condition after asthma.[246] The *DSM-5* criteria define 4 dimensions of ADHD:

1. ADHD/I (314.00 [F90.0]);
2. ADHD/HI (314.01 [F90.1]);
3. ADHD/C (314.01 [F90.2]); and
4. ADHD other specified and unspecified ADHD (314.01 [F90.8]).

National survey data from 2016 reveal that 9.4% of 2- to 17-year-old US children received an ADHD diagnosis during childhood, and 8.4% currently have ADHD.[247] Prevalence estimates from community-based samples are somewhat higher, ranging from 8.7% to 15.5%.[9,10] Most children with ADHD (67%) had at least 1 other comorbidity, and 18% had 3 or more comorbidities, such as mental health disorders and/or learning disorders. These comorbidities increase the complexity of the diagnostic and treatment processes.[66]

The majority of care for children and adolescents with ADHD is provided by the child's PCC, particularly when the ADHD is uncomplicated in nature. In addition, families typically have a high degree of confidence and trust in pediatricians' ability to provide this professional care. Because of the high prevalence of ADHD in children and adolescents, it is essential that PCCs, particularly pediatricians, be able to diagnose, treat, and coordinate this care or identify an appropriate clinician who can provide this needed care. Despite having a higher prevalence than other conditions that PCCs see and manage, such as urinary tract infections and sports injuries, ADHD is often viewed as different from other pediatric conditions and beyond the purview of primary care. In addition, several barriers to care hamper effective and timely diagnosis and treatment of these children and adolescents and must be addressed and corrected to achieve optimum outcomes for these children.[153] These barriers include the following:

1. limited access to care because of inadequate developmental-behavioral and mental health care training during residencies and other clinical training and shortages of consultant specialists and referral resources;
2. inadequate payment for needed services and payer coverage limitations for needed medications;
3. challenges in practice organization and staffing; and
4. fragmentation of care and resulting communication barriers.

Addressing these barriers from a clinical and policy standpoint will enhance clinicians' ability to provide high-quality care for children and adolescents who are being evaluated and/or treated for ADHD. Strategies for improvement in the delivery of care to patients with ADHD and their families are offered for consideration for practice and for advocacy.

BARRIERS TO HIGH-QUALITY CARE FOR CHILDREN AND ADOLESCENTS WITH ADHD

Multiple barriers exist in the primary medical care of children and adolescents that are impediments to excellent ADHD care.

Limited Access to Care Because of Inadequate Developmental-Behavioral and Mental Health Care Training During Pediatric Residency and Other Clinical Training Programs and Shortages of Consultant Specialists and Referral Resources

There is an overall lack of adequate pediatric residency and other training programs for pediatric clinicians on developmental-behavioral and mental health conditions, including ADHD. The current curriculum and the nature of pediatric training still focus on the diagnosis and treatment of inpatient and intensive care conditions despite the fact that many primary care pediatricians spend less and less time providing these services, which are increasingly managed by pediatric hospitalists and intensive care specialists. Pediatric and family medicine residents do not receive sufficient training in the diagnosis and treatment of developmental-behavioral and mental health conditions, including ADHD, despite the high frequency in which they will encounter these conditions in their practices.[152,248]

SUPPLEMENTAL TABLE 2 Core Symptoms of ADHD From the *DSM-5*

Inattention Dimension	Hyperactivity-Impulsivity Dimension	
	Hyperactivity	Impulsivity
Careless mistakes	Fidgeting	Blurting answers before questions completed
Difficulty sustaining attention	Unable to stay seated	Difficulty awaiting turn
Seems not to listen	Moving excessively (restless)	Interrupting and/or intruding on others
Fails to finish tasks	Difficulty engaging in leisure activities quietly	—
Difficulty organizing	"On the go"	—
Avoids tasks requiring sustained attention	Talking excessively	—
Loses things	—	—
Easily distracted	—	—
Forgetful	—	—

Adapted from American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders. 5th ed.* Washington, DC: American Psychiatric Association; 2000:59–60. —, *not applicable.*

In addition, many experienced pediatric clinicians believe that general pediatric and family medicine residencies do not fully ensure that clinicians who enter primary care practice have the organizational tools to develop, join, or function in medical home settings and address chronic developmental and behavioral conditions like ADHD.[152] The current funding of residency and other training programs for pediatric clinicians and the needs of hospitals tend to limit those aspects of training. The training challenges are subsequently not sufficiently addressed by practicing pediatric and family medicine practitioners, in part because of the limited number and varying quality of continuing medical education (CME) opportunities and quality improvement projects focused on medical home models and/or the chronic care of developmental and behavioral pediatric and mental health conditions.

The lack of training is compounded by the national shortage of child and adolescent psychiatrists and developmental-behavioral pediatricians: the United States has only 8300 child psychiatrists[249] and 662 developmental-behavioral pediatricians.[250] The additional training required for child psychiatry and developmental-behavioral pediatrics certification increases education time and costs yet results in little or no return on this investment in terms of increased compensation for these specialists.[249] Given the high cost of medical school and the increasing educational debt incurred by graduating medical students, physicians lack a financial incentive to add the extra years of training required for these specialties.[251] As a result, there are insufficient numbers of mental health professionals, including child psychiatrists and developmental-behavioral pediatricians, to serve as subspecialty referral options and/or provide PCCs with consultative support to comanage their patients effectively.

The specialist shortage is exacerbated by the geographically skewed distribution of extant child psychiatrists and developmental-behavioral pediatricians who are concentrated in academic medical centers and urban environments. Almost three quarters (74%) of US counties have no child and adolescent psychiatrists; almost half (44%) do not even have any pediatricians.[252] As a result, many PCCs lack an adequate pool of pediatric behavioral and mental health specialists who can accept referrals to treat complicated pediatric ADHD patients and an adequate pool of behavioral therapists to provide evidence-based behavioral interventions. The result is that patients must often travel untenable distances and endure long waits to obtain these specialty services.

Suggested Strategies for Change to Address Limited Access to Care: Policy-Oriented Strategies for Change

- Promote changes in pediatric and family medicine residency curricula to devote more time to developmental, behavioral, learning, and mental health issues with a focus on prevention, early detection, assessment, diagnosis, and treatment. Changes in the national and individual training program requirements and in funding of training should foster practitioners' understanding of the family perspective; promote communication skills, including motivational interviewing; and bolster understanding and readiness in the use of behavioral interventions and medication as treatment options for ADHD.
- Emphasize teaching and practice activities within general pediatric residencies and other clinical training, so pediatricians and other PCCs gain the skills and ability they need to function within a medical home setting.
- Support pediatric primary care mental health specialist certification for advanced practice registered nurses through the

Pediatric Nursing Certification Board to provide advanced practice care to help meet evidence-based needs of children or adolescents with ADHD.

- Encourage the development and maintenance of affordable programs to provide CME and other alternative posttraining learning opportunities on behavioral and developmental health, including ADHD. These opportunities will help stakeholders, including PCCs, mental health clinicians, and educators, become more comfortable in providing such services within the medical home and/or educational settings.
- Develop, implement, and support collaborative care models that facilitate PCCs' rapid access to behavioral and mental health expertise and consultation. Examples include integration (such as collaborative care or colocation), on-call consultation, and support teams such as the Massachusetts Child Psychiatry Access Program,[253] the "Project Teach Initiative" of the New York State Department of Mental Health,[254] and Project Extension for Community Healthcare Outcomes, a collaborative model of medical education and care management that can be targeted to pediatric mental health.[255] In addition, federal funding had provided grants to18 states to develop Child Psychiatry Access Programs through Health Resources and Services Administration's Pediatric Mental Health Care Access Program.[256,257] Promote incentives such as loan forgiveness to encourage medical students to enter the fields of child and adolescent psychiatry and developmental and behavioral pediatrics, particularly for those who are willing to practice in underserved communities.
- Expand posttraining opportunities to include postpediatric portal programs, which provide alternative ways to increase number of child and adolescent psychiatrists.

Inadequate Payment for Needed Services and Payer Coverage Limitations for Needed Medications

Although proper diagnostic and procedure codes currently exist for ADHD care in pediatrics, effective and adequate third-party payment is not guaranteed for any covered services.[258] In addition, many payment mechanisms impede the delivery of comprehensive ADHD care. These impediments include restrictions to medication treatment choices such as step therapy, previous approval, narrow formularies, and frequent formulary changes. Some payers define ADHD as a "mental health problem" and implement a "carve-out" health insurance benefit that bars PCCs from participation.[259] This designation results in denial of coverage for primary care ADHD services. Some payers have restrictive service and/or medication approval practices that prevent patients from receiving or continuing needed care and treatment. Examples include approval of only a limited number of specialist visits, limited ADHD medication options, mandatory step therapy, frequent formulary changes resulting in clinical destabilization, and disproportionally high out-of-pocket copays for mental health care or psychotropic medications.

Payments for mental health and cognitive services are frequently lower than equivalents (by relative value unit measurement) paid for physical health care services, particularly those entailing specific procedures.[258] Longer and more frequent visits are often necessary to successfully address ADHD, yet time-based billing yields lower payment compared to multiple shorter visits. These difficulties financially limit a practice's ability to provide these needed services. Payments for E/M codes for chronic care are often insufficient to cover the staff and clinician time needed to provide adequate care. Furthermore, many payers deny payment for the use of rating scales, which are the currently recommended method for monitoring ADHD patients. The use of rating scales takes both the PCC's time and the practice's organizational resources. Arbitrary denial of payment is a disincentive to the provisions of this essential and appropriate service.

Finally, payers commonly decline to pay or provide inadequate payment for care coordination services. Yet, office staff and clinicians are asked to spend large amounts of uncompensated time on these activities, including communicating with parents, teachers, and other stakeholders. Proposed new practice structures such as accountable care organizations (ACOs) are predicated on value-based services and may provide new financial mechanisms to support expanded care coordination services. Originally implemented for Medicare, all-payer ACO models are under development in many states. To date, however, the specifics of these ACO models have not been delineated, and their effectiveness has not yet been documented.[260]

The seemingly arbitrary and ever-changing standards for approval of services; the time-consuming nature of previous approval procedures; and restrictive, opaque pharmacy rules combine to create substantial barriers that result in many PCCs declining to care for children and adolescents with ADHD.[252] According to a recent AAP Periodic Survey of Fellows, 41% of pediatricians reported that "inadequate reimbursement is

a major barrier to providing mental health counseling."[258] Of note, 46% reported that they would be interested in hiring mental health clinicians in their practice "if payment and financial resources were not an issue."[258]

Payers' practices regarding medication approval also create challenges for treating pediatric ADHD. In conflict with best-practice or evidence-based guidelines, payers commonly favor 1 ADHD medication and refuse to approve others, even when the latter may be more appropriate for a specific patient. Decisions seem to be made on cost, which at times can be variable. Certain drugs may be allowed only after review processes; others are refused for poorly delineated reasons. Reviewers of insurance denial appeals often lack pediatric experience and are unfamiliar with the effect of the patient's coexisting condition(s) or developmental stage on the medication choice. Step therapy protocols that require specific medications at treatment initiation may require patients to undergo time-consuming treatment failures before an effective therapy can be started. Changes to formularies may force medication changes on patients whose ADHD had been well-controlled, leading to morbidity or delays in finding alternative covered medications that might be equally effective in restoring clinical control.

Similarly, payers may inappropriately insist that a newer replacement drug be used in a patient whose ADHD has been well-controlled by another drug of the same or similar class. The assumption that generic psychoactive preparations are equal to brand-name compounds in efficacy and duration of action is not always accurate.[261] Although generic substitution is generally appropriate, a change in a patient's response may necessitate return to the nongeneric formulation. In addition, because of the variation in covered medications across insurance companies, when a family changes health plans, clinicians have to spend more time to clarify treatments and reduce family stress and their economic burden.

Suggested Strategies for Change to Address Inadequate Payment and Payer Coverage Limitations: Policy-Oriented Strategies

- Revise payment systems to reflect the time and cognitive effort required by primary care, developmental-behavioral, and mental health clinicians to diagnose, treat, and manage pediatric ADHD and compensate these services at levels that incentivize and support their use.
- Support innovative partnerships between payers and clinicians to facilitate high-quality ADHD care. As new payment models are proposed, include input from practicing clinicians to inform insurance plans' understanding of the resources needed to provide comprehensive ADHD care.
- Require that payers' medical directors who review pediatric ADHD protocols and medication formularies either have pediatric expertise or seek such expertise before making decisions that affect the management of pediatric patients with ADHD.
- Advocate that health care payers' rules for approval of developmental-behavioral and mental health care services and medications are consistent with best-practice recommendations based on scientific evidence such as the AAP ADHD guideline. Payers should not use arbitrary step-based medication approval practices or force changes to a patient's stable and effective medication plans because of cost-based formulary changes.
- Advocate for better monitoring by the FDA of ADHD medication generic formulations to verify their equivalency to brand-name preparations in terms of potency and delivery.
- Partner with CHADD and other parent support groups to help advocate for positive changes in payers' rules; these organizations provide a strong voice from families who face the challenges on a day-to-day basis.

Challenges in Practice Organization

ADHD is a chronic condition. Comprehensive ADHD care requires additional clinician time for complex visits, consultation and communication with care team members, and extended staff time to coordinate delivery of chronic care. Children and adolescents with ADHD have a special health care condition and should be cared for in a manner similar to that of other children and youth with special health care needs.[262] Such care is ideally delivered by practices that are established as patient- and family-centered medical homes. Yet, the number of patient- and family-centered medical homes is insufficient to meet the needs of many children with ADHD and their families. Pediatricians and other PCCs who have not adopted a patient- and family-centered medical home model may benefit from the use of similar systems to facilitate ADHD management. For more information, see the recommendations and descriptions from the AAP and the American Academy of Family Medicine regarding medical homes.[262]

Caring for children and adolescents with ADHD requires practices to modify office systems to address their patients' mental health care needs. Specifically, practices need to be

familiar with local area mental health referral options, where available, and communicate these options to families. Once a referral has been made, the office flow needs to support communication with other ADHD care team members.[263] Other team members, especially those in mental health, need to formally communicate with the referring clinician in a bidirectional process.

Making a referral does not always mean that the patient is able to access care, however. Practices need to consider that many families face difficulties in following through with referrals for ADHD diagnosis and treatment. These difficulties may arise for a variety of reasons, including lack of insurance coverage, lengthy wait lists for mental health providers, transportation difficulties, reluctance to engage with an unfamiliar care system, cultural factors, and/or the perceived stigma of receiving mental health–specific services.[145,146,155,158]

Many of these barriers can be addressed by the integration of mental health services within primary care practices and other innovative collaborative care models. These models can help increase the opportunities for families to receive care in a familiar and accessible location and provide a "warm hand off" of the patient into the mental health arena. The implementation of these models can be hindered by cost; collaboration with mental health agencies may be fruitful.

Another challenge is the difficulty in determining which mental health subspecialists use evidence-based treatments for ADHD. Pediatricians and other PCCs can increase the likelihood that families receive evidence-based services by establishing a referral network of clinicians who are known to use evidence-based practices and educating parents about effective psychosocial treatments for children and adolescents to help them be wise consumers. It is also important to be cognizant of the fact that for some families, accessing these services may present challenges, such as the need to take time off from work or cover any program costs.

Finding professionals who use evidence-based treatments is of the utmost importance, because exposure to non–evidence-based treatments has the potential to harm patients in several ways. First, the treatment is less likely to be effective and may be harmful (eg, adverse events can and do occur in psychosocial treatments).[264] Second, the effort and money spent on ineffective treatment interferes with the ability to meaningfully engage in evidence-based treatments. Finally, when a treatment does not yield benefits, families are likely to become disillusioned with psychosocial treatments generally, even those that are evidence-based, decreasing the likelihood of future engagement. Each of these harms may place the child at greater risk of problematic outcomes over time.

Suggested Strategies to Address Challenges in Practice Organization

Clinician-Focused Implementation Strategies

- Develop ADHD-specific office workflows, as detailed in the Preparing the Practice section of the PoCA (see Supplemental Information).
- Ensure that the practice is welcoming and inclusive to patients and families of all backgrounds and cultures.
- Enable office systems to support communication with parents, education professionals, and mental health specialists, possibly through electronic communication systems (discussed below).
- Consider office certification as a patient- and family-centered medical home.
- If certification as a patient- and family-centered medical home is not feasible, implement medical home policies and procedures, including care conferences and management. Explore care management opportunities, including adequate resourcing and payment, with third-party payers.
- Identify and establish relationships with mental health consultation and referral sources in the community and within region, if available, and investigate integration of services as well as the resources to support them.
- Promote communication between ADHD care team members by integrating health and mental health services and using collaborative care model treatments when possible.
- Be aware of the community mental health crisis providers' referral processes and be prepared to educate families about evidence-based psychosocial treatments for ADHD across the life span.

Policy-Oriented Suggested Strategies

- Encourage efforts to support the development and maintenance of patient- and family-centered medical homes or related systems to enable patients with chronic complex disorders to receive comprehensive care.
- Support streamlined, coordinated ADHD care across systems by providing incentives for the integration of health and mental health services and collaborative care models.

Fragmentation of Care and Resulting Communication Barriers

Multiple team members provide care for children and adolescents with ADHD, including those in the fields of physical health, mental health, and education. Each of these systems has its own professional standards and terminologies, environments, and hierarchical systems. Moreover, they protect communication via different privacy rules: the Health Insurance Portability and Accountability Act (HIPAA)[265] for the physical and mental health systems and the Family Educational Rights and Privacy Act (FERPA)[266] for the education system. These factors complicate communication not only within but also across these fields. The lack of communication interferes with clinicians' abilities to make accurate diagnoses of ADHD and co-occurring conditions, monitor progress in symptom reduction when providing treatment, identify patient resources, and coordinate the most effective services for children and adolescents with ADHD.

Electronic systems can help address these communication barriers by facilitating asynchronous communication among stakeholders. This is particularly useful for disparate stakeholders, such as parents, teachers, and clinicians, who often cannot all be available simultaneously for a telephone or in-person conference. Electronic systems can also facilitate the timely completion and submission of standardized ADHD rating scales, which are the best tools to assess and treat the condition.[267] Because implementation of electronic systems lies partially within the PCC's control, additional information is provided below on the strengths and weaknesses of a variety of such systems, including telemedicine.

Stand-alone Software Platforms and EHRs

Stand-alone software platforms and EHRs have the potential to improve communication and care coordination among ADHD care team members. Commercially available stand-alone software platforms typically use electronic survey interfaces (either Web or mobile) to collect rating data from parents and teachers, use algorithms to score the data, and display the results cross-sectionally or longitudinally for the clinician's review. Advantages of stand-alone platforms include the fact that they are designed specifically for ADHD care and can be accessed via the Internet through computers and mobile devices. Once implemented, these user-friendly systems allow parents, teachers, and practitioners from multiple disciplines or practices to conveniently complete rating scales remotely. Stand-alone platforms also offer the ability to customize rating scales and their frequency of use for individual patients. Submitted data are stored automatically in a database, mitigating the transcription errors that are often associated with manual data entry. Data are available for clinical care, quality improvement, or research, including quality metrics.

A substantial downside to stand-alone ADHD care systems is the lack of data integration into EHRs. Practitioners must log in to disparate systems for different facets of patient care: the stand-alone system to track ADHD symptoms and the EHR to track medications records, visit notes, and patient or family phone calls. To achieve data accuracy in the 2 different systems, the practitioner must copy medication information from the EHR into the stand-alone system and ADHD symptom and adverse effect ratings from the stand-alone system into the EHR. In addition, stand-alone systems require clinicians to log in before each visit to review the relevant ADHD care data. Patients may use a variety of ADHD stand-alone tracking systems, requiring the PCC to remember several accounts and passwords in addition to his or her own office and hospital EHR systems, creating an added burden that may reduce enthusiasm for such platforms. Finally, stand-alone systems typically charge fees to support the maintenance of servers, cybersecurity, and technical and customer support functionalities.

An issue over which the PCC has little control is the fact that other stakeholders may use stand-alone systems inconsistently. Parents (who may themselves have ADHD) must log in to the platform and complete the requisite ADHD rating scales. Teachers may be required to log in and complete the evaluation process, often for several students, on top of their other obligations. The fact that different pediatricians may use different systems, each with their own log-in and interface, adds to the activity's complexity, particularly for teachers who need to report on multiple students to a variety of PCCs.

EHRs for ADHD Management

EHRs can be adapted to improve the timely collection of parent and teacher ratings of ADHD symptoms, impairment, and medication adverse effects. Some EHRs use an electronic survey functionality or patient portal, similar to that provided by ADHD care stand-alone systems, to allow parents' access to online rating scales. A clear advantage of these EHR systems is that they increase the ability to access documentation about an individual patient's past treatment modalities and medications in the same place as information about his or her ADHD symptoms. The functionality of these EHRs may facilitate other care-related

activities, including evidence-based decision support, quality improvement efforts, and outcomes reporting.[268]

Despite these benefits, there are numerous limitations to managing ADHD care with EHRs. First, health care systems' confidentiality barriers often prevent teachers from entering ratings directly into the child's medical record. The large number and heterogeneity of EHR systems and their lack of interoperability are additional barriers to their use for ADHD care.[269] Even when institutions use the same vendor's EHR, exchanging respective ADHD documentation among a variety of clinicians and therapists is frequently impossible.[270] The inability to share information and the lack of interoperability often results in incomplete information in the EHR about a given patient's interventions, symptoms, impairments, and adverse effects over time. Systems for tracking and comparing these aspects of a patient's care are not standard for most EHR packages. The ability to construct templates that are congruent with a clinician's workflow may be limited by the EHR itself. ADHD functionality must often be custom-built for each organization, a cumbersome, expensive, and lengthy process, resulting in lost productivity, clinical effectiveness, and revenue.

General Issues With ADHD Electronic Tracking Systems

EHRs have been linked to increased clinician stress. For this reason, it is important to consider the potential for added burden when either stand-alone or EHR-embedded systems are used to facilitate ADHD care.[271] Although the use of electronic ADHD systems to monitor patients remotely may be advantageous, clinicians and practices may not be equipped or staffed to manage the burden of additional clinical information arriving between visits (ie, intervisit data).

Clinicians must also consider the liability associated with potentially actionable information that families may report electronically without realizing the information might not be reviewed in real time. Examples of such liabilities include a severe medication adverse effect, free-text report of suicidal ideation, and sudden deterioration in ADHD symptoms and/or functioning. In addition, parents and teachers may receive numerous requests to complete rating scales, leading them to experience "survey fatigue" and ignore the requests to complete these scales. Conversely, they may forget how to use the system if they engage with it on an infrequent basis. Some parents or teachers may be uncomfortable using electronic systems and within the medical home might prefer paper rating scales, and others may not have ready access to electronic systems or the Internet.

Telemedicine for ADHD Management

Telemedicine is a new and rapidly growing technology that has the potential, when properly implemented within the medical home, to expand access to care and to improve clinicians' ability to communicate with schools, consultants, care management team members, and especially patients and parents.[213,272,273] Well-run telemedicine programs offer some promise as a way to deliver evidence-based psychosocial treatments, although few evidence-based programs have been tested via telemental health trials.[274,275] Telemedicine is one of the foundations of the new advanced medical home and offers advantages as follows:

- offering communication opportunities (either face-to-face and synchronous as a conversation or asynchronous as messaging), which can be prescheduled to minimize interruption of office flow;
- enabling communication on a one-on-one basis or one-to-many basis (for conference situations);
- replacing repeated office visits for patient follow-up and monitoring, which reduces time and the need for patients to travel to the PCC's office;
- facilitating digital storage of the telemedicine episode and its incorporation into multiple EHR systems as part of the patient record; and
- enhancing cooperation among all parties in the evaluation and treatment processes.

Telemedicine has great potential but needs to be properly implemented and integrated into the practice workflow to achieve maximum effectiveness and flexibility. Although some new state insurance regulations mandate payment for telemedicine services, such mandates have not yet been implemented in all states, limiting telemedicine's utility. Finally, payment for services needs to include the added cost of equipment and staff to provide them.

Suggested Strategies to Address Fragmentation of Care and Resulting Communication Barriers

Clinician-Focused Implementation Strategies

- Ensure the practice is aware of, and in compliance with, HIPAA and FERPA policies, as well as confidentiality laws and cybersecurity safeguards that impact EHRs' communication with school personnel and parents.[276]
- Maintain open lines of communication with all team members involved in the patient's ADHD care within the practical limits of existing systems, time, and economic constraints. As noted,

team members include teachers, other school personnel, clinicians, and mental health practitioners. This activity involves a team-based approach and agreeing on a communication method and process to track ADHD interventions, symptoms, impairments, and adverse effects over time. Communication can be accomplished through a variety of means, including electronic systems, face-to-face meetings, conference calls, emails, and/or faxes.

- Consider using electronic communication via stand-alone ADHD management systems and electronic portals, after evaluating EHR interoperability and other administrative considerations.
- Integrate electronic ADHD systems into the practice's clinical workflow: decide who will review the data and when, how actionable information will be flagged and triaged, how information and related decision-making will be documented in the medical record, etc.
- Set and clarify caregivers' expectations about the practice's review of information provided electronically versus actionable information that should be communicated directly by phone.
- Promote the implementation of telemedicine for ADHD management in states where payment for such services is established; ensure the telemedicine system chosen is patient centered, HIPAA and FERPA compliant, and practice enhancing.

Policy-Oriented Suggested Strategies

- Promote the development of mechanisms for online communication to enhance ADHD care collaboration, including electronic portals and stand-alone ADHD software systems, to serve as communication platforms for families, health professionals, mental health professionals, and educators. Ideally, these portals would be integrated with the most commonly used EHR systems.
- Advocate for regulations that mandate a common standard of interoperability for certified EHR systems. Interoperability facilitates the use of EHRs as a common repository of ADHD care information and communication platform for ADHD care team members.[276]
- Advocate for exceptions to HIPAA and FERPA regulations to allow more communication between education and health and mental health practitioners while maintaining privacy protections.
- Ensure that billing, coding, and payment systems provide adequate resources and time for clinicians to communicate with teachers and mental health clinicians, as discussed previously.
- Provide incentives for integration of health and mental health services, collaborative care models, and telemedicine to facilitate communication among ADHD care team members, including telemedicine services that cross state lines.
- Fund research in telehealth to learn more about who responds well to these approaches and whether telehealth is feasible for underserved populations.

CONCLUSIONS

Appropriate and comprehensive ADHD care requires a well-trained and adequately resourced multidisciplinary workforce, with office workflows that are organized to provide collaborative services that are consistent with a chronic care model and to promote communication among treatment team members.[277–280] Many barriers in the current health care system must be addressed to support this care.

First and foremost, the shortage of clinicians, such as child and adolescent psychiatrists and developmental-behavioral pediatricians who provide consultation and referral ADHD care, must also be addressed. The shortages are driven by the lack of residency and other training programs for pediatric clinicians in the management of ADHD and other behavioral health issues, the lack of return on investment in the additional training and debt required to specialize in this area, and inadequate resourcing at all levels of ADHD care. The shortage is exacerbated by geographic maldistribution of practitioners and lack of adequate mental health training as a whole during residency and in CME projects. These challenges must be addressed on a system-wide level.

A significant review and change in the ADHD care payment for cognitive services is required to ensure that practitioners are backed by appropriate resources that support the provision of high-quality ADHD care. The lack of adequate compensation for ADHD care is a major challenge to reaching children and adolescents with the care they need. Improved payment is a major need to encourage primary care clinicians to train in ADHD subspecialty care and incentivize child and adolescent psychiatry and developmental-behavioral pediatrics practitioners to provide ADHD care in the primary care setting, so the provision of such care does not result in financial hardship for the families or the practice. Improvement should also include changes to payer policies to improve compensation for care

coordination services and mental health care.

Because the pediatrician is often the first contact for a parent seeking help for a child with symptoms that may be caused by ADHD, barriers to payment need to be addressed before providing these time-consuming services. Some insurance plans direct all claims with a diagnosis reported by *International Classification of Diseases, 10th Revision, Clinical Modification* codes F01–F99 to their mental and behavioral health benefits system. Because pediatricians are generally not included in networks for mental and behavioral health plans, this can create delays or denials of payment. This is not always the case, though, and with a little preventive footwork, practices can identify policy guidelines for plans that are commonly seen in the practice patient population.

The first step in identifying coverage for services to diagnose or treat ADHD is to determine what payment guidelines have been published by plans that contract with your practice. Many health plans post their payment guidelines on their Web sites, but even when publicly available, the documents do not always clearly address whether payment for primary care diagnosis and management of ADHD are covered. It may be necessary to send a written inquiry to provider relations and the medical director of a plan seeking clarification of what diagnoses and procedure codes should pass through the health benefit plan's adjudication system without denial or crossover to a mental health benefit plan. It is important to recognize that even with documentation that the plan covers primary care services related to ADHD, claims adjudication is an automated process that may erroneously cause denials. Billing and payment reconciliation staff should always refer such denials for appeal.

Once plans that do and do not provide medical benefits for the diagnosis and treatment of ADHD have been identified, advocacy to the medical directors of those plans that do not recognize the role of the medical home in mental health care can be initiated. The AAP template letter, Increasing Access to Mental Health Care, is a resource for this purpose. Practices should also be prepared to offer advance notice to parents when their plan is likely to deny or pay out of network for services. A list of referral sources for mental and behavioral health is also helpful for parents whose financial limitations may require alternative choices and for patients who may require referral for additional evaluation.

For services rendered, identify the codes that represent covered diagnoses and services and be sure that these codes are appropriately linked and reported on claims.

When ADHD is suspected but not yet diagnosed, symptoms such as attention and concentration deficit (R41.840) should be reported. Screening for ADHD in the absence of signs or symptoms may be reported with code Z13.4, encounter for screening for certain developmental disorders in childhood. *Current Procedural Terminology* codes 96110 and 96112 to 96113 should be reported for developmental screening and testing services.

Services related to diagnosis and management of ADHD are more likely to be paid under the patient's medical benefits when codes reported are not those for psychiatric or behavioral health services. Reporting of E/M service codes based on face-to-face time of the visit when more than 50% of that time was spent in counseling or coordination of care will likely be more effective than use of codes such as 90791, psychiatric diagnostic evaluation. *Current Procedural Terminology* E/M service guidelines define counseling as a discussion with a patient or family concerning 1 or more of the following areas:

- diagnostic results, impressions, or recommended diagnostic studies;
- prognosis;
- risks and benefits of management (treatment) options;
- instructions for management (treatment) or follow-up;
- importance of compliance with chosen management (treatment) options;
- risk factor reduction; and
- patient and family education.

Finally, staff should track claim payment trends for services related to ADHD, including the number of claims requiring appeal and status of appeal determinations to inform future advocacy efforts and practice policy.

Many AAP chapters have developed pediatric councils that meet with payers on pediatric coding issues. Sharing your experiences with your chapter pediatric council will assist in its advocacy efforts. AAP members can also report carrier issues on the AAP Hassle Factor Form.

These system-wide barriers are challenging, if not impossible, for individual practitioners to address on their own. Practice organization and communication changes can be made, however, that have the potential to improve access to ADHD care. Clinicians and other practitioners can implement the office work-flow recommendations made in the Preparing the Practice section of the updated PoCA (see Supplemental Information). Implementing a patient- and family-centered medical home model, colocating health and mental health services, and adopting collaborative care models can also help overcome communication barriers and minimize fragmentation of care. It is noted that these models must be adequately resourced to be effective.

Finally, practitioners can implement innovative communication and record-keeping solutions to overcome barriers to ADHD care. Potential solutions could include the use of EHRs, other electronic systems, and high-quality telemedicine to support enhanced communication and record-keeping on the part of myriad ADHD care team members. These solutions can also aid with monitoring treatment responses on the part of the child or adolescent with ADHD. Telemedicine also has the distinct benefit of compensating for the maldistribution of specialists and other clinicians who can treat pediatric ADHD.

Many stakeholders have a role in addressing the barriers that prevent children and adolescents from receiving needed evidenced-based treatment of ADHD. Pediatric councils, the national AAP, and state and local AAP chapters must be advocates for broad changes in training, CME, and payment policies to overcome the systemic challenges that hamper access to care. On an individual level, practitioners can effect change in their own practice systems and professional approaches and implement systems that address fragmentation of care and communication. Practitioners are important agents for change in ADHD care. The day-to-day interactions that practitioners have with patients, families, educators, payers, state insurance regulators, and others can foster comprehensive, contemporary, and effective care that becomes a pillar of advocacy and change.

SUBCOMMITTEE ON CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

The Council on Quality Improvement and Patient Safety oversees the Subcommittee

Mark L. Wolraich, MD, FAAP (Chairperson: Section on Developmental Behavioral Pediatrics).

Joseph F. Hagan, Jr, MD, FAAP (Vice Chairperson: Section on Developmental Behavioral Pediatrics).

Carla Allan, PhD (Society of Pediatric Psychology).

Eugenia Chan, MD, MPH, FAAP (Implementation Scientist).

Dale Davison, MSpEd, PCC (Parent Advocate, Children and Adults with ADHD).

Marian Earls, MD, MTS, FAAP (Mental Health Leadership Work Group).

Steven W. Evans, PhD (Clinical Psychologist).

Tanya Froehlich, MD, FAAP (Section on Developmental Behavioral Pediatrics/Society for Developmental and Behavioral Pediatrics).

Jennifer L. Frost, MD, FAAFP (American Academy of Family Physicians).

Herschel R. Lessin, MD, FAAP, Section on Administration and Practice Management).

Karen L. Pierce, MD, DFAACAP (American Academy of Child and Adolescent Psychiatry).

Christoph Ulrich Lehmann, MD, FAAP (Partnership for Policy Implementation).

Jonathan D. Winner, MD, FAAP (Committee on Practice and Ambulatory Medicine).

William Zurhellen, MD, FAAP (Section on Administration and Practice Management).

STAFF

Kymika Okechukwu, MPA, Senior Manager, Evidence-Based Medicine Initiatives

Jeremiah Salmon, MPH, Program Manager, Policy Dissemination and Implementation

CONSULTANT

Susan K. Flinn, MA, Medical Editor

SUPPLEMENTAL REFERENCES

157. Bright Futures Available at: https://brightfutures.aap.org. Accessed September 8, 2019

158. American Academy of Pediatrics. AAP Diversity and Inclusion Statement. *Pediatrics*. 2018;141(4): e20180193

159. Chronis AM, Lahey BB, Pelham WE Jr, Kipp HL, Baumann BL, Lee SS. Psychopathology and substance abuse in parents of young children with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2003;42(12):1424–1432

160. Foy JM, ed. Iterative Mental Health Assessement, Appendix 2: Mental Health Tools for Pediatrics. In: *Mental Health Care of Children and Adolescents: A Guide for Primary Care Clinicians*. Itasca, IL: American Academy of Pediatrics; 2018:817–868

161. Wolraich ML, Bard DE, Neas B, Doffing M, Beck L. The psychometric properties of the Vanderbilt attention-deficit hyperactivity disorder diagnostic teacher rating scale in a community population. *J Dev Behav Pediatr*. 2013;34(2):83–93

162. Bard DE, Wolraich ML, Neas B, Doffing M, Beck L. The psychometric properties of the Vanderbilt attention-deficit hyperactivity disorder diagnostic parent rating scale in a community population. *J Dev Behav Pediatr*. 2013;34(2):72–82

163. Goodman R. The extended version of the Strengths and Difficulties Questionnaire as a guide to child psychiatric caseness and consequent burden. *J Child Psychol Psychiatry*. 1999;40(5):791–799

164. Shaffer D, Gould MS, Brasic J, et al. A children's global assessment scale (CGAS). *Arch Gen Psychiatry*. 1983; 40(11):1228–1231

165. Brown RT, Freeman WS, Perrin JM, et al. Prevalence and assessment of attention-deficit/hyperactivity disorder in primary care settings. *Pediatrics*. 2001;107(3). Available at:

www.pediatrics.org/cgi/content/full/107/3/E43

166. Evans SW, Allen J, Moore S, Strauss V. Measuring symptoms and functioning of youth with ADHD in middle schools. *J Abnorm Child Psychol*. 2005;33(6):695–706

167. Wolraich ML, Lambert EW, Bickman L, Simmons T, Doffing MA, Worley KA. Assessing the impact of parent and teacher agreement on diagnosing attention-deficit hyperactivity disorder. *J Dev Behav Pediatr*. 2004;25(1):41–47

168. DiPerna JC, Elliott SN. *Academic Competence Evaluation Scales (ACES)*. San Antonio, TX: The Psychological Corporation; 2000

169. Smith BH, Pelham WE, Gnagy E, Molina B, Evans S. The reliability, validity, and unique contributions of self-report by adolescents receiving treatment for attention-deficit/hyperactivity disorder. *J Consult Clin Psychol*. 2000;68(3):489–499

170. Hoza B, Pelham WE Jr, Dobbs J, Owens JS, Pillow DR. Do boys with attention-deficit/hyperactivity disorder have positive illusory self-concepts? *J Abnorm Psychol*. 2002;111(2):268–278

171. Zuckerbrot RA, Cheung AH, Jensen PS, Stein RE, Laraque D; GLAD-PC Steering Group. Guidelines for adolescent depression in primary care (GLAD-PC): I. Identification, assessment, and initial management. *Pediatrics*. 2007;120(5). Available at: www.pediatrics.org/cgi/content/full/120/5/e1299

172. Cheung AH, Zuckerbrot RA, Jensen PS, Ghalib K, Laraque D, Stein RE; GLAD-PC Steering Group. Guidelines for adolescent depression in primary care (GLAD-PC): II. Treatment and ongoing management. *Pediatrics*. 2007;120(5). Available at: www.pediatrics.org/cgi/content/full/120/5/e1313

173. Foy JM, ed. Low Mood, Appendix 2: Mental Health Tools for Pediatrics. In: *Mental Health Care of Children and Adolescents: A Guide for Primary Care Clinicians*. Itasca, IL: American Academy of Pediatrics; 2018:817–868

174. The Center for Adolescent Substance Use Research, Children's Hospital Boston. *CRAFFT: Screening Adolescents for Alcohol and Drugs*. Boston, MA: Children's Hospital Boston; 2001. Available at: http://www.childrenshospital.org/~/media/microsites/ceasar/2016-2sided-crafft-card_clinician-interview.ashx?la=en. Accessed September 8, 2019

175. Levy S, Weiss R, Sherritt L, et al. An electronic screen for triaging adolescent substance use by risk levels. *JAMA Pediatr*. 2014;168(9):822–828

176. University of Pittsburgh Child and Adolescent Bipolar Spectrum Services. Instruments: Screen for Child Anxiety Related Emotional Disorders (SCARED). Available at: https://www.pediatricbipolar.pitt.edu/resources/instruments. Accessed September 8, 2019

177. Kovacs M. *CDI 2: Children's Depression Inventory*. 2nd ed. North Tonawanda, NY: Multi-Health Systems Assessments; 2018. Available at: https://www.mhs.com/MHS-Assessment?prodname=cdi2. Accessed September 8, 2019

178. Richardson LP, McCauley E, Grossman DC, et al. Evaluation of the Patient Health Questionnaire-9 Item for detecting major depression among adolescents. *Pediatrics*. 2010;126(6):1117–1123

179. Sleator EK, Ullmann RK. Can the physician diagnose hyperactivity in the office? *Pediatrics*. 1981;67(1):13–17

180. American Academy of Pediatrics. Fetal alcohol spectrum disorders program: toolkit. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/fetal-alcohol-spectrum-disorders-toolkit/Pages/default.aspx. Accessed September 8, 2019

181. Hagan JF Jr, Balachova T, Bertrand J, et al; Neurobehavioral Disorder Associated With Prenatal Alcohol Exposure Workgroup; American Academy of Pediatrics. Neurobehavioral disorder associated with prenatal alcohol exposure. *Pediatrics*. 2016;138(4):e20151553

182. Gardner W, Murphy M, Childs G, et al. The PSC-17: a brief pediatric symptom checklist including psychosocial problem subscales: a report from PROS and ASPN. *Ambul Child Health*. 1999;5:225–236

183. National Institutes of Health. *Screening to Brief Intervention (S2BI)*. Bethesda, MD: National Institute on Drug Abuse. Available at: https://www.drugabuse.gov/ast/s2bi/#/. Accessed September 8, 2019

184. Levy SJ, Williams JF; Committee on Substance Use and Prevention. Substance use screening, brief intervention, and referral to treatment. *Pediatrics*. 2016;138(1):e20161211

185. University of Washington Harborview Center for Sexual Assault and Traumatic Stress. Standardized measures. Available at: https://depts.washington.edu/hcsats/PDF/TF-%20CBT/pages/assessment.html. Accessed September 8, 2019

186. Gordon M, Barkley RA, Lovett B. Tests and observational measures. In: Barkley RA, ed. *Attention-Deficit Hyperactivity Disorder Third Edition: A Handbook for Diagnosis and Treatment*. 3rd ed. New York, NY: Guilford Press; 2005:369–388

187. Edwards MC, Gardner ES, Chelonis JJ, Schulz EG, Flake RA, Diaz PF. Estimates of the validity and utility of the Conners' Continuous Performance Test in the assessment of inattentive and/or hyperactive-impulsive behaviors in children. *J Abnorm Child Psychol*. 2007;35(3):393–404

188. Li J, Olsen J, Vestergaard M, Obel C. Attention-deficit/hyperactivity disorder in the offspring following prenatal maternal bereavement: a nationwide follow-up study in Denmark. *Eur Child Adolesc Psychiatry*. 2010;19(10):747–753

189. Angold A, Erkanli A, Egger HL, Costello EJ. Stimulant treatment for children: a community perspective. *J Am Acad Child Adolesc Psychiatry*. 2000;39(8):975–984; discussion 984–994

190. Konofal E, Lecendreux M, Cortese S. Sleep and ADHD. *Sleep Med*. 2010;11(7):652–658

191. Gozal D, Kheirandish-Gozal L. Neurocognitive and behavioral morbidity in children with sleep disorders. *Curr Opin Pulm Med*. 2007;13(6):505–509

192. Capdevila OS, Kheirandish-Gozal L, Dayyat E, Gozal D. Pediatric obstructive sleep apnea: complications, management, and long-term

outcomes. *Proc Am Thorac Soc*. 2008; 5(2):274–282

193. Cortese S, Konofal E, Lecendreux M, et al. Restless legs syndrome and attention-deficit/hyperactivity disorder: a review of the literature. *Sleep*. 2005;28(8):1007–1013

194. Weiss MD, Wasdell MB, Bomben MM, Rea KJ, Freeman RD. Sleep hygiene and melatonin treatment for children and adolescents with ADHD and initial insomnia. *J Am Acad Child Adolesc Psychiatry*. 2006;45(5):512–519

195. Stein MA, Sarampote CS, Waldman ID, et al. A dose-response study of OROS methylphenidate in children and adolescents with attention-deficit/hyperactivity disorder. *Pediatrics*. 2003;112(5). Available at: www.pediatrics.org/cgi/content/full/112/5/e404

196. Corkum P, Panton R, Ironside S, Macpherson M, Williams T. Acute impact of immediate release methylphenidate administered three times a day on sleep in children with attention-deficit/hyperactivity disorder. *J Pediatr Psychol*. 2008;33(4): 368–379

197. O'Brien LM, Ivanenko A, Crabtree VM, et al. The effect of stimulants on sleep characteristics in children with attention deficit/hyperactivity disorder. *Sleep Med*. 2003;4(4): 309–316

198. Owens J, Sangal RB, Sutton VK, Bakken R, Allen AJ, Kelsey D. Subjective and objective measures of sleep in children with attention-deficit/hyperactivity disorder. *Sleep Med*. 2009;10(4):446–456

199. Owens JA. A clinical overview of sleep and attention-deficit/hyperactivity disorder in children and adolescents. *J Can Acad Child Adolesc Psychiatry*. 2009;18(2):92–102

200. Mick E, Biederman J, Jetton J, Faraone SV. Sleep disturbances associated with attention deficit hyperactivity disorder: the impact of psychiatric comorbidity and pharmacotherapy. *J Child Adolesc Psychopharmacol*. 2000;10(3):223–231

201. van der Heijden KB, Smits MG, van Someren EJ, Boudewijn Gunning W. Prediction of melatonin efficacy by pretreatment dim light melatonin onset in children with idiopathic chronic sleep onset insomnia. *J Sleep Res*. 2005;14(2):187–194

202. Cortese S, Faraone SV, Konofal E, Lecendreux M. Sleep in children with attention-deficit/hyperactivity disorder: meta-analysis of subjective and objective studies. *J Am Acad Child Adolesc Psychiatry*. 2009;48(9):894–908

203. Golan N, Shahar E, Ravid S, Pillar G. Sleep disorders and daytime sleepiness in children with attention-deficit/hyperactive disorder. *Sleep*. 2004;27(2):261–266

204. Lecendreux M, Konofal E, Bouvard M, Falissard B, Mouren-Siméoni MC. Sleep and alertness in children with ADHD. *J Child Psychol Psychiatry*. 2000;41(6): 803–812

205. Owens JA, Dalzell V. Use of the 'BEARS' sleep screening tool in a pediatric residents' continuity clinic: a pilot study. *Sleep Med*. 2005;6(1):63–69

206. Chervin RD, Hedger K, Dillon JE, Pituch KJ. Pediatric sleep questionnaire (PSQ): validity and reliability of scales for sleep-disordered breathing, snoring, sleepiness, and behavioral problems. *Sleep Med*. 2000;1(1):21–32

207. Owens JA, Spirito A, McGuinn M. The Children's Sleep Habits Questionnaire (CSHQ): psychometric properties of a survey instrument for school-aged children. *Sleep*. 2000;23(8):1043–1051

208. Aurora RN, Zak RS, Karippot A, et al; American Academy of Sleep Medicine. Practice parameters for the respiratory indications for polysomnography in children. *Sleep (Basel)*. 2011;34(3):379–388

209. Aurora RN, Lamm CI, Zak RS, et al. Practice parameters for the non-respiratory indications for polysomnography and multiple sleep latency testing for children. *Sleep (Basel)*. 2012;35(11):1467–1473

210. Gruber R, Wiebe S, Montecalvo L, Brunetti B, Amsel R, Carrier J. Impact of sleep restriction on neurobehavioral functioning of children with attention deficit hyperactivity disorder. *Sleep (Basel)*. 2011;34(3):315–323

211. Bunford N, Evans SW, Wymbs F. ADHD and emotion dysregulation among children and adolescents. *Clin Child Fam Psychol Rev*. 2015;18(3):185–217

212. Langberg JM, Vaughn AJ, Brinkman WB, Froehlich T, Epstein JN. Clinical utility of the Vanderbilt ADHD Rating Scale for ruling out comorbid learning disorders. *Pediatrics*. 2010;126(5). Available at: www.pediatrics.org/cgi/content/full/126/5/e1033

213. Kressly SJ. Extending the medical home to meet your patients' mental health needs: is telehealth the answer? *Pediatrics*. 2019;143(3): e20183765

214. Dudek E, Henschen E, Finkle E, Vyas S, Fiszbein D, Shukla A. Improving continuity in a patient centered medical home. *Pediatrics*. 2018;142(1): 366

215. Dessie AS, Hirway P, Gjelsvik A. Children with developmental, behavioral, or emotional problems are less likely to have a medical home. *Pediatrics*. 2018;141(1):23

216. Foy JM. The medical home and integrated behavioral health. *Pediatrics*. 2015;135(5):930–931

217. Ader J, Stille CJ, Keller D, Miller BF, Barr MS, Perrin JM. The medical home and integrated behavioral health: advancing the policy agenda. *Pediatrics*. 2015;135(5):909–917

218. American Academy of Pediatrics. Collaboration in practice: implementing team-based care. *Pediatrics*. 2016;138(2):e20161486

219. Kressley SJ. Team-based care for children: who should be included and who should lead? *AAP News*. July 24, 2017. Available at: https://www.aappublications.org/news/2017/07/24/TeamBased072417. Accessed September 8, 2019

220. Katkin JP, Kressly SJ, Edwards AR, et al; Task Force on Pediatric Practice Change. Guiding principles for team-based pediatric care. *Pediatrics*. 2017; 140(2):e20171489

221. Godoy L, Hodgkinson S, Robertson HA, et al. Increasing mental health engagement from primary care: the potential role of family navigation. *Pediatrics*. 2019;143(4):e20182418

222. Wolraich ML, Hagan JF Jr. *ADHD: What Every Parent Needs to Know*. 3rd ed.

Itasca, IL: American Academy of Pediatrics; 2019. Available at: https://shop.aap.org/adhd-paperback/. Accessed September 8, 2019

223. American Academy of Pediatrics. *Understanding ADHD*. Itasca, IL: American Academy of Pediatrics; 2017. Available at: https://shop.aap.org/understanding-adhd-brochure-50pk-brochure/. Accessed September 8, 2019

224. HealthyChildren.org. ADHD. 2018. Available at: https://www.healthychildren.org/English/health-issues/conditions/adhd/Pages/default.aspx. Accessed September 8, 2019

225. American Academy of Pediatrics. *ADHD Provider Toolkit*. 3rd ed. In production

226. Reiff MI. *ADHD: What Every Parent Needs to Know*. 2nd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2011

227. Charach A, Fernandez R. Enhancing ADHD medication adherence: challenges and opportunities. *Curr Psychiatry Rep*. 2013;15(7):371

228. Greenhill LL, Abikoff HB, Arnold LE, et al. Medication treatment strategies in the MTA Study: relevance to clinicians and researchers. *J Am Acad Child Adolesc Psychiatry*. 1996;35(10):1304–1313

229. Cortese S, Adamo N, Del Giovane C, et al. Comparative efficacy and tolerability of medications for attention-deficit hyperactivity disorder in children, adolescents, and adults: a systematic review and network meta-analysis. *Lancet Psychiatry*. 2018;5(9):727–738

230. Pozzi M, Carnovale C, Peeters GGAM, et al. Adverse drug events related to mood and emotion in paediatric patients treated for ADHD: a meta-analysis. *J Affect Disord*. 2018;238:161–178

231. Robin AL, Foster SL. *Negotiating Parent Adolescent Conflict: A Behavioral-Family Systems Approach*. New York, NY: Guilford Press; 1989

232. Barkley RA, Edwards G, Laneri M, Fletcher K, Metevia L. The efficacy of problem-solving communication training alone, behavior management training alone, and their combination for parent-adolescent conflict in teenagers with ADHD and ODD. *J Consult Clin Psychol*. 2001;69(6):926–941

233. Bloch MH, Qawasmi A. Omega-3 fatty acid supplementation for the treatment of children with attention-deficit/hyperactivity disorder symptomatology: systematic review and meta-analysis. *J Am Acad Child Adolesc Psychiatry*. 2011;50(10):991–1000

234. Understood.org. Get personalized recommendations for you and your child. Available at: https://www.understood.org/en/learning-attention-issues/treatments-approaches/working-with-clinicians. Accessed September 8, 2019

235. ImpactADHD. Free resources for parents. Available at: https://impactadhd.com/resources/free-impactadhd-resources-for-parents/. Accessed September 8, 2019

236. ImpactADHD. ImpactADHD. Available at: https://www.youtube.com/user/ImpactADHD. Accessed September 8, 2019

237. Halfon N, Forrest CB, Lerner RM, Faustman EM. *Handbook of Life Course Health Development*. Cham, Switzerland: Springer; 2018

238. Evans SW, Owens JS, Mautone JA, DuPaul GJ, Power TJ. Toward a comprehensive, Life Course Model of care for youth with ADHD. In: Weist M, Lever N, Bradshaw C, Owens J, eds. *Handbook of School Mental Health*. 2nd ed. New York, NY: Springer; 2014:413–426

239. Pfiffner LJ, Hinshaw SP, Owens E, et al. A two-site randomized clinical trial of integrated psychosocial treatment for ADHD-inattentive type. *J Consult Clin Psychol*. 2014;82(6):1115–1127

240. Charach A, Volpe T, Boydell KM, Gearing RE. A theoretical approach to medication adherence for children and youth with psychiatric disorders. *Harv Rev Psychiatry*. 2008;16(2):126–135

241. Foy JM, ed. *Mental Health Care of Children and Adolescents: A Guide for Primary Care Clinicians*. Itasca, IL: American Academy of Pediatrics; 2018

242. Chan E. Complementary and alternative medicine in developmental-behavioral pediatrics. In: Wolraich ML, Drotar DD, Dworkin PH, Perrin EC, eds. *Developmental-Behavioral Pediatrics: Evidence and Practice*. Philadelphia, PA: Mosby Elsevier; 2008:259–280

243. Chan E. The role of complementary and alternative medicine in attention-deficit hyperactivity disorder. *J Dev Behav Pediatr*. 2002;23(suppl 1):S37–S45

244. James S, Stevenson SW, Silove N, Williams K. Chelation for autism spectrum disorder (ASD). *Cochrane Database Syst Rev*. 2015;(5):CD010766

245. Foy JM, ed. Office and network systems to support mental health care. In: *Mental Health Care of Children and Adolescents: A Guide for Primary Care Clinicians*. Itasca, IL: American Academy of Pediatrics; 2018:73–126

246. kidsdata.org. *Children With Special Health Care Needs, by Condition (California & U.S. Only)*. Palo Alto, CA: Lucille Packard Foundation for Children's Health; 2010. Available at: https://www.kidsdata.org/topic/486/special-needs-condition/table#fmt=640&loc=1,2&tf=74&ch=152,1039,854,154,845,1040,1041,858,157,158,1042,1043,160,161,861,1044,1045,1046,165,166. Accessed September 8, 2019

247. Danielson ML, Visser SN, Gleason MM, Peacock G, Claussen AH, Blumberg SJ. A national profile of attention-deficit hyperactivity disorder diagnosis and treatment among US children aged 2 to 5 years. *J Dev Behav Pediatr*. 2017;38(7):455–464

248. American Academy of Pediatrics. Mental health initiatives: residency curriculum. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Mental-Health/Pages/Residency-Curriculum.aspx. Accessed September 8, 2019

249. American Academy of Child & Adolescent Psychiatry. *Workforce Issues*. Washington, DC: American Academy of Child & Adolescent Psychiatry; 2016. Available at: https://www.aacap.org/aacap/Resources_for_Primary_Care/Workforce_Issues.aspx. Accessed September 8, 2019

250. Thomas CR, Holzer CE III. The continuing shortage of child and adolescent psychiatrists. *J Am Acad Child Adolesc Psychiatry*. 2006;45(9): 1023–1031

251. Rohlfing J, Navarro R, Maniya OZ, Hughes BD, Rogalsky DK. Medical student debt and major life choices other than specialty. *Med Educ Online*. 2014;19:25603

252. Centers for Disease Control and Prevention. *ADHD: Behavioral Health Services – Where They Are and Who Provides Them*. Atlanta, GA: Centers for Disease Control and Prevention; 2018. Available at: https://www.cdc.gov/ncbddd/adhd/stateprofiles-providers/index.html. Accessed September 8, 2019

253. Massachusetts Child Psychiatry Access Program. MCPAP: connecting primary care with child psychiatry. Available at: https://www.mcpap.com. Accessed September 8, 2019

254. Project Training and Education for the Advancement of Children's Health. Project TEACH (Training and Education for the Advancement of Children's Health). 2018. Available at: https://projectteachny.org/. Accessed September 8, 2019

255. Project Extension for Community Healthcare Outcomes. About ECHO. Available at: https://echo.unm.edu/about-echo/. Accessed September 8, 2019

256. Health Resources and Services Administration, Maternal and Child Health Bureau. Pediatric mental health care access program. Available at: https://mchb.hrsa.gov/training/projects.asp?program=34. Accessed July 2, 2019

257. National Network of Child Psychiatry Access Programs. Integrating mental and behavioral health care for every child. Available at: https://nncpap.org/. Accessed July 2, 2019

258. Horwitz SM, Storfer-Isser A, Kerker BD, et al. Barriers to the identification and management of psychosocial problems: changes from 2004 to 2013. *Acad Pediatr*. 2015;15(6):613–620

259. American Academy of Child and Adolescent Psychiatry Committee on Health Care Access and Economics Task Force on Mental Health. Improving mental health services in primary care: reducing administrative and financial barriers to access and collaboration [published correction appears in *Pediatrics. 2009;123(6):1611]. Pediatrics*. 2009;123(4):1248–1251

260. Centers for Medicare and Medicaid Services. *Accountable Care Organizations (ACOs)*. Baltimore, MD: Centers for Medicare and Medicaid Services; 2018. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/. Accessed September 8, 2019

261. Fallu A, Dabouz F, Furtado M, Anand L, Katzman MA. A randomized, double-blind, cross-over, phase IV trial of oros-methylphenidate (CONCERTA(®)) and generic novo-methylphenidate ER-C (NOVO-generic). *Ther Adv Psychopharmacol*. 2016;6(4):237–251

262. Hagan JF, Shaw JS, Duncan PM, eds. *Bright Futures Guidelines for Health Supervision of Infants, Children, and Adolescents*. 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017

263. Foy JM, Kelleher KJ, Laraque D; American Academy of Pediatrics Task Force on Mental Health. Enhancing pediatric mental health care: strategies for preparing a primary care practice.*Pediatrics*. 2010;125(suppl 3): S87–S108

264. Allan C, Chacko A. Adverse events in behavioral parent training for children with ADHD: an under-appreciated phenomenon. *ADHD Rep*. 2018;26(1):4–9

265. US Department of Health and Human Services. Health information privacy. Available at: https://www.hhs.gov/hipaa/index.html. Accessed September 8, 2019

266. US Department of Education. *Family Educational Rights and Privacy Act (FERPA)*. Washington, DC: Department of Education; 2018. Available at: https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html. Accessed September 8, 2019

267. Epstein JN, Langberg JM, Lichtenstein PK, Kolb R, Altaye M, Simon JO. Use of an Internet portal to improve community-based pediatric ADHD care: a cluster randomized trial. *Pediatrics*. 2011;128(5). Available at: www.pediatrics.org/cgi/content/full/128/5/e1201

268. Centers for Medicare and Medicaid Services. *Electronic Health Records*. Baltimore, MD: Centers for Medicare and Medicaid Services; 2012. Available at: https://www.cms.gov/Medicare/E-Health/EHealthRecords/index.html. Accessed September 8, 2019

269. Ohno-Machado L. Electronic health record systems: risks and benefits. *J Am Med Inform Assoc*. 2014;21(e1):e1

270. Koppel R, Lehmann CU. Implications of an emerging EHR monoculture for hospitals and healthcare systems. *J Am Med Inform Assoc*. 2015;22(2):465–471

271. Babbott S, Manwell LB, Brown R, et al. Electronic medical records and physician stress in primary care: results from the MEMO Study. *J Am Med Inform Assoc*. 2014;21(e1):e100–e106

272. Burke BL Jr, Hall RW; Section on Telehealth Care. Telemedicine: pediatric applications. *Pediatrics*. 2015;136(1). Available at: www.pediatrics.org/cgi/content/full/136/1/e293

273. Marcin JP, Rimsza ME, Moskowitz WB; Committee on Pediatric Workforce. The use of telemedicine to address access and physician workforce shortages. *Pediatrics*. 2015;136(1): 202–209

274. Sibley MH, Comer JS, Gonzalez J. Delivering parent-teen therapy for ADHD through videoconferencing: a preliminary investigation. *J Psychopathol Behav Assess*. 2017; 39(3):467–485

275. Comer JS, Furr JM, Miguel EM, et al. Remotely delivering real-time parent training to the home: an initial randomized trial of Internet-delivered parent-child interaction therapy (I-PCIT). *J Consult Clin Psychol*. 2017;85(9): 909–917

276. American Academy of Child and Adolescent Psychiatry; American Academy of Pediatrics. HIPAA privacy rule and provider to provider communication. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Mental-Health/Pages/HIPAA-Privacy-Rule-and-Provider-to-Provider-Communication.aspx. Accessed September 8, 2019

277. Kolko DJ, Campo J, Kilbourne AM, Hart J, Sakolsky D, Wisniewski S. Collaborative care outcomes for

pediatric behavioral health problems: a cluster randomized trial. *Pediatrics*. 2014;133(4). Available at: www.pediatrics.org/cgi/content/full/133/4/e981

278. Pordes E, Gordon J, Sanders LM, Cohen E. Models of care delivery for children with medical complexity. *Pediatrics*. 2018;141(suppl 3): S212–S223

279. Silverstein M, Hironaka LK, Walter HJ, et al. Collaborative care for children with ADHD symptoms: a randomized comparative effectiveness trial. *Pediatrics*. 2015;135(4). Available at: www.pediatrics.org/cgi/content/full/135/4/e858

280. Liddle M, Birkett K, Bonjour A, Risma K. A collaborative approach to improving health care for children with developmental disabilities. *Pediatrics*. 2018;142(6):e20181136

Attention-Deficit/Hyperactivity Disorder Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  - — Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents
- *ICD-10-CM* Coding Quick Reference for ADHD
- Bonus Features
  - — ADHD Coding Fact Sheet for Primary Care Physicians
  - — Continuum Model for ADHD
- AAP Patient Education Handouts
  - — *ADHD—What Is Attention-Deficit/Hyperactivity Disorder?*
  - — *What Are the Symptoms of Attention-Deficit/Hyperactivity Disorder?*
  - — *How Is Attention-Deficit/Hyperactivity Disorder Diagnosed?*
  - — *What Causes Attention-Deficit/Hyperactivity Disorder and How Is It Treated?*

Action Statement Summary

Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents

Key Action Statement 1

The pediatrician or other PCC should initiate an evaluation for ADHD for any child or adolescent age 4 years to the 18th birthday who presents with academic or behavioral problems and symptoms of inattention, hyperactivity, or impulsivity. (Grade B: strong recommendation.)

Key Action Statement 2

To make a diagnosis of ADHD, the PCC should determine that *DSM-5* criteria have been met, including documentation of symptoms and impairment in more than 1 major setting (ie, social, academic, or occupational), with information obtained primarily from reports from parents or guardians, teachers, other school personnel, and mental health clinicians who are involved in the child or adolescent's care. The PCC should also rule out any alternative cause. (Grade B: strong recommendation.)

Key Action Statement 3

In the evaluation of a child or adolescent for ADHD, the PCC should include a process to at least screen for comorbid conditions, including emotional or behavioral conditions (eg, anxiety, depression, oppositional defiant disorder, conduct disorders, substance use), developmental conditions (eg, learning and language disorders, autism spectrum disorders), and physical conditions (eg, tics, sleep apnea). (Grade B: strong recommendation.)

Key Action Statement 4

ADHD is a chronic condition; therefore, the PCC should manage children and adolescents with ADHD in the same manner that they would children and youth with special health care needs, following the principles of the chronic care model and the medical home. (Grade B: strong recommendation.)

Key Action Statement 5a

For preschool-aged children (age 4 years to the sixth birthday) with ADHD, the PCC should prescribe evidence-based behavioral PTBM and/or behavioral classroom interventions as the first line of treatment, if available (grade A: strong recommendation). Methylphenidate may be considered if these behavioral interventions do not provide significant improvement and there is moderate-to-severe continued disturbance in the 4- through 5-year-old child's functioning. In areas in which evidence-based behavioral treatments are not available, the clinician needs to weigh the risks of starting medication before the age of 6 years against the harm of delaying treatment. (Grade B: strong recommendation.)

Key Action Statement 5b

For elementary and middle school–aged children (age 6 years to the 12th birthday) with ADHD, the PCC should prescribe US Food and Drug Administration (FDA)–approved medications for ADHD, along with PTBM and/or behavioral classroom intervention (preferably both PTBM and behavioral classroom interventions). Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an Individualized Education Program (IEP) or a rehabilitation plan (504 plan). (Grade A: strong recommendation for medications; grade A: strong recommendation for PTBM training and behavioral treatments for ADHD implemented with the family and school.)

Key Action Statement 5c

For adolescents (age 12 years to the 18th birthday) with ADHD, the PCC should prescribe FDA-approved medications for ADHD with the adolescent's assent (grade A: strong recommendation). The PCC is encouraged to prescribe evidence-based training interventions and/or behavioral interventions as treatment of ADHD, if available. Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an IEP or a rehabilitation plan (504 plan). (Grade A: strong recommendation.)

Key Action Statement 6

The PCC should titrate doses of medication for ADHD to achieve maximum benefit with tolerable side effects. (Grade B: strong recommendation.)

Key Action Statement 7

The PCC, if trained or experienced in diagnosing comorbid conditions, may initiate treatment of such conditions or make a referral to an appropriate subspecialist for treatment. After detecting possible comorbid conditions, if the PCC is not trained or experienced in making the diagnosis or initiating treatment, the patient should be referred to an appropriate subspecialist to make the diagnosis and initiate treatment. (Grade C: recommendation.)

Coding Quick Reference for ADHD	
ICD-10-CM	
F90.0	Attention-deficit hyperactivity disorder, predominantly inattentive type
F90.1	Attention-deficit hyperactivity disorder, predominantly hyperactive type

ADHD Coding Fact Sheet for Primary Care Physicians

Current Procedural Terminology (CPT®) (Procedure) Codes

Initial assessment usually involves a lot of time in determining the differential diagnosis, a diagnostic plan, and potential treatment options. Therefore, most pediatricians will report either an office or an outpatient evaluation and management (E/M) code using time or a consultation code for the initial assessment. Remember there are new guidelines (https://services.aap.org/en/practice-management/2021-office-based-em-changes) for office or other outpatient E/M service reporting *only*. Code-level section based on time or medical decision-making (MDM).

Physician E/M Services

***▲99202** Office or other outpatient visit, *new*[a] patient; straightforward MDM, 15–29 min.
***▲99203** low MDM, 30–44 min.
***▲99204** moderate MDM, 45–59 min.
***▲99205** high MDM, 60–74 min.
***▲99211** Office or other outpatient visit, *established* patient; not requiring the presence of a physician or other qualified health care professional.
***▲99212** straightforward MDM, 10–19 min.
***▲99213** low MDM, 20–29 min.
***▲99214** moderate MDM, 30–39 min.
***▲99215** high MDM, 40–54 min.
***•+99417** Prolonged office or other outpatient E/M service(s) beyond the minimum required time of the primary procedure which has been selected using total time, requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service, each 15 minutes of total time (use only in conjunction with codes **99205**, **99215**)
***99241** Office or other outpatient *consultation*,[b–d] new or established patient; self-limited or minor problem, 15 min.
***99242** low severity problem, 30 min.
***99243** moderate severity problem, 45 min.
***99244** moderate to high severity problem, 60 min.
***99245** moderate to high severity problem, 80 min.
***+99354** Prolonged physician services in office or other outpatient setting, with direct patient contact; first hour (*use in conjunction with time-based codes* **99241–99245**, **99301–99350**, **90837**)
***+99355** each additional 30 min. (*use in conjunction with* **99354**)

- Used when a physician provides prolonged services beyond the usual service (ie, beyond the typical time).
- Time spent does not have to be continuous.

[a] A new patient is one who has not received any professional services (face-to-face services) rendered by physicians and other qualified health care professionals who may report E/M services using 1 or more specific *CPT* codes from the physician/qualified health care professional, or another physician/qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past 3 years.

[b] Use of these codes (**99241–99245**) requires the following actions:
1. Written or verbal request for consultation is documented in the medical record.
2. Consultant's opinion and any services ordered or performed are documented in the medical record.
3. Consultant's opinion and any services that are performed are prepared in a written report, which is sent to the requesting physician or other appropriate source.

[c] Patients/parents may not initiate a consultation.

[d] For more information on consultation code changes for 2010, see www.aap.org/en-us/professional-resources/practice-transformation/getting-paid/Coding-at-the-AAP/Pages/ADHD-Coding-Fact-Sheet.aspx.

• New *CPT* code
▲ Revised *CPT* code
+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.
* Indicates a *CPT*-approved telemedicine service.

Reporting E/M Services Using "Time"

In this example we will look at office-based E/M service reporting only. Time rules will now vary between these services and consultations.

- Now based on total time including face-to-face and non-face-to-face time on date of encounter
- Does not have to be continuous on that day
- Are set by defined ranges
- No longer limited to time spent in counseling or care coordination
- Time may not include clinical staff time or time spent on a previous or subsequent day
- May only add Prolonged Services (https://services.aap.org/link/efbedcca82284a2c8dfc2820f0c41d38.aspx) (**+99417**) when choosing your code based on time and only when **99205** and **99215** have been exceeded
  - **Example:** A physician sees an established patient in the office to discuss the current attention-deficit/hyperactivity disorder (ADHD) medication the patient was placed on. The total face-to-face time was 30 minutes. Prior to the visit the physician also reviews notes from the teacher and school counselor to assist with the assessment. This took an additional 10 minutes. After the encounter the physician wrote a summary and sent it off to the school counselor as requested. This was an additional 7 minutes. Total time spent is 47 minutes. Based on time, the physician may report a **99215** because the total time spent (cumulative direct and non-direct) is used to get to the level in lieu of MDM.

ADHD Follow-up During a Routine Preventive Medicine Service

- A good time to follow up with a patient regarding his or her ADHD could be during a preventive medicine service.
- If the follow-up requires little additional work on behalf of the physician, it should be reported under the preventive medicine service, rather than as a separate service.
- If the follow-up work requires an additional E/M service in addition to the preventive medicine service, it should be reported as a separate service.
- Chronic conditions should be reported only if they are separately addressed.
- When reporting a preventive medicine service in addition to an office-based E/M service and the services are significant and separately identifiable, modifier **25** will be required on the office-based E/M service.
  - **Example:** A 12-year-old established patient presents for his routine preventive medicine service and, while he and Mom are there, Mom asks about changing his ADHD medication because of some side effects he is experiencing. The physician completes the routine preventive medicine check and then addresses the mom's concerns in a separate service. The additional E/M service takes 15 minutes face-to-face. Due to an issue at the pharmacy, the physician spends an additional 7 minutes on the phone. Total time is 22 minutes for this patient.
    - Code **99394** and **99213-25** account for both E/M services and link each to the appropriate *International Classification of Diseases, 10th Revision, Clinical Modification* (*ICD-10-CM*) code.
    - Modifier **25** is required on the problem-oriented office visit code (eg, **99213**) when it is significant and separately identifiable from another service.

- Prolonged service of less than 15 minutes beyond the first hour or less than 15 minutes beyond the final 30 minutes is not reported separately.
- If reporting E/M service according to time and not key factors (history, examination, and medical decision-making), the physician must reach the typical time in the highest code in the code set being reported (eg, **99205**, **99215**, **99245**) before face-to-face prolonged services can be reported.
- Refer to *CPT* for clinical staff prolonged services.

Physician Non–face-to-face Services

99339 Care Plan Oversight—Individual physician supervision of a patient (patient not present) in home, domiciliary or rest home (e.g., assisted living facility) requiring complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of related laboratory and other studies, communication (including telephone calls) for purposes of assessment or care decisions with health care professional(s), family member(s), surrogate decision maker(s) (e.g., legal guardian) and/or key caregiver(s) involved in patient's care, integration of new information into the medical treatment plan and/or adjustment of medical therapy, within a calendar month; 15–29 minutes

99340 30 minutes or more

99358 Prolonged physician services without direct patient contact; first hour

+99359 each additional 30 min. (+ *use in conjunction with* **99358**)
Do not report **99358–99359** on the same day as **99202–99215**

99367 Medical team conference by physician with interdisciplinary team of health care professionals, patient and/or family not present, 30 minutes or more

Telephone Care

99441 Telephone evaluation and management to patient, parent or guardian not originating from a related E/M service within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion

99442 11–20 minutes of medical discussion

99443 21–30 minutes of medical discussion

Digital Online E/M Services

Are patient-initiated services with physicians or other advanced practitioners (NP/PA).

Require evaluation, assessment, and management of the patient.

The patient must be established, but the condition can be new.

The digital communication must take place over a secure platform which allows digital communication.

Online digital E/M services are reported once for the *cumulative time* devoted to the service, which includes

- review of the initial inquiry,
- review of patient records or data pertinent to assessment of the patient's problem,
- interaction with clinical staff focused on the patient's problem, development of management plans, including generation of prescriptions or ordering of tests, and subsequent communication with the patient through online, telephone, email, or other digitally supported communication during a seven-day period.

The seven-day period begins with the personal review of the patient-generated inquiry.

Online digital E/M services require permanent documentation storage

99421 Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes

99422 11–20 minutes

99423 21 or more minutes

Care Management Services

Codes are selected according to the amount of time spent by clinical staff (**99490**)/physician (**99491**) providing care coordination activities. *CPT* clearly defines which activities are care coordination activities. To report chronic care management codes, you must

1. Provide 24/7 access to physicians or other qualified health care professionals or clinical staff.
2. Use a standardized methodology to identify patients who require chronic complex care coordination services.
3. Have an internal care coordination process/function whereby a patient identified as meeting the requirements for these services starts receiving them in a timely manner.
4. Use a form and format in the medical record that is standardized within the practice.
5. An electronic and/or printed plan of care must be documented and shared with the patient and/or caregiver.
6. Be able to engage and educate patients and caregivers, as well as coordinate care among all service professionals, as appropriate for each patient (also applies to code **99490** under NPP services).

99491 Chronic care management services, provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements:
- multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- comprehensive care plan established, implemented, revised, or monitored.

Psychiatry

+90785 Interactive complexity (Use in conjunction with codes for diagnostic psychiatric evaluation [**90791**, **90792**], psychotherapy [**90832**, **90834**, **90837**], psychotherapy when performed with an evaluation and management service [**90833**, **90836**, **90838**, **99202–99255**, **99304–99337**, **99341–99350**], and group psychotherapy [**90853**])

Psychiatric Diagnostic or Evaluative Interview Procedures

90791 Psychiatric diagnostic interview examination evaluation

90792 Psychiatric diagnostic evaluation with medical services

Psychotherapy

***90832** Psychotherapy, 30 min with patient;

***+90833** with medical E/M (Use in conjunction with **99202–99255**, **99304–99337**, **99341–99350**)

***90834** Psychotherapy, 45 min with patient;

***+90836** with medical E/M services (Use in conjunction with **99202–99255**, **99304–99337**, **99341–99350**)

• New *CPT* code
▲ Revised *CPT* code
+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.
* Indicates a *CPT*-approved telemedicine service.

***90837** Psychotherapy, 60 min with patient;
***+90838** with medical E/M services (Use in conjunction with **99202–99255**, **99304–99337**, **99341–99350**)

+90785 Interactive complexity (Use in conjunction with codes for diagnostic psychiatric evaluation [**90791**, **90792**], psychotherapy [**90832**, **90834**, **90837**], psychotherapy when performed with an evaluation and management service [**90833**, **90836**, **90838**, **99202–99255**, **99304–99337**, **99341–99350**], and group psychotherapy [**90853**])
- Refers to specific communication factors that complicate the delivery of a psychiatric procedure. Common factors include more difficult communication with discordant or emotional family members and engagement of young and verbally undeveloped or impaired patients. Typical encounters include
  — Patients who have other individuals legally responsible for their care
  — Patients who request others to be present or involved in their care such as translators, interpreters, or additional family members
  — Patients who require the involvement of other third parties such as child welfare agencies, schools, or probation officers

***90846** Family psychotherapy (without patient present), 50 min
***90847** Family psychotherapy (conjoint psychotherapy) (with patient present), 50 min

Other Psychiatric Services/Procedures

90863 Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services (Use in conjunction with **90832**, **90834**, **90837**)
- For pharmacologic management with psychotherapy services performed by a physician or other qualified health care professional who may report E/M codes, use the appropriate E/M codes (**99202–99255**, **99281–99285**, **99304–99337**, **99341–99350**) and the appropriate psychotherapy with E/M service (**90833**, **90836**, **90838**).

90887 Interpretation or explanation of results of psychiatric, other medical exams, or other accumulated data to family or other responsible persons, or advising them how to assist patient

90889 Preparation of reports on patient's psychiatric status, history, treatment, or progress (other than for legal or consultative purposes) for other physicians, agencies, or insurance carriers

97127 Therapeutic interventions that focus on cognitive function (eg, attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (eg, managing time or schedules, initiating, organizing and sequencing tasks), direct (one-on-one) patient contact

Developmental/Psychological Testing

96110 Developmental screening, with scoring and documentation, per standardized instrument (Do not use for ADHD screens or assessments)

96112 Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour

+96113 each additional 30 minutes (Report with **96112**)

***96116** Neurobehavioral status examination (clinical assessment of thinking, reasoning and judgment [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour

***96121** each additional hour (Report with **96116**)

96127 Brief emotional/behavioral assessment (eg, depression inventory, attention-deficit/hyperactivity disorder [ADHD] scale), with scoring and documentation, per standardized instrument

96130 Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour

+96131 each additional hour (code with **96130**)

96136 Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes

+96137 each additional 30 minutes

Nonphysician Provider (NPP) Services

99366 Medical team conference with interdisciplinary team of health care professionals, face-to-face with patient and/or family, 30 minutes or more, participation by a nonphysician qualified health care professional

99368 Medical team conference with interdisciplinary team of health care professionals, patient and/or family not present, 30 minutes or more, participation by a nonphysician qualified health care professional

96146 Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only

Health and Behavior (Re-) Assessment and Intervention

The following codes are reported to describe services offered to patients who present with primary *physical illnesses, diagnoses,* or *symptoms* and may benefit from assessments and interventions that focus on the psychological and/or psychosocial factors related to the patient's health status.

•96156 Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)

•96158 Health behavior intervention, individual, face-to-face; initial 30 minutes

•+96159 each additional 15 minutes (code with **96158**)

•96164 Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes

•+96165 each additional 15 minutes (code with **96164**)

•96167 Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes

•+96168 each additional 15 minutes (code with **96167**)

•96170 Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes

•+96171 each additional 15 minutes (code with **96170**)

• New *CPT* code
▲ Revised *CPT* code
+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.
* Indicates a *CPT*-approved telemedicine service.

Non–face-to-face Services: NPP

98966 Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent or guardian not originating from a related assessment and management service provided within the previous seven days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion

98967 11–20 minutes of medical discussion

98968 21–30 minutes of medical discussion

98969 Online assessment and management service provided by a qualified nonphysician health care professional to an established patient or guardian not originating from a related assessment and management service provided within the previous seven days nor using the internet or similar electronic communications network

NPP Online Digital E/M Service

Reported only once per 7 days.

Report these codes for qualified health care professionals such as speech pathologists, registered dieticians, or physical therapists.

Do not report for physician's or advanced practitioners (NP/PA).

For additional information see codes **99421–99423** in this resource or refer to the *CPT* manual.

98970 Qualified nonphysician health care professional online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes

98971 11–20 minutes

98972 21 or more minutes

Clinical Staff Services

99490 *Chronic care management services,* at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient;
- chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline;
- comprehensive care plan established, implemented, revised, or monitored.

+•99439 each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code **99490**)

Chronic care management services are provided when medical needs or psychosocial needs (or both types of needs) of the patient require establishing, implementing, revising, or monitoring the care plan. If 20 minutes is not met within a calendar month, you do not report chronic care management. Refer to code **99491** in this resource and *CPT* for more information.

Clinical Staff

99484 Care management services for *behavioral health conditions*, at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional, per calendar month, with the following required elements:

- initial assessment or follow-up monitoring, including the use of applicable validated rating scales;
- behavioral health care planning in relation to behavioral/ psychiatric health problems, including revision for patients who are not progressing or whose status changes;
- facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation; and
- continuity of care with a designated member of the care team.

E/M services, including care management services (**99439**, **99487**, **99489**, **99490**, **99495**, **99496**), and psychiatric services (**90785–90899**) may be reported separately by the same physician or other qualified health care professional on the same day or during the same calendar month, but time and activities used to meet criteria for another reported service do not count toward meeting criteria for **99484**.

99492 Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

- outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional;
- initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan;
- review by the psychiatric consultant with modifications of the plan if recommended;
- entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and
- provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.

99493 Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements:

- tracking patient follow-up and progress using the registry, with appropriate documentation;
- participation in weekly caseload consultation with the psychiatric consultant;
- ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers;
- additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;
- provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;

• New *CPT* code
▲ Revised *CPT* code
+ Codes are *add-on codes,* meaning they are reported separately in addition to the appropriate code for the service provided.
* Indicates a *CPT*-approved telemedicine service.

- monitoring of patient outcomes using validated rating scales; and
- relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.

+99494 Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (Use **99494** in conjunction with **99492**, **99493**)

Miscellaneous Services

99071 Educational supplies, such as books, tapes, or pamphlets, provided by the physician for the patient's education at cost to the physician

ICD-10-CM Codes

- Use as many diagnosis codes that apply to document the patient's complexity and report the patient's symptoms or adverse environmental circumstances (or both).
- Once a definitive diagnosis is established, report any appropriate definitive diagnosis codes as the primary codes, plus any other symptoms that the patient is exhibiting as secondary diagnoses that are not part of the usual disease course or are considered incidental.

Depressive Disorders

F34.1 Dysthymic disorder (depressive personality disorder, dysthymia neurotic depression)
F39 Mood (affective) disorder, unspecified
F30.8 Other manic episode

Anxiety Disorders

F06.4 Anxiety disorder due to known physiological conditions
F40.10 Social phobia, unspecified
F40.11 Social phobia, generalized
F40.8 Phobic anxiety disorders, other (phobic anxiety disorder of childhood)
F40.9 Phobic anxiety disorder, unspecified
F41.1 Generalized anxiety disorder
F41.9 Anxiety disorder, unspecified

Feeding and Eating Disorders/Elimination Disorders

F50.89 Eating disorders, other
F50.9 Eating disorder, unspecified
F98.0 Enuresis not due to a substance or known physiological condition
F98.1 Encopresis not due to a substance or known physiological condition
F98.3 Pica (infancy or childhood)

Impulse Disorders

F63.9 Impulse disorder, unspecified

Trauma- and Stressor-Related Disorders

F43.20 Adjustment disorder, unspecified
F43.21 Adjustment disorder with depressed mood
F43.22 Adjustment disorder with anxiety
F43.23 Adjustment disorder with mixed anxiety and depressed mood
F43.24 Adjustment disorder with disturbance of conduct

Neurodevelopmental/Other Developmental Disorders

F70 Mild intellectual disabilities
F71 Moderate intellectual disabilities
F72 Severe intellectual disabilities
F73 Profound intellectual disabilities
F79 Unspecified intellectual disabilities
F80.0 Phonological (speech) disorder (speech-sound disorder)
F80.1 Expressive language disorder
F80.2 Mixed receptive-expressive language disorder
F80.4 Speech and language developmental delay due to hearing loss (code also hearing loss)
F80.81 Stuttering
F80.82 Social pragmatic communication disorder
F80.89 Other developmental disorders of speech and language
F80.9 Developmental disorder of speech and language, unspecified
F81.0 Specific reading disorder
F81.2 Mathematics disorder
F81.89 Other developmental disorders of scholastic skills
F82 Developmental coordination disorder
F84.0 Autistic disorder (Autism spectrum disorder)
F88 Specified delays in development; other
F89 Unspecified delay in development
F81.9 Developmental disorder of scholastic skills, unspecified

Behavioral/Emotional Disorders

F90.0 Attention-deficit hyperactivity disorder, predominantly inattentive type
F90.1 Attention-deficit hyperactivity disorder, predominantly hyperactive type
F90.8 Attention-deficit hyperactivity disorder, other type
F90.9 Attention-deficit hyperactivity disorder, unspecified type
F91.1 Conduct disorder, childhood-onset type
F91.2 Conduct disorder, adolescent-onset type
F91.3 Oppositional defiant disorder
F91.9 Conduct disorder, unspecified
F93.0 Separation anxiety disorder
F93.8 Other childhood emotional disorders (relationship problems)
F93.9 Childhood emotional disorder, unspecified
F94.9 Childhood disorder of social functioning, unspecified
F95.0 Transient tic disorder
F95.1 Chronic motor or vocal tic disorder
F95.2 Tourette's disorder
F95.9 Tic disorder, unspecified
F98.8 Other specified behavioral and emotional disorders with onset usually occurring in childhood and adolescence (nail-biting, nose-picking, thumb-sucking)

Other

F07.81 Postconcussional syndrome
F07.89 Personality and behavioral disorders due to known physiological condition, other
F07.9 Personality and behavioral disorder due to known physiological condition, unspecified
F45.41 Pain disorder exclusively related to psychological factors
F48.8 Nonpsychotic mental disorders, other (neurasthenia)
F48.9 Nonpsychotic mental disorders, unspecified

• New *CPT* code
▲ Revised *CPT* code
+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.
* Indicates a *CPT*-approved telemedicine service.

F51.01 Primary insomnia
F51.02 Adjustment insomnia
F51.03 Paradoxical insomnia
F51.04 Psychophysiologic insomnia
F51.05 Insomnia due to other mental disorder (Code also associated mental disorder)
F51.09 Insomnia, other (not due to a substance or known physiological condition)
F51.3 Sleepwalking [somnambulism]
F51.4 Sleep terrors [night terrors]
F51.8 Other sleep disorders
F93.8 Childhood emotional disorders, other
R46.89 Other symptoms and signs involving appearance and behavior

Substance-Related and Addictive Disorders

If a provider documents multiple patterns of use, only 1 should be reported. Use the following hierarchy: use–abuse–dependence (eg, if use and dependence are documented, only code for dependence).

When a minus symbol (-) is included in codes **F10–F17**, a last character is required. Be sure to include the last character from the following list:

0 anxiety disorder

2 sleep disorder

8 other disorder

9 unspecified disorder

Alcohol

F10.10 Alcohol abuse, uncomplicated (alcohol use disorder, mild)
F10.14 Alcohol abuse with alcohol-induced mood disorder
F10.159 Alcohol abuse with alcohol-induced psychotic disorder, unspecified
F10.18- Alcohol abuse with alcohol-induced
F10.19 Alcohol abuse with unspecified alcohol-induced disorder
F10.20 Alcohol dependence, uncomplicated
F10.21 Alcohol dependence, in remission
F10.24 Alcohol dependence with alcohol-induced mood disorder
F10.259 Alcohol dependence with alcohol-induced psychotic disorder, unspecified
F10.28- Alcohol dependence with alcohol-induced
F10.29 Alcohol dependence with unspecified alcohol-induced disorder
F10.94 Alcohol use, unspecified with alcohol-induced mood disorder
F10.959 Alcohol use, unspecified with alcohol-induced psychotic disorder, unspecified
F10.98- Alcohol use, unspecified with alcohol-induced
F10.99 Alcohol use, unspecified with unspecified alcohol-induced disorder

Cannabis

F12.10 Cannabis abuse, uncomplicated (cannabis use disorder, mild)
F12.18- Cannabis abuse with cannabis-induced
F12.19 Cannabis abuse with unspecified cannabis-induced disorder
F12.20 Cannabis dependence, uncomplicated
F12.21 Cannabis dependence, in remission
F12.28- Cannabis dependence with cannabis-induced
F12.29 Cannabis dependence with unspecified cannabis-induced disorder
F12.90 Cannabis use, unspecified, uncomplicated
F12.98- Cannabis use, unspecified with
F12.99 Cannabis use, unspecified with unspecified cannabis-induced disorder

Sedatives

F13.10 Sedative, hypnotic or anxiolytic abuse, uncomplicated (sedative, hypnotic, or anxiolytic use disorder, mild)
F13.129 Sedative, hypnotic or anxiolytic abuse with intoxication, unspecified
F13.14 Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced mood disorder
F13.18- Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced
F13.21 Sedative, hypnotic or anxiolytic dependence, in remission
F13.90 Sedative, hypnotic or anxiolytic use, unspecified, uncomplicated
F13.94 Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic or anxiolytic-induced mood disorder
F13.98- Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic or anxiolytic-induced
F13.99 Sedative, hypnotic or anxiolytic use, unspecified with unspecified sedative, hypnotic or anxiolytic-induced disorder

Stimulants (eg, caffeine, amphetamines)

F15.10 Other stimulant (amphetamine-related disorders or caffeine) abuse, uncomplicated (amphetamine, other or unspecified type substance use disorder, mild)
F15.14 Other stimulant (amphetamine-related disorders or caffeine) abuse with stimulant-induced mood disorder
F15.18- Other stimulant (amphetamine-related disorders or caffeine) abuse with stimulant-induced
F15.19 Other stimulant (amphetamine-related disorders or caffeine) abuse with unspecified stimulant-induced disorder
F15.20 Other stimulant (amphetamine-related disorders or caffeine) dependence, uncomplicated
F15.21 Other stimulant (amphetamine-related disorders or caffeine) dependence, in remission
F15.24 Other stimulant (amphetamine-related disorders or caffeine) dependence with stimulant-induced mood disorder
F15.28- Other stimulant (amphetamine-related disorders or caffeine) dependence with stimulant-induced
F15.29 Other stimulant (amphetamine-related disorders or caffeine) dependence with unspecified stimulant-induced disorder
F15.90 Other stimulant (amphetamine-related disorders or caffeine) use, unspecified, uncomplicated
F15.94 Other stimulant (amphetamine-related disorders or caffeine) use, unspecified with stimulant-induced mood disorder
F15.98- Other stimulant (amphetamine-related disorders or caffeine) use, unspecified with stimulant-induced
F15.99 Other stimulant (amphetamine-related disorders or caffeine) use, unspecified with unspecified stimulant-induced disorder

• New *CPT* code
▲ Revised *CPT* code
+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.
* Indicates a *CPT*-approved telemedicine service.

Nicotine (eg, cigarettes)

F17.200 Nicotine dependence, unspecified, uncomplicated (tobacco use disorder, mild, moderate or severe)
F17.201 Nicotine dependence, unspecified, in remission
F17.203 Nicotine dependence, unspecified, with withdrawal
F17.20- Nicotine dependence, unspecified, with
F17.210 Nicotine dependence, cigarettes, uncomplicated
F17.211 Nicotine dependence, cigarettes, in remission
F17.213 Nicotine dependence, cigarettes, with withdrawal
F17.218- Nicotine dependence, cigarettes, with

Symptoms, Signs, and Ill-defined Conditions

Use these codes in absence of a definitive mental diagnosis or when the sign or symptom is not part of the disease course or is considered incidental.

G47.9 Sleep disorder, unspecified
H90.0 Conductive hearing loss, bilateral
H90.11 Conductive hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.12 Conductive hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.A1- Conductive hearing loss, unilateral, with restricted hearing on the contralateral side
H90.A2- Sensorineural hearing loss, unilateral, with restricted hearing on the contralateral side
H90.A3- Mixed conductive and sensorineural hearing loss, unilateral, with restricted hearing on the contralateral side
(Codes under category **H90** require a 6th digit: 1–right ear, 2–left ear)
K11.7 Disturbance of salivary secretions
K59.00 Constipation, unspecified
N39.44 Nocturnal enuresis
R10.0 Acute abdomen pain
R11.11 Vomiting without nausea
R11.2 Nausea with vomiting, unspecified
R19.7 Diarrhea, unspecified
R21 Rash, NOS
R25.0 Abnormal head movements
R25.1 Tremor, unspecified
R25.3 Twitching, NOS
R25.8 Other abnormal involuntary movements
R25.9 Unspecified abnormal involuntary movements
R27.8 Other lack of coordination (excludes ataxia)
R27.9 Unspecified lack of coordination
R41.83 Borderline intellectual functioning
R42 Dizziness
R48.0 Alexia/dyslexia, NOS
R51.9 Headache
R62.0 Delayed milestone in childhood
R62.52 Short stature (child)
R63.3 Feeding difficulties
R63.4 Abnormal weight loss
R63.5 Abnormal weight gain
R68.2 Dry mouth, unspecified
T56.0X1A Toxic effect of lead and its compounds, accidental (unintentional), initial encounter

Z Codes

Z codes represent reasons for encounters. Categories **Z00–Z99** are provided for occasions when circumstances other than a disease, an injury, or an external cause classifiable to categories **A00–Y89** are recorded as *diagnoses* or *problems.* This can arise in 2 main ways.

1. When a person who may or may not be sick encounters the health services for some specific purpose, such as to receive limited care or service for a current condition, to donate an organ or tissue, to receive prophylactic vaccination (immunization), or to discuss a problem that is, in itself, not a disease or an injury
2. When some circumstance or problem is present that influences the person's health status but is not, in itself, a current illness or injury

Z55.0 Illiteracy and low-level literacy
Z55.2 Failed school examinations
Z55.3 Underachievement in school
Z55.4 Educational maladjustment and discord with teachers and classmates
Z55.8 Other problems related to education and literacy
Z55.9 Problems related to education and literacy, unspecified
(**Z55** codes exclude those conditions reported with **F80–F89**)
Z60.4 Social exclusion and rejection
Z60.8 Other problems related to social environment
Z60.9 Problem related to social environment, unspecified
Z62.0 Inadequate parental supervision and control
Z62.21 Foster care status (child welfare)
Z62.6 Inappropriate (excessive) parental pressure
Z62.810 Personal history of physical and sexual abuse in childhood
Z62.811 Personal history of psychological abuse in childhood
Z62.820 Parent-biological child conflict
Z62.821 Parent-adopted child conflict
Z62.822 Parent-foster child conflict
Z63.72 Alcoholism and drug addiction in family
Z63.8 Other specified problems related to primary support group
Z65.3 Problems related to legal circumstances
Z71.89 Counseling, other specified
Z71.9 Counseling, unspecified
Z72.0 Tobacco use
Z77.011 Contact with and (suspected) exposure to lead
Z79.899 Other long term (current) drug therapy
Z81.0 Family history of intellectual disabilities (conditions classifiable to **F70–F79**)
Z81.8 Family history of other mental and behavioral disorders
Z83.2 Family history of diseases of the blood and blood-forming organs (anemia) (conditions classifiable to **D50–D89**)
Z86.2 Personal history of diseases of the blood and blood-forming organs
Z86.39 Personal history of other endocrine, nutritional, and metabolic disease
Z86.59 Personal history of other mental and behavioral disorders
Z86.69 Personal history of other diseases of the nervous system and sense organs
Z87.09 Personal history of other diseases of the respiratory system
Z87.19 Personal history of other diseases of the digestive system
Z87.798 Personal history of other (corrected) congenital malformations

• New *CPT* code
▲ Revised *CPT* code
+ Codes are *add-on codes*, meaning they are reported separately in addition to the appropriate code for the service provided.
* Indicates a *CPT*-approved telemedicine service.

Z87.820 Personal history of traumatic brain injury
Z91.128 Patient's intentional underdosing of medication regimen for other reason (report drug code)
Z91.138 Patient's unintentional underdosing of medication regimen for other reason (report drug code)
Z91.14 Patient's other noncompliance with medication regimen
Z91.19 Patient's noncompliance with other medical treatment and regimen
Z91.411 Personal history of adult psychological abuse

• New *CPT* code
▲ Revised *CPT* code
+ Codes are *add-on codes,* meaning they are reported separately in addition to the appropriate code for the service provided.
* Indicates a *CPT*-approved telemedicine service.

Continuum Model for Attention-Deficit/Hyperactivity Disorder

*Code selection at any level above **99211** may be based on the complexity of MDM or the total time spent by the physician or other qualified health care professional on the date of the encounter. (Code **99211** is not included due to lack of indication for follow-up by clinical staff.)*

	MDM (2 of 3 elements required)		
***CPT* Code With Total Physician Time and Vignette**	**Number and Complexity of Problems Addressed**	**Amount and/or Complexity of Data Reviewed and Analyzed**	**Risk of Complications and/or Morbidity or Mortality of Patient Management**
99211 Nurse visit to check growth or blood pressure prior to renewing prescription for psychoactive drugs	*Time and MDM do not apply. Must indicate continuation of physician's plan of care, medical necessity, assessment, and/or education provided.* CC: Check growth or blood pressure. Documentation: Height, weight, and blood pressure. Existing medications and desired/undesired effects. Assessment: Doing well. Obtained physician approval for prescription refill. Keep appointment with physician in 1 month.		
99212 (Time: 10–19 min) 4-year-old whose parents are concerned about ADHD symptoms	**Minimal:** 1 self-limited problem	**Limited:** Assessment requiring an independent historian	**Minimal:** Parent education
99213 (Time: 20–29 min) Initial follow-up after initiation of medication, patient responding well	**Low:** 1 stable chronic illness	**Limited:** Assessment requiring an independent historian	**Moderate:** Prescription drug management, delayed prescribing
99214 (Time: 30–39 min) Follow-up recent weight loss in patient with established ADHD otherwise stable on stimulant medication	**Moderate:** 1 chronic illness with side effects of treatment	**Limited:** Assessment requiring an independent historian	**Moderate:** Prescription drug management
99215 (Time: 40–54 min) Initial evaluation of patient with ADHD and new onset of suicidal ideation. Patient and mother refuse hospitalization due to cost. *Tip:* Add **99417** if time on the date of service is ≥55 minutes. Add **99058** if service(s) are provided on an emergency basis in the office, which disrupts other scheduled office services.	**High:** 1 acute or chronic illness or injury that poses a threat to life or bodily function	**Moderate:** Assessment requiring an independent historian; discussion with behavioral health specialist; psychiatric testing	**High:** Decision regarding hospitalization

Abbreviations: ADHD, attention-deficit hyperactivity disorder; CC, chief complaint; *CPT*, *Current Procedural Terminology*; MDM, medical decision-making.

ADHD—What is Attention Deficit/ Hyperactivity Disorder?

Almost all children can experience times of decreased attention and/or increased activity. However, for some children, decreased attention and/or increased activity is more than an occasional problem. Read on for information from the American Academy of Pediatrics about attention deficit/hyperactivity disorder (ADHD).

What is ADHD?

ADHD is a condition of the brain that makes it difficult for children to manage their attention, activity, and impulses. It is one of the most common chronic conditions of childhood. It affects 6% to 12% of school-aged children. ADHD is diagnosed about 3 times more often in boys than in girls (who more frequently have the inattentive type that goes unnoticed). The condition affects children in specific ways.

Children with attention-deficit/hyperactivity disorder (ADHD) have neurobehavioral problems that can interfere with their daily lives. An impulsive nature may put them into physical danger. Children with ADHD may speed about in constant motion, make noise nonstop, refuse to wait their turn, or crash into things. At other times, they may drift as if in a daydream, be unable to pay attention, or be unable to or finish what they start because they are paying attention to another thought or something they see. Those who have trouble paying attention may have trouble learning. Keep in mind that not all children with ADHD have all the symptoms. Each child is unique. For example, some may only have problems paying attention, while others may have problems with both attention and activity.

Recognition is important as early as possible to help minimize or prevent serious, lifelong problems, such as difficulty in school, at home, or at work and/or difficulty in making and keeping friends. Children with ADHD may have trouble getting along with siblings and other children. They may be labeled "bad kids."

If your child has ADHD, effective treatment is available. Your child's doctor can offer a long-term treatment plan to help your child lead a happy and healthy life. As a parent, you have a very important role in this treatment.

Visit HealthyChildren.org for more information.

Resources

American Academy of Pediatrics

www.AAP.org and www.HealthyChildren.org

Here is a list of ADHD support groups and resources. Also, your child's doctor may know about specific resources in your community.

ADDA (Attention Deficit Disorder Association)

www.add.org

CHADD (Children and Adults with Attention-Deficit/ Hyperactivity Disorder)—The National Resource Center on ADHD

800/233-4050

www.chadd.org

Center for Parent Information and Resources

www.parentcenterhub.org

National Institute of Mental Health

866/615-6464 www.nimh.nih.gov

Tourette Association of America

888/4-TOURET (486-8738)

www.tourette.org

From Your Doctor

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

healthychildren.org
Powered by pediatricians. Trusted by parents. from the American Academy of Pediatrics

The American Academy of Pediatrics (AAP) is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

Adapted from the American Academy of Pediatrics patient education booklet, *Understanding ADHD: Information for Parents About Attention-Deficit/Hyperactivity Disorder.* Any websites, brand names, products, or manufacturers are mentioned for informational and identification purposes only and do not imply an endorsement by the American Academy of Pediatrics (AAP). The AAP is not responsible for the content of external resources. Information was current at the time of publication. The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

ADHD—What are the Symptoms of Attention Deficit/Hyperactivity Disorder?

Are you concerned your child may have attention deficit/hyperactivity disorder (ADHD)? Read on for information from the American Academy of Pediatrics about the symptoms and types of ADHD.

What are the symptoms of ADHD?

Children with ADHD have symptoms that fall into 3 groups: inattention, hyperactivity, and impulsivity. See Table 1.

Table 1. Symptoms of ADHD

Symptom	How a Child With This Symptom May Behave
Inattention	Often has a hard time paying attention; daydreams
	Often does not seem to listen
	Is easily distracted from work or play
	Often does not seem to notice details; makes careless mistakes
	Frequently does not follow through on instructions or finish tasks
	Is disorganized
	Frequently loses a lot of important things
	Often forgets things
	Frequently avoids doing things that require ongoing mental efforts
Hyperactivity	Is in constant motion, as if "driven by a motor"
	Has trouble staying seated
	Frequently squirms and fidgets
	Talks a lot
	Often runs, jumps, and climbs when this is not permitted
	Has trouble playing quietly
Impulsivity	Frequently acts and speaks without thinking
	May run into the street without looking for traffic first
	Frequently has trouble taking turns
	Cannot wait for things
	Often calls out an answer before the question is complete
	Frequently interrupts others

Are there different types of ADHD?

Children with ADHD may have one or more of the symptoms listed in Table 1. The symptoms are usually classified as the following types of ADHD:

- Inattentive only (formerly known as attention-deficit disorder [ADD])—Children with this form of ADHD are not overly active. Because they do not disrupt the classroom or other activities, their symptoms may not be noticed. Among girls with ADHD, this form is more common.
- Hyperactive-impulsive—Children with this type of ADHD have increased activity and impulsivity with typical attention spans. This is the least common type and often occurs in younger children.
- Combined inattentive–hyperactive-impulsive—Children with this type of ADHD have all 3 symptoms. It is the type most people think of when they think of ADHD.

How can I tell if my child has ADHD?

Remember, it is common for all children to show some of these symptoms from time to time. Your child may be reacting to stress at school or at home. He may be bored or going through a difficult stage of life. It does not mean he has ADHD.

Sometimes a teacher is the first to notice inattention, hyperactivity, and/or impulsivity and will inform the parents.

Visit HealthyChildren.org for more information.

From Your Doctor

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

healthychildren.org
Powered by pediatricians. Trusted by parents. from the American Academy of Pediatrics

The American Academy of Pediatrics (AAP) is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

Adapted from the American Academy of Pediatrics patient education booklet, *Understanding ADHD: Information for Parents About Attention-Deficit/Hyperactivity Disorder*. The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

ADHD—How is Attention Deficit/ Hyperactivity Disorder Diagnosed?

There is no single test for attention deficit/hyperactivity disorder (ADHD). Diagnosis requires several steps and involves gathering information from multiple sources. You, your child, your child's school, and other caregivers should be involved in observing your child. Read on for information from the American Academy of Pediatrics about diagnosing ADHD.

How is ADHD diagnosed?

Your child's or teen's doctor will determine whether your child or teen has ADHD by using standard guidelines developed by the American Academy of Pediatrics specifically for children, teens, and young adults 4 to 18 years of age.

It is difficult to diagnose ADHD in children younger than 4 years. This is because younger children change very rapidly. It is also more difficult to diagnose ADHD once a child becomes a teen.

Children with ADHD show signs of inattention, hyperactivity, and/or impulsivity in specific ways. Your child's doctor will consider how your child's actions compare with that of other children his age, using the information reported about your child by you, his teacher, and any other caregivers who spend time with your child, such as coaches, grandparents, or child care workers.

Here are guidelines used to confirm a diagnosis of ADHD.

- Some symptoms occur in 2 or more settings such as home, school, and social situations and cause some impairment.
- In a child or teen 4 to 17 years of age, 6 or more symptoms must be identified.
- In a teen or young adult 17 years and older, 5 or more symptoms must be identified.
- Symptoms significantly impair your child's ability to function in some daily activities, such as doing schoolwork, maintaining relationships with parents and siblings, building relationships with friends, or having the ability to function in groups such as sports teams.

Your child's doctor will conduct a physical and neurological examination. A full medical history will be needed to put your child's action into context and screen for other conditions that may affect behavior. Your child's doctor will also talk with your child about how he acts and feels.

Your child's doctor may refer your child to a pediatric subspecialist or mental health professionals if there are concerns of

- Intellectual disability (previously called mental retardation)
- Developmental disorders, such as in speech, coordination, or learning
- Chronic illness being treated with a medication that may interfere with learning
- Trouble seeing and/or hearing
- History of abuse
- Major anxiety or major depression
- Severe aggression
- Possible seizure disorder
- Possible sleep disorder

How can parents help with the diagnosis?

As a parent, you will provide crucial information about your child's actions and how they affect life at home, in school, and in other social settings. Your child's doctor will want to know what symptoms your child is showing, how long the symptoms have occurred, and how these affect him and your family. You will likely be asked to fill in checklists or rating scales about your child's actions.

In addition, sharing your family history can offer important clues about your child's behavior.

How will my child's school be involved?

For an accurate diagnosis, your child's doctor will need to get information about your child directly from his classroom teacher or another school professional. Children at least 4 years and older spend many of their waking hours at preschool or school. Teachers provide valuable insights. Your child's teacher may write a report or discuss the following topics with your child's doctor:

- Your child's actions in the classroom
- Your child's learning patterns
- How long the symptoms have been a problem
- How the symptoms are affecting your child's progress at school
- Ways the classroom program is being adapted to help your child
- Whether other conditions may be affecting the symptoms
- If there are evaluations and help the school can provide

In addition, your child's doctor may want to see report cards, standardized tests, and samples of your child's schoolwork.

How will others who care for my child be involved?

Other caregivers may also provide important information about your child's actions. Former teachers, religious and scout leaders, grandparents, or coaches may have valuable input. If your child is homeschooled, it is especially important to assess his actions in settings outside the home.

Your child may not behave the same way at home as he does in other settings. Direct information about the way your child acts in more than one setting is a requirement to make a diagnosis. It is important to consider other possible causes of your child's symptoms in these settings.

In some cases, other mental health care professionals, such as child psychologists or psychiatrists, may also need to be involved in gathering information for the diagnosis.

Are there other tests for ADHD?

You may have heard theories about other tests for ADHD. There are no other proven diagnostic tests at this time.

Many theories have been presented, but studies have shown that the following evaluations add little value in diagnosing the disorder:

- Screening for thyroid problems
- Computerized continuous performance tests
- Brain imaging studies, such as computed tomography (CT) and magnetic resonance imaging (MRI)
- Electroencephalography (EEG) or brain-wave testing

While these evaluations are not helpful in diagnosing ADHD, your child's doctor may see other signs or symptoms in your child that warrant additional tests.

What are coexisting conditions?

As part of the diagnosis, your child's doctor will look for other conditions that cause the same types of symptoms as ADHD. Your child may simply have a different condition or ADHD combined with another condition (a coexisting condition). Most children with a diagnosis of ADHD have at least one additional condition.

Common coexisting conditions include

- **Learning disabilities**—Learning disabilities are conditions that make it difficult for a child to master specific skills, such as reading or math. ADHD is not a learning disability per se. However, ADHD can make it hard for a child to learn and do well in school. Diagnosing learning disabilities requires conducting evaluations, such as intelligence quotient (IQ) and academic achievement tests, and it requires educational interventions. The school will usually be able to assess whether your child has a learning disability and what his educational needs are.
- **Oppositional defiant disorder or conduct disorder**—Up to 35% of children with ADHD may have inappropriate actions because of an oppositional defiant or conduct disorder.
  - Children with oppositional defiant disorder tend to lose their temper easily and to annoy people on purpose, and they can be defiant and hostile toward authority figures.
  - Children with conduct disorder may break rules, destroy property, be suspended or expelled from school, violate the rights of other people, or show cruelty to other children or animals.
  - Children with coexisting conduct disorder are at higher risk of having trouble with the law or having substance use problems than children who have only ADHD. Studies show that this type of coexisting condition is more common among children with the combined type of ADHD.
- **Anxiety disorders**—About 25% of children with ADHD also have anxiety disorders. Children with anxiety disorders have extreme feelings of fear, worry, or panic that make it difficult to function. These disorders can produce physical symptoms such as racing pulse, sweating, diarrhea, and nausea. Counseling and/or different medication may be needed to treat these coexisting conditions.
- **Mood disorders, including depression**—About 18% of children with ADHD also have mood disorders, usually depression and less commonly bipolar disorder (formerly called manic depressive disorder). There may be a family history of these conditions. Coexisting mood disorders may put children and teens at higher risk for self-harm or suicide, especially during the teen years. These disorders are more common among children with inattentive or combined type of ADHD. Children with mood disorders or depression often require additional interventions or a different type of medication than those typically used to treat ADHD.
- **Language disorders**—Children with ADHD may have difficulty with how they use language. This is referred to as a pragmatic language disorder. It may not show up with standard tests of language. A speech-language clinician can detect it by observing how a child uses language in his day-to-day activities.

Visit HealthyChildren.org for more information.

From Your Doctor

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

healthychildren.org
Powered by pediatricians. Trusted by parents. from the American Academy of Pediatrics

ADHD—What Causes Attention Deficit/ Hyperactivity Disorder and How Is It Treated?

Understanding attention deficit/hyperactivity disorder (ADHD) helps you understand how it affects your child. Read on for information from the American Academy of Pediatrics about the causes and treatments for ADHD.

What causes ADHD?

ADHD is one of the most studied conditions of childhood, and it may be caused by a number of things.

Research to date has shown

- ADHD is a neurobiological condition whose symptoms can also depend on the child's environment.
- A lower level of activity in the parts of the brain that control attention and activity level may be associated with ADHD.
- ADHD often runs in families.
- In very rare cases, toxins in the environment may lead to ADHD-like symptoms. For instance, lead in the body can affect child development.
- Significant head injuries may cause ADHD-like symptoms in some children.
- Preterm birth increases the risk of developing ADHD.
- Prenatal substance exposures, such as to alcohol or nicotine from smoking, increase the risk of developing ADHD-like symptoms.

There is no scientific evidence that ADHD is caused by

- Eating too much sugar
- Food additives or food colorings
- Allergies
- Immunizations

How is ADHD treated?

Once the diagnosis is confirmed, the outlook for most children who receive treatment of ADHD is encouraging. There is no specific cure for ADHD, but many treatment options are available to manage the condition. Some children and adults learn to compensate for the symptoms as they mature so that they no longer require treatment.

Each child's treatment must be tailored to meet his individual needs. In most cases, treatment of ADHD should include A long-term management plan with

- Target outcomes for behavior
  - Follow-up activities
  - Monitoring
  - Education about ADHD
- Teamwork among doctors, parents, teachers, caregivers, other health care professionals, and the child
- Behavioral parent training
- Behavioral school programs
- Medication

Treatment of ADHD is based on the same principles that are used to treat other chronic conditions, such as asthma or diabetes. Long-term planning for many children is needed. Families must manage chronic conditions continually. In the case of ADHD, schools and other caregivers must also be involved in managing the condition.

Educating the people involved with your child is a key part of treatment of ADHD. As a parent, you will need to learn about the condition. Read about it and talk with people who understand it. This will help you manage the ways ADHD affects your child and your family day to day. It will also help your child learn to help himself.

What are target outcomes?

At the beginning of treatment, your child's doctor should help your family set up to 3 target outcomes (goals) for your child. These target outcomes will guide the treatment plan. Your child's target outcomes should be chosen to help him function as well as possible at home, at school, and in your community. You and your child should identify what is preventing him from succeeding.

Here are examples of target outcomes.

- Improved relationships with parents, siblings, teachers, and friends—for example, fewer arguments with siblings or being invited more often to friends' houses or parties
- Better schoolwork practices—for example, completing all classwork or homework assignments
- More independence in self-care or homework—for example, getting ready for school in the morning without supervision
- Improved self-esteem, such as feeling that he can get his work done
- Fewer disruptive actions—for example, decreasing the number of times he refuses to obey rules
- Safer behavior in the community—for example, being careful when crossing streets

The target outcomes should be

- Realistic
- Something your child will be able to do
- Behaviors that you can observe and count (with rating scales when possible)

Your child's treatment plan will be set up to help achieve these goals.

Visit HealthyChildren.org for more information.

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

healthychildren.org
Powered by pediatricians. Trusted by parents. from the American Academy of Pediatrics

The American Academy of Pediatrics (AAP) is an organization of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

Adapted from the American Academy of Pediatrics patient education booklet, *Understanding ADHD: Information for Parents About Attention-Deficit/Hyperactivity Disorder*. The information contained in this publication should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.

Brief Resolved Unexplained Events (Formerly Apparent Life-Threatening Events) and Evaluation of Lower-Risk Infants

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

- *Executive Summary*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Brief Resolved Unexplained Events (Formerly Apparent Life-Threatening Events) and Evaluation of Lower-Risk Infants

Joel S. Tieder, MD, MPH, FAAP, Joshua L. Bonkowsky, MD, PhD, FAAP, Ruth A. Etzel, MD, PhD, FAAP, Wayne H. Franklin, MD, MPH, MMM, FAAP, David A. Gremse, MD, FAAP, Bruce Herman, MD, FAAP, Eliot S. Katz, MD, FAAP, Leonard R. Krilov, MD, FAAP, J. Lawrence Merritt II, MD, FAAP, Chuck Norlin, MD, FAAP, Jack Percelay, MD, MPH, FAAP, Robert E. Sapién, MD, MMM, FAAP, Richard N. Shiffman, MD, MCIS, FAAP, Michael B.H. Smith, MB, FRCPCH, FAAP, for the SUBCOMMITTEE ON APPARENT LIFE THREATENING EVENTS

abstract

This is the first clinical practice guideline from the American Academy of Pediatrics that specifically applies to patients who have experienced an apparent life-threatening event (ALTE). This clinical practice guideline has 3 objectives. First, it recommends the replacement of the term ALTE with a new term, brief resolved unexplained event (BRUE). Second, it provides an approach to patient evaluation that is based on the risk that the infant will have a repeat event or has a serious underlying disorder. Finally, it provides management recommendations, or key action statements, for lower-risk infants. The term BRUE is defined as an event occurring in an infant younger than 1 year when the observer reports a sudden, brief, and now resolved episode of ≥1 of the following: (1) cyanosis or pallor; (2) absent, decreased, or irregular breathing; (3) marked change in tone (hyper- or hypotonia); and (4) altered level of responsiveness. A BRUE is diagnosed only when there is no explanation for a qualifying event after conducting an appropriate history and physical examination. By using this definition and framework, infants younger than 1 year who present with a BRUE are categorized either as (1) a lower-risk patient on the basis of history and physical examination for whom evidence-based recommendations for evaluation and management are offered or (2) a higher-risk patient whose history and physical examination suggest the need for further investigation and treatment but for whom recommendations are not offered. This clinical practice guideline is intended to foster a patient- and family-centered approach to care, reduce unnecessary and costly medical interventions, improve patient outcomes, support implementation, and provide direction for future research. Each key action statement indicates a level of evidence, the benefit-harm relationship, and the strength of recommendation.

DOI: 10.1542/peds.2016-0590

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Tieder JS, Bonkowsky JL, Etzel RA, et al. Brief Resolved Unexplained Events (Formerly Apparent Life-Threatening Events) and Evaluation of Lower-Risk Infants. *Pediatrics*. 2016;137(5):e20160590

INTRODUCTION

This clinical practice guideline applies to infants younger than 1 year and is intended for pediatric clinicians. This guideline has 3 primary objectives. First, it recommends the replacement of the term apparent life-threatening event (ALTE) with a new term, brief resolved unexplained event (BRUE). Second, it provides an approach to patient evaluation that is based on the risk that the infant will have a recurring event or has a serious underlying disorder. Third, it provides evidence-based management recommendations, or key action statements, for lower-risk patients whose history and physical examination are normal. It does not offer recommendations for higher-risk patients whose history and physical examination suggest the need for further investigation and treatment (because of insufficient evidence or the availability of clinical practice guidelines specific to their presentation). This clinical practice guideline also provides implementation support and suggests directions for future research.

The term ALTE originated from a 1986 National Institutes of Health Consensus Conference on Infantile Apnea and was intended to replace the term "near-miss sudden infant death syndrome" (SIDS).[1] An ALTE was defined as "an episode that is frightening to the observer and that is characterized by some combination of apnea (central or occasionally obstructive), color change (usually cyanotic or pallid but occasionally erythematous or plethoric), marked change in muscle tone (usually marked limpness), choking, or gagging. In some cases, the observer fears that the infant has died."[2] Although the definition of ALTE eventually enabled researchers to establish that these events are separate entities from SIDS, the clinical application of this classification, which describes a constellation of observed, subjective, and nonspecific symptoms, has raised significant challenges for clinicians and parents in the evaluation and care of these infants.[3] Although a broad range of disorders can present as an ALTE (eg, child abuse, congenital abnormalities, epilepsy, inborn errors of metabolism, and infections), for a majority of infants who appear well after the event, the risk of a serious underlying disorder or a recurrent event is extremely low.[2]

CHANGE IN TERMINOLOGY AND DIAGNOSIS

The imprecise nature of the original ALTE definition is difficult to apply to clinical care and research.[3] As a result, the clinician is often faced with several dilemmas. First, under the ALTE definition, the infant is often, but not necessarily, asymptomatic on presentation. The evaluation and management of symptomatic infants (eg, those with fever or respiratory distress) need to be distinguished from that of asymptomatic infants. Second, the reported symptoms under the ALTE definition, although often concerning to the caregiver, are not intrinsically life-threatening and frequently are a benign manifestation of normal infant physiology or a self-limited condition. A definition needs enough precision to allow the clinician to base clinical decisions on events that are characterized as abnormal after conducting a thorough history and physical examination. For example, a constellation of symptoms suggesting hemodynamic instability or central apnea needs to be distinguished from more common and less concerning events readily characterized as periodic breathing of the newborn, breath-holding spells, dysphagia, or gastroesophageal reflux (GER). Furthermore, events defined as ALTEs are rarely a manifestation of a more serious illness that, if left undiagnosed, could lead to morbidity or death. Yet, the perceived potential for recurring events or a serious underlying disorder often provokes concern in caregivers and clinicians.[2,4,5] This concern can compel testing or admission to the hospital for observation, which can increase parental anxiety and subject the patient to further risk and does not necessarily lead to a treatable diagnosis or prevention of future events. A more precise definition could prevent the overuse of medical interventions by helping clinicians distinguish infants with lower risk. Finally, the use of ALTE as a diagnosis may reinforce the caregivers' perceptions that the event was indeed "life-threatening," even when it most often was not. For these reasons, a replacement of the term ALTE with a more specific term could improve clinical care and management.

In this clinical practice guideline, a more precise definition is introduced for this group of clinical events: brief resolved unexplained event (BRUE). The term BRUE is intended to better reflect the transient nature and lack of clear cause and removes the "life-threatening" label. The authors of this guideline recommend that the term ALTE no longer be used by clinicians to describe an event or as a diagnosis. Rather, the term BRUE should be used to describe events occurring in infants younger than 1 year of age that are characterized by the observer as "brief" (lasting <1 minute but typically <20–30 seconds) and "resolved" (meaning the patient returned to baseline state of health after the event) and with a reassuring history, physical examination, and vital signs at the time of clinical evaluation by trained medical providers (Table 1). For example, the presence of respiratory symptoms or fever would preclude classification of an event as a BRUE. BRUEs are also "unexplained," meaning that a clinician is unable to explain the cause of the event after

an appropriate history and physical examination. Similarly, an event characterized as choking or gagging associated with spitting up is not included in the BRUE definition, because clinicians will want to pursue the cause of vomiting, which may be related to GER, infection, or central nervous system (CNS) disease. However, until BRUE-specific codes are available, for billing and coding purposes, it is reasonable to apply the ALTE International Classification of Diseases, 9th Revision, and International Classification of Diseases, 10th revision, codes to patients determined to have experienced a BRUE (see section entitled "Dissemination and Implementation").

TABLE 1 BRUE Definition and Factors for Inclusion and Exclusion

	Includes	Excludes
Brief	Duration <1 min; typically 20–30 s	Duration ≥1 min
Resolved	Patient returned to his or her baseline state of health after the event	At the time of medical evaluation:
	Normal vital signs	Fever or recent fever
	Normal appearance	Tachypnea, bradypnea, apnea
		Tachycardia or bradycardia
		Hypotension, hypertension, or hemodynamic instability
		Mental status changes, somnolence, lethargy
		Hypotonia or hypertonia
		Vomiting
		Bruising, petechiae, or other signs of injury/trauma
		Abnormal weight, growth, or head circumference
		Noisy breathing (stridor, sturgor, wheezing)
		Repeat event(s)
Unexplained	Not explained by an identifiable medical condition	Event consistent with GER, swallow dysfunction, nasal congestion, etc
		History or physical examination concerning for child abuse, congenital airway abnormality, etc
Event Characterization		
Cyanosis or pallor	Central cyanosis: blue or purple coloration of face, gums, trunk	Acrocyanosis or perioral cyanosis
	Central pallor: pale coloration of face or trunk	Rubor
Absent, decreased, or irregular breathing	Central apnea	Periodic breathing of the newborn
	Obstructive apnea	Breath-holding spell
	Mixed obstructive apnea	
Marked change in tone (hyper- or hypotonia)	Hypertonia	Hypertonia associated with crying, choking, or gagging due to GER or feeding problems
	Hypotonia	Tone changes associated with breath-holding spell
		Tonic eye deviation or nystagmus
		Tonic-clonic seizure activity
		Infantile spasms
Altered responsiveness	Loss of consciousness	Loss of consciousness associated with breath-holding spell
	Mental status change	
	Lethargy	
	Somnolence	
	Postictal phase	

BRUE DEFINITION

Clinicians should use the term BRUE to describe an event occurring in an infant <1 year of age when the observer reports a sudden, brief, and now resolved episode of ≥1 of the following:

- **cyanosis or pallor**
- **absent, decreased, or irregular breathing**
- **marked change in tone (hyper- or hypotonia)**
- **altered level of responsiveness**

Moreover, clinicians should diagnose a BRUE only when there is no explanation for a qualifying event after conducting an appropriate history and physical examination (Tables 2 and 3).

Differences between the terms ALTE and BRUE should be noted. First, the BRUE definition has a strict age limit. Second, an event is only a BRUE if there is no other likely explanation. Clinical symptoms such as fever, nasal congestion, and increased work of breathing may indicate temporary airway obstruction from viral infection. Events characterized as choking after vomiting may indicate a gastrointestinal cause, such as GER. Third, a BRUE diagnosis is based on the clinician's characterization of features of the event and not on a caregiver's perception that the event was life-threatening. Although such perceptions are understandable and important to address, such risk can only be assessed after the event has been objectively characterized by a clinician. Fourth, the clinician should determine whether the infant had episodic cyanosis or pallor, rather than just determining whether "color change" occurred. Episodes of rubor or redness are not consistent with BRUE, because they are common in healthy infants. Fifth, BRUE expands the respiratory criteria beyond "apnea" to include absent breathing, diminished breathing, and other breathing irregularities. Sixth, instead of the less specific criterion of "change in muscle tone," the clinician should determine whether there was marked change in tone, including

hypertonia or hypotonia. Seventh, because choking and gagging usually indicate common diagnoses such as GER or respiratory infection, their presence suggests an event was not a BRUE. Finally, the use of "altered level of responsiveness" is a new criterion, because it can be an important component of an episodic but serious cardiac, respiratory, metabolic, or neurologic event.

For infants who have experienced a BRUE, a careful history and physical examination are necessary to characterize the event, assess the risk of recurrence, and determine the presence of an underlying disorder (Tables 2 and 3). The recommendations provided in this guideline focus on infants with a lower risk of a subsequent event or serious underlying disorder (see section entitled "Risk Assessment: Lower- Versus Higher-Risk BRUE"). In the absence of identifiable risk factors, infants are at lower risk and laboratory studies, imaging studies, and other diagnostic procedures are unlikely to be useful or necessary. However, if the clinical history or physical examination reveals abnormalities, the patient may be at higher risk and further evaluation should focus on the specific areas of concern. For example,

- possible child abuse may be considered when the event history is reported inconsistently or is incompatible with the child's developmental age, or when, on physical examination, there is unexplained bruising or a torn labial or lingual frenulum;
- a cardiac arrhythmia may be considered if there is a family history of sudden, unexplained death in first-degree relatives; and
- infection may be considered if there is fever or persistent respiratory symptoms.

TABLE 2 Historical Features To Be Considered in the Evaluation of a Potential BRUE

Features To Be Considered
Considerations for possible child abuse:
Multiple or changing versions of the history/circumstances
History/circumstances inconsistent with child's developmental stage
History of unexplained bruising
Incongruence between caregiver expectations and child's developmental stage, including assigning negative attributes to the child
History of the event
General description
Who reported the event?
Witness of the event? Parent(s), other children, other adults? Reliability of historian(s)?
State immediately before the event
Where did it occur (home/elsewhere, room, crib/floor, etc)?
Awake or asleep?
Position: supine, prone, upright, sitting, moving?
Feeding? Anything in the mouth? Availability of item to choke on? Vomiting or spitting up?
Objects nearby that could smother or choke?
State during the event
Choking or gagging noise?
Active/moving or quiet/flaccid?
Conscious? Able to see you or respond to voice?
Muscle tone increased or decreased?
Repetitive movements?
Appeared distressed or alarmed?
Breathing: yes/no, struggling to breathe?
Skin color: normal, pale, red, or blue?
Bleeding from nose or mouth?
Color of lips: normal, pale, or blue?
End of event
Approximate duration of the event?
How did it stop: with no intervention, picking up, positioning, rubbing or clapping back, mouth-to-mouth, chest compressions, etc?
End abruptly or gradually?
Treatment provided by parent/caregiver (eg, glucose-containing drink or food)?
911 called by caregiver?
State after event
Back to normal immediately/gradually/still not there?
Before back to normal, was quiet, dazed, fussy, irritable, crying?
Recent history
Illness in preceding day(s)?
If yes, detail signs/symptoms (fussiness, decreased activity, fever, congestion, rhinorrhea, cough, vomiting, diarrhea, decreased intake, poor sleep)
Injuries, falls, previous unexplained bruising?
Past medical history
Pre-/perinatal history
Gestational age
Newborn screen normal (for IEMs, congenital heart disease)?
Previous episodes/BRUE?
Reflux? If yes, obtain details, including management
Breathing problems? Noisy ever? Snoring?
Growth patterns normal?
Development normal? Assess a few major milestones across categories, any concerns about development or behavior?
Illnesses, injuries, emergencies?
Previous hospitalization, surgery?
Recent immunization?
Use of over-the-counter medications?
Family history
Sudden unexplained death (including unexplained car accident or drowning) in first- or second-degree family members before age 35, and particularly as an infant?
Apparent life-threatening event in sibling?
Long QT syndrome?
Arrhythmia?

TABLE 2 Continued

Features To Be Considered
Inborn error of metabolism or genetic disease?
Developmental delay?
Environmental history
Housing: general, water damage, or mold problems?
Exposure to tobacco smoke, toxic substances, drugs?
Social history
Family structure, individuals living in home?
Housing: general, mold?
Recent changes, stressors, or strife?
Exposure to smoke, toxic substances, drugs?
Recent exposure to infectious illness, particularly upper respiratory illness, paroxysmal cough, pertussis?
Support system(s)/access to needed resources?
Current level of concern/anxiety; how family manages adverse situations?
Potential impact of event/admission on work/family?
Previous child protective services or law enforcement involvement (eg, domestic violence, animal abuse), alerts/reports for this child or others in the family (when available)?
Exposure of child to adults with history of mental illness or substance abuse?

The key action statements in this clinical practice guideline do not apply to higher-risk patients but rather apply only to infants who meet the lower-risk criteria by having an otherwise normal history and physical examination.

RISK ASSESSMENT: LOWER- VERSUS HIGHER-RISK BRUE

Patients who have experienced a BRUE may have a recurrent event or an undiagnosed serious condition (eg, child abuse, pertussis, etc) that confers a risk of adverse outcomes. Although this risk has been difficult to quantify historically and no studies have fully evaluated patient-centered outcomes (eg, family experience survey), the systematic review of the ALTE literature identified a subset of BRUE patients who are unlikely to have a recurrent event or undiagnosed serious conditions, are at lower risk of adverse outcomes, and can likely be managed safely without extensive diagnostic evaluation or hospitalization.[3] In the systematic review of ALTE studies in which it was possible to identify BRUE patients, the following characteristics most consistently conferred higher risk: infants <2 months of age, those with a history of prematurity, and those with more than 1 event. There was generally an increased risk from prematurity in infants born at <32 weeks' gestation, and the risk attenuated once infants born at <32 weeks' gestation reached 45 weeks' postconceptional age. Two ALTE studies evaluated the duration of the event.[6,7] Although duration did not appear to be predictive of hospital admission, it was difficult to discern a BRUE population from the heterogeneous ALTE populations. Nonetheless, most events were less than one minute. By consensus, the subcommittee established <1 minute as the upper limit of a "brief event," understanding that objective, verifiable measurements were rarely, if ever, available. Cariopulmonary resuscitation (CPR) was identified as a risk factor in the older ALTE studies and confirmed in a recent study,[6] but it was unclear how the need for CPR was determined. Therefore, the committee agreed by consensus that the need for CPR should be determined by trained medical providers.

PATIENT FACTORS THAT DETERMINE A LOWER RISK

To be designated lower risk, the following criteria should be met (see Fig 1):

- Age >60 days
- Prematurity: gestational age ≥32 weeks and postconceptional age ≥45 weeks
- First BRUE (no previous BRUE ever and not occurring in clusters)
- Duration of event <1 minute
- No CPR required by trained medical provider
- No concerning historical features (see Table 2)
- No concerning physical examination findings (see Table 3)

Infants who have experienced a BRUE who do not qualify as lower-risk patients are, by definition, at higher risk. Unfortunately, the outcomes data from ALTE studies in the heterogeneous higher-risk population are unclear and preclude the derivation of evidence-based recommendations regarding management. Thus, pending further research, this guideline does not provide recommendations for the management of the higher-risk infant. Nonetheless, it is important for clinicians and researchers to recognize that some studies suggest that higher-risk BRUE patients may be more likely to have a serious underlying cause, recurrent event, or an adverse outcome. For example, infants younger than 2 months who experience a BRUE may be more likely to have a congenital or infectious cause and be at higher risk of an adverse outcome. Infants who have experienced multiple events or a concerning social assessment for child abuse may warrant increased observation to better document the events or contextual factors. A list of differential diagnoses for BRUE patients is provided in Supplemental Table 6.

METHODS

In July 2013, the American Academy of Pediatrics (AAP) convened a multidisciplinary subcommittee composed of primary care clinicians

TABLE 3 Physical Examination Features To Be Considered in the Evaluation of a Potential BRUE

Physical Examination
General appearance
Craniofacial abnormalities (mandible, maxilla, nasal)
Age-appropriate responsiveness to environment
Growth variables
Length, weight, occipitofrontal circumference
Vital signs
Temperature, pulse, respiratory rate, blood pressure, oxygen saturation
Skin
Color, perfusion, evidence of injury (eg, bruising or erythema)
Head
Shape, fontanelles, bruising or other injury
Eyes
General, extraocular movement, pupillary response
Conjunctival hemorrhage
Retinal examination, if indicated by other findings
Ears
Tympanic membranes
Nose and mouth
Congestion/coryza
Blood in nares or oropharynx
Evidence of trauma or obstruction
Torn frenulum
Neck
Mobility
Chest
Auscultation, palpation for rib tenderness, crepitus, irregularities
Heart
Rhythm, rate, auscultation
Abdomen
Organomegaly, masses, distention
Tenderness
Genitalia
Any abnormalities
Extremities
Muscle tone, injuries, limb deformities consistent with fracture
Neurologic
Alertness, responsiveness
Response to sound and visual stimuli
General tone
Pupillary constriction in response to light
Presence of symmetrical reflexes
Symmetry of movement/tone/strength

and experts in the fields of general pediatrics, hospital medicine, emergency medicine, infectious diseases, child abuse, sleep medicine, pulmonary medicine, cardiology, neurology, biochemical genetics, gastroenterology, environmental health, and quality improvement. The subcommittee also included a parent representative, a guideline methodologist/informatician, and an epidemiologist skilled in systematic reviews. All panel members declared potential conflicts on the basis of the AAP policy on Conflict of Interest and Voluntary Disclosure. Subcommittee members repeated this process annually and upon publication of the guideline. All potential conflicts of interest are listed at the end of this document. The project was funded by the AAP.

The subcommittee performed a comprehensive review of the literature related to ALTEs from 1970 through 2014. Articles from 1970 through 2011 were identified and evaluated by using "Management of Apparent Life Threatening Events in Infants: A Systematic Review," authored by the Society of Hospital Medicine's ALTE Expert Panel (which included 4 members of the subcommittee).[3] The subcommittee partnered with the Society of Hospital Medicine Expert Panel and a librarian to update the original systematic review with articles published through December 31, 2014, with the use of the same methodology as the original systematic review. PubMed, Cumulative Index to Nursing and Allied Health Literature, and Cochrane Library databases were searched for studies involving children younger than 24 months by using the stepwise approach specified in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[8] Search terms included "ALTE(s)," "apparent life threatening event(s)," "life threatening event(s)," "near miss SIDS" or "near miss sudden infant death syndrome," "aborted crib death" or "aborted sudden infant death syndrome," and "aborted SIDS" or "aborted cot death" or "infant death, sudden." The Medical Subject Heading "infantile apparent life-threatening event," introduced in 2011, was also searched but did not identify additional articles.

In updating the systematic review published in 2012, pairs of 2 subcommittee members used validated methodology to independently score the newly identified abstracts from English-language articles (n = 120) for relevance to the clinical questions (Supplemental Fig 3).[9,10] Two independent reviewers then critically appraised the full text of the identified articles (n = 23) using a structured data collection form based on published guidelines for evaluating medical literature.[11,12] They recorded each study's relevance to the clinical question, research design, setting, time period covered, sample size, patient eligibility criteria, data source, variables collected, key results, study

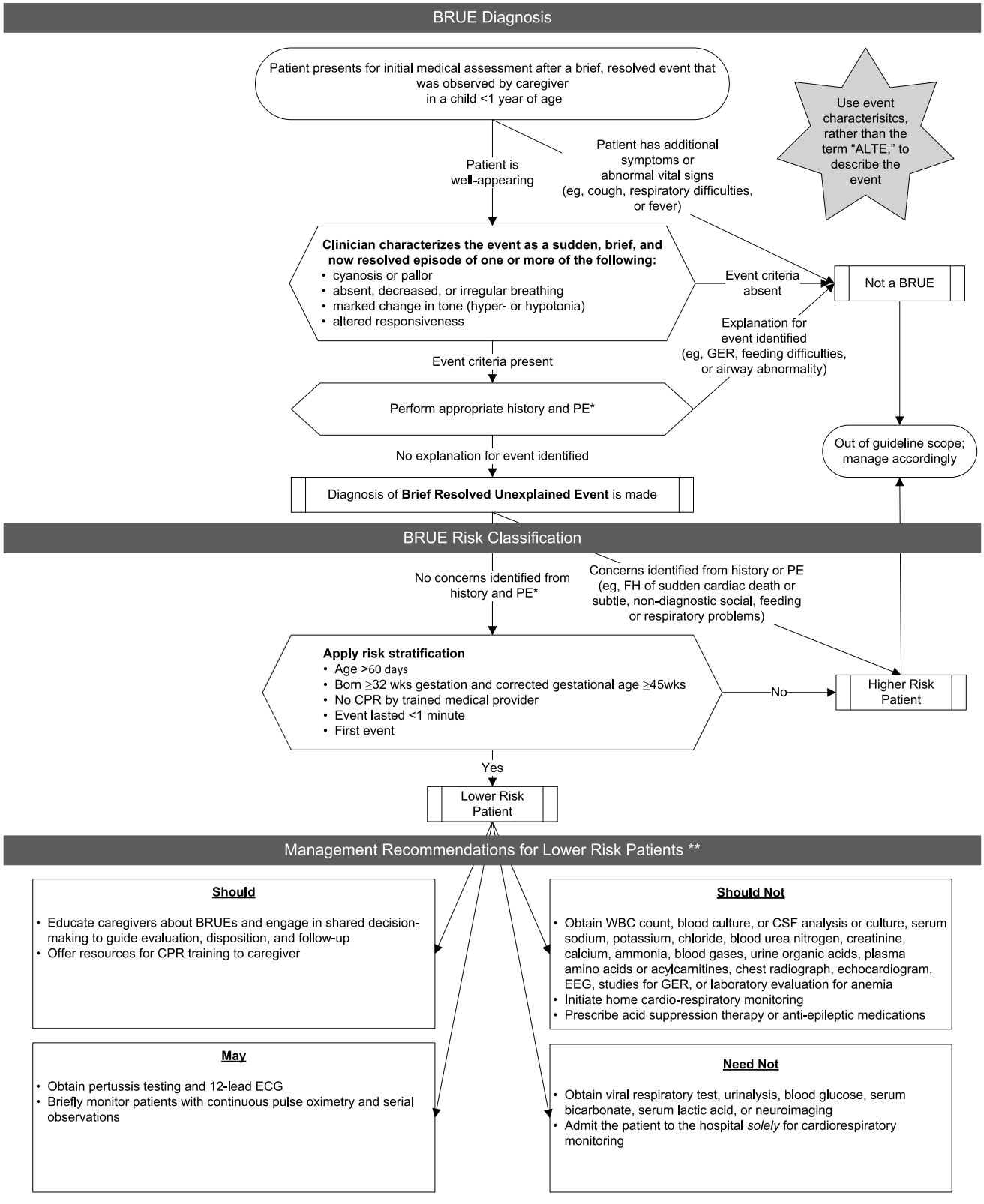


FIGURE 1

Diagnosis, risk classification, and recommended management of a BRUE. *See Tables 3 and 4 for the determination of an appropriate and negative FH and PE. **See Fig 2 for the AAP method for rating of evidence and recommendations. CSF, cerebrospinal fluid; FH, family history; PE, physical examination; WBC, white blood cell.

Figure 1, shown here, has been updated per the erratum at http://pediatrics.aappublications.org/content/138/2/e20161487.

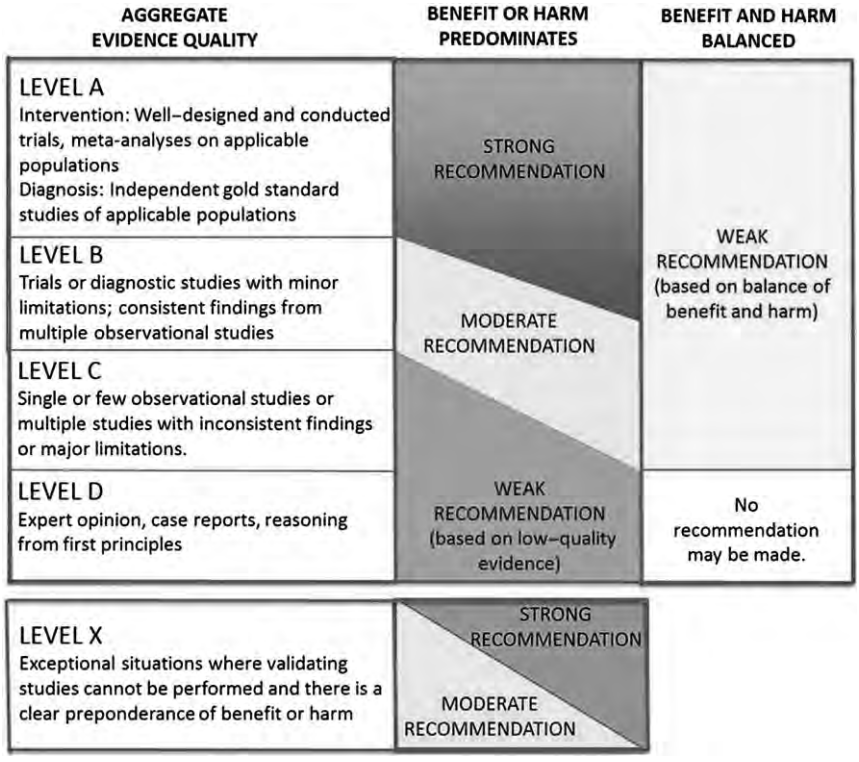


FIGURE 2
AAP rating of evidence and recommendations.

limitations, potential sources of bias, and stated conclusions. If at least 1 reviewer judged an article to be relevant on the basis of the full text, subsequently at least 2 reviewers critically appraised the article and determined by consensus what evidence, if any, should be cited in the systematic review. Selected articles used in the earlier review were also reevaluated for their quality. The final recommendations were based on articles identified in the updated (n = 18) and original (n = 37) systematic review (Supplemental Table 7).[6,7,13–28] The resulting systematic review was used to develop the guideline recommendations by following the policy statement from the AAP Steering Committee on Quality Improvement and Management, "Classifying Recommendations for Clinical Practice Guidelines."[29] Decisions and the strength of recommendations were based on a systematic grading of the quality of evidence from the updated literature review by 2 independent reviewers and incorporation of the previous systematic review. Expert consensus was used when definitive data were not available. If committee members disagreed with the rest of the consensus, they were encouraged to voice their concern until full agreement was reached. If full agreement could not be reached, each committee member reserved the right to state concern or disagreement in the publication (which did not occur). Because the recommendations of this guideline were based on the ALTE literature, we relied on the studies and outcomes that could be attributable to the new definition of lower- or higher-risk BRUE patients.

Key action statements (summarized in Table 5) were generated by using BRIDGE-Wiz (Building Recommendations in a Developers Guideline Editor), an interactive software tool that leads guideline development teams through a series of questions that are intended to create clear, transparent, and actionable key action statements.[30] BRIDGE-Wiz integrates the quality of available evidence and a benefit-harm assessment into the final determination of the strength of each recommendation. Evidence-based guideline recommendations from the AAP may be graded as strong,

TABLE 4 Guideline Definitions for Key Action Statements

Statement	Definition	Implication
Strong recommendation	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa) and quality of evidence is excellent or unobtainable.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Moderate recommendation	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa) and the quality of evidence is good but not excellent (or is unobtainable).	Clinicians would be prudent to follow a moderate recommendation but should remain alert to new information and sensitive to patient preferences.
Weak recommendation (based on low-quality evidence)	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), but the quality of evidence is weak.	Clinicians would be prudent follow a weak recommendation but should remain alert to new information and very sensitive to patient preferences.
Weak recommendation (based on balance of benefits and harms)	Weak recommendation is provided when the aggregate database shows evidence of both benefit and harm that appear to be similar in magnitude for any available courses of action.	Clinicians should consider the options in their decision-making, but patient preference may have a substantial role.

TABLE 5 Summary of Key Action Statements for Lower-Risk BRUEs

When managing an infant aged >60 d and <1 y and who, on the basis of a thorough history and physical examination, meets criteria for having experienced a lower-risk BRUE, clinicians:	Evidence Quality; Strength of Recommendation
1. Cardiopulmonary evaluation	
1A. Need not admit infants to the hospital solely for cardiorespiratory monitoring.	B; Weak
1B. May briefly monitor patients with continuous pulse oximetry and serial observations.	D; Weak
1C. Should not obtain a chest radiograph.	B; Moderate
1D. Should not obtain a measurement of venous or arterial blood gas.	B; Moderate
1E. Should not obtain an overnight polysomnograph.	B; Moderate
1F. May obtain a 12-lead electrocardiogram.	C; Weak
1G. Should not obtain an echocardiogram.	C; Moderate
1H. Should not initiate home cardiorespiratory monitoring.	B; Moderate
2. Child abuse evaluation	
2A. Need not obtain neuroimaging (CT, MRI, or ultrasonography) to detect child abuse.	C; Weak
2B. Should obtain an assessment of social risk factors to detect child abuse.	C; Moderate
3. Neurologic evaluation	
3A. Should not obtain neuroimaging (CT, MRI, or ultrasonography) to detect neurologic disorders.	C; Moderate
3B. Should not obtain an EEG to detect neurologic disorders.	C; Moderate
3C. Should not prescribe antiepileptic medications for potential neurologic disorders.	C; Moderate
4. Infectious disease evaluation	
4A. Should not obtain a WBC count, blood culture, or cerebrospinal fluid analysis or culture to detect an occult bacterial infection.	B; Strong
4B. Need not obtain a urinalysis (bag or catheter).	C; Weak
4C. Should not obtain chest radiograph to assess for pulmonary infection.	B; Moderate
4D. Need not obtain respiratory viral testing if rapid testing is available.	C; Weak
4E. May obtain testing for pertussis.	B; Weak
5. Gastrointestinal evaluation	
5A. Should not obtain investigations for GER (eg, upper gastrointestinal tract series, pH probe, endoscopy, barium contrast study, nuclear scintigraphy, and ultrasonography).	C; Moderate
5B. Should not prescribe acid suppression therapy.	C; Moderate
6. IEM evaluation	
6A. Need not obtain measurement of serum lactic acid or serum bicarbonate.	C; Weak
6B. Should not obtain a measurement of serum sodium, potassium, chloride, blood urea nitrogen, creatinine, calcium, or ammonia.	C; Moderate
6C. Should not obtain a measurement of venous or arterial blood gases.	C; Moderate
6D. Need not obtain a measurement of blood glucose.	C; Weak
6E. Should not obtain a measurement of urine organic acids, plasma amino acids, or plasma acylcarnitines.	C; Moderate
7. Anemia evaluation	
7A. Should not obtain laboratory evaluation for anemia.	C; Moderate
8. Patient- and family-centered care	
8A. Should offer resources for CPR training to caregiver.	C; Moderate
8B. Should educate caregivers about BRUEs.	C; Moderate
8C. Should use shared decision-making.	C; Moderate

CPR, cardiopulmonary resuscitation; CT, computed tomography; GER, gastroesophageal reflux; WBC, white blood cell.

moderate, weak based on low-quality evidence, or weak based on balance between benefits and harms. Strong and moderate recommendations are associated with "should" and "should not" recommendation statements, whereas weak recommendation may be recognized by use of "may" or "need not" (Fig 2, Table 4).

A strong recommendation means that the committee's review of the evidence indicates that the benefits of the recommended approach clearly exceed the harms of that approach (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the evidence supporting this approach is excellent. Clinicians are advised to follow such guidance unless a clear and compelling rationale for acting in a contrary manner is present. A moderate recommendation means that the committee believes that the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of the evidence on which this recommendation is based is not as strong. Clinicians are also encouraged to follow such guidance but also should be alert to new information and sensitive to patient preferences.

A weak recommendation means either that the evidence quality that exists is suspect or that well-designed, well-conducted studies have shown little clear advantage to one approach versus another. Weak recommendations offer clinicians flexibility in their decision-making regarding appropriate practice, although they may set boundaries on alternatives. Family and patient preference should have a substantial role in influencing clinical

1A. Clinicians Need Not Admit Infants Presenting With a Lower-Risk BRUE to the Hospital Solely for Cardiorespiratory Monitoring (Grade B, Weak Recommendation)

Aggregate Evidence Quality	Grade B
Benefits	Reduce unnecessary testing and caregiver/infant anxiety Avoid consequences of false-positive result, health care–associated infections, and other patient safety risks
Risks, harm, cost	May rarely miss a recurrent event or diagnostic opportunity for rare underlying condition
Benefit-harm assessment	The benefits of reducing unnecessary testing, nosocomial infections, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for an underlying condition
Intentional vagueness	None
Role of patient preferences	Caregiver anxiety and access to quality follow-up care may be important considerations in determining whether a hospitalization for cardiovascular monitoring is indicated
Exclusions	None
Strength	Weak recommendation (because of equilibrium between benefits and harms)
Key references	31, 32

1B. Clinicians May Briefly Monitor Infants Presenting With a Lower-Risk BRUE With Continuous Pulse Oximetry and Serial Observations (Grade D, Weak Recommendation)

Aggregate Evidence Quality	Grade D
Benefits	Identification of hypoxemia
Risks, harm, cost	Increased costs due to monitoring over time and the use of hospital resources False-positive results may lead to subsequent testing and hospitalization False reassurance from negative test results
Benefit-harm assessment	The potential benefit of detecting hypoxemia outweighs the harm of cost and false results
Intentional vagueness	Duration of time to monitor patients with continuous pulse oximetry and the number and frequency of serial observations may vary
Role of patient preferences	Level of caregiver concern may influence the duration of oximetry monitoring
Exclusions	None
Strength	Weak recommendation (based on low quality of evidence)
Key references	33, 36

decision-making, particularly when recommendations are expressed as weak. Key action statements based on that evidence and expert consensus are provided. A summary is provided in Table 5.

The practice guideline underwent a comprehensive review by stakeholders before formal approval by the AAP, including AAP councils, committees, and sections; selected outside organizations; and individuals identified by the subcommittee as experts in the field. All comments were reviewed by the subcommittee and incorporated into the final guideline when appropriate.

This guideline is intended for use primarily by clinicians providing care for infants who have experienced a BRUE and their families. This guideline may be of interest to parents and payers, but it is not intended to be used for reimbursement or to determine insurance coverage. This guideline is not intended as the sole source of guidance in the evaluation and management of BRUEs but rather is intended to assist clinicians by providing a framework for clinical decision-making.

KEY ACTION STATEMENTS FOR LOWER-RISK BRUE

1. Cardiopulmonary

1A. Clinicians Need Not Admit Infants Presenting With a Lower-Risk BRUE to the Hospital Solely for Cardiorespiratory Monitoring (Grade B, Weak Recommendation)

Infants presenting with an ALTE often have been admitted for observation and testing. Observational data indicate that 12% to 14% of infants presenting with a diagnosis of ALTE had a subsequent event or condition that required hospitalization.[7,31] Thus, research has sought to identify risk factors that could be used to identify infants likely to benefit from hospitalization. A long-term follow-up study in infants hospitalized with an ALTE showed that no infants subsequently had SIDS but 11% were victims of child abuse and 4.9% had adverse neurologic outcomes (see 3. Neurology).[32] The ALTE literature supports that infants presenting with a lower-risk BRUE do not have an increased rate of cardiovascular or other events during admission and hospitalization may not be required, but close follow-up is recommended. Careful outpatient follow-up is advised (repeat clinical history and physical examination within 24 hours after the initial evaluation) to identify infants with ongoing medical concerns that would indicate further evaluation and treatment.

Al-Kindy et al[33] used documented monitoring in 54% of infants admitted for an ALTE (338 of 625) and identified 46 of 338 (13.6%) with "extreme" cardiovascular events (central apnea >30 seconds, oxygen saturation <80% for 10 seconds, decrease in heart rate <50–60/ minutes for 10 seconds on the basis

of postconceptional age). However, no adverse outcomes were noted for any of their cohort (although whether there is a protective effect of observation alone is not known). Some of the infants with extreme events developed symptoms of upper respiratory infection 1 to 2 days after the ALTE presentation. The risk factors for "extreme" events were prematurity, postconceptional age <43 weeks, and (presence of) upper respiratory infection symptoms. Importantly, infants with a postconceptional age >48 weeks were not documented as having an extreme event in this cohort. A previous longitudinal study also identified "extreme" events that occurred with comparable frequency in otherwise normal term infants and that were not statistically increased in term infants with a history of ALTE.[34]

Preterm infants have been shown to have more serious events, although an ALTE does not further increase that risk compared with asymptomatic preterm infants without ALTE.[34] Claudius and Keens[31] performed an observational prospective study in 59 infants presenting with ALTE who had been born at >30 weeks' gestation and had no significant medical illness. They evaluated factors in the clinical history and physical examination that, according to the authors, would warrant hospital admission on the basis of adverse outcomes (including recurrent cardiorespiratory events, infection, child abuse, or any life-threatening condition). Among these otherwise well infants, those with multiple ALTEs or age <1 month experienced adverse outcomes necessitating hospitalization. Prematurity was also a risk factor predictive of subsequent adverse events after an ALTE. Paroxysmal decreases in oxygen saturation in infants immediately before and during viral illnesses have been well documented.[33,35] However, the significance of these brief hypoxemic events has not been established.

1B. Clinicians May Briefly Monitor Infants Presenting With a Lower-Risk BRUE With Continuous Pulse Oximetry and Serial Observations (Grade D, Weak Recommendation)

A normal physical examination, including vital signs and oximetry, is needed for a patient who has experienced a BRUE to be considered lower-risk. An evaluation at a single point in time may not be as accurate as a longer interval of observation. Unfortunately, there are few data to suggest the optimal duration of this period, the value of repeat examinations, and the effect of false-positive evaluations on family-centered care. Several studies have documented intermittent episodes of hypoxemia after admission for ALTE.[7,31,33] Pulse oximetry identified more infants with concerning paroxysmal events than cardiorespiratory monitoring alone.[33] However, occasional oxygen desaturations are commonly observed in normal infants, especially during sleep.[36] Furthermore, normative oximetry data are dependent on the specific machine, averaging interval, altitude, behavioral state, and postconceptional age. Similarly, there may be considerable variability in the vital signs and the clinical appearance of an infant. Pending further research into this important issue, clinicians may choose to monitor and provide serial examinations of infants in the lower-risk group for a brief period of time, ranging from 1 to 4 hours, to establish that the vital signs, physical examination, and symptomatology remain stable.

1C. Clinicians Should Not Obtain a Chest Radiograph in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Infectious processes can precipitate apnea. In 1 ALTE study, more than 80% of these infections involved the respiratory tract.[37] Most, but not all, infants with significant lower respiratory tract infections will be symptomatic at the time of ALTE presentation. However, 2 studies have documented pneumonia in infants presenting with ALTE and an otherwise noncontributory history and physical examination.[4,37] These rare exceptions have generally been in infants younger than 2 months and would have placed them in the higher-risk category for a BRUE in this guideline. Similarly, Davies and Gupta[38] reported that 9 of 65 patients (ages unknown) who had ALTEs had abnormalities on chest radiography (not fully specified) despite no suspected respiratory disorder on clinical history or physical examination. Some of the radiographs were performed up to 24 hours after presentation. Davies and Gupta further reported that 33% of infants with ALTEs that were ultimately associated with a respiratory disease had a normal initial respiratory examination.[38] Kant et al[18] reported that 2 of 176 infants discharged after admission for ALTE died within 2 weeks, both of pneumonia. One infant had a normal chest radiograph initially; the other, with a history of prematurity, had a "possible" infiltrate. Thus, most experience has shown that a chest radiograph in otherwise well-appearing infants rarely alters clinical management.[7] Careful follow-up within 24 hours is important in infants with a nonfocal clinical history and physical examination to identify those who will ultimately have a lower respiratory tract infection diagnosed.

1D. Clinicians Should Not Obtain Measurement of Venous or Arterial Blood Gases in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Blood gas measurements have not been shown to add significant clinical information in otherwise well-appearing infants presenting with an ALTE.[4] Although not part of

1C. Clinicians Should Not Obtain Chest Radiograph in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Aggregate Evidence Quality	Grade B
Benefits	Reduce costs, unnecessary testing, radiation exposure, and caregiver/infant anxiety
	Avoid consequences of false-positive results
Risks, harm, cost	May rarely miss diagnostic opportunity for early lower respiratory tract or cardiac disease
Benefit-harm assessment	The benefits of reducing unnecessary testing, radiation exposure, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for lower respiratory tract or cardiac disease
Intentional vagueness	None
Role of patient preferences	Caregiver may express concern regarding a longstanding breathing pattern in his/her infant or a recent change in breathing that might influence the decision to obtain chest radiography
Exclusions	None
Strength	Moderate recommendation
Key references	4, 37

1D. Clinicians Should Not Obtain Measurement of Venous or Arterial Blood Gases in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Aggregate Evidence Quality	Grade B
Benefits	Reduce costs, unnecessary testing, pain, risk of thrombosis, and caregiver/infant anxiety
	Avoid consequences of false-positive results
Risks, harm, cost	May miss rare instances of hypercapnia and acid-base imbalances
Benefit-harm assessment	The benefits of reducing unnecessary testing and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for hypercapnia and acid-base imbalances
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Key reference	4

this guideline, future research may demonstrate that blood gases are helpful in select infants with a higher risk BRUE to support the diagnosis of pulmonary disease, control-of-breathing disorders, or inborn errors of metabolism (IEMs).

1E. Clinicians Should Not Obtain an Overnight Polysomnograph in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Polysomnography consists of 8 to 12 hours of documented monitoring, including EEG, electro-oculography, electromyography, nasal/oral airflow, electrocardiography, end-tidal carbon dioxide, chest/abdominal excursion, and oximetry. Polysomnography is considered by many to be the gold standard for identifying obstructive sleep apnea (OSA), central sleep apnea, and periodic breathing and may identify seizures. Some data have suggested using polysomnography in infants presenting with ALTEs as a means to predict the likelihood of recurrent significant cardiorespiratory events. A study in which polysomnography was performed in a cohort of infants with ALTEs (including recurrent episodes) reported that polysomnography may reveal respiratory pauses of >20 seconds or brief episodes of bradycardia that are predictive of ensuing events over the next several months.[40] However, without a control population, the clinical significance of these events is uncertain, because respiratory pauses are frequently observed in otherwise normal infants.[35] Similarly, Kahn and Blum[41] reported that 10 of 71 infants with a clinical history of "benign" ALTEs had an abnormal polysomnograph, including periodic breathing (7 of 10) or obstructive apnea (4 of 100), but specific data were not presented. These events were not found in a control group of 181 infants. The severity of the periodic breathing (frequency of arousals and extent of oxygen desaturation) could not be evaluated from these data. Daniëls et al[42] performed polysomnography in 422 infants with ALTEs and identified 11 infants with significant bradycardia, OSA, and/or oxygen desaturation. Home monitoring revealed episodes of bradycardia (<50 per minute) in 7 of 11 infants and concluded that polysomnography is a useful modality. However, the clinical history, physical examination, and laboratory findings were not presented. GER has also been associated with specific episodes of severe bradycardia in monitored infants.[43] Overall, most polysomnography studies have shown minimal or nonspecific findings in infants presenting with ALTEs.[44,45] Polysomnography studies generally have not been predictive of ALTE recurrence and do not identify those infants at risk of SIDS.[46] Thus, the routine use of polysomnography in infants presenting with a lower-risk BRUE is likely to have a low diagnostic yield and is unlikely to lead to changes in therapy.

OSA has been occasionally associated with ALTEs in many series, but not all.[39,47–49] The use of overnight polysomnography to evaluate for OSA should be guided by an assessment of risk on the basis of a

1E. Clinicians Should Not Obtain an Overnight Polysomnograph in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Aggregate Evidence Quality	Grade B
Benefits	Reduce costs, unnecessary testing, and caregiver/infant anxiety Avoid consequences of false-positive results
Risks, harm, cost	May miss rare instances of hypoxemia, hypercapnia, and/or bradycardia that would be detected by polysomnography
Benefit-harm assessment	The benefits of reducing unnecessary testing and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for hypoxemia, hypercapnia, and/or bradycardia
Intentional vagueness	None
Role of patient preferences	Caregivers may report concern regarding some aspects of their infant's sleep pattern that may influence the decision to perform polysomnography
Exclusions	None
Strength	Moderate recommendation
Key reference	39

1F. Clinicians May Obtain a 12-Lead Electrocardiogram for Infants Presenting With Lower-Risk BRUE (Grade C, Weak Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	May identify BRUE patients with channelopathies (long QT syndrome, short QT syndrome, and Brugada syndrome), ventricular pre-excitation (Wolff-Parkinson-White syndrome), cardiomyopathy, or other heart disease
Risks, harm, cost	False-positive results may lead to further workup, expert consultation, anxiety, and cost False reassurance from negative results Cost and availability of electrocardiography testing and interpretation
Benefit-harm assessment	The benefit of identifying patients at risk of sudden cardiac death outweighs the risk of cost and false results
Intentional vagueness	None
Role of patient preferences	Caregiver may decide not to have testing performed
Exclusions	None
Strength	Weak recommendation (because of equilibrium between benefits and harms)
Key references	4, 16

comprehensive clinical history and physical examination.[50] Symptoms of OSA, which may be subtle or absent in infants, include snoring, noisy respirations, labored breathing, mouth breathing, and profuse sweating.[51] Occasionally, infants with OSA will present with failure to thrive, witnessed apnea, and/or developmental delay.[52] Snoring may be absent in younger infants with OSA, including those with micrognathia. In addition, snoring in otherwise normal infants is present at least 2 days per week in 11.8% and at least 3 days per week in 5.3% of infants.[53] Some infants with OSA may be asymptomatic and have a normal physical examination.[54] However, some studies have reported a high incidence of snoring in infants with (26%–44%) and without (22%–26%) OSA, making the distinction difficult.[55] Additional risk factors for infant OSA include prematurity, maternal smoking, bronchopulmonary dysplasia, obesity, and specific medical conditions including laryngomalacia, craniofacial abnormalities, neuromuscular weakness, Down syndrome, achondroplasia, Chiari malformations, and Prader-Willi syndrome.[34,56–58]

1F. Clinicians May Obtain a 12-Lead Electrocardiogram for Infants Presenting With Lower-Risk BRUE (Grade C, Weak Recommendation)

ALTE studies have examined screening electrocardiograms (ECGs). A study by Brand et al[4] found no positive findings on 24 ECGs performed on 72 patients (33%) without a contributory history or physical examination. Hoki et al[16] reported a 4% incidence of cardiac disease found in 485 ALTE patients; ECGs were performed in 208 of 480 patients (43%) with 3 of 5 abnormal heart rhythms identified by the ECG and the remaining 2 showing structural heart disease. Both studies had low positive-predictive values of ECGs (0% and 1%, respectively). Hoki et al had a negative predictive value of 100% (96%–100%), and given the low prevalence of disease, there is little need for further testing in patients with a negative ECG.

Some cardiac conditions that may present as a BRUE include channelopathies (long QT syndrome, short QT syndrome, Brugada syndrome, and catecholaminergic polymorphic ventricular tachycardia), ventricular pre-excitation (Wolff-Parkinson-White syndrome), and cardiomyopathy/myocarditis (hypertrophic cardiomyopathy, dilated cardiomyopathy). Resting ECGs are ineffective in identifying patients with catecholaminergic polymorphic ventricular tachycardia. Family history is important in identifying individuals with channelopathies.

Severe potential outcomes of any of these conditions, if left undiagnosed or untreated, include sudden death or neurologic injury.[59] However, many patients do not ever experience symptoms in their lifetime and adverse outcomes are uncommon. A genetic autopsy study in infants who died of SIDS in Norway showed an association between 9.5% and 13.0% of infants with abnormal

1G. Clinicians Should Not Obtain an Echocardiogram in Infants Presenting With Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce costs, unnecessary testing, caregiver/infant anxiety, and sedation risk
	Avoid consequences of false-positive results
Risks, harm, cost	May miss rare diagnosis of cardiac disease
Benefit-harm assessment	The benefits of reducing unnecessary testing and sedation risk, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for cardiac causes
Intentional vagueness	Abnormal cardiac physical examination reflects the clinical judgment of the clinician
Role of patient preferences	Some caregivers may prefer to have echocardiography performed
Exclusions	Patients with an abnormal cardiac physical examination
Strength	Moderate recommendation
Key references	4, 16

1H. Clinicians Should Not Initiate Home Cardiorespiratory Monitoring in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Aggregate Evidence Quality	Grade B
Benefits	Reduce costs, unnecessary testing, and caregiver/infant anxiety
	Avoid consequences of false-positive results
Risks, harm, cost	May rarely miss an infant with recurrent central apnea or cardiac arrhythmias
Benefit-harm assessment	The benefits of reducing unnecessary testing and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for recurrent apnea or cardiac arrhythmias
Intentional vagueness	None
Role of patient preferences	Caregivers will frequently request monitoring be instituted after an ALTE in their infant; a careful explanation of the limitations and disadvantages of this technology should be given
Exclusions	None
Strength	Moderate recommendation
Key reference	34

or novel gene findings at the long QT loci.[60] A syncopal episode, which could present as a BRUE, is strongly associated with subsequent sudden cardiac arrest in patients with long QT syndrome.[61] The incidence and risk in those with other channelopathies have not been adequately studied. The incidence of sudden cardiac arrest in patients with ventricular pre-excitation (Wolff-Parkinson-White syndrome) is 3% to 4% over the lifetime of the individual.[62]

1G. Clinicians Should Not Obtain an Echocardiogram in Infants Presenting With Lower-Risk BRUE (Grade C, Moderate Recommendation)

Cardiomyopathy (hypertrophic and dilated cardiomyopathy) and myocarditis could rarely present as a lower-risk BRUE and can be identified with echocardiography. The cost of an echocardiogram is high and accompanied by sedation risks.

In a study in ALTE patients, Hoki et al[16] did not recommend echocardiography as an initial cardiac test unless there are findings on examination or from an echocardiogram consistent with heart disease. The majority of abnormal echocardiogram findings in their study were not perceived to be life-threatening or related to a cause for the ALTE (eg, septal defects or mild valve abnormalities), and they would have been detected on echocardiogram or physical examination. Brand et al[4] reported 32 echocardiograms in 243 ALTE patients and found only 1 abnormal echocardiogram, which was suspected because of an abnormal history and physical examination (double aortic arch).

1H. Clinicians Should Not Initiate Home Cardiorespiratory Monitoring in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

The use of ambulatory cardiorespiratory monitors in infants presenting with ALTEs has been proposed as a modality to identify subsequent events, reduce the risk of SIDS, and alert caregivers of the need for intervention. Monitors can identify respiratory pauses and bradycardia in many infants presenting with ALTE; however, these events are also occasionally observed in otherwise normal infants.[34,40] In addition, infant monitors are prone to artifact and have not been shown to improve outcomes or prevent SIDS or improve neurodevelopmental outcomes.[63] Indeed, caregiver anxiety may be exacerbated with the use of infant monitors and potential false alarms. The overwhelming majority of monitor-identified alarms, including many with reported clinical symptomatology, do not reveal abnormalities on cardiorespiratory recordings.[64–66] Finally, there are several studies showing a lack of correlation between ALTEs and SIDS.[24,32]

Kahn and Blum[41] monitored 50 infants considered at "high risk" of SIDS and reported that 80% had alarms at home. All infants with alarms had at least 1 episode of parental intervention motivated by the alarms, although the authors acknowledged that some cases of parental intervention may have been attributable to parental anxiety. Nevertheless, the stimulated infants did not die of SIDS or require rehospitalization and therefore it was concluded that monitoring

resulted in successful resuscitation, but this was not firmly established. Côté et al[40] reported "significant events" involving central apnea and bradycardia with long-term monitoring. However, these events were later shown to be frequently present in otherwise well infants.[34] There are insufficient data to support the use of commercial infant monitoring devices marketed directly to parents for the purposes of SIDS prevention.[63] These monitors may be prone to false alarms, produce anxiety, and disrupt sleep. Furthermore, these machines are frequently used without a medical support system and in the absence of specific training to respond to alarms. Although it is beyond the scope of this clinical practice guideline, future research may show that home monitoring (cardiorespiratory and/or oximetry) is appropriate for some infants with higher-risk BRUE.

2. Child Abuse

2A. Clinicians Need Not Obtain Neuroimaging (Computed Tomography, MRI, or Ultrasonography) To Detect Child Abuse in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

2B. Clinicians Should Obtain an Assessment of Social Risk Factors To Detect Child Abuse in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Child abuse is a common and serious cause of an ALTE. Previous research has suggested that this occurs in up to 10% of ALTE cohorts.[3,67] Abusive head trauma is the most common form of child maltreatment associated with an ALTE. Other forms of child abuse that can present as an ALTE, but would not be identified by radiologic evaluations, include caregiver-fabricated illness (formally known as Münchausen by proxy), smothering, and poisoning.

Children who have experienced child abuse, most notably abusive head trauma, may present with a

2A. Clinicians Need Not Obtain Neuroimaging (Computed Tomography, MRI, or Ultrasonography) To Detect Child Abuse in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Decrease cost
	Avoid sedation, radiation exposure, consequences of false-positive results
Risks, harm, cost	May miss cases of child abuse and potential subsequent harm
Benefit-harm assessment	The benefits of reducing unnecessary testing, sedation, radiation exposure, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for child abuse
Intentional vagueness	None
Role of patient preferences	Caregiver concerns may lead to requests for CNS imaging
Exclusions	None
Strength	Weak recommendation (based on low quality of evidence)
Key references	3, 67

2B. Clinicians Should Obtain an Assessment of Social Risk Factors To Detect Child Abuse in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Identification of child abuse
	May benefit the safety of other children in the home
	May identify other social risk factors and needs and help connect caregivers with appropriate resources (eg, financial distress)
Risks, harm, cost	Resource intensive and not always available, particularly for smaller centers
	Some social workers may have inadequate experience in child abuse assessment
	May decrease caregiver's trust in the medical team
Benefit-harm assessment	The benefits of identifying child abuse and identifying and addressing social needs outweigh the cost of attempting to locate the appropriate resources or decreasing the trust in the medical team
Intentional vagueness	None
Role of patient preferences	Caregivers may perceive social services involvement as unnecessary and intrusive
Exclusions	None
Strength	Moderate recommendation
Key reference	68

BRUE. Four studies reported a low incidence (0.54%–2.5%) of abusive head trauma in infants presenting to the emergency department with an ALTE.[22,37,67,69] If only those patients meeting lower-risk BRUE criteria were included, the incidence of abusive head trauma would have been <0.3%. Although missing abusive head trauma can result in significant morbidity and mortality, the yield of performing neuroimaging to screen for abusive head trauma is extremely low and has associated risks of sedation and radiation exposure.[32,70]

Unfortunately, the subtle presentation of child abuse may lead to a delayed diagnosis of abuse and result in significant morbidity and mortality.[70] A thorough history and physical examination is the best way to identify infants at risk of these

conditions.[67,71] Significant concerning features for child abuse (especially abusive head trauma) can include a developmentally inconsistent or discrepant history provided by the caregiver(s), a previous ALTE, a recent emergency service telephone call, vomiting, irritability, or bleeding from the nose or mouth.[67,71]

Clinicians and medical team members (eg, nurses and social workers) should obtain an assessment of social risk factors in infants with a BRUE, including negative attributions to and unrealistic expectations of the child, mental health problems, domestic violence/intimate partner violence, social service involvement, law enforcement involvement, and substance abuse.[68] In addition, clinicians and medical team members can help families identify and use resources that may expand and strengthen their network of social support.

In previously described ALTE cohorts, abnormal physical findings were associated with an increased risk of abusive head trauma. These findings include bruising, subconjunctival hemorrhage, bleeding from the nose or mouth, and a history of rapid head enlargement or head circumference >95th percentile.[67,70–74] It is important to perform a careful physical examination to identify subtle findings of child abuse, including a large or full/bulging anterior fontanel, scalp bruising or bogginess, oropharynx or frenula damage, or skin findings such as bruising or petechiae, especially on the trunk, face, or ears. A normal physical examination does not rule out the possibility of abusive head trauma. Although beyond the scope of this guideline, it is important for the clinician to note that according to the available evidence, brain neuroimaging is probably indicated in patients who qualify as higher-risk because of concerns about abuse resulting from abnormal history or physical findings.[67]

A social and environmental assessment should evaluate the risk of intentional poisoning, unintentional poisoning, and environmental exposure (eg, home environment), because these can be associated with the symptoms of ALTEs in infants.[75–78] In 1 study, 8.4% of children presenting to the emergency department after an ALTE were found to have a clinically significant, positive comprehensive toxicology screen.[76] Ethanol or other drugs have also been associated with ALTEs.[79] Pulmonary hemorrhage can be caused by environmental exposure to moldy, water-damaged homes; it would usually present with hemoptysis and thus probably would not qualify as a BRUE.[80]

3. Neurology

3A. Clinicians Should Not Obtain Neuroimaging (Computed Tomography, MRI, or Ultrasonography) To Detect Neurologic Disorders in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Epilepsy or an abnormality of brain structure can present as a lower-risk BRUE. CNS imaging is 1 method for evaluating whether underlying abnormalities of brain development or structure might have led to the BRUE. The long-term risk of a diagnosis of neurologic disorders ranges from 3% to 11% in historical cohorts of ALTE patients.[2,32] One retrospective study in 243 ALTE patients reported that CNS imaging contributed to a neurologic diagnosis in 3% to 7% of patients.[4] However, the study population included all ALTEs, including those with a significant past medical history, non–well-appearing infants, and those with tests ordered as part of the emergency department evaluation.

In a large study of ALTE patients, the utility of CNS imaging studies in potentially classifiable lower-risk BRUE patients was found to be low.[32] The cohort of 471 patients was followed both acutely and long-term for the development of epilepsy and other neurologic disorders, and the sensitivity and positive-predictive value of abnormal CNS imaging for subsequent development of epilepsy was 6.7% (95% confidence interval [CI]: 0.2%–32%) and 25% (95% CI: 0.6%–81%), respectively.

The available evidence suggests minimal utility of CNS imaging to evaluate for neurologic disorders, including epilepsy, in lower-risk patients. This situation is particularly true for pediatric epilepsy, in which even if a patient is determined ultimately to have seizures/epilepsy, there is no evidence of benefit from starting therapy after the first seizure compared with starting therapy after a second seizure in terms of achieving seizure remission.[81–83] However, our recommendations for BRUEs are not based on any prospective studies and only on a single retrospective study. Future work should track both short- and long-term neurologic outcomes when considering this issue.

3B. Clinicians Should Not Obtain an EEG To Detect Neurologic Disorders in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Epilepsy may first present as a lower-risk BRUE. The long-term risk of epilepsy ranges from 3% to 11% in historical cohorts of ALTE patients.[2,32] EEG is part of the typical evaluation for diagnosis of seizure disorders. However, the utility of obtaining an EEG routinely was found to be low in 1 study.[32] In a cohort of 471 ALTE patients followed both acutely and long-term for the development of epilepsy, the sensitivity and positive-predictive value of an abnormal EEG for subsequent development of epilepsy was 15% (95% CI: 2%–45%) and 33% (95% CI: 4.3%–48%), respectively. In contrast, another retrospective study in 243 ALTE patients reported that EEG contributed to a neurologic diagnosis in 6% of patients.[4] This study

3A. Clinicians Should Not Obtain Neuroimaging (Computed Tomography, MRI, or Ultrasonography) To Detect Neurologic Disorders in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce unnecessary testing, radiation exposure, sedation, caregiver/infant anxiety, and costs
	Avoid consequences of false-positive results
Risks, harm, cost	May rarely miss diagnostic opportunity for CNS causes of BRUEs
	May miss unexpected cases of abusive head trauma
Benefit-harm assessment	The benefits of reducing unnecessary testing, radiation exposure, sedation, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for CNS cause
Intentional vagueness	None
Role of patient preferences	Caregivers may seek reassurance from neuroimaging and may not understand the risks from radiation and sedation
Exclusions	None
Strength	Moderate recommendation
Key references	2, 32, 81

3B. Clinicians Should Not Obtain an EEG To Detect Neurologic Disorders in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce unnecessary testing, sedation, caregiver/infant anxiety, and costs
	Avoid consequences of false-positive or nonspecific results
Risks, harm, cost	Could miss early diagnosis of seizure disorder
Benefit-harm assessment	The benefits of reducing unnecessary testing, sedation, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for epilepsy
Intentional vagueness	None
Role of patient preferences	Caregivers may seek reassurance from an EEG, but they may not appreciate study limitations and the potential of false-positive results
Exclusions	None
Strength	Moderate recommendation
Key references	32, 84, 85

population differed significantly from that of Bonkowsky et al[32] in that all ALTE patients with a significant past medical history and non–well-appearing infants were included in the analysis and that tests ordered in the emergency department evaluation were also included in the measure of EEG yield.

A diagnosis of seizure is difficult to make from presenting symptoms of an ALTE.[30] Although EEG is recommended by the American Academy of Neurology after a first-time nonfebrile seizure, the yield and sensitivity of an EEG after a first-time ALTE in a lower-risk child are low.[86] Thus, the evidence available suggests no utility for routine EEG to evaluate for epilepsy in a lower-risk BRUE. However, our recommendations for BRUEs are based on no prospective studies and on only a single retrospective study. Future work should track both short- and long-term epilepsy when considering this issue.

Finally, even if a patient is determined ultimately to have seizures/epilepsy, the importance of an EEG for a first-time ALTE is low, because there is little evidence that shows a benefit from starting therapy after the first seizure compared with after a second seizure in terms of achieving seizure remission.[81–83,85]

3C. Clinicians Should Not Prescribe Antiepileptic Medications for Potential Neurologic Disorders in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Once epilepsy is diagnosed, treatment can consist of therapy with an antiepileptic medication. In a cohort of 471 ALTE patients followed both acutely and long-term for the development of epilepsy, most patients who developed epilepsy had a second event within 1 month of their initial presentation.[32,87] Even if a patient is determined ultimately to have seizures/epilepsy, there is no evidence of benefit from starting therapy after the first seizure compared with starting therapy after a second seizure in terms of achieving seizure remission.[81–83,85] Sudden unexpected death in epilepsy (SUDEP) has a frequency close to 1 in 1000 patient-years, but the risks of SUDEP are distinct from ALTEs/BRUEs and include adolescent age and presence of epilepsy for more than 5 years. These data do not support prescribing an antiepileptic medicine for a first-time possible seizure because of a concern for SUDEP. Thus, the evidence available for ALTEs suggests lack of benefit for starting an antiepileptic medication for a lower-risk BRUE. However, our recommendations for BRUEs are based on no prospective studies and on only a single retrospective study. Future work should track both short- and long-term epilepsy when considering this issue.

4. Infectious Diseases

4A. Clinicians Should Not Obtain a White Blood Cell Count, Blood Culture, or Cerebrospinal Fluid Analysis or Culture To Detect an Occult Bacterial Infection in Infants Presenting With a Lower-Risk BRUE (Grade B, Strong Recommendation)

Some studies reported that ALTEs are the presenting complaint of an invasive infection, including bacteremia and/or meningitis

3C. Clinicians Should Not Prescribe Antiepileptic Medications for Potential Neurologic Disorders in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce medication adverse effects and risks, avoid treatment with unproven efficacy, and reduce cost
Risks, harm, cost	Delay in treatment of epilepsy could lead to subsequent BRUE or seizure
Benefit-harm assessment	The benefits of reducing medication adverse effects, avoiding unnecessary treatment, and reducing cost outweigh the risk of delaying treatment of epilepsy
Intentional vagueness	None
Role of patient preferences	Caregivers may feel reassured by starting a medicine but may not understand the medication risks
Exclusions	None
Strength	Moderate recommendation
Key references	32, 85, 87

4A. Clinicians Should Not Obtain a White Blood Cell Count, Blood Culture, or Cerebrospinal Fluid Analysis or Culture To Detect an Occult Bacterial Infection in Infants Presenting With a Lower-Risk BRUE (Grade B, Strong Recommendation)

Aggregate Evidence Quality	Grade B
Benefits	Reduce unnecessary testing, pain, exposure, caregiver/infant anxiety, and costs Avoid unnecessary antibiotic use and hospitalization pending culture results Avoid consequences of false-positive results/contaminants
Risks, harm, cost	Could miss serious bacterial infection at presentation
Benefit-harm assessment	The benefits of reducing unnecessary testing, pain, exposure, costs, unnecessary antibiotic use, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for a bacterial infection
Intentional vagueness	None
Role of patient preferences	Caregiver concerns over possible infectious etiology may lead to requests for antibiotic therapy
Exclusions	None
Strength	Strong recommendation
Key references	4, 37, 88

detected during the initial workup. However, on further review of such cases with serious bacterial infections, these infants did not qualify as lower-risk BRUEs, because they had risk factors (eg, age <2 months) and/or appeared ill and had abnormal findings on physical examination (eg, meningeal signs, nuchal rigidity, hypothermia, shock, respiratory failure) suggesting a possible severe bacterial infection. After eliminating those cases, it appears extremely unlikely that meningitis or sepsis will be the etiology of a lower-risk BRUE.[2–4,37,88,89] Furthermore, performing these tests for bacterial infection may then lead the clinician to empirically treat with antibiotics with the consequent risks of medication adverse effects, intravenous catheters, and development of resistant organisms. Furthermore, false-positive blood cultures (eg, coagulase negative staphylococci, *Bacillus* species, *Streptococcus viridans)* are likely to occur at times, leading to additional testing, longer hospitalization and antibiotic use, and increased parental anxiety until they are confirmed as contaminants.

Thus, the available evidence suggests that a complete blood cell count, blood culture, and lumbar puncture are not of benefit in infants with the absence of risk factors or findings from the patient's history, vital signs, and physical examination (ie, a lower-risk BRUE).

4B. Clinicians Need Not Obtain a Urinalysis (Bag or Catheter) in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

Case series of infants with ALTEs have suggested that a urinary tract infection (UTI) may be detected at the time of first ALTE presentation in up to 8% of cases.[3,4,37,88] Claudius et al[88] provided insight into 17 cases of certain (n = 13) or possible (n = 4) UTI. However, 14 of these cases would not meet the criteria for a lower-risk BRUE on the basis of age younger than 2 months or being ill-appearing and/or having fever at presentation.

Furthermore, these studies do not always specify the method of urine collection, urinalysis findings, and/or the specific organisms and colony-forming units per milliliter of the isolates associated with the reported UTIs that would confirm the diagnosis. AAP guidelines for the diagnosis and management of UTIs in children 2 to 24 months of age assert that the diagnosis of UTI requires "*both* urinalysis results that suggest infection (pyuria and/or bacteruria) *and* the presence of at least 50 000 colony-forming units/mL of a uropathogen cultured from a urine specimen obtained through catheterization or suprapubic aspirate."[90] Thus, it seems unlikely for a UTI to present as a lower-risk BRUE.

Pending more detailed studies that apply a rigorous definition of UTI to infants presenting with a lower-risk BRUE, a screening urinalysis need not be obtained routinely. If it is decided to evaluate the infant for a possible UTI, then a urinalysis can be obtained but should only be followed up with a culture if the urinalysis has

4B. Clinicians Need Not Obtain a Urinalysis (Bag or Catheter) in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce unnecessary testing, pain, iatrogenic infection, caregiver/infant anxiety, and costs Avoid consequences of false-positive results Avoid delay from time it takes to obtain a bag urine
Risks, harm, cost	May delay diagnosis of infection
Benefit-harm assessment	The benefits of reducing unnecessary testing, iatrogenic infection, pain, costs, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for a urinary tract infection
Intentional vagueness	None
Role of patient preferences	Caregiver concerns may lead to preference for testing
Exclusions	None
Strength	Weak recommendation (based on low quality of evidence)
Key references	4, 88

4C. Clinicians Should Not Obtain a Chest Radiograph To Assess for Pulmonary Infection in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Aggregate Evidence Quality	Grade B
Benefits	Reduce costs, unnecessary testing, radiation exposure, and caregiver/infant anxiety Avoid consequences of false-positive results
Risks, harm, cost	May miss early lower respiratory tract infection
Benefit-harm assessment	The benefits of reducing unnecessary testing, radiation exposure, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for pulmonary infection
Intentional vagueness	None
Role of patient preferences	Caregiver concerns may lead to requests for a chest radiograph
Exclusions	None
Strength	Moderate recommendation
Key references	4, 18, 37

abnormalities suggestive of possible infection (eg, increased white blood cell count, positive nitrates, and/or leukocyte esterase).

4C. Clinicians Should Not Obtain a Chest Radiograph To Assess for Pulmonary Infection in Infants Presenting With a Lower-Risk BRUE (Grade B, Moderate Recommendation)

Chest radiography is unlikely to yield clinical benefit in a well-appearing infant presenting with a lower-risk BRUE. In the absence of abnormal respiratory findings (eg, cough, tachypnea, decreased oxygen saturation, auscultatory changes), lower respiratory tract infection is unlikely to be present.

Studies in children presenting with an ALTE have described occasional cases with abnormal findings on chest radiography in the absence of respiratory findings on history or physical examination.[4,37] However, the nature of the abnormalities and their role in the ALTE presentation in the absence of further details about the radiography results make it difficult to interpret the significance of these observations. For instance, descriptions of increased interstitial markings or small areas of atelectasis would not have the same implication as a focal consolidation or pleural effusion.

Kant et al,[18] in a follow-up of 176 children admitted for an ALTE, reported that 2 infants died within 2 weeks of discharge and both were found to have pneumonia on postmortem examination. This observation does not support the potential indication for an initial radiograph. In fact, one of the children had a normal radiograph during the initial evaluation. The finding of pneumonia on postmortem examination may reflect an agonal aspiration event. Brand et al[4] reported 14 cases of pneumonia identified at presentation in their analysis of 95 cases of ALTEs. However, in 13 of the patients, findings suggestive of lower respiratory infection, such as tachypnea, stridor, retractions, use of accessory muscles, or adventitious sounds on auscultation, were detected at presentation, leading to the request for chest radiography.

4D. Clinicians Need Not Obtain Respiratory Viral Testing If Rapid Testing Is Available in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

Respiratory viral infections (especially with respiratory syncytial virus [RSV]) have been reported as presenting with apnea or an ALTE, with anywhere from 9% to 82% of patients tested being positive for RSV.[2,4,37,88] However, this finding was observed predominantly in children younger than 2 months and/or those who were born prematurely. Recent data suggest that apnea or an ALTE presentation is not unique to RSV and may be seen with a spectrum of respiratory viral infections.[90] The data in ALTE cases do not address the potential role of other respiratory viruses in ALTEs or BRUEs.

In older children, respiratory viral infection would be expected to present with symptoms ranging from upper respiratory to lower respiratory tract infection rather than as an isolated BRUE. A history of respiratory symptoms and illness exposure; findings of congestion and/or cough, tachypnea, or lower respiratory tract abnormalities; and local epidemiology regarding currently circulating viruses are

4D. Clinicians Need Not Obtain Respiratory Viral Testing If Rapid Testing Is Available in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce costs, unnecessary testing, and caregiver/infant discomfort Avoid false-negative result leading to missed diagnosis and false reassurance
Risks, harm, cost	Failure to diagnose a viral etiology Not providing expectant management for progression and appropriate infection control interventions for viral etiology
Benefit-harm assessment	The benefits of reducing unnecessary testing, pain, costs, false reassurance, and false-positive results, as well as alleviating caregiver and infant anxiety and challenges associated with providing test results in a timely fashion, outweigh the rare missed diagnostic opportunity for a viral infection
Intentional vagueness	"Rapid testing"; time to results may vary
Role of patient preferences	Caregiver may feel reassured by a specific viral diagnosis
Exclusions	None
Strength	Weak recommendation (based on low-quality evidence)
Key references	4, 37, 91

4E. Clinicians May Obtain Testing for Pertussis in Infants Presenting With a Lower-Risk BRUE (Grade B, Weak Recommendation)

Aggregate Evidence Quality	Grade B
Benefits	Identify a potentially treatable infection Monitor for progression of symptoms, additional apneic episodes Potentially prevent secondary spread and/or identify and treat additional cases
Risks, harm, cost	Cost of test Discomfort of nasopharyngeal swab False-negative results leading to missed diagnosis and false reassurance Rapid testing not always available False reassurance from negative results
Benefit-harm assessment	The benefits of identifying and treating pertussis and preventing apnea and secondary spread outweigh the cost, discomfort, and consequences of false test results and false reassurance; the benefits are greatest in at-risk populations (exposed, underimmunized, endemic, and during outbreaks)
Intentional vagueness	None
Role of patient preferences	Caregiver may feel reassured if a diagnosis is obtained and treatment can be implemented
Exclusions	None
Strength	Weak recommendation (based on balance of benefit and harm)
Key reference	93

considerations in deciding whether to order rapid testing for respiratory viruses. Because lower-risk BRUE patients do not have these symptoms, clinicians need not perform such testing.

In addition, until recently and in reports of ALTE patients to date, RSV testing was performed by using antigen detection tests. More recently, automated nucleic acid amplification-based tests have entered clinical practice. These assays are more sensitive than antigen detection tests and can detect multiple viruses from a single nasopharyngeal swab. The use of these tests in future research may allow better elucidation of the role of respiratory viruses in patients presenting with an ALTE in general and whether they play a role in BRUEs.

As a cautionary note, detection of a virus in a viral multiplex assay may not prove causality, because some agents, such as rhinovirus and adenovirus, may persist for periods beyond the acute infection (up to 30 days) and may or may not be related to the present episode.[92] In a lower-risk BRUE without respiratory symptoms testing for viral infection may not be indicated, but in the presence of congestion and/or cough, or recent exposure to a viral respiratory infection, such testing may provide useful information regarding the cause of the child's symptoms and for infection control management. Anticipatory guidance and arranging close follow-up at the initial presentation could be helpful if patients subsequently develop symptoms of a viral infection.

4E. Clinicians May Obtain Testing for Pertussis in Infants Presenting With a Lower-Risk BRUE (Grade B, Weak Recommendation)

Pertussis infection has been reported to cause ALTEs in infants, because it can cause gagging, gasping, and color change followed by respiratory pause. Such infants can be afebrile and may not develop cough or lower respiratory symptoms for several days afterward.

The decision to test a lower-risk BRUE patient for pertussis should consider potential exposures, vaccine history (including intrapartum immunization of the mother as well as the infant's vaccination history), awareness of pertussis activity in the community, and turnaround time for results. Polymerase chain reaction testing for pertussis on a nasopharyngeal specimen, if available, offers the advantage of rapid turnaround time to results.[94] Culture for the organism requires selective media and will take days to yield results but may still be useful in the face of identified risk of exposure. In patients in whom there is a high index of suspicion on the basis of

the aforementioned risk factors, clinicians may consider prolonging the observation period and starting empirical antibiotics while awaiting test results (more information is available from the Centers for Disease Control and Prevention).[95]

5. Gastroenterology

5A. Clinicians Should Not Obtain Investigations for GER (eg, Upper Gastrointestinal Series, pH Probe, Endoscopy, Barium Contrast Study, Nuclear Scintigraphy, and Ultrasonography) in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

GER occurs in more than two-thirds of infants and is the topic of discussion with pediatricians at one-quarter of all routine 6-month infant visits.[96] GER can lead to airway obstruction, laryngospasm, or aspiration. Although ALTEs that can be attributed to GER symptoms (eg, choking after spitting up) qualify as an ALTE according to the National Institutes of Health definition, importantly, they do not qualify as a BRUE.

GER may still be a contributing factor to a lower-risk BRUE if the patient's GER symptoms were not witnessed or well described by caregivers. However, the available evidence suggests no utility of routine diagnostic testing to evaluate for GER in these patients. The brief period of observation that occurs during an upper gastrointestinal series is inadequate to rule out the occurrence of pathologic reflux at other times, and the high prevalence of nonpathologic reflux that often occurs during the study can encourage false-positive diagnoses. In addition, the observation of the reflux of a barium column into the esophagus during gastrointestinal contrast studies may not correlate with the severity of GER or the degree of esophageal mucosal inflammation in patients with reflux esophagitis. Routine performance of an upper gastrointestinal series to diagnose GER is not justified and should be reserved to screen for anatomic abnormalities associated with vomiting (which is a symptom that precludes the diagnosis of a lower-risk BRUE).[98] Gastroesophageal scintigraphy scans for reflux of ^{99m}Tc-labeled solids or liquids into the esophagus or lungs after the administration of the test material into the stomach. The lack of standardized techniques and age-specific normal values limits the usefulness of this test. Therefore, gastroesophageal scintigraphy is not recommended in the routine evaluation of pediatric patients with GER symptoms or a lower-risk BRUE.[97] Multiple intraluminal impedance (MII) is useful for detecting both acidic and nonacidic reflux, thereby providing a more detailed picture of esophageal events than pH monitoring. Combined pH/MII testing is evolving into the test of choice to detect temporal relationships between specific symptoms and the reflux of both acid and nonacid gastric contents. In particular, MII has been used in recent years to investigate how GER correlates with respiratory symptoms, such as apnea or cough. Performing esophageal pH +/- impedance monitoring is not indicated in the routine evaluation of infants presenting with a lower-risk BRUE, although it may be considered in patients with recurrent BRUEs and GER symptoms even if these occur independently.

5A. Clinicians Should Not Obtain Investigations for GER (eg, Upper Gastrointestinal Series, pH Probe, Endoscopy, Barium Contrast Study, Nuclear Scintigraphy, and Ultrasonography) in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce unnecessary testing, procedural complications (sedation, intestinal perforation, bleeding), pain, radiation exposure, caregiver/infant anxiety, and costs Avoid consequences of false-positive results
Risks, harm, cost	Delay diagnosis of rare but serious gastrointestinal abnormalities (eg, tracheoesophageal fistula) Long-term morbidity of repeated events (eg, chronic lung disease)
Benefit-harm assessment	The benefits of reducing unnecessary testing, complications, radiation, pain, costs, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for a gastrointestinal abnormality or morbidity from repeat events
Intentional vagueness	None
Role of patient preferences	Caregiver may be reassured by diagnostic evaluation of GER
Exclusions	None
Strength	Moderate recommendation
Key references	96, 97

Problems with the coordination of feedings can lead to ALTEs and BRUEs. In a study in Austrian newborns, infants who experienced an ALTE had a more than twofold increase in feeding difficulties (multivariate relative risk: 2.5; 95% CI: 1.3–4.6).[99] In such patients, it is likely that poor suck-swallow-breathe coordination triggered choking or laryngospasm. A clinical speech therapy evaluation may help to evaluate any concerns for poor coordination swallowing with feeding.

5B. Clinicians Should Not Prescribe Acid Suppression Therapy for Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

The available evidence suggests no proven efficacy of acid suppression therapy for esophageal reflux in patients presenting with a lower-risk BRUE. Acid suppression therapy with H2-receptor antagonists or proton

5B. Clinicians Should Not Prescribe Acid Suppression Therapy for Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce unnecessary medication use, adverse effects, and cost from treatment with unproven efficacy
Risks, harm, cost	Delay treatment of rare but undiagnosed gastrointestinal disease, which could lead to complications (eg, esophagitis)
Benefit-harm assessment	The benefits of reducing medication adverse effects, avoiding unnecessary treatment, and reducing cost outweigh the risk of delaying treatment of gastrointestinal disease
Intentional vagueness	None
Role of patient preferences	Caregiver concerns may lead to requests for treatment
Exclusions	None
Strength	Moderate recommendation
Key reference	98

pump inhibitors may be indicated in selected pediatric patients with GER disease (GERD), which is diagnosed in patients when reflux of gastric contents causes troublesome symptoms or complications.[98] Infants with spitting up or throat-clearing coughs that are not troublesome do not meet diagnostic criteria for GERD. Indeed, the inappropriate administration of acid suppression therapy may have harmful adverse effects because it exposes infants to an increased risk of pneumonia or gastroenteritis.[100]

GER leading to apnea is not always clinically apparent and can be the cause of a BRUE. Acid reflux into the esophagus has been shown to be temporally associated with oxygen desaturation and obstructive apnea, suggesting that esophageal reflux may be one of the underlying conditions in selected infants presenting with BRUEs.[101] Respiratory symptoms are more likely to be associated with GER when gross emesis occurs at the time of a BRUE, when episodes occur while the infant is awake and supine (sometimes referred to as "awake apnea"), and when a pattern of obstructive apnea is observed while the infant is making respiratory efforts without effective air movement.[102]

Wenzl et al[103] reported a temporal association between 30% of the nonpathologic, short episodes of central apnea and GER by analyzing combined data from simultaneous esophageal and cardiorespiratory monitoring. These findings cannot be extrapolated to pathologic infant apnea and may represent a normal protective cessation of breathing during regurgitation. Similarly, Mousa et al[104] analyzed data from 527 apneic events in 25 infants and observed that only 15.2% were temporally associated with GER. Furthermore, there was no difference in the linkage between apneic events and acid reflux (7.0%) and nonacid reflux (8.2%). They concluded that there is little evidence for an association between acid reflux or nonacid reflux and the frequency of apnea. Regression analysis revealed a significant association between apnea and reflux in 4 of 25 infants. Thus, in selected infants, a clear temporal relationship between apnea and ALTE can be shown. However, larger studies have not proven a causal relationship between pathologic apnea and GER.[105]

As outlined in the definition of a BRUE, when an apparent explanation for the event, such as GER, is evident at the time of initial evaluation, the patient should be managed as appropriate for the clinical situation. However, BRUEs can be caused by episodes of reflux-related laryngospasm (sometimes referred to as "silent reflux"), which may not be clinically apparent at the time of initial evaluation. Laryngospasm may also occur during feeding in the absence of GER. Measures that have been shown to be helpful in the nonpharmacologic management of GER in infants include avoiding overfeeding, frequent burping during feeding, upright positioning in the caregiver's arms after feeding, and avoidance of secondhand smoke.[106] Thickening feedings with commercially thickened formula for infants without milk-protein intolerance does not alter esophageal acid exposure detected by esophageal pH study but has been shown to decrease the frequency of regurgitation. Given the temporal association observed between GER and respiratory symptoms in selected infants, approaches that decrease the height of the reflux column, the volume of refluxate, and the frequency of reflux episodes may theoretically be beneficial.[98] Combined pH/MII testing has shown that, although the frequency of reflux events is unchanged with thickened formula, the height of the column of refluxate is decreased. Studies have shown that holding the infant on the caregiver's shoulders for 10 to 20 minutes to allow for adequate burping after a feeding before placing the infant in the "back to sleep position" can decrease the frequency of GER in infants. In contrast, placing an infant in a car seat or in other semisupine positions, such as in an infant carrier, exacerbates esophageal reflux and should be avoided.[98] The frequency of GER has been reported to be decreased in breastfed compared with formula-fed infants. Thus, the benefits of breastfeeding are preferred over the theoretical effect of thickened formula feeding, so exclusive breastfeeding should be encouraged whenever possible.

6. Inborn Errors of Metabolism

6A. Clinicians Need Not Obtain Measurement of Serum Lactic Acid or Serum Bicarbonate To Detect an IEM in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

6B. Clinicians Should Not Obtain a Measurement of Serum Sodium, Potassium, Chloride, Blood Urea Nitrogen, Creatinine, Calcium, or Ammonia To Detect an IEM on Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

6C. Clinicians Should Not Obtain a Measurement of Venous or Arterial Blood Gases To Detect an IEM in Infants Presenting With Lower-Risk BRUE (Grade C, Moderate Recommendation)

6D. Clinicians Need Not Obtain a Measurement of Blood Glucose To Detect an IEM in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

6E. Clinicians Should Not Obtain Measurements of Urine Organic Acids, Plasma Amino Acids, or Plasma Acylcarnitines To Detect an IEM in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

6A. Clinicians Need Not Obtain Measurement of Serum Lactic Acid or Serum Bicarbonate To Detect an IEM in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce unnecessary testing, caregiver/infant anxiety, and costs Avoid consequences of false-positive or nonspecific results
Risks, harm, cost	May miss detection of an IEM
Benefit-harm assessment	The benefits of reducing unnecessary testing, cost, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for an IEM
Intentional vagueness	Detection of higher lactic acid or lower bicarbonate levels should be considered to have a lower likelihood of being a false-positive result and may warrant additional investigation
Role of patient preferences	Caregiver concerns may lead to requests for diagnostic testing
Exclusions	None
Strength	Weak recommendation (based on low-quality evidence)
Key reference	38

6B. Clinicians Should Not Obtain a Measurement of Serum Sodium, Potassium, Chloride, Blood Urea Nitrogen, Creatinine, Calcium, or Ammonia To Detect an IEM on Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce costs, unnecessary testing, pain, and caregiver/infant anxiety Avoid consequences of false-positive results
Risks, harm, cost	May miss detection of an IEM
Benefit-harm assessment	The benefits of reducing unnecessary testing, cost, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for an IEM
Intentional vagueness	None
Role of patient preferences	Caregiver concerns may lead to requests for diagnostic testing
Exclusions	None
Strength	Moderate recommendation
Key reference	4

IEMs are reported to cause an ALTE in 0% to 5% of cases.[2,27,38,99,107,108] On the basis of the information provided by the authors for these patients, it seems unlikely that events could have been classified as a lower-risk BRUE, either because the patient had a positive history or physical examination or a recurrent event. The most commonly reported disorders include fatty acid oxidation disorders or urea cycle disorders.[107,109] In cases of vague or resolved symptoms, a careful history can help determine whether the infant had not received previous treatment (eg, feeding after listlessness for suspected hypoglycemia). These rare circumstances could include milder or later-onset presentations of IEMs.

Infants may be classified as being at a higher risk of BRUE because of a family history of an IEM, developmental disabilities, SIDS, or a medical history of abnormal newborn screening results, unexplained infant death, age younger than 2 months, a prolonged event (>1 minute), or multiple events without an explanation. Confirmation that a newborn screen is complete and is negative is an important aspect of the medical history, but the clinician must consider that not all potential disorders are included in current newborn screening panels in the United States.

Lactic Acid

Measurement of lactic acid can result in high false-positive rates if the sample is not collected properly, making the decision to check a lactic acid problematic. In addition, lactic acid may be elevated because of metabolic abnormalities attributable to other conditions, such as sepsis, and are not specific for IEMs.

Only 2 studies evaluated the specific measurement of lactic acid.[27,38] Davies and Gupta[38] reported 65 infants with consistent laboratory evaluations and found that 54% of infants had a lactic acid >2 mmol/L but only 15% had levels >3 mmol/L. The latter percentage of infants are more likely to be clinically significant and less likely to reflect a false-positive result. Five of 7 infants with a lactic acid >3 mmol/L had a "specific, serious diagnosis," although the specifics of these diagnoses were not included and no IEM was

6C. Clinicians Should Not Obtain a Measurement of Venous or Arterial Blood Gases To Detect an IEM in Infants Presenting With Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce costs, unnecessary testing, pain, risk of thrombosis, and caregiver/infant anxiety Avoid consequences of false-positive results
Risks, harm, cost	May miss detection of an IEM
Benefit-harm assessment	The benefits of reducing unnecessary testing, cost, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for an IEM
Intentional vagueness	None
Role of patient preferences	Caregiver concerns may lead to requests for diagnostic testing
Exclusions	None
Strength	Moderate recommendation
Key reference	4

6D. Clinicians Need Not Obtain a Measurement of Blood Glucose To Detect an IEM in Infants Presenting With a Lower-Risk BRUE (Grade C, Weak Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce costs, unnecessary testing, pain, risk of thrombosis, and caregiver/infant anxiety Avoid consequences of false-positive results
Risks, harm, cost	May miss rare instances of hypoglycemia attributable to undiagnosed IEM
Benefit-harm assessment	The benefits of reducing unnecessary testing, cost, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for an IEM
Intentional vagueness	Measurement of glucose is often performed immediately through a simple bedside test; no abnormalities have been reported in asymptomatic infants, although studies often do not distinguish between capillary or venous measurement
Role of patient preferences	Caregiver concerns may lead to requests for diagnostic testing
Exclusions	None
Strength	Weak recommendation (based on low-quality evidence)
Key reference	4

confirmed in this study. This study also reported a 20% positive yield of testing for a bicarbonate <20 mmol/L and commented that there was a trend for lower bicarbonate and higher lactic acid levels in those with a recurrent event or a definitive diagnosis. The second publication[27] found no elevations of lactate in 4 of 49 children who had an initial abnormal venous blood gas, of which all repeat blood gas measurements were normal.

Serum Bicarbonate

Abnormal serum bicarbonate levels have been studied in 11 infants, of whom 7 had a diagnosis of sepsis or seizures.[38] Brand et al[4] studied 215 infants who had bicarbonate measured and found only 9 abnormal results, and only 3 of these contributed to the final diagnosis. Although unknown, it is most likely that the event in those infants would not have been classified as a BRUE under the new classification, because those infants were most likely symptomatic on presentation.

Serum Glucose

Abnormal blood glucose levels were evaluated but not reported in 3 studies.[4,38,110] Although abnormalities of blood glucose can occur from various IEMs, such as medium-chain acyl–coenzyme A dehydrogenase deficiency or other fatty acid oxidation disorders, their prevalence has not been increased in SIDS and near-miss SIDS but could be considered as a cause of higher-risk BRUEs.[111] It is important to clarify through a careful medical history evaluation that the infant was not potentially hypoglycemic at discovery of the event and improved because of enteral treatment, because these disorders will not typically self-resolve without intervention (ie, feeding).

Serum Electrolytes and Calcium

ALTE studies evaluating the diagnostic value of electrolytes, including sodium, potassium, blood urea nitrogen, and creatinine, reported the rare occurrence of abnormalities, ranging from 0% to 4.3%.[4,38,110] Abnormal calcium levels have been reported in 0% to 1.5% of infants with ALTE, although these reports did not provide specific causes of hypocalcemia. Another study reported profound vitamin D deficiency with hypocalcemia in 5 of 25 infants with a diagnosis of an ALTE over a 2-year period in Saudi Arabia.[4,21,38,110] In lower-risk BRUE infants, clinicians should not obtain a calcium measurement unless the clinical history raises suspicion of hypocalcemia (eg, vitamin D deficiency or hypoparathyroidism).

Ammonia

Elevations of ammonia are typically associated with persistent symptoms and recurring events, and therefore testing would not be indicated in lower-risk BRUEs. Elevations of ammonia were reported in 11 infants (7 whom had an IEM) in a report of infants with recurrent ALTE and SIDS, limiting extrapolation to

lower-risk BRUEs.[109] Elevations of ammonia >100 mmol/L were found in 4% of 65 infants, but this publication did not document a confirmed IEM.[38] Weiss et al[27] reported no abnormal elevations of ammonia in 4 infants with abnormal venous blood gas.

Venous or Arterial Blood Gas

Blood gas abnormalities leading to a diagnosis have not been reported in previous ALTE studies. Brand et al[4] reported 53 of 60 with positive findings, with none contributing to the final diagnosis. Weiss et al[27] reported 4 abnormal findings of 49 completed, all of which were normal on repeat measurements (along with normal lactate and ammonia levels). Blood gas detection is a routine test performed in acutely symptomatic patients who are being evaluated for suspected IEMs and may be considered in higher-risk BRUEs.

Urine Organic Acids, Plasma Amino Acids, Plasma Acylcarnitines

The role of advanced screening for IEMs has been reported in only 1 publication. Davies and Gupta[38] reported abnormalities of urine organic acids in 2% of cases and abnormalities of plasma amino acids in 4% of cases. Other reports have described an "unspecified metabolic screen" that was abnormal in 4.5% of cases but did not provide further description of specifics within that "screen."[4] Other reports have frequently included the descriptions of ALTEs with urea cycle disorders, organic acidemias, lactic acidemias, and fatty acid oxidation disorders such as medium chain acyl–coenzyme A dehydrogenase deficiency but did not distinguish between SIDS and near-miss SIDS.[107,109,111] Specific testing of urine organic acids, plasma amino acids, or plasma acylcarnitines may have a role in patients with a higher-risk BRUE.

6E. Clinicians Should Not Obtain Measurements of Urine Organic Acids, Plasma Amino Acids, or Plasma Acylcarnitines To Detect an IEM in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce costs, unnecessary testing, pain, risk of thrombosis, and caregiver/infant anxiety Avoid consequences of false-positive results
Risks, harm, cost	May miss detection of an IEM
Benefit-harm assessment	The benefits of reducing unnecessary testing, cost, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the rare missed diagnostic opportunity for an IEM
Intentional vagueness	Lower-risk BRUEs will have a very low likelihood of disease, but these tests may be indicated in rare cases in which there is no documentation of a newborn screen being performed
Role of patient preferences	Caregiver concerns may lead to requests for diagnostic testing
Exclusions	None
Strength	Moderate recommendation
Key references	4, 38

7A. Clinicians Should Not Obtain Laboratory Evaluation for Anemia in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Reduce costs, unnecessary testing, pain, risk of thrombosis, and caregiver/infant anxiety Avoid consequences of false-positive results
Risks, harm, cost	May miss diagnosis of anemia
Benefit-harm assessment	The benefits of reducing unnecessary testing, cost, and false-positive results, as well as alleviating caregiver and infant anxiety, outweigh the missed diagnostic opportunity for anemia
Intentional vagueness	None
Role of patient preferences	Caregivers may be reassured by testing
Exclusions	None
Strength	Moderate recommendation
Key reference	22

7. Anemia

7A. Clinicians Should Not Obtain Laboratory Evaluation for Anemia in Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Anemia has been associated with ALTEs in infants, but the significance and causal association with the event itself are unclear.[38,112,113] Normal hemoglobin concentrations have also been reported in many other ALTE populations.[69,112,114] Brand et al[4] reported an abnormal hemoglobin in 54 of 223 cases, but in only 2 of 159 was the hemoglobin concentration associated with the final diagnosis (which was abusive head injury in both). Parker and Pitetti[22] also reported that infants who presented with ALTEs and ultimately were determined to be victims of child abuse were more likely to have a lower mean hemoglobin (10.6 vs 12.7 g/dL; $P = .02$).

8. Patient- and Family-Centered Care

8A. Clinicians Should Offer Resources for CPR Training to Caregivers (Grade C, Moderate Recommendation)

The majority of cardiac arrests in children result from a respiratory deterioration. Bystander CPR has been reported to have been conducted in 37% to 48% of pediatric out-of-hospital cardiac arrests and

in 34% of respiratory arrests.[116] Bystander CPR results in significant improvement in 1-month survival rates in both cardiac and respiratory arrest.[117–119]

Although lower-risk BRUEs are neither a cardiac nor a respiratory arrest, the AAP policy statement on CPR recommends that pediatricians advocate for life-support training for caregivers and the general public.[115] A technical report that accompanies the AAP policy statement on CPR proposes that this can improve overall community health.[115] CPR training has not been shown to increase caregiver anxiety, and in fact, caregivers have reported a sense of empowerment.[120–122] There are many accessible and effective methods for CPR training (eg, e-learning).

8B. Clinicians Should Educate Caregivers About BRUEs (Grade C, Moderate Recommendation)

Pediatric providers are an important source of this health information and can help guide important conversations around BRUEs. A study by Feudtner et al[123] identified 4 groups of attributes of a "good parent": (1) making sure the child feels loved, (2) focusing on the child's health, (3) advocating for the child and being informed, and (4) ensuring the child's spiritual well-being. Clinicians should be the source of information for caregivers. Informed caregivers can advocate for their child in all of the attribute areas/domains, and regardless of health literacy levels, prefer being offered choices and being asked for information.[124] A patient- and family-centered care approach results in better health outcomes.[125,126]

8C. Clinicians Should Use Shared Decision-Making for Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Shared decision-making is a partnership between the clinician and the patient and family.[125,126] The general principles of shared decision-making are as follows: (1) information sharing, (2) respect and honoring differences, (3) partnership and collaboration, (4) negotiation, and (5) care in the context of family and community.[125] The benefits include improved care and outcomes; improved patient, family, and clinician satisfaction; and better use of health resources.[126] It is advocated for by organizations such as the AAP and the Institute of Medicine.[126,127] The 5 principles can be applied to all aspects of the infant who has experienced a BRUE, through each step (assessment, stabilization, management, disposition, and follow-up). Shared decision-making will empower families and foster a stronger clinician-patient/family alliance as they make decisions together in the face of a seemingly uncertain situation.

8A. Clinicians Should Offer Resources for CPR Training to Caregivers (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Decrease caregiver anxiety and increase confidence Benefit to society
Risks, harm, cost	May increase caregiver anxiety Cost and availability of training
Benefit-harm assessment	The benefits of decreased caregiver anxiety and increased confidence, as well as societal benefits, outweigh the increase in caregiver anxiety, cost, and resources
Intentional vagueness	None
Role of patient preferences	Caregiver may decide not to seek out the training
Exclusions	None
Strength	Moderate recommendation
Key reference	115

8B. Clinicians Should Educate Caregivers About BRUEs (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Improve caregiver empowerment and health literacy and decrease anxiety May reduce unnecessary return visits Promotion of the medical home
Risks, harm, cost	Increase caregiver anxiety and potential for caregiver intimidation in voicing concerns Increase health care costs and length of stay
Benefit-harm assessment	The benefits of decreased caregiver anxiety and increased empowerment and health literacy outweigh the increase in cost, length of stay, and caregiver anxiety and intimidation
Intentional vagueness	None
Role of patient preferences	Caregiver may decide not to listen to clinician
Exclusions	None
Strength	Moderate recommendation
Key references	None

DISSEMINATION AND IMPLEMENTATION

Dissemination and implementation efforts are needed to facilitate guideline use across pediatric medicine, family medicine, emergency medicine, research, and patient/family communities.[128] The following general approaches and a Web-based toolkit are proposed for the dissemination and implementation of this guideline.

8C. Clinicians Should Use Shared Decision-Making for Infants Presenting With a Lower-Risk BRUE (Grade C, Moderate Recommendation)

Aggregate Evidence Quality	Grade C
Benefits	Improve caregiver empowerment and health literacy and decrease anxiety May reduce unnecessary return visits Promotion of the medical home
Risks, harm, cost	Increase cost, length of stay, and caregiver anxiety and intimidation in voicing concerns
Benefit-harm assessment	The benefits of decreased caregiver anxiety and unplanned return visits and increased empowerment, health, literacy, and medical home promotion outweigh the increase in cost, length of stay, and caregiver anxiety and information
Intentional vagueness	None
Role of patient preferences	Caregiver may decide not to listen to clinician
Exclusions	None
Strength	Moderate recommendation
Key references	None

1. Education

Education will be partially achieved through the AAP communication outlets and educational services (*AAP News, Pediatrics,* and PREP). Further support will be sought from stakeholder organizations (American Academy of Family Physicians, American College of Emergency Physicians, American Board of Pediatrics, Society of Hospital Medicine). A Web-based toolkit (to be published online) will include caregiver handouts and a shared decision-making tool to facilitate patient- and family-centered care. Efforts will address appropriate disease classification and diagnosis coding.

2. Integration of Clinical Workflow

An algorithm is provided (Fig 1) for diagnosis and management. Structured history and physical examination templates also are provided to assist in addressing all of the relevant risk factors for BRUEs (Tables 2 and 3). Order sets and modified documents will be hosted on a Web-based learning platform that promotes crowd-sourcing.

3. Administrative and Research

International Classification of Diseases, 9th Revision, and International Classification of Diseases, 10th Revision, diagnostic codes are used for billing, quality improvement, and research; and new codes for lower- and higher-risk BRUEs will need to be developed. In the interim, the current code for an ALTE (799.82) will need to be used for billing purposes. Efforts will be made to better reflect present knowledge and to educate clinicians and payers in appropriate use of codes for this condition.

4. Quality Improvement

Quality improvement initiatives that provide Maintenance of Certification credit, such as the AAP's PREP and EQIPP courses, or collaborative opportunities through the AAP's Quality Improvement Innovation Networks, will engage clinicians in the use and improvement of the guideline. By using proposed quality measures, adherence and outcomes can be assessed and benchmarked with others to inform continual improvement efforts. Proposed measures include process evaluation (use of definition and evaluation), outcome assessment (family experience and diagnostic outcomes), and balancing issues (cost and length of visit). Future research will need to be conducted to validate any measures.

FUTURE RESEARCH

The transition in nomenclature from the term ALTE to BRUE after 30 years reflects the expanded understanding of the etiology and consequences of this entity. Previous research has been largely retrospective or observational in nature, with little long-term follow-up data available. The more-precise definition, the classification of lower- and higher-risk groups, the recommendations for the lower-risk group, and the implementation toolkit will serve as the basis for future research. Important areas for future prospective research include the following.

1. Epidemiology

- Incidence of BRUEs in all infants (in addition to those seeking medical evaluation)
- Influence of race, gender, ethnicity, seasonality, environmental exposures, and socioeconomic status on incidence and outcomes

2. Diagnosis

- Use and effectiveness of the BRUE definition
- Screening tests and risk of UTI
- Quantify and better understand risk in higher- and lower-risk groups
- Risk and benefit of screening tests
- Risk and benefit and optimal duration of observation and monitoring periods
- Effect of prematurity on risk
- Appropriate indications for subspecialty referral
- Early recognition of child maltreatment
- Importance of environmental history taking
- Role of human psychology on accuracy of event characterization

- Type and length of monitoring in the acute setting

3. Pathophysiology

- Role of abnormalities of swallowing, laryngospasm, GER, and autonomic function

4. Outcomes

- Patient- and family-centered outcomes, including caregiver satisfaction, anxiety, and family dynamics (eg, risk of vulnerable child syndrome)
- Long-term health and cognitive consequences

5. Treatment

- Empirical GER treatment on recurrent BRUEs
- Caregiver education strategies, including basic life support, family-centered education, and postpresentation clinical visits

6. Follow-up

- Strategies for timely follow-up and surveillance

SUBCOMMITTEE ON BRIEF RESOLVED UNEXPLAINED EVENTS (FORMERLY REFERRED TO AS APPARENT LIFE THREATENING EVENTS) (OVERSIGHT BY THE COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY)

Joel S. Tieder, MD, MPH, FAAP, Chair (no financial conflicts, published research related to BRUEs/ALTEs)

Joshua L. Bonkowsky, MD, PhD, FAAP, Pediatric Neurologist

Ruth A. Etzel, MD, PhD, FAAP, Pediatric Epidemiologist

Wayne H. Franklin, MD, MPH, MMM, FAAP, Pediatric Cardiologist

David A. Gremse, MD, FAAP, Pediatric Gastroenterologist

Bruce Herman, MD, FAAP, Child Abuse and Neglect

Eliot Katz, MD, FAAP, Pediatric Pulmonologist

Leonard R. Krilov, MD, FAAP, Pediatric Infectious Diseases

J. Lawrence Merritt II, MD, FAAP, Clinical Genetics and Biochemical Genetics

Chuck Norlin, MD, FAAP, Pediatrician

Robert E. Sapién, MD, MMM, FAAP, Pediatric Emergency Medicine

Richard Shiffman, MD, FAAP, Partnership for Policy Implementation Representative

Michael B.H. Smith, MB, FRCPCH, FAAP, Hospital Medicine

Jack Percelay, MD, MPH, FAAP, Liaison, Society for Hospital Medicine

STAFF

Kymika Okechukwu, MPA

ABBREVIATIONS

AAP: American Academy of Pediatrics
ALTE: apparent life-threatening event
BRUE: brief resolved unexplained event
CI: confidence interval
CNS: central nervous system
CPR: cardiopulmonary resuscitation
ECG: electrocardiogram
GER: gastroesophageal reflux
IEM: inborn error of metabolism
MII: multiple intraluminal impedance
OSA: obstructive sleep apnea
RSV: respiratory syncytial virus
SIDS: sudden infant death syndrome
SUDEP: sudden unexpected death in epilepsy
UTI: urinary tract infection

REFERENCES

1. National Institutes of Health Consensus Development Conference on Infantile Apnea and Home Monitoring, Sept 29 to Oct 1, 1986. *Pediatrics*. 1987;79(2):292–299
2. McGovern MC, Smith MB. Causes of apparent life threatening events in infants: a systematic review. *Arch Dis Child*. 2004;89(11):1043–1048
3. Tieder JS, Altman RL, Bonkowsky JL, et al Management of apparent life-threatening events in infants: a systematic review. *J Pediatr*. 2013;163(1):94–99, e91–e96
4. Brand DA, Altman RL, Purtill K, Edwards KS. Yield of diagnostic testing in infants who have had an apparent life-threatening event. *Pediatrics*. 2005;115(4):885–893
5. Green M. Vulnerable child syndrome and its variants. *Pediatr Rev*. 1986;8(3):75–80
6. Kaji AH, Claudius I, Santillanes G, et al. Apparent life-threatening event: multicenter prospective cohort study to develop a clinical decision rule for admission to the hospital. *Ann Emerg Med*. 2013;61(4):379–387.e4
7. Mittal MK, Sun G, Baren JM. A clinical decision rule to identify infants with apparent life-threatening event who can be safely discharged from the emergency department. *Pediatr Emerg Care*. 2012;28(7):599–605
8. Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Ann Intern Med*. 2009;151(4):264–269, W64
9. Haynes RB, Cotoi C, Holland J, et al; McMaster Premium Literature Service (PLUS) Project. Second-order peer review of the medical literature for clinical practitioners. *JAMA*. 2006;295(15):1801–1808
10. Lokker C, McKibbon KA, McKinlay RJ, Wilczynski NL, Haynes RB. Prediction of citation counts for clinical articles at two years using data available within three weeks of publication: retrospective cohort study. *BMJ*. 2008;336(7645):655–657
11. Laupacis A, Wells G, Richardson WS, Tugwell P; Evidence-Based Medicine Working Group. Users' guides to the medical literature. V. How to use an article about prognosis. *JAMA*. 1994;272(3):234–237
12. Jaeschke R, Guyatt G, Sackett DL. Users' guides to the medical literature. III. How to use an article about a diagnostic test. A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA*. 1994;271(5):389–391
13. Anjos AM, Nunes ML. Prevalence of epilepsy and seizure disorders as causes of apparent life-threatening event (ALTE) in children admitted to a tertiary hospital. *Arq Neuropsiquiatr*. 2009;67(3a 3A):616–620

14. Doshi A, Bernard-Stover L, Kuelbs C, Castillo E, Stucky E. Apparent lifethreatening event admissions and gastroesophageal reflux disease: the value of hospitalization. *Pediatr Emerg Care*. 2012;28(1):17–21

15. Franco P, Montemitro E, Scaillet S, et al. Fewer spontaneous arousals in infants with apparent life-threatening event. *Sleep*. 2011;34(6):733–743

16. Hoki R, Bonkowsky JL, Minich LL, Srivastava R, Pinto NM. Cardiac testing and outcomes in infants after an apparent life-threatening event. *Arch Dis Child*. 2012;97(12):1034–1038

17. Kaji AH, Santillanes G, Claudius I, et al. Do infants less than 12 months of age with an apparent life-threatening event need transport to a pediatric critical care center? *Prehosp Emerg Care*. 2013;17(3):304–311

18. Kant S, Fisher JD, Nelson DG, Khan S. Mortality after discharge in clinically stable infants admitted with a fi rsttime apparent life-threatening event. *Am J Emerg Med*. 2013;31(4):730–733

19. Miano S, Castaldo R, Ferri R, et al. Sleep cyclic alternating pattern analysis in infants with apparent life-threatening events: a daytime polysomnographic study. *Clin Neurophysiol*. 2012;123(7):1346–1352

20. Mittal MK, Donda K, Baren JM. Role of pneumography and esophageal pH monitoring in the evaluation of infants with apparent life-threatening event: a prospective observational study. *Clin Pediatr (Phila)*. 2013;52(4):338–343

21. Mosalli RM, Elsayed YY, Paes BA. Acute life threatening events associated with hypocalcemia and vitamin D defi ciency in early infancy: a single center experience from the Kingdom of Saudi Arabia. *Saudi Med J*. 2011;32(5):528–530

22. Parker K, Pitetti R. Mortality and child abuse in children presenting with apparent life-threatening events. *Pediatr Emerg Care*. 2011;27(7):591–595

23. Poets A, Urschitz MS, Steinfeldt R, Poets CF. Risk factors for early sudden deaths and severe apparent lifethreatening events. *Arch Dis Child Fetal Neonatal Ed*. 2012;97(6):F395–F397

24. Semmekrot BA, van Sleuwen BE, Engelberts AC, et al. Surveillance study of apparent life-threatening events (ALTE) in the Netherlands. *Eur J Pediatr*. 2010;169(2):229–236

25. Tieder JS, Altman RL, Bonkowsky JL, et al. Management of apparent life-threatening events in infants: a systematic review. *J Pediatr*. 2013;163(1):94–9.e1, 6

26. Wasilewska J, Sienkiewicz-Szłapka E, Kuźbida E, Jarmołowska B, Kaczmarski M, Kostyra E. The exogenous opioid peptides and DPPIV serum activity in infants with apnoea expressed as apparent life threatening events (ALTE). *Neuropeptides*. 2011;45(3):189–195

27. Weiss K, Fattal-Valevski A, Reif S. How to evaluate the child presenting with an apparent life-threatening event? *Isr Med Assoc J*. 2010;12(3):154–157

28. Zimbric G, Bonkowsky JL, Jackson WD, Maloney CG, Srivastava R. Adverse outcomes associated with gastroesophageal reflux disease are rare following an apparent life-threatening event. *J Hosp Med*. 2012;7(6):476–481

29. American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877

30. Shiffman RN, Michel G, Rosenfeld RM, Davidson C. Building better guidelines with BRIDGE-Wiz: development and evaluation of a software assistant to promote clarity, transparency, and implementability. *J Am Med Inform Assoc*. 2012;19(1):94–101

31. Claudius I, Keens T. Do all infants with apparent life-threatening events need to be admitted? *Pediatrics*. 2007;119(4):679–683

32. Bonkowsky JL, Guenther E, Filloux FM, Srivastava R. Death, child abuse, and adverse neurological outcome of infants after an apparent lifethreatening event. *Pediatrics*. 2008;122(1):125–131

33. Al-Kindy HA, Gelinas JF, Hatzakis G, Cote A. Risk factors for extreme events in infants hospitalized for apparent life-threatening events. *J Pediatr*. 2009;154(3):332–337, 337.e1–337.e2

34. Ramanathan R, Corwin MJ, Hunt CE, et al; Collaborative Home Infant Monitoring Evaluation (CHIME) Study Group. Cardiorespiratory events recorded on home monitors: comparison of healthy infants with those at increased risk for SIDS. *JAMA*. 2001;285(17):2199–2207

35. Poets CF, Stebbens VA, Alexander JR, Arrowsmith WA, Salfield SA, Southall DP. Hypoxaemia in infants with respiratory tract infections. *Acta Paediatr*. 1992;81(6–7):536–541

36. Hunt CE, Corwin MJ, Lister G, et al; Collaborative Home Infant Monitoring Evaluation (CHIME) Study Group. Longitudinal assessment of hemoglobin oxygen saturation in healthy infants during the first 6 months of age. *J Pediatr*. 1999;135(5):580–586

37. Altman RL, Li KI, Brand DA. Infections and apparent life-threatening events. *Clin Pediatr (Phila)*. 2008;47(4):372–378

38. Davies F, Gupta R. Apparent life threatening events in infants presenting to an emergency department. *Emerg Med J*. 2002;19(1):11–16

39. Guilleminault C, Ariagno R, Korobkin R, et al. Mixed and obstructive sleep apnea and near miss for sudden infant death syndrome: 2. Comparison of near miss and normal control infants by age. *Pediatrics*. 1979;64(6):882–891

40. Côté A, Hum C, Brouillette RT, Themens M. Frequency and timing of recurrent events in infants using home cardiorespiratory monitors. *J Pediatr*. 1998;132(5):783–789

41. Kahn A, Blum D. Home monitoring of infants considered at risk for the sudden infant death syndrome: four years' experience (1977-1981). *Eur J Pediatr*. 1982;139(2):94–100

42. Daniëls H, Naulaers G, Deroost F, Devlieger H. Polysomnography and home documented monitoring of cardiorespiratory pattern. *Arch Dis Child*. 1999;81(5):434–436

43. Marcus CL, Hamer A. Significance of isolated bradycardia detected

by home monitoring. *J Pediatr*. 1999;135(3):321–326

44. Rebuffat E, Groswasser J, Kelmanson I, Sottiaux M, Kahn A. Polygraphic evaluation of night-to-night variability in sleep characteristics and apneas in infants. *Sleep*. 1994;17(4):329–332
45. Horemuzova E, Katz-Salamon M, Milerad J. Increased inspiratory effort in infants with a history of apparent life-threatening event. *Acta Paediatr*. 2002;91(3):280–286; discussion: 260–261
46. Schechtman VL, Harper RM, Wilson AJ, Southall DP. Sleep state organization in normal infants and victims of the sudden infant death syndrome. *Pediatrics*. 1992;89(5 Pt 1):865–870
47. Arad-Cohen N, Cohen A, Tirosh E. The relationship between gastroesophageal reflux and apnea in infants. *J Pediatr*. 2000;137(3):321–326
48. Harrington C, Kirjavainen T, Teng A, Sullivan CE. Altered autonomic function and reduced arousability in apparent life-threatening event infants with obstructive sleep apnea. *Am J Respir Crit Care Med*. 2002;165(8):1048–1054
49. Guilleminault C, Pelayo R, Leger D, Philip P. Apparent life-threatening events, facial dysmorphia and sleep-disordered breathing. *Eur J Pediatr*. 2000;159(6):444–449
50. Aurora RN, Zak RS, Karippot A, et al; American Academy of Sleep Medicine. Practice parameters for the respiratory indications for polysomnography in children. *Sleep*. 2011;34(3):379–388
51. Kahn A, Groswasser J, Sottiaux M, Rebuffat E, Franco P. Mechanisms of obstructive sleep apneas in infants. *Biol Neonate*. 1994;65(3–4):235–239
52. Leiberman A, Tal A, Brama I, Sofer S. Obstructive sleep apnea in young infants. *Int J Pediatr Otorhinolaryngol*. 1988;16(1):39–44
53. Montgomery-Downs HE, Gozal D. Sleep habits and risk factors for sleep-disordered breathing in infants and young toddlers in Louisville, Kentucky. *Sleep Med*. 2006;7(3):211–219
54. Brouillette RT, Fernbach SK, Hunt CE. Obstructive sleep apnea in infants and children. *J Pediatr*. 1982;100(1):31–40
55. Kahn A, Groswasser J, Sottiaux M, et al. Clinical symptoms associated with brief obstructive sleep apnea in normal infants. *Sleep*. 1993;16(5):409–413
56. Kahn A, Groswasser J, Sottiaux M, et al. Prenatal exposure to cigarettes in infants with obstructive sleep apneas. *Pediatrics*. 1994;93(5):778–783
57. Kahn A, Mozin MJ, Rebuffat E, et al. Sleep pattern alterations and brief airway obstructions in overweight infants. *Sleep*. 1989;12(5):430–438
58. Fajardo C, Alvarez J, Wong A, Kwiatkowski K, Rigatto H. The incidence of obstructive apneas in preterm infants with and without bronchopulmonary dysplasia. *Early Hum Dev*. 1993;32(2–3):197–206
59. Horigome H, Nagashima M, Sumitomo N, et al. Clinical characteristics and genetic background of congenital long-QT syndrome diagnosed in fetal, neonatal, and infantile life: a nationwide questionnaire survey in Japan. *Circ Arrhythm Electrophysiol*. 2010;3(1):10–17
60. Arnestad M, Crotti L, Rognum TO, et al. Prevalence of long-QT syndrome gene variants in sudden infant death syndrome. *Circulation*. 2007;115(3):361–367
61. Goldenberg I, Moss AJ, Peterson DR, et al. Risk factors for aborted cardiac arrest and sudden cardiac death in children with the congenital long-QT syndrome. *Circulation*. 2008;117(17):2184–2191
62. Munger TM, Packer DL, Hammill SC, et al. A population study of the natural history of Wolff-Parkinson-White syndrome in Olmsted County, Minnesota, 1953-1989. *Circulation*. 1993;87(3):866–873
63. American Academy of Pediatrics, Committee on Fetus and Newborn. Apnea, sudden infant death syndrome, and home monitoring. *Pediatrics*. 2003;111(4 pt 1):914–917
64. Krongrad E, O'Neill L. Near miss sudden infant death syndrome episodes? A clinical and electrocardiographic correlation. *Pediatrics*. 1986;77(6):811–815
65. Nathanson I, O'Donnell J, Commins MF. Cardiorespiratory patterns during alarms in infants using apnea/bradycardia monitors. *Am J Dis Child*. 1989;143(4):476–480
66. Weese-Mayer DE, Brouillette RT, Morrow AS, Conway LP, Klemka-Walden LM, Hunt CE. Assessing validity of infant monitor alarms with event recording. *J Pediatr*. 1989;115(5 pt 1):702–708
67. Guenther E, Powers A, Srivastava R, Bonkowsky JL. Abusive head trauma in children presenting with an apparent life-threatening event. *J Pediatr*. 2010;157(5):821–825
68. Pierce MC, Kaczor K, Thompson R. Bringing back the social history. *Pediatr Clin North Am*. 2014;61(5):889–905
69. Pitetti RD, Maffei F, Chang K, Hickey R, Berger R, Pierce MC. Prevalence of retinal hemorrhages and child abuse in children who present with an apparent life-threatening event. *Pediatrics*. 2002;110(3):557–562
70. Jenny C, Hymel KP, Ritzen A, Reinert SE, Hay TC. Analysis of missed cases of abusive head trauma. *JAMA*. 1999;281(7):621–626
71. Southall DP, Plunkett MC, Banks MW, Falkov AF, Samuels MP. Covert video recordings of life-threatening child abuse: lessons for child protection. *Pediatrics*. 1997;100(5):735–760
72. Sugar NF, Taylor JA, Feldman KW; Puget Sound Pediatric Research Network. Bruises in infants and toddlers: those who don't cruise rarely bruise. *Arch Pediatr Adolesc Med*. 1999;153(4):399–403
73. Harper NS, Feldman KW, Sugar NF, Anderst JD, Lindberg DM; Examining Siblings To Recognize Abuse Investigators. Additional injuries in young infants with concern for abuse and apparently isolated bruises. *J Pediatr*. 2014;165(2):383–388, e1
74. DeRidder CA, Berkowitz CD, Hicks RA, Laskey AL. Subconjunctival hemorrhages in infants and children: a sign of nonaccidental trauma. *Pediatr Emerg Care*. 2013;29(2):222–226
75. Buck ML, Blumer JL. Phenothiazine-associated apnea in two siblings. *DICP*. 1991;25(3):244–247
76. Hardoin RA, Henslee JA, Christenson CP, Christenson PJ, White M. Colic

medication and apparent life-threatening events. *Clin Pediatr (Phila)*. 1991;30(5):281–285

77. Hickson GB, Altemeier WA, Martin ED, Campbell PW. Parental administration of chemical agents: a cause of apparent life-threatening events. *Pediatrics*. 1989;83(5):772–776
78. Pitetti RD, Whitman E, Zaylor A. Accidental and nonaccidental poisonings as a cause of apparent life-threatening events in infants. *Pediatrics*. 2008;122(2). Available at: www.pediatrics.org/cgi/content/full/122/2/e359
79. McCormick T, Levine M, Knox O, Claudius I. Ethanol ingestion in two infants under 2 months old: a previously unreported cause of ALTE. *Pediatrics*. 2013;131(2). Available at: www.pediatrics.org/cgi/content/full/131/2/e604
80. Dearborn DG, Smith PG, Dahms BB, et al. Clinical profile of 30 infants with acute pulmonary hemorrhage in Cleveland. *Pediatrics*. 2002;110(3):627–637
81. Leone MA, Solari A, Beghi E; First Seizure Trial (FIRST) Group. Treatment of the first tonic-clonic seizure does not affect long-term remission of epilepsy. *Neurology*. 2006;67(12):2227–2229
82. Musicco M, Beghi E, Solari A, Viani F; First Seizure Trial (FIRST) Group. Treatment of first tonic-clonic seizure does not improve the prognosis of epilepsy. *Neurology*. 1997;49(4):991–998
83. Camfield P, Camfield C, Smith S, Dooley J, Smith E. Long-term outcome is unchanged by antiepileptic drug treatment after a first seizure: a 15-year follow-up from a randomized trial in childhood. *Epilepsia*. 2002;43(6):662–663
84. Gilbert DL, Buncher CR. An EEG should not be obtained routinely after first unprovoked seizure in childhood. *Neurology*. 2000;54(3):635–641
85. Arts WF, Geerts AT. When to start drug treatment for childhood epilepsy: the clinical-epidemiological evidence. *Eur J Paediatr Neurol*. 2009;13(2):93–101
86. Hirtz D, Ashwal S, Berg A, et al. Practice parameter: evaluating a first nonfebrile seizure in children: report of the Quality Standards Subcommittee of the American Academy of Neurology, The Child Neurology Society, and The American Epilepsy Society. *Neurology*. 2000;55(5):616–623
87. Bonkowsky JL, Guenther E, Srivastava R, Filloux FM. Seizures in children following an apparent life-threatening event. *J Child Neurol*. 2009;24(6):709–713
88. Claudius I, Mittal MK, Murray R, Condie T, Santillanes G. Should infants presenting with an apparent life-threatening event undergo evaluation for serious bacterial infections and respiratory pathogens? *J Pediatr*. 2014;164(5):1231–1233, e1
89. Mittal MK, Shofer FS, Baren JM. Serious bacterial infections in infants who have experienced an apparent life-threatening event. *Ann Emerg Med*. 2009;54(4):523–527
90. Roberts KB; Subcommittee on Urinary Tract Infection, Steering Committee on Quality Improvement and Management. Urinary tract infection: clinical practice guideline for the diagnosis and management of the initial UTI in febrile infants and children 2 to 24 months. *Pediatrics*. 2011;128(3):595–610
91. Schroeder AR, Mansbach JM, Stevenson M, et al. Apnea in children hospitalized with bronchiolitis. *Pediatrics*. 2013;132(5). Available at: www.pediatrics.org/cgi/content/full/132/5/e1194
92. Loeffelholz MJ, Trujillo R, Pyles RB, et al. Duration of rhinovirus shedding in the upper respiratory tract in the first year of life. *Pediatrics*. 2014;134(6):1144–1150
93. Crowcroft NS, Booy R, Harrison T, et al. Severe and unrecognised: pertussis in UK infants. *Arch Dis Child*. 2003;88(9):802–806
94. Centers for Disease Control and Prevention. Pertussis (whooping cough): diagnostic testing. Available at: www.cdc.gov/pertussis/clinical/diagnostic-testing/index.html. Accessed June 26, 2015
95. Centers for Disease Control and Prevention. Pertussis (whooping cough): treatment. Available at: www.cdc.gov/pertussis/clinical/treatment.html. Accessed June 26, 2015
96. Campanozzi A, Boccia G, Pensabene L, et al. Prevalence and natural history of gastroesophageal reflux: pediatric prospective survey. *Pediatrics*. 2009;123(3):779–783
97. Lightdale JR, Gremse DA; American Academy of Pediatrics, Section on Gastroenterology, Hepatology, and Nutrition. Gastroesophageal reflux: management guidance for the pediatrician. *Pediatrics*. 2013;131(5). Available at: www.pediatrics.org/cgi/content/full/131/5/e1684
98. Vandenplas Y, Rudolph CD, Di Lorenzo C, et al; North American Society for Pediatric Gastroenterology Hepatology and Nutrition; European Society for Pediatric Gastroenterology Hepatology and Nutrition. Pediatric gastroesophageal reflux clinical practice guidelines: joint recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN). *J Pediatr Gastroenterol Nutr*. 2009;49(4):498–547
99. Kiechl-Kohlendorfer U, Hof D, Peglow UP, Traweger-Ravanelli B, Kiechl S. Epidemiology of apparent life threatening events. *Arch Dis Child*. 2005;90(3):297–300
100. Chung EY, Yardley J. Are there risks associated with empiric acid suppression treatment of infants and children suspected of having gastroesophageal reflux disease? *Hosp Pediatr*. 2013;3(1):16–23
101. Herbst JJ, Minton SD, Book LS. Gastroesophageal reflux causing respiratory distress and apnea in newborn infants. *J Pediatr*. 1979;95(5 pt 1):763–768
102. Orenstein SR. An overview of reflux-associated disorders in infants: apnea, laryngospasm, and aspiration. *Am J Med*. 2001;111(suppl 8A):60S–63S
103. Wenzl TG, Schenke S, Peschgens T, Silny J, Heimann G, Skopnik H. Association of

apnea and nonacid gastroesophageal reflux in infants: investigations with the intraluminal impedance technique. *Pediatr Pulmonol*. 2001;31(2):144–149

104. Mousa H, Woodley FW, Metheney M, Hayes J. Testing the association between gastroesophageal reflux and apnea in infants. *J Pediatr Gastroenterol Nutr*. 2005;41(2):169–177
105. Kahn A, Rebuffat E, Sottiaux M, Dufour D, Cadranel S, Reiterer F. Lack of temporal relation between acid reflux in the proximal oesophagus and cardiorespiratory events in sleeping infants. *Eur J Pediatr*. 1992;151(3):208–212
106. Orenstein SR, McGowan JD. Efficacy of conservative therapy as taught in the primary care setting for symptoms suggesting infant gastroesophageal reflux. *J Pediatr*. 2008;152(3):310–314
107. Kahn A; European Society for the Study and Prevention of Infant Death. Recommended clinical evaluation of infants with an apparent life-threatening event: consensus document of the European Society for the Study and Prevention of Infant Death, 2003. *Eur J Pediatr*. 2004;163(2):108–115
108. Veereman-Wauters G, Bochner A, Van Caillie-Bertrand M. Gastroesophageal reflux in infants with a history of near-miss sudden infant death. *J Pediatr Gastroenterol Nutr*. 1991;12(3):319–323
109. Arens R, Gozal D, Williams JC, Ward SL, Keens TG. Recurrent apparent life-threatening events during infancy: a manifestation of inborn errors of metabolism. *J Pediatr*. 1993;123(3):415–418
110. See CC, Newman LJ, Berezin S, et al. Gastroesophageal reflux-induced hypoxemia in infants with apparent life-threatening event(s). *Am J Dis Child*. 1989;143(8):951–954
111. Penzien JM, Molz G, Wiesmann UN, Colombo JP, Bühlmann R, Wermuth B. Medium-chain acyl-CoA dehydrogenase deficiency does not correlate with apparent life-threatening events and the sudden infant death syndrome: results from phenylpropionate loading tests and DNA analysis. *Eur J Pediatr*. 1994;153(5):352–357
112. Pitetti RD, Lovallo A, Hickey R. Prevalence of anemia in children presenting with apparent life-threatening events. *Acad Emerg Med*. 2005;12(10):926–931
113. Gray C, Davies F, Molyneux E. Apparent life-threatening events presenting to a pediatric emergency department. *Pediatr Emerg Care*. 1999;15(3):195–199
114. Poets CF, Samuels MP, Wardrop CA, Picton-Jones E, Southall DP. Reduced haemoglobin levels in infants presenting with apparent life-threatening events—a retrospective investigation. *Acta Paediatr*. 1992;81(4):319–321
115. Pyles LA, Knapp J; American Academy of Pediatrics Committee on Pediatric Emergency Medicine. Role of pediatricians in advocating life support training courses for parents and the public. *Pediatrics*. 2004;114(6). Available at: www.pediatrics.org/cgi/content/full/114/6/e761
116. Tunik MG, Richmond N, Treiber M, et al. Pediatric prehospital evaluation of NYC respiratory arrest survival (PHENYCS). *Pediatr Emerg Care*. 2012;28(9):859–863
117. Foltin GL, Richmond N, Treiber M, et al. Pediatric prehospital evaluation of NYC cardiac arrest survival (PHENYCS). *Pediatr Emerg Care*. 2012;28(9):864–868
118. Akahane M, Tanabe S, Ogawa T, et al. Characteristics and outcomes of pediatric out-of-hospital cardiac arrest by scholastic age category. *Pediatr Crit Care Med*. 2013;14(2):130–136
119. Atkins DL, Everson-Stewart S, Sears GK, et al; Resuscitation Outcomes Consortium Investigators. Epidemiology and outcomes from out-of-hospital cardiac arrest in children: the Resuscitation Outcomes Consortium Epistry-Cardiac Arrest. *Circulation*. 2009;119(11):1484–1491
120. McLauchlan CA, Ward A, Murphy NM, Griffith MJ, Skinner DV, Camm AJ. Resuscitation training for cardiac patients and their relatives—its effect on anxiety. *Resuscitation*. 1992;24(1):7–11
121. Higgins SS, Hardy CE, Higashino SM. Should parents of children with congenital heart disease and life-threatening dysrhythmias be taught cardiopulmonary resuscitation? *Pediatrics*. 1989;84(6):1102–1104
122. Dracup K, Moser DK, Taylor SE, Guzy PM. The psychological consequences of cardiopulmonary resuscitation training for family members of patients at risk for sudden death. *Am J Public Health*. 1997;87(9):1434–1439
123. Feudtner C, Walter JK, Faerber JA, et al. Good-parent beliefs of parents of seriously ill children. *JAMA Pediatr*. 2015;169(1):39–47
124. Yin HS, Dreyer BP, Vivar KL, MacFarland S, van Schaick L, Mendelsohn AL. Perceived barriers to care and attitudes towards shared decision-making among low socioeconomic status parents: role of health literacy. *Acad Pediatr*. 2012;12(2):117–124
125. Kuo DZ, Houtrow AJ, Arango P, Kuhlthau KA, Simmons JM, Neff JM. Family-centered care: current applications and future directions in pediatric health care. *Matern Child Health J*. 2012;16(2):297–305
126. American Academy of Pediatrics, Committee on Hospital Care; Institute for Patient- and Family-Centered Care. Patient- and family-centered care and the pediatrician's role. *Pediatrics*. 2012;129(2):394–404
127. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: Institute of Medicine, Committee on Quality Healthcare in America National Academies Press; 2001
128. Pronovost PJ. Enhancing physicians' use of clinical guidelines. *JAMA*. 2013;310(23):2501–2502

CLINICAL PRACTICE GUIDELINE Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Brief Resolved Unexplained Events (Formerly Apparent Life-Threatening Events) and Evaluation of Lower-Risk Infants: Executive Summary

Joel S. Tieder, MD, MPH, FAAP, Joshua L. Bonkowsky, MD, PhD, FAAP, Ruth A. Etzel, MD, PhD, FAAP, Wayne H. Franklin, MD, MPH, MMM, FAAP, David A. Gremse, MD, FAAP, Bruce Herman, MD, FAAP, Eliot S. Katz, MD, FAAP, Leonard R. Krilov, MD, FAAP, J. Lawrence Merritt II, MD, FAAP, Chuck Norlin, MD, FAAP, Jack Percelay, MD, MPH, FAAP, Robert E. Sapién, MD, MMM, FAAP, Richard N. Shiffman, MD, MCIS, FAAP, Michael B.H. Smith, MB, FRCPCH, FAAP, SUBCOMMITTEE ON APPARENT LIFE THREATENING EVENTS

EXECUTIVE SUMMARY

This clinical practice guideline has 2 primary objectives. First, it recommends the replacement of the term "apparent life-threatening event" (ALTE) with a new term, "brief resolved unexplained event" (BRUE). Second, it provides an approach to evaluation and management that is based on the risk that the infant will have a repeat event or has a serious underlying disorder.

Clinicians should use the term BRUE to describe an event occurring in an infant younger than 1 year when the observer reports a sudden, brief, and now resolved episode of ≥1 of the following: (1) cyanosis or pallor; (2) absent, decreased, or irregular breathing; (3) marked change in tone (hyper- or hypotonia); and (4) altered level of responsiveness. Moreover, clinicians should diagnose a BRUE only when there is no explanation for a qualifying event after conducting an appropriate history and physical examination (see Tables 2 and 3 in www.pediatrics.org/cgi/doi/10.1542/peds.2016-0590). Among infants who present for medical attention after a BRUE, the guideline identifies (1) lower-risk patients on the basis of history and physical examination, for whom evidence-based guidelines for evaluation and management are offered, and (2) higher-risk patients, whose history and physical examination suggest the need for further investigation, monitoring, and/or treatment, but for whom recommendations are not offered (because of insufficient evidence or the availability of guidance from other clinical practice guidelines specific to their presentation or diagnosis). Recommendations in this guideline apply only to lower-risk patients,

DOI: 10.1542/peds.2016-0591

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Tieder JS, Bonkowsky JL, Etzel RA, et al. Brief Resolved Unexplained Events (Formerly Apparent Life-Threatening Events) and Evaluation of Lower-Risk Infants: Executive Summary. *Pediatrics.* 2016;137(5):e20160591

who are defined by (1) age >60 days; (2) gestational age ≥32 weeks and postconceptional age ≥45 weeks; (3) occurrence of only 1 BRUE (no prior BRUE ever and not occurring in clusters); (4) duration of BRUE <1 minute; (5) no cardiopulmonary resuscitation by trained medical provider required; (6) no concerning historical features; and (7) no concerning physical examination findings (Fig 1). This clinical practice guideline also provides implementation support and suggests directions for future research.

The term ALTE originated from a 1986 National Institutes of Health Consensus Conference on Infantile Apnea and was intended to replace the term "near-miss sudden infant death syndrome (SIDS)."[1] An ALTE was defined as "[a]n episode that is frightening to the observer and that is characterized by some combination of apnea (central or occasionally obstructive), color change (usually cyanotic or pallid but occasionally erythematous or plethoric), marked change in muscle tone (usually marked limpness), choking, or gagging. In some cases, the observer fears that the infant has died."[2] Although the definition of ALTE enabled researchers to establish over time that these events were a separate entity from SIDS, the clinical application of this classification, which describes a constellation of observed, subjective, and nonspecific symptoms, has raised significant challenges for clinicians and parents in the evaluation and care of these infants.[3] Although a broad range of disorders can present as an ALTE (eg, child abuse, congenital abnormalities, epilepsy, inborn errors of metabolism, and infections), for a majority of well-appearing infants, the risk of a recurrent event or a serious underlying disorder is extremely low.

ALTEs can create a feeling of uncertainty in both the caregiver and the clinician. Clinicians may feel compelled to perform tests and hospitalize the patient even though this may subject the patient to unnecessary risk and is unlikely to lead to a treatable diagnosis or prevent future events.[2,4,5] Understanding the risk of an adverse outcome for an infant who has experienced an ALTE has been difficult because of the nonspecific nature and variable application of the ALTE definition in research. A recent systematic review of nearly 1400 ALTE publications spanning 4 decades concluded that risk of a subsequent or underlying disorder could not be quantified because of the variability in case definitions across studies.[3] Although there are history and physical examination factors that can determine lower or higher risk, it is clear that the term ALTE must be replaced to advance the quality of care and improve research.

This guideline is intended for use primarily by clinicians providing care for infants who have experienced a BRUE, as well as their families. The guideline may be of interest to payers, but it is not intended to be used for reimbursement or to determine insurance coverage. This guideline is not intended as the sole source of guidance in the evaluation and management of BRUEs and specifically does not address higher-risk BRUE patients. Rather, it is intended to assist clinicians by providing a framework for clinical decision making. It is not intended to replace clinical judgment, and these recommendations may not provide the only appropriate approach to the management of this problem.

This guideline is intended to provide a patient- and family-centered approach to care, reduce unnecessary and costly medical interventions, and improve patient outcomes. It includes recommendations for diagnosis, risk-based stratification, monitoring, disposition planning, effective communication with the patient and family, guideline implementation and evaluation, and future research. In addition, it aims to help clinicians determine the presence of a serious underlying cause and a safe disposition by alerting them to the most significant features of the clinical history and physical examination on which to base an approach for diagnostic testing and hospitalization. Key action statements are summarized in Table 1.

SUBCOMMITTEE ON BRIEF RESOLVED UNEXPLAINED EVENTS (FORMERLY REFERRED TO AS APPARENT LIFE THREATENING EVENTS); OVERSIGHT BY THE COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY

Joel S. Tieder, MD, MPH, FAAP, Chair
Joshua L. Bonkowsky, MD, PhD, FAAP, Pediatric Neurologist
Ruth A. Etzel, MD, PhD, FAAP, Pediatric Epidemiologist
Wayne H. Franklin, MD, MPH, MMM, FAAP, Pediatric Cardiologist
David A. Gremse, MD, FAAP, Pediatric Gastroenterologist
Bruce Herman, MD, FAAP, Child Abuse and Neglect
Eliot Katz, MD, FAAP, Pediatric Pulmonologist
Leonard R. Krilov, MD, FAAP, Pediatric Infectious Diseases
J. Lawrence Merritt, II, MD, FAAP, Clinical Genetics and Biochemical Genetics
Chuck Norlin, MD, FAAP, Pediatrician
Robert E. Sapién, MD, MMM, FAAP, Pediatric Emergency Medicine
Richard Shiffman, MD, FAAP, Partnership for Policy Implementation Representative
Michael B.H. Smith, MB, FRCPCH, FAAP, Hospital Medicine

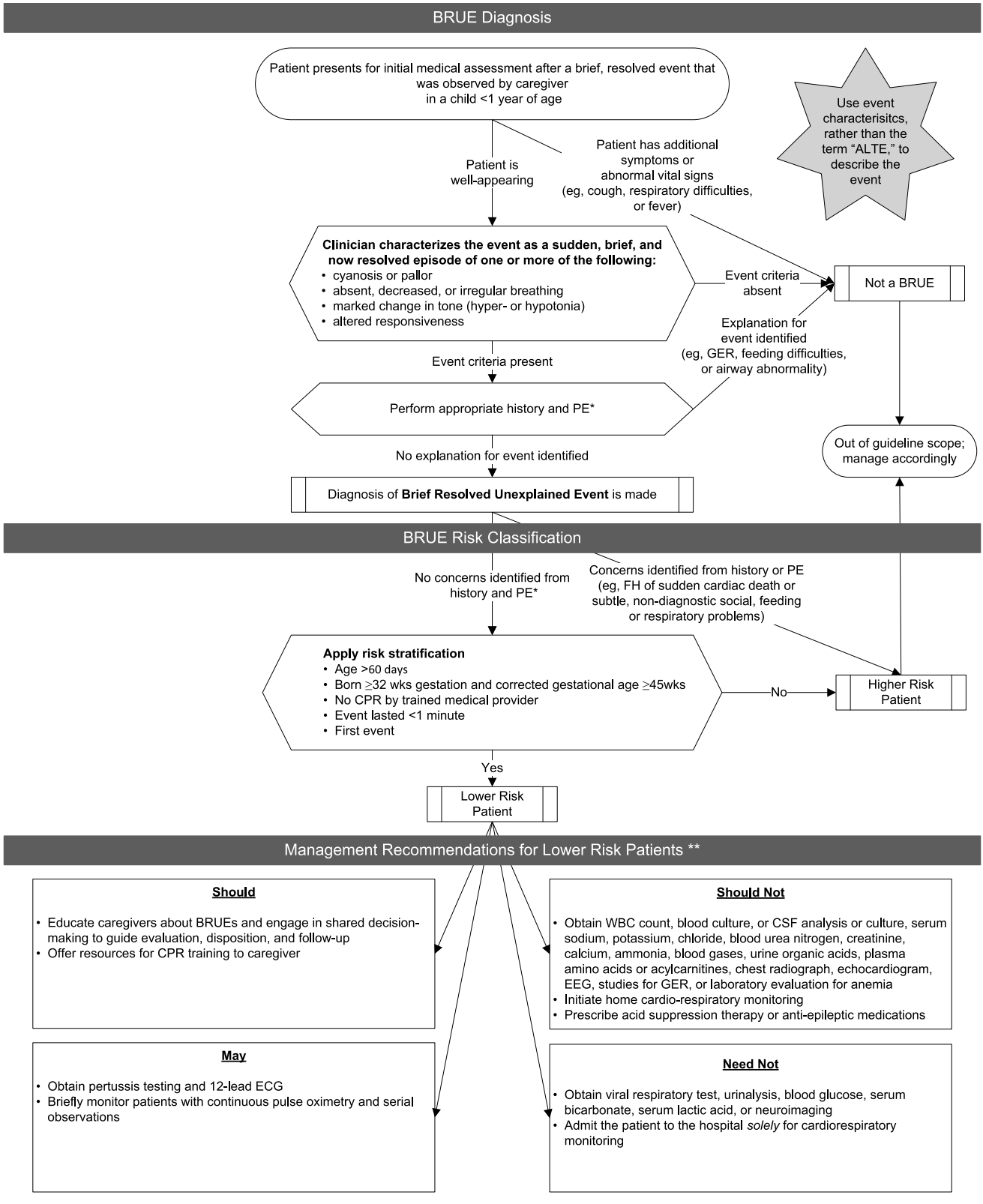


FIGURE 1

Diagnosis, risk classification, and recommended management of a BRUE. *Refer to Tables 3 and 4 in www.pediatrics.org/cgi/doi/10.1542/peds.2016-0591 for the determination of an appropriate and negative history and PE. **Refer to Figure 2 in www.pediatrics.org/cgi/doi/10.1542/peds.2016-0591 for the American Academy of Pediatrics method for rating of evidence and recommendations. CPR, cardiopulmonary resuscitation; CSF, cerebrospinal fluid; ECG, electrocardiogram; FH, family history; GER, gastroesophageal reflux; PE, physical examination; WBC, white blood cell.

Figure 1, shown here, has been updated per the erratum at http://pediatrics.aappublications.org/content/138/2/e20161488.

TABLE 1 Summary of Key Action Statements for Lower-Risk BRUEs

When managing an infant who is >60 d and <1 y of age and who, on the basis of a thorough history and physical examination, meets criteria for having experienced a lower-risk BRUE, clinicians:	Evidence Quality; Strength of Recommendation
1. Cardiopulmonary Evaluation	
1A. Need not admit infants to the hospital solely for cardiorespiratory monitoring.	B; Weak
1B. May briefly monitor patients with continuous pulse oximetry and serial observations.	D; Weak
1C. Should not obtain chest radiograph.	B; Moderate
1D. Should not obtain a measurement of venous or arterial blood gas.	B; Moderate
1E. Should not obtain an overnight polysomnograph.	B; Moderate
1F. May obtain a 12-lead electrocardiogram.	C; Weak
1G. Should not obtain an echocardiogram.	C; Moderate
1H. Should not initiate home cardiorespiratory monitoring.	B; Moderate
2. Child Abuse Evaluation	
2A. Need not obtain neuroimaging (CT, MRI, or ultrasonography) to detect child abuse.	C; Weak
2B. Should obtain an assessment of social risk factors to detect child abuse.	C; Moderate
3. Neurologic Evaluation	
3A. Should not obtain neuroimaging (CT, MRI, or ultrasonography) to detect neurologic disorders.	C; Moderate
3B. Should not obtain an EEG to detect neurologic disorders.	C; Moderate
3C. Should not prescribe antiepileptic medications for potential neurologic disorders.	C; Moderate
4. Infectious Disease Evaluation	
4A. Should not obtain a WBC count, blood culture, or cerebrospinal fluid analysis or culture to detect an occult bacterial infection.	B; Strong
4B. Need not obtain a urinalysis (bag or catheter).	C; Weak
4C. Should not obtain chest radiograph to assess for pulmonary infection.	B; Moderate
4D. Need not obtain respiratory viral testing if rapid testing is available.	C; Weak
4E. May obtain testing for pertussis.	B; Weak
5. Gastrointestinal Evaluation	
5A. Should not obtain investigations for GER (eg, upper gastrointestinal tract series, pH probe, endoscopy, barium contrast study, nuclear scintigraphy, and ultrasonography).	C; Moderate
5B. Should not prescribe acid suppression therapy.	C; Moderate
6. Inborn Error of Metabolism Evaluation	
6A. Need not obtain measurement of serum lactic acid or serum bicarbonate.	C; Weak
6B. Should not obtain a measurement of serum sodium, potassium, chloride, blood urea nitrogen, creatinine, calcium, or ammonia.	C; Moderate
6C. Should not obtain a measurement of venous or arterial blood gases.	C; Moderate
6D. Need not obtain a measurement of blood glucose.	C; Weak
6E. Should not obtain measurements of urine organic acids, plasma amino acids, or plasma acylcarnitines.	C; Moderate
7. Anemia Evaluation	
7A. Should not obtain laboratory evaluation for anemia.	C; Moderate
8. Patient- and Family-Centered Care	
8A. Should offer resources for CPR training to caregiver.	C; Moderate
8B. Should educate caregivers about BRUEs.	C; Moderate
8C. Should use shared decision making.	C; Moderate

CPR, cardiopulmonary resuscitation; CT, computed tomography; GER, gastroesophageal reflux; WBC, white blood cell.

Jack Percelay, MD, MPH, FAAP, Liaison, Society for Hospital Medicine

STAFF

Kymika Okechukwu, MPA

ABBREVIATIONS

ALTE: apparent life-threatening event
BRUE: brief resolved unexplained event
SIDS: sudden infant death syndrome

REFERENCES

1. National Institutes of Health Consensus Development Conference on Infantile Apnea and Home Monitoring, Sept 29 to Oct 1, 1986. *Pediatrics*. 1987;79(2). Available at: www.pediatrics.org/cgi/content/full/79/2/e292
2. McGovern MC, Smith MB. Causes of apparent life threatening events in infants: a systematic review. *Arch Dis Child*. 2004;89(11):1043–1048
3. Tieder JS, Altman RL, Bonkowsky JL, et al Management of apparent life-threatening events in infants: a systematic review. *J Pediatr*. 2013;163(1):94–99, e91–e96
4. Brand DA, Altman RL, Purtill K, Edwards KS. Yield of diagnostic testing in infants who have had an apparent life-threatening event. *Pediatrics*. 2005;115(4). Available at: www.pediatrics.org/cgi/content/full/115/4/e885
5. Green M. Vulnerable child syndrome and its variants. *Pediatr Rev*. 1986; 8(3):75–80

Brief Resolved Unexplained Events Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — Brief Resolved Unexplained Events (Formerly Apparent Life-Threatening Events) and Evaluation of Lower-Risk Infants
- *ICD-10-CM* Coding Quick Reference for Brief Resolved Unexplained Events
- AAP Patient Education Handout
  — *Brief Resolved Unexplained Event: What Parents and Caregivers Need to Know*

Action Statement Summary

Brief Resolved Unexplained Events (Formerly Apparent Life-Threatening Events) and Evaluation of Lower-Risk Infants

Key Action Statement 1

Cardiopulmonary

Key Action Statement 1A

Clinicians need not admit infants presenting with a lower-risk BRUE to the hospital solely for cardiorespiratory monitoring (grade B, weak recommendation)

Key Action Statement 1B

Clinicians may briefly monitor infants presenting with a lower-risk BRUE with continuous pulse oximetry and serial observations (grade D, weak recommendation)

Key Action Statement 1C

Clinicians should not obtain a chest radiograph in infants presenting with a lower-risk BRUE (grade B, moderate recommendation)

Key Action Statement 1D

Clinicians should not obtain measurement of venous or arterial blood gases in infants presenting with a lower-risk BRUE (grade B, moderate recommendation)

Key Action Statement 1E

Clinicians should not obtain an overnight polysomnograph in infants presenting with a lower-risk BRUE (grade B, moderate recommendation)

Key Action Statement 1F

Clinicians may obtain a 12-lead electrocardiogram for infants presenting with lower-risk BRUE (grade C, weak recommendation)

Key Action Statement 1G

Clinicians should not obtain an echocardiogram in infants presenting with lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 1H

Clinicians should not initiate home cardiorespiratory monitoring in infants presenting with a lower-risk BRUE (grade B, moderate recommendation)

Key Action Statement 2

Child abuse

Key Action Statement 2A

Clinicians need not obtain neuroimaging (computed tomography, MRI, or ultrasonography) to detect child abuse in infants presenting with a lower-risk BRUE (grade C, weak recommendation)

Key Action Statement 2B

Clinicians should obtain an assessment of social risk factors to detect child abuse in infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 3

Neurology

Key Action Statement 3A

Clinicians should not obtain neuroimaging (computed tomography, MRI, or ultrasonography) to detect neurologic disorders in infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 3B

Clinicians should not obtain an EEG to detect neurologic disorders in infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 3C

Clinicians should not prescribe antiepileptic medications for potential neurologic disorders in infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 4

Infectious diseases

Key Action Statement 4A

Clinicians should not obtain a white blood cell count, blood culture, or cerebrospinal fluid analysis or culture to detect an occult bacterial infection in infants presenting with a lower-risk BRUE (grade B, strong recommendation)

Key Action Statement 4B

Clinicians need not obtain a urinalysis (bag or catheter) in infants presenting with a lower-risk BRUE (grade C, weak recommendation)

Key Action Statement 4C

Clinicians should not obtain a chest radiograph to assess for pulmonary infection in infants presenting with a lower-risk BRUE (grade B, moderate recommendation)

Key Action Statement 4D

Clinicians need not obtain respiratory viral testing if rapid testing is available in infants presenting with a lower-risk BRUE (grade C, weak recommendation)

Key Action Statement 4E

Clinicians may obtain testing for pertussis in infants presenting with a lower-risk BRUE (grade B, weak recommendation)

Key Action Statement 5

Gastroenterology

Key Action Statement 5A

Clinicians should not obtain investigations for GER (eg, upper gastrointestinal series, pH probe, endoscopy, barium contrast study, nuclear scintigraphy, and ultrasonography) in infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 5B

Clinicians should not prescribe acid suppression therapy for infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 6

Inborn errors of metabolism

Key Action Statement 6A

Clinicians need not obtain measurement of serum lactic acid or serum bicarbonate to detect an IEM in infants presenting with a lower-risk BRUE (grade C, weak recommendation)

Key Action Statement 6B

Clinicians should not obtain a measurement of serum sodium, potassium, chloride, blood urea nitrogen, creatinine, calcium, or ammonia to detect an IEM in infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 6C

Clinicians should not obtain a measurement of venous or arterial blood gases to detect an IEM in infants presenting with lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 6D

Clinicians need not obtain a measurement of blood glucose to detect an IEM in infants presenting with a lower-risk BRUE (grade C, weak recommendation)

Key Action Statement 6E

Clinicians should not obtain measurements of urine organic acids, plasma amino acids, or plasma acylcarnitines to detect an IEM in infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 7

Anemia

Key Action Statement 7A

Clinicians should not obtain laboratory evaluation for anemia in infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Key Action Statement 8

Patient- and family-centered care

Key Action Statement 8A

Clinicians should offer resources for CPR training to caregivers (grade C, moderate recommendation)

Key Action Statement 8B

Clinicians should educate caregivers about BRUEs (grade C, moderate recommendation)

Key Action Statement 8C

Clinicians should use shared decision-making for infants presenting with a lower-risk BRUE (grade C, moderate recommendation)

Coding Quick Reference for Brief Resolved Unexplained Events
ICD-10-CM
R68.13 Apparent life threatening event (ALTE) in infant (includes brief resolved unexplained events [BRUE])

Brief Resolved Unexplained Event:
What Parents and Caregivers Need to Know

What is a brief resolved unexplained event?

A **b**rief **r**esolved **u**nexplained **e**vent (or BRUE for short) occurs suddenly and can be scary for parents and caregivers. A brief resolved unexplained event is a diagnosis made after your baby's doctor or health care professional has examined your baby and determined that there was no known concerning cause for the event.

When a brief resolved unexplained event occurs, babies may seem to stop breathing, their skin color may change to pale or blue, their muscles may relax or tighten, or they may seem to pass out. After a brief period of time, they recover (with or without any medical help) and are soon back to normal.

Though we can never say that a baby who has had a brief resolved unexplained event is at *no* risk for future problems, we can say that babies are at lower risk if

- They are older than 60 days.
- They were born on time (not premature).
- They did not need CPR (cardiopulmonary resuscitation) by a health care professional.
- The brief resolved unexplained event lasted less than 1 minute.
- This was their only such event.

Frequently asked questions after a brief resolved unexplained event

Q: Why did my baby have this event?

A: Your baby's doctor was unable to find a cause based on the results of your baby's examination and cannot tell you why this event happened. If it happens again or your baby develops additional problems, contact your baby's doctor or health care professional. The doctor may decide to have your baby return for another visit.

Q: Should my baby stay in the hospital?

A: Babies who are felt to be at lower risk by their doctors or health care professionals do not need to stay in the hospital. They are safe to go home without doing blood tests or imaging that uses x-rays, and they do not need home monitoring of their heart or lungs.

Q: Does having a brief resolved unexplained event increase my baby's risk for sudden infant death syndrome (SIDS)?

A: No—though the causes of SIDS are not known, events like these do not increase the risk of SIDS. For all babies, it is important to create a safe home and sleeping environment. Your baby should not be exposed to smoky environments. Visit **www.HealthyChildren.org/safesleep** to learn more about how to create a safe sleeping environment for your baby.

Q: What should I do if it happens again?

A: If you are worried that this new event is life threatening, call 911 or your local emergency numbers. If not, call your baby's doctor if you have any questions or worries and to let the doctor know about the event.

Q: Does my baby need extra care after having a brief resolved unexplained event? Is my baby more delicate or weak?

A: No special care is needed. Continue to love and care for your baby as you normally do.

A few important reminders for parents and caregivers of healthy infants

- Remember to take your baby to regular well-child visits to help keep your child healthy and safe.
- Though your baby is not more likely to need it, it is a good idea for everyone who cares for an infant to learn CPR. If you know CPR, you may also use it one day to help someone else in need. For classes near you, contact your child's doctor, the American Red Cross, the American Heart Association, or a national or local organization that offers training.

From your doctor

American Academy of Pediatrics

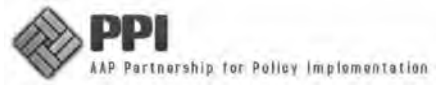
DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics (AAP) is an organization of 64,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of all infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site— www.HealthyChildren.org

The Diagnosis, Management, and Prevention of Bronchiolitis

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.



CLINICAL PRACTICE GUIDELINE

Clinical Practice Guideline: The Diagnosis, Management, and Prevention of Bronchiolitis

abstract

FREE

This guideline is a revision of the clinical practice guideline, "Diagnosis and Management of Bronchiolitis," published by the American Academy of Pediatrics in 2006. The guideline applies to children from 1 through 23 months of age. Other exclusions are noted. Each key action statement indicates level of evidence, benefit-harm relationship, and level of recommendation. Key action statements are as follows: *Pediatrics* 2014;134:e1474–e1502

DIAGNOSIS

1a. Clinicians should diagnose bronchiolitis and assess disease severity on the basis of history and physical examination (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

1b. Clinicians should assess risk factors for severe disease, such as age less than 12 weeks, a history of prematurity, underlying cardiopulmonary disease, or immunodeficiency, when making decisions about evaluation and management of children with bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

1c. When clinicians diagnose bronchiolitis on the basis of history and physical examination, radiographic or laboratory studies should not be obtained routinely (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

TREATMENT

2. Clinicians should not administer albuterol (or salbutamol) to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

3. Clinicians should not administer epinephrine to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

4a. Nebulized hypertonic saline should not be administered to infants with a diagnosis of bronchiolitis in the emergency department (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

4b. Clinicians may administer nebulized hypertonic saline to infants and children hospitalized for bronchiolitis (Evidence Quality: B; Recommendation Strength: Weak Recommendation [based on randomized controlled trials with inconsistent findings]).

Shawn L. Ralston, MD, FAAP, Allan S. Lieberthal, MD, FAAP, H. Cody Meissner, MD, FAAP, Brian K. Alverson, MD, FAAP, Jill E. Baley, MD, FAAP, Anne M. Gadomski, MD, MPH, FAAP, David W. Johnson, MD, FAAP, Michael J. Light, MD, FAAP, Nizar F. Maraqa, MD, FAAP, Eneida A. Mendonca, MD, PhD, FAAP, FACMI, Kieran J. Phelan, MD, MSc, Joseph J. Zorc, MD, MSCE, FAAP, Danette Stanko-Lopp, MA, MPH, Mark A. Brown, MD, Ian Nathanson, MD, FAAP, Elizabeth Rosenblum, MD, Stephen Sayles III, MD, FACEP, and Sinsi Hernandez-Cancio, JD

KEY WORDS

bronchiolitis, infants, children, respiratory syncytial virus, evidence-based, guideline

ABBREVIATIONS

AAP—American Academy of Pediatrics
AOM—acute otitis media
CI—confidence interval
ED—emergency department
KAS—Key Action Statement
LOS—length of stay
MD—mean difference
PCR—polymerase chain reaction
RSV—respiratory syncytial virus
SBI—serious bacterial infection

Dedicated to the memory of Dr Caroline Breese Hall.

www.pediatrics.org/cgi/doi/10.1542/peds.2014-2742

doi:10.1542/peds.2014-2742

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

5. Clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting (Evidence Quality: A; Recommendation Strength: Strong Recommendation).

6a. Clinicians may choose not to administer supplemental oxygen if the oxyhemoglobin saturation exceeds 90% in infants and children with a diagnosis of bronchiolitis (Evidence Quality: D; Recommendation Strength: Weak Recommendation [based on low level evidence and reasoning from first principles]).

6b. Clinicians may choose not to use continuous pulse oximetry for infants and children with a diagnosis of bronchiolitis (Evidence Quality: D; Recommendation Strength: Weak Recommendation [based on low-level evidence and reasoning from first principles]).

7. Clinicians should not use chest physiotherapy for infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

8. Clinicians should not administer antibacterial medications to infants and children with a diagnosis of bronchiolitis unless there is a concomitant bacterial infection, or a strong suspicion of one (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

9. Clinicians should administer nasogastric or intravenous fluids for infants with a diagnosis of bronchiolitis who cannot maintain hydration orally (Evidence Quality: X; Recommendation Strength: Strong Recommendation).

PREVENTION

10a. Clinicians should not administer palivizumab to otherwise healthy infants with a gestational age of 29 weeks, 0 days or greater (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

10b. Clinicians should administer palivizumab during the first year of life to infants with hemodynamically significant heart disease or chronic lung disease of prematurity defined as preterm infants <32 weeks 0 days' gestation who require >21% oxygen for at least the first 28 days of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

10c. Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the respiratory syncytial virus season to infants who qualify for palivizumab in the first year of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

11a. All people should disinfect hands before and after direct contact with patients, after contact with inanimate objects in the direct vicinity of the patient, and after removing gloves (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

11b. All people should use alcohol-based rubs for hand decontamination when caring for children with bronchiolitis. When alcohol-based rubs are not available, individuals should wash their hands with soap and water (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

12a. Clinicians should inquire about the exposure of the infant or child to tobacco smoke when assessing infants and children for bronchiolitis (Evidence Quality: C; Recommendation Strength: Moderate Recommendation).

12b. Clinicians should counsel caregivers about exposing the infant or child to environmental tobacco smoke and smoking cessation when assessing a child for bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong).

13. Clinicians should encourage exclusive breastfeeding for at least 6 months to decrease the morbidity of respiratory infections. (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

14. Clinicians and nurses should educate personnel and family members on evidence-based diagnosis, treatment, and prevention in bronchiolitis. (Evidence Quality: C; observational studies; Recommendation Strength: Moderate Recommendation).

INTRODUCTION

In October 2006, the American Academy of Pediatrics (AAP) published the clinical practice guideline "Diagnosis and Management of Bronchiolitis."[1] The guideline offered recommendations ranked according to level of evidence and the benefit-harm relationship. Since completion of the original evidence review in July 2004, a significant body of literature on bronchiolitis has been published. This update of the 2006 AAP bronchiolitis guideline evaluates published evidence, including that used in the 2006 guideline as well as evidence published since 2004. Key action statements (KASs) based on that evidence are provided.

The goal of this guideline is to provide an evidence-based approach to the diagnosis, management, and prevention of bronchiolitis in children from 1 month through 23 months of age. The guideline is intended for pediatricians, family physicians, emergency medicine specialists, hospitalists, nurse practitioners,

and physician assistants who care for these children. The guideline does not apply to children with immunodeficiencies, including those with HIV infection or recipients of solid organ or hematopoietic stem cell transplants. Children with underlying respiratory illnesses, such as recurrent wheezing, chronic neonatal lung disease (also known as bronchopulmonary dysplasia), neuromuscular disease, or cystic fibrosis and those with hemodynamically significant congenital heart disease are excluded from the sections on management unless otherwise noted but are included in the discussion of prevention. This guideline will not address long-term sequelae of bronchiolitis, such as recurrent wheezing or risk of asthma, which is a field with a large and distinct literature.

Bronchiolitis is a disorder commonly caused by viral lower respiratory tract infection in infants. Bronchiolitis is characterized by acute inflammation, edema, and necrosis of epithelial cells lining small airways, and increased mucus production. Signs and symptoms typically begin with rhinitis and cough, which may progress to tachypnea, wheezing, rales, use of accessory muscles, and/or nasal flaring.[2]

Many viruses that infect the respiratory system cause a similar constellation of signs and symptoms. The most common etiology of bronchiolitis is respiratory syncytial virus (RSV), with the highest incidence of infection occurring between December and March in North America; however, regional variations occur[3] (Fig 1).[4] Ninety percent of children are infected with RSV in the first 2 years of life,[5] and up to 40% will experience lower respiratory tract infection during the initial infection.[6,7] Infection with RSV does not grant permanent or long-term immunity, with reinfections common throughout life.[8] Other viruses that cause bronchiolitis include human rhinovirus, human metapneumovirus, influenza, adenovirus, coronavirus, human, and parainfluenza viruses. In a study of inpatients and outpatients with bronchiolitis,[9] 76% of patients had RSV, 39% had human rhinovirus, 10% had influenza, 2% had coronavirus, 3% had human metapneumovirus, and 1% had parainfluenza viruses (some patients had coinfections, so the total is greater than 100%).

Bronchiolitis is the most common cause of hospitalization among infants during the first 12 months of life. Approximately 100 000 bronchiolitis admissions occur annually in the United States at an estimated cost of $1.73 billion.[10] One prospective, population-based study sponsored by the Centers for Disease Control and Prevention reported the average RSV hospitalization rate was 5.2 per 1000 children younger than 24 months of age during the 5-year period between 2000 and 2005.[11] The highest age-specific rate of RSV hospitalization occurred among infants between 30 days and 60 days of age (25.9 per 1000 children). For preterm infants (<37 weeks' gestation), the RSV hospitalization rate was 4.6 per 1000 children, a number similar to the RSV hospitalization rate for term infants of 5.2 per 1000. Infants born at <30 weeks' gestation had the highest hospitalization rate at 18.7 children per 1000, although the small number of infants born before 30 weeks' gestation make this number unreliable. Other studies indicate the RSV hospitalization rate in extremely

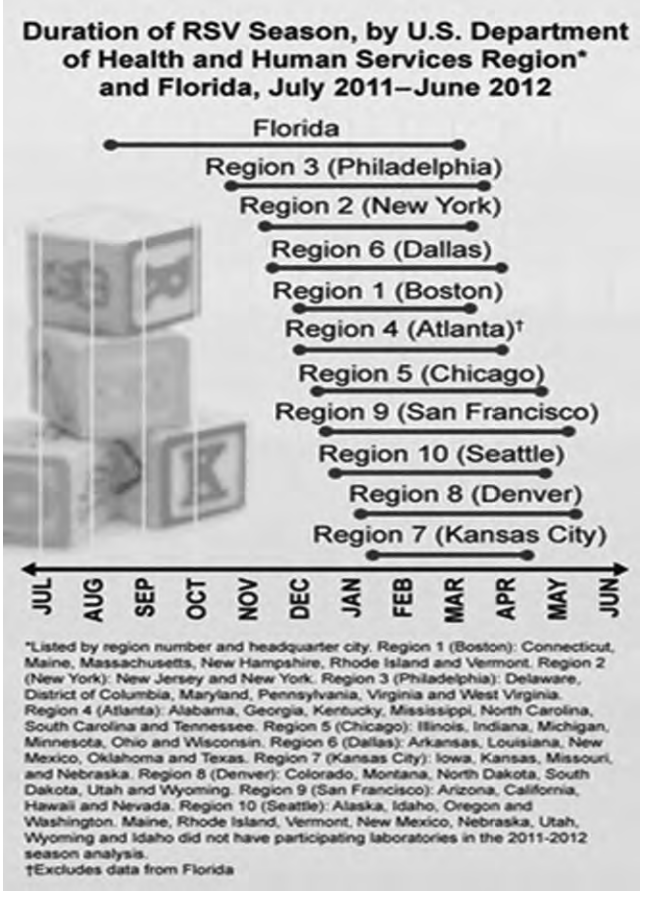


FIGURE 1
RSV season by US regions. Centers for Disease Control and Prevention. RSV activity—United States, July 2011–Jan 2013. *MMWR Morb Mortal Wkly Rep.* 2013;62(8):141–144.

preterm infants is similar to that of term infants.[12,13]

METHODS

In June 2013, the AAP convened a new subcommittee to review and revise the 2006 bronchiolitis guideline. The subcommittee included primary care physicians, including general pediatricians, a family physician, and pediatric subspecialists, including hospitalists, pulmonologists, emergency physicians, a neonatologist, and pediatric infectious disease physicians. The subcommittee also included an epidemiologist trained in systematic reviews, a guideline methodologist/informatician, and a parent representative. All panel members reviewed the AAP Policy on Conflict of Interest and Voluntary Disclosure and were given an opportunity to declare any potential conflicts. Any conflicts can be found in the author listing at the end of this guideline. All funding was provided by the AAP, with travel assistance from the American Academy of Family Physicians, the American College of Chest Physicians, the American Thoracic Society, and the American College of Emergency Physicians for their liaisons.

The evidence search and review included electronic database searches in *The Cochrane Library*, Medline via Ovid, and CINAHL via EBSCO. The search strategy is shown in the Appendix. Related article searches were conducted in PubMed. The bibliographies of articles identified by database searches were also reviewed by 1 of 4 members of the committee, and references identified in this manner were added to the review. Articles included in the 2003 evidence report on bronchiolitis in preparation of the AAP 2006 guideline2 also were reviewed. In addition, the committee reviewed articles published after completion of the systematic review for these updated guidelines. The current literature review encompasses the period from 2004 through May 2014.

The evidence-based approach to guideline development requires that the evidence in support of a policy be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement "Classifying Recommendations for Clinical Practice"[14] was followed in designating levels of recommendation (Fig 2; Table 1).

A draft version of this clinical practice guideline underwent extensive peer review by committees, councils, and sections within AAP; the American Thoracic Society, American College of Chest Physicians, American Academy of Family Physicians, and American College of Emergency Physicians; other outside organizations; and other individuals identified by the subcommittee as experts in the field. The resulting comments were reviewed by the subcommittee and, when appropriate, incorporated into the guideline.

This clinical practice guideline is not intended as a sole source of guidance in the management of children with bronchiolitis. Rather, it is intended to assist clinicians in decision-making. It is not intended to replace clinical judgment or establish a protocol for the care of all children with bronchiolitis. These recommendations may not provide the only appropriate approach to the management of children with bronchiolitis.

All AAP guidelines are reviewed every 5 years.

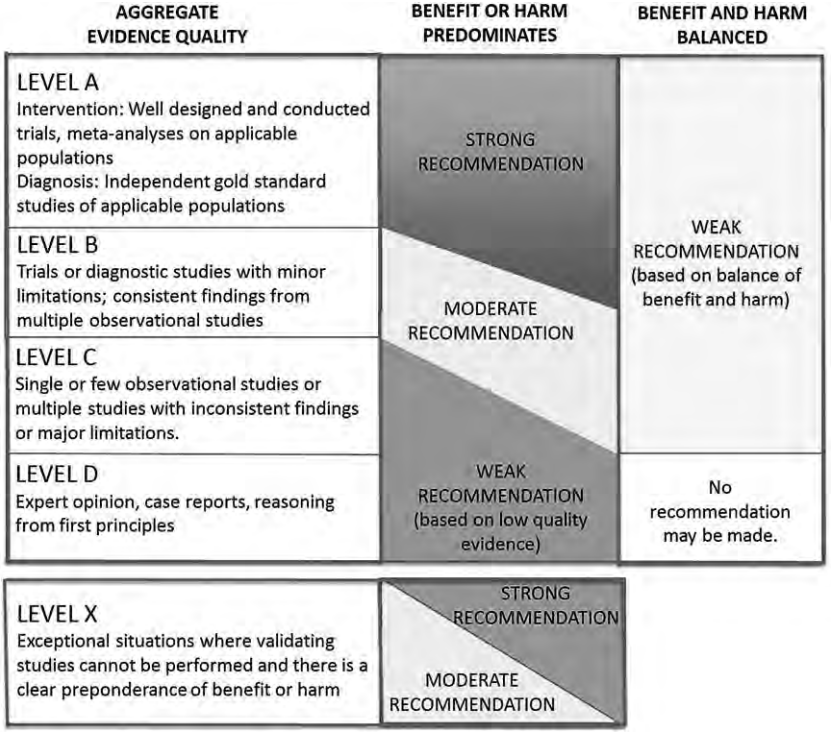


FIGURE 2
Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms leads to designation of a policy as a strong recommendation, moderate recommendation, or weak recommendation.

TABLE 1 Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), and quality of evidence is excellent or unobtainable.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Moderate recommendation	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), and the quality of evidence is good but not excellent (or is unobtainable).	Clinicians would be prudent to follow a moderate recommendation but should remain alert to new information and sensitive to patient preferences.
Weak recommendation (based on low-quality evidence	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), but the quality of evidence is weak.	Clinicians would be prudent to follow a weak recommendation but should remain alert to new information and very sensitive to patient preferences.
Weak recommendation (based on balance of benefits and harms)	Weak recommendation is provided when the aggregate database shows evidence of both benefit and harm that appear similar in magnitude for any available courses of action	Clinicians should consider the options in their decision making, but patient preference may have a substantial role.

DIAGNOSIS

Key Action Statement 1a

Clinicians should diagnose bronchiolitis and assess disease severity on the basis of history and physical examination (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 1a

Aggregate evidence quality	B
Benefits	Inexpensive, noninvasive, accurate
Risk, harm, cost	Missing other diagnoses
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Key Action Statement 1b

Clinicians should assess risk factors for severe disease, such as age <12 weeks, a history of prematurity, underlying cardiopulmonary disease, or immunodeficiency, when making decisions about evaluation and management of children with bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 1b

Aggregate evidence quality	B
Benefits	Improved ability to predict course of illness, appropriate disposition
Risk, harm, cost	Possible unnecessary hospitalization parental anxiety
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	"Assess" is not defined
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Key Action Statement 1c

When clinicians diagnose bronchiolitis on the basis of history and physical examination, radiographic or laboratory studies should not be obtained routinely (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 1b

Aggregate evidence quality	B
Benefits	Decreased radiation exposure, noninvasive (less procedure-associated discomfort), decreased antibiotic use, cost savings, time saving
Risk, harm, cost	Misdiagnosis, missed diagnosis of comorbid condition
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Infants and children with unexpected worsening disease
Strength	Moderate recommendation
Differences of opinion	None

The main goals in the history and physical examination of infants presenting with wheeze or other lower respiratory tract symptoms, particularly in the winter season, is to differentiate infants with probable viral bronchiolitis from those with other disorders. In addition, an estimate of disease severity (increased respiratory rate, retractions, decreased oxygen saturation) should

be made. Most clinicians recognize bronchiolitis as a constellation of clinical signs and symptoms occurring in children younger than 2 years, including a viral upper respiratory tract prodrome followed by increased respiratory effort and wheezing. Clinical signs and symptoms of bronchiolitis consist of rhinorrhea, cough, tachypnea, wheezing, rales, and increased respiratory effort manifested as grunting, nasal flaring, and intercostal and/or subcostal retractions.

The course of bronchiolitis is variable and dynamic, ranging from transient events, such as apnea, to progressive respiratory distress from lower airway obstruction. Important issues to assess in the history include the effects of respiratory symptoms on mental status, feeding, and hydration. The clinician should assess the ability of the family to care for the child and to return for further evaluation if needed. History of underlying conditions, such as prematurity, cardiac disease, chronic pulmonary disease, immunodeficiency, or episodes of previous wheezing, should be identified. Underlying conditions that may be associated with an increased risk of progression to severe disease or mortality include hemodynamically significant congenital heart disease, chronic lung disease (bronchopulmonary dysplasia), congenital anomalies,[15–17] in utero smoke exposure,[18] and the presence of an immunocompromising state.[19,20] In addition, genetic abnormalities have been associated with more severe presentation with bronchiolitis.[21]

Assessment of a child with bronchiolitis, including the physical examination, can be complicated by variability in the disease state and may require serial observations over time to fully assess the child's status. Upper airway obstruction contributes to work of breathing. Suctioning and positioning may decrease the work of breathing and improve the quality of the examination. Respiratory rate in otherwise healthy children changes considerably over the first year of life.[22–25] In hospitalized children, the 50th percentile for respiratory rate decreased from 41 at 0 to 3 months of age to 31 at 12 to 18 months of age.[26] Counting respiratory rate over the course of 1 minute is more accurate than shorter observations.[27] The presence of a normal respiratory rate suggests that risk of significant viral or bacterial lower respiratory tract infection or pneumonia in an infant is low (negative likelihood ratio approximately 0.5),[27–29] but the presence of tachypnea does not distinguish between viral and bacterial disease.[30,31]

The evidence relating the presence of specific findings in the assessment of bronchiolitis to clinical outcomes is limited. Most studies addressing this issue have enrolled children when presenting to hospital settings, including a large, prospective, multicenter study that assessed a variety of outcomes from the emergency department (ED) and varied inpatient settings.[18,32,33] Severe adverse events, such as ICU admission and need for mechanical ventilation, are uncommon among children with bronchiolitis and limit the power of these studies to detect clinically important risk factors associated with disease progression.[16,34,35] Tachypnea, defined as a respiratory rate $\geq$70 per minute, has been associated with increased risk of severe disease in some studies[35–37] but not others.[38] Many scoring systems have been developed in an attempt to objectively quantify respiratory distress, although none has achieved widespread acceptance and few have demonstrated any predictive validity, likely because of the substantial temporal variability in physical findings in infants with bronchiolitis.[39]

Pulse oximetry has been rapidly adopted into clinical assessment of children with bronchiolitis on the basis of data suggesting that it reliably detects hypoxemia not suspected on physical examination[36,40]; however, few studies have assessed the effectiveness of pulse oximetry to predict clinical outcomes. Among inpatients, perceived need for supplemental oxygen on the basis of pulse oximetry has been associated with prolonged hospitalization, ICU admission, and mechanical ventilation.[16,34,41] Among outpatients, available evidence differs on whether mild reductions in pulse oximetry (<95% on room air) predict progression of disease or need for a return observational visit.[38]

Apnea has been reported to occur with a wide range of prevalence estimates and viral etiologies.[42,43] Retrospective, hospital-based studies have included a high proportion of infants with risk factors, such as prematurity or neuromuscular disease, that may have biased the prevalence estimates. One large study found no apnea events for infants assessed as low risk by using several risk factors: age >1 month for full-term infants or 48 weeks' postconceptional age for preterm infants, and absence of any previous apneic event at presentation to the hospital.[44] Another large multicenter study found no association between the specific viral agent and risk of apnea in bronchiolitis.[42]

The literature on viral testing for bronchiolitis has expanded in recent years with the availability of sensitive polymerase chain reaction (PCR) assays. Large studies of infants hospitalized for bronchiolitis have consistently found that 60% to 75% have positive test results for RSV, and have noted coinfections in up to one-third of infants.[32,33,45] In the event an infant receiving monthly prophylaxis is hospitalized with bronchiolitis, testing should be performed to determine if RSV is the etiologic agent. If a breakthrough RSV infection is determined to be present based on antigen detection or other

assay, monthly palivizumab prophylaxis should be discontinued because of the very low likelihood of a second RSV infection in the same year. Apart from this setting, routine virologic testing is not recommended.

Infants with non-RSV bronchiolitis, in particular human rhinovirus, appear to have a shorter courses and may represent a different phenotype associated with repeated wheezing.[32] PCR assay results should be interpreted cautiously, given that the assay may detect prolonged viral shedding from an unrelated previous illness, particularly with rhinovirus. In contrast, RSV detected by PCR assay almost always is associated with disease. At the individual patient level, the value of identifying a specific viral etiology causing bronchiolitis has not been demonstrated.[33]

Current evidence does not support routine chest radiography in children with bronchiolitis. Although many infants with bronchiolitis have abnormalities on chest radiography, data are insufficient to demonstrate that chest radiography correlates well with disease severity. Atelectasis on chest radiography was associated with increased risk of severe disease in 1 outpatient study.[16] Further studies, including 1 randomized trial, suggest children with suspected lower respiratory tract infection who had radiography performed were more likely to receive antibiotics without any difference in outcomes.[46,47] Initial radiography should be reserved for cases in which respiratory effort is severe enough to warrant ICU admission or where signs of an airway complication (such as pneumothorax) are present.

TREATMENT

ALBUTEROL

Key Action Statement 2

Clinicians should not administer albuterol (or salbutamol) to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 2

Aggregate evidence quality	B
Benefits	Avoid adverse effects, avoid ongoing use of ineffective medication, lower costs
Risk, harm, cost	Missing transient benefit of drug
Benefit-harm assessment	Benefits outweigh harms
Value judgments	Overall ineffectiveness outweighs possible transient benefit
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None
Notes	This guideline no longer recommends a trial of albuterol, as was considered in the 2006 AAP bronchiolitis guideline

Although several studies and reviews have evaluated the use of bronchodilator medications for viral bronchiolitis, most randomized controlled trials have failed to demonstrate a consistent benefit from α- or β-adrenergic agents. Several meta-analyses and systematic reviews[48–53] have shown that bronchodilators may improve clinical symptom scores, but they do not affect disease resolution, need for hospitalization, or length of stay (LOS). Because clinical scores may vary from one observer to the next[39,54] and do not correlate with more objective measures, such as pulmonary function tests,[55] clinical scores are not validated measures of the efficacy of bronchodilators. Although transient improvements in clinical score have been observed, most infants treated with bronchodilators will not benefit from their use.

A recently updated Cochrane systematic review assessing the impact of bronchodilators on oxygen saturation, the primary outcome measure, reported 30 randomized controlled trials involving 1992 infants in 12 countries.[56] Some studies included in this review evaluated agents other than albuterol/salbutamol (eg, ipratropium and metaproterenol) but did not include epinephrine. Small sample sizes, lack of standardized methods for outcome evaluation (eg, timing of assessments), and lack of standardized intervention (various bronchodilators, drug dosages, routes of administration, and nebulization delivery systems) limit the interpretation of these studies. Because of variable study designs as well as the inclusion of infants who had a history of previous wheezing in some studies, there was considerable heterogeneity in the studies. Sensitivity analysis (ie, including only studies at low risk of bias) significantly reduced heterogeneity measures for oximetry while having little effect on the overall effect size of oximetry (mean difference [MD] −0.38, 95% confidence interval [CI] −0.75 to 0.00). Those studies showing benefit[57–59] are methodologically weaker than other studies and include older children with recurrent wheezing. Results of the Cochrane review indicated no benefit in the clinical course of infants with bronchiolitis who received bronchodilators. The potential adverse effects (tachycardia and tremors) and cost of these agents outweigh any potential benefits.

In the previous iteration of this guideline, a trial of β-agonists was included as an option. However, given the greater strength of the evidence demonstrating no benefit, and that there is no well-established way to determine an "objective method of response" to bronchodilators in bronchiolitis, this option has been removed. Although it is true that a small subset of children

with bronchiolitis may have reversible airway obstruction resulting from smooth muscle constriction, attempts to define a subgroup of responders have not been successful to date. If a clinical trial of bronchodilators is undertaken, clinicians should note that the variability of the disease process, the host's airway, and the clinical assessments, particularly scoring, would limit the clinician's ability to observe a clinically relevant response to bronchodilators.

Chavasse et al[60] reviewed the available literature on use of β-agonists for children younger than 2 years with recurrent wheezing. At the time of that review, there were 3 studies in the outpatient setting, 2 in the ED, and 3 in the pulmonary function laboratory setting. This review concluded there were no clear benefits from the use of β-agonists in this population. The authors noted some conflicting evidence, but further study was recommended only if the population could be clearly defined and meaningful outcome measures could be identified.

The population of children with bronchiolitis studied in most trials of bronchodilators limits the ability to make recommendations for all clinical scenarios. Children with severe disease or with respiratory failure were generally excluded from these trials, and this evidence cannot be generalized to these situations. Studies using pulmonary function tests show no effect of albuterol among infants hospitalized with bronchiolitis.[56,61] One study in a critical care setting showed a small decrease in inspiratory resistance after albuterol in one group and levalbuterol in another group, but therapy was accompanied by clinically significant tachycardia.[62] This small clinical change occurring with significant adverse effects does not justify recommending albuterol for routine care.

EPINEPHRINE

Key Action Statement 3

Clinicians should not administer epinephrine to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 3

Aggregate evidence quality	B
Benefits	Avoiding adverse effects, lower costs, avoiding ongoing use of ineffective medication
Risk, harm, cost	Missing transient benefit of drug
Benefit-harm assessment	Benefits outweigh harms
Value judgments	The overall ineffectiveness outweighs possible transient benefit
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Rescue treatment of rapidly deteriorating patients
Strength	Strong recommendation
Differences of opinion	None

Epinephrine is an adrenergic agent with both β- and α-receptor agonist activity that has been used to treat upper and lower respiratory tract illnesses both as a systemic agent and directly into the respiratory tract, where it is typically administered as a nebulized solution. Nebulized epinephrine has been administered in the racemic form and as the purified L-enantiomer, which is commercially available in the United States for intravenous use. Studies in other diseases, such as croup, have found no difference in efficacy on the basis of preparation,[63] although the comparison has not been specifically studied for bronchiolitis. Most studies have compared L-epinephrine to placebo or albuterol. A recent Cochrane meta-analysis by Hartling et al[64] systematically evaluated the evidence on this topic and found no evidence for utility in the inpatient setting. Two large, multicenter randomized trials comparing nebulized epinephrine to placebo[65] or albuterol[66] in the hospital setting found no improvement in LOS or other inpatient outcomes. A recent, large multicenter trial found a similar lack of efficacy compared with placebo and further demonstrated longer LOS when epinephrine was used on a fixed schedule compared with an as-needed schedule.[67] This evidence suggests epinephrine should not be used in children hospitalized for bronchiolitis, except potentially as a rescue agent in severe disease, although formal study is needed before a recommendation for the use of epinephrine in this setting.

The role of epinephrine in the outpatient setting remains controversial. A major addition to the evidence base came from the Canadian Bronchiolitis Epinephrine Steroid Trial.[68] This multicenter randomized trial enrolled 800 patients with bronchiolitis from 8 EDs and compared hospitalization rates over a 7-day period. This study had 4 arms: nebulized epinephrine plus oral dexamethasone, nebulized epinephrine plus oral placebo, nebulized placebo plus oral dexamethasone, and nebulized placebo plus oral placebo. The group of patients who received epinephrine concomitantly with corticosteroids had a lower likelihood of hospitalization by day 7 than the double placebo group, although this effect was no longer statistically significant after adjusting for multiple comparisons.

The systematic review by Hartling et al[64] concluded that epinephrine reduced hospitalizations compared with placebo on the day of the ED visit but not overall. Given that epinephrine

has a transient effect and home administration is not routine practice, discharging an infant after observing a response in a monitored setting raises concerns for subsequent progression of illness. Studies have not found a difference in revisit rates, although the numbers of revisits are small and may not be adequately powered for this outcome. In summary, the current state of evidence does not support a routine role for epinephrine for bronchiolitis in outpatients, although further data may help to better define this question.

HYPERTONIC SALINE

Key Action Statement 4a

Nebulized hypertonic saline should not be administered to infants with a diagnosis of bronchiolitis in the emergency department (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 4a

Aggregate evidence quality	B
Benefits	Avoiding adverse effects, such as wheezing and excess secretions, cost
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Key Action Statement 4b

Clinicians may administer nebulized hypertonic saline to infants and children hospitalized for bronchiolitis (Evidence Quality: B; Recommendation Strength: Weak Recommendation [based on randomized controlled trials with inconsistent findings]).

Action Statement Profile KAS 4b

Aggregate evidence quality	B
Benefits	May shorten hospital stay if LOS is >72 h
Risk, harm, cost	Adverse effects such as wheezing and excess secretions; cost
Benefit-harm assessment	Benefits outweigh harms for longer hospital stays
Value judgments	Anticipating an individual child's LOS is difficult. Most US hospitals report an average LOS of <72 h for patients with bronchiolitis. This weak recommendation applies only if the average length of stay is >72 h
Intentional vagueness	This weak recommendation is based on an average LOS and does not address the individual patient.
Role of patient preferences	None
Exclusions	None
Strength	Weak
Differences of opinion	None

Nebulized hypertonic saline is an increasingly studied therapy for acute viral bronchiolitis. Physiologic evidence suggests that hypertonic saline increases mucociliary clearance in both normal and diseased lungs.[69–71] Because the pathology in bronchiolitis involves airway inflammation and resultant mucus plugging, improved mucociliary clearance should be beneficial, although there is only indirect evidence to support such an assertion. A more specific theoretical mechanism of action has been proposed on the basis of the concept of rehydration of the airway surface liquid, although again, evidence remains indirect.[72]

A 2013 Cochrane review[73] included 11 trials involving 1090 infants with mild to moderate disease in both inpatient and emergency settings. There were 6 studies involving 500 inpatients providing data for the analysis of LOS with an aggregate 1-day decrease reported, a result largely driven by the inclusion of 3 studies with relatively long mean length of stay of 5 to 6 days. The analysis of effect on clinical scores included 7 studies involving 640 patients in both inpatient and outpatient settings and demonstrated incremental positive effect with each day posttreatment from day 1 to day 3 (–0.88 MD on day 1, –1.32 MD on day 2, and –1.51 MD on day 3). Finally, Zhang et al[73] found no effect on hospitalization rates in the pooled analysis of 1 outpatient and 3 ED studies including 380 total patients.

Several randomized trials published after the Cochrane review period further informed the current guideline recommendation. Four trials evaluated admission rates from the ED, 3 using 3% saline and 1 using 7% saline.[74–76] A single trial[76] demonstrated a difference in admission rates from the ED favoring hypertonic saline, although the other 4 studies were concordant with the studies included in the Cochrane review. However, contrary to the studies included in the Cochrane review, none of the more recent trials reported improvement in LOS and, when added to the older studies for an updated meta-analysis, they significantly attenuate the summary estimate of the effect on LOS.[76,77] Most of the trials included in the Cochrane review occurred in settings with typical LOS of more than 3 days in their usual care arms. Hence, the significant decrease in LOS noted by Zhang et al[73] may not be generalizable to the United States where the average LOS is 2.4 days.[10] One other ongoing clinical trial performed in the United States, unpublished except in abstract form, further supports the observation that hypertonic saline does not decrease LOS in settings where expected stays are less than 3 days.[78]

The preponderance of the evidence suggests that 3% saline is safe and effective at improving symptoms of mild to moderate bronchiolitis after 24 hours of use and reducing hospital LOS in settings in which

the duration of stay typically exceeds 3 days. It has not been shown to be effective at reducing hospitalization in emergency settings or in areas where the length of usage is brief. It has not been studied in intensive care settings, and most trials have included only patients with mild to moderate disease. Most studies have used a 3% saline concentration, and most have combined it with bronchodilators with each dose; however, there is retrospective evidence that the rate of adverse events is similar without bronchodilators,[79] as well as prospective evidence extrapolated from 2 trials without bronchodilators.[79,80] A single study was performed in the ambulatory outpatient setting[81]; however, future studies in the United States should focus on sustained usage on the basis of pattern of effects discerned in the available literature.

CORTICOSTEROIDS

Key Action Statement 5

Clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting (Evidence Quality: A; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 5

Aggregate evidence quality	A
Benefits	No clinical benefit, avoiding adverse effects
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Although there is good evidence of benefit from corticosteroids in other respiratory diseases, such as asthma and croup,[82–84] the evidence on corticosteroid use in bronchiolitis is negative. The most recent Cochrane systematic review shows that corticosteroids do not significantly reduce outpatient admissions when compared with placebo (pooled risk ratio, 0.92; 95% CI, 0.78 to 1.08; and risk ratio, 0.86; 95% CI, 0.7 to 1.06, respectively) and do not reduce LOS for inpatients (MD –0.18 days; 95% CI –0.39 to 0.04).[85] No other comparisons showed relevant differences for either primary or secondary outcomes. This review contained 17 trials with 2596 participants and included 2 large ED-based randomized trials, neither of which showed reductions in hospital admissions with treatment with corticosteroids as compared with placebo.[69,86]

One of these large trials, the Canadian Bronchiolitis Epinephrine Steroid Trial, however, did show a reduction in hospitalizations 7 days after treatment with combined nebulized epinephrine and oral dexamethasone as compared with placebo.[69] Although an unadjusted analysis showed a relative risk for hospitalization of 0.65 (95% CI 0.45 to 0.95; $P = .02$) for combination therapy as compared with placebo, adjustment for multiple comparison rendered the result insignificant ($P = .07$). These results have generated considerable controversy.[87] Although there is no standard recognized rationale for why combination epinephrine and dexamethasone would be synergistic in infants with bronchiolitis, evidence in adults and children older than 6 years with asthma shows that adding inhaled long-acting β agonists to moderate/high doses of inhaled corticosteroids allows reduction of the corticosteroid dose by, on average, 60%.[88] Basic science studies focused on understanding the interaction between β agonists and corticosteroids have shown potential mechanisms for why simultaneous administration of these drugs could be synergistic.[89–92] However, other bronchiolitis trials of corticosteroids administered by using fixed simultaneous bronchodilator regimens have not consistently shown benefit[93–97]; hence, a recommendation regarding the benefit of combined dexamethasone and epinephrine therapy is premature.

The systematic review of corticosteroids in children with bronchiolitis cited previously did not find any differences in short-term adverse events as compared with placebo.[86] However, corticosteroid therapy may prolong viral shedding in patients with bronchiolitis.[17]

In summary, a comprehensive systematic review and large multicenter randomized trials provide clear evidence that corticosteroids alone do not provide significant benefit to children with bronchiolitis. Evidence for potential benefit of combined corticosteroid and agents with both α- and β-agonist activity is at best tentative, and additional large trials are needed to clarify whether this therapy is effective.

Further, although there is no evidence of short-term adverse effects from corticosteroid therapy, other than prolonged viral shedding, in infants and children with bronchiolitis, there is inadequate evidence to be certain of safety.

OXYGEN

Key Action Statement 6a

Clinicians may choose not to administer supplemental oxygen if the oxyhemoglobin saturation exceeds 90% in infants and children with a diagnosis of bronchiolitis (Evidence Quality: D; Recommendation Strength: Weak Recommendation [based on low-level evidence and reasoning from first principles]).

Action Statement Profile KAS 6a

Benefits	Decreased hospitalizations, decreased LOS
Risk, harm, cost	Hypoxemia, physiologic stress, prolonged LOS, increased hospitalizations, increased LOS, cost
Benefit-harm assessment	Benefits outweigh harms
Value judgments	Oxyhemoglobin saturation >89% is adequate to oxygenate tissues; the risk of hypoxemia with oxyhemoglobin saturation >89% is minimal
Intentional vagueness	None
Role of patient preferences	Limited
Exclusions	Children with acidosis or fever
Strength	Weak recommendation (based on low-level evidence/ reasoning from first principles)
Differences of opinion	None

Key Action Statement 6b

Clinicians may choose not to use continuous pulse oximetry for infants and children with a diagnosis of bronchiolitis (Evidence Quality: C; Recommendation Strength: Weak Recommendation [based on lower-level evidence]).

Action Statement Profile KAS 6b

Aggregate evidence quality	C
Benefits	Shorter LOS, decreased alarm fatigue, decreased cost
Risk, harm, cost	Delayed detection of hypoxemia, delay in appropriate weaning of oxygen
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Limited
Exclusions	None
Strength	Weak recommendation (based on lower level of evidence)
Differences of opinion	None

Although oxygen saturation is a poor predictor of respiratory distress, it is associated closely with a perceived need for hospitalization in infants with bronchiolitis.[98,99] Additionally, oxygen saturation has been implicated as a primary determinant of LOS in bronchiolitis.[40,100,101]

Physiologic data based on the oxyhemoglobin dissociation curve (Fig 3) demonstrate that small increases in arterial partial pressure of oxygen are associated with marked improvement in pulse oxygen saturation when the latter is less than 90%; with pulse oxygen saturation readings greater than 90% it takes very large elevations in arterial partial pressure of oxygen to affect further increases. In infants and children with bronchiolitis, no data exist to suggest such increases result in any clinically significant difference in physiologic function, patient symptoms, or clinical outcomes. Although it is well understood that acidosis, temperature, and 2,3-diphosphoglutarate influence the oxyhemoglobin dissociation curve, there has never been research to demonstrate how those influences practically affect infants with hypoxemia. The risk of hypoxemia must be weighed against the risk of hospitalization when making any decisions about site of care. One study of hospitalized children with bronchiolitis, for example, noted a 10% adverse error or near-miss rate for harm-causing interventions.[103] There are no studies on the effect of short-term, brief periods of hypoxemia such as may be seen in bronchiolitis. Transient hypoxemia is common in healthy infants.[104] Travel of healthy children even to moderate altitudes of 1300 m results in transient sleep desaturation to an average of 84% with no known adverse consequences.[105] Although children with chronic hypoxemia do incur developmental and behavioral problems, children who suffer intermittent hypoxemia from diseases such as asthma do not have impaired intellectual abilities or behavioral disturbance.[106–108]

Supplemental oxygen provided for infants not requiring additional respiratory support is best initiated with nasal prongs, although exact measurement of fraction of inspired oxygen is unreliable with this method.[109]

Pulse oximetry is a convenient method to assess the percentage of hemoglobin bound by oxygen in children. Pulse oximetry has been erroneously used in bronchiolitis as a proxy for respiratory distress. Accuracy of pulse oximetry is poor, especially in the 76% to 90% range.[110] Further, it has been well demonstrated that oxygen saturation has much less impact on respiratory drive than carbon dioxide concentrations in the blood.[111] There is very poor correlation between respiratory distress and oxygen saturations among infants with lower respiratory tract infections.[112] Other than cyanosis, no published clinical sign, model, or score accurately identifies hypoxemic children.[113]

Among children admitted for bronchiolitis, continuous pulse oximetry measurement is not well studied and potentially problematic for children who do not require oxygen. Transient desaturation is a normal phenomenon in healthy infants. In 1 study of 64 healthy infants between 2 weeks and 6 months of age, 60% of these infants exhibited a transient oxygen desaturation below 90%, to values as low as 83%.[105] A retrospective study of the role of continuous measurement of oxygenation in infants hospitalized with bronchiolitis found that 1 in 4 patients incur unnecessarily prolonged hospitalization as a result of a perceived need for oxygen outside of other symptoms[40] and no evidence of benefit was found.

Pulse oximetry is prone to errors of measurement. Families of infants hospitalized with continuous pulse oximeters are exposed to frequent alarms that

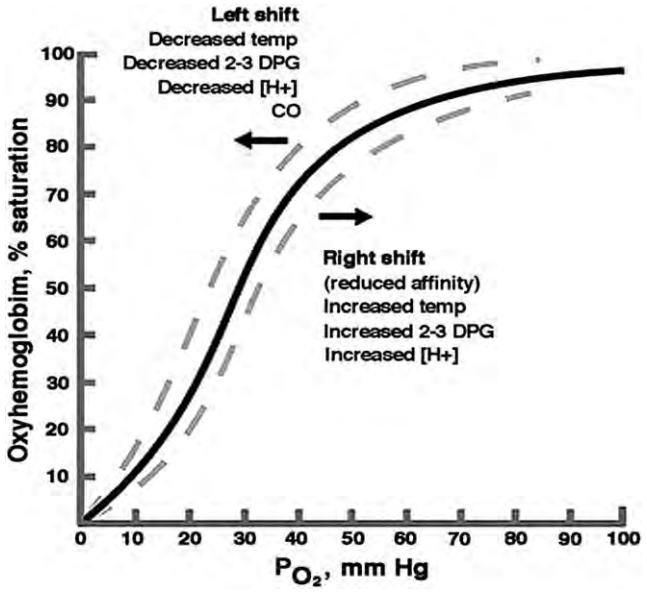


FIGURE 3
Oxyhemoglobin dissociation curve showing percent saturation of hemoglobin at various partial pressures of oxygen (reproduced with permission from the educational Web site www.anaesthesiauk.com).[102]

may negatively affect sleep. Alarm fatigue is recognized by The Joint Commission as a contributor toward in-hospital morbidity and mortality.[114] One adult study demonstrated very poor documentation of hypoxemia alerts by pulse oximetry, an indicator of alarm fatigue.[115] Pulse oximetry probes can fall off easily, leading to inaccurate measurements and alarms.[116] False reliance on pulse oximetry may lead to less careful monitoring of respiratory status. In one study, continuous pulse oximetry was associated with increased risk of minor adverse events in infants admitted to a general ward.[117] The pulse oximetry–monitored patients were found to have less-effective surveillance of their severity of illness when controlling for other variables.

There are a number of new approaches to oxygen delivery in bronchiolitis, 2 of which are home oxygen and high-frequency nasal cannula. There is emerging evidence for the role of home oxygen in reducing LOS or admission rate for infants with bronchiolitis, including 2 randomized trials.[118,119] Most of the studies have been performed in areas of higher altitude, where prolonged hypoxemia is a prime determinant of LOS in the hospital.[120,121] Readmission rates may be moderately higher in patients discharged with home oxygen; however, overall hospital use may be reduced,[122] although not in all settings.[123] Concerns have been raised that home pulse oximetry may complicate care or confuse families.[124] Communication with follow-up physicians is important, because primary care physicians may have difficulty determining safe pulse oximetry levels for discontinuation of oxygen.[125] Additionally, there may be an increased demand for follow-up outpatient visits associated with home oxygen use.[124]

Use of humidified, heated, high-flow nasal cannula to deliver air-oxygen mixtures provides assistance to infants with bronchiolitis through multiple proposed mechanisms.[126] There is evidence that high-flow nasal cannula improves physiologic measures of respiratory effort and can generate continuous positive airway pressure in bronchiolitis.[127–130] Clinical evidence suggests it reduces work of breathing[131,132] and may decrease need for intubation,[133–136] although studies are generally retrospective and small. The therapy has been studied in the ED[136,137] and the general inpatient setting,[134,138] as well as the ICU. The largest and most rigorous retrospective study to date was from Australia,[138] which showed a decline in intubation rate in the subgroup of infants with bronchiolitis (n = 330) from 37% to 7% after the introduction of high-flow nasal cannula, while the national registry intubation rate remained at 28%. A single pilot for a randomized trial has been published to date.[139] Although promising, the absence of any completed randomized trial of the efficacy of high-flow nasal cannula in bronchiolitis precludes specific recommendations on it use at present. Pneumothorax is a reported complication.

CHEST PHYSIOTHERAPY

Key Action Statement 7

Clinicians should not use chest physiotherapy for infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 7

Aggregate evidence quality	B
Benefits	Decreased stress from therapy, reduced cost
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Airway edema, sloughing of respiratory epithelium into airways, and generalized hyperinflation of the lungs, coupled with poorly developed collateral ventilation, put infants with bronchiolitis at risk for atelectasis. Although lobar atelectasis is not characteristic of this disease, chest radiographs may show evidence of subsegmental atelectasis, prompting clinicians to consider ordering chest physiotherapy to promote airway clearance. A Cochrane Review[140] found 9 randomized controlled trials that evaluated chest physiotherapy in hospitalized patients with bronchiolitis. No clinical benefit was found by using vibration or percussion (5 trials)[141–144] or passive expiratory techniques (4 trials).[145–148] Since that review, a study[149] of the passive expiratory technique found a small, but significant reduction in duration of oxygen therapy, but no other benefits.

Suctioning of the nasopharynx to remove secretions is a frequent practice in infants with bronchiolitis. Although suctioning the nares may provide temporary relief of nasal congestion or upper airway obstruction, a retrospective study reported that deep suctioning[150] was associated with longer LOS in hospitalized infants 2 to 12 months of age. The same study also noted that lapses of greater than 4 hours in noninvasive, external nasal suctioning were also associated with longer LOS. Currently, there are insufficient data to make a recommendation about suctioning, but it appears that routine use of "deep" suctioning[151,153] may not be beneficial.

ANTIBACTERIALS

Key Action Statement 8

Clinicians should not administer antibacterial medications to infants and children with a diagnosis of bronchiolitis unless there is a concomitant bacterial infection, or a strong suspicion of one. (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 8

Aggregate evidence quality	B
Benefits	Fewer adverse effects, less resistance to antibacterial agents, lower cost
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	Strong suspicion is not specifically defined and requires clinician judgment. An evaluation for the source of possible serious bacterial infection should be completed before antibiotic use
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Infants with bronchiolitis frequently receive antibacterial therapy because of fever,[152] young age,[153] and concern for secondary bacterial infection.[154] Early randomized controlled trials[155,156] showed no benefit from routine antibacterial therapy for children with bronchiolitis. Nonetheless, antibiotic therapy continues to be overused in young infants with bronchiolitis because of concern for an undetected bacterial infection. Studies have shown that febrile infants without an identifiable source of fever have a risk of bacteremia that may be as high as 7%. However, a child with a distinct viral syndrome, such as bronchiolitis, has a lower risk (much less than 1%) of bacterial infection of the cerebrospinal fluid or blood.[157]

Ralston et al[158] conducted a systematic review of serious bacterial infections (SBIs) occurring in hospitalized febrile infants between 30 and 90 days of age with bronchiolitis. Instances of bacteremia or meningitis were extremely rare. Enteritis was not evaluated. Urinary tract infection occurred at a rate of approximately 1%, but asymptomatic bacteriuria may have explained this finding. The authors concluded routine screening for SBI among hospitalized febrile infants with bronchiolitis between 30 and 90 days of age is not justified. Limited data suggest the risk of bacterial infection in hospitalized infants with bronchiolitis younger than 30 days of age is similar to the risk in older infants. An abnormal white blood cell count is not useful for predicting a concurrent SBI in infants and young children hospitalized with RSV lower respiratory tract infection.[159] Several retrospective studies support this conclusion.[160–166] Four prospective studies of SBI in patients with bronchiolitis and/or RSV infections also demonstrated low rates of SBI.[167–171]

Approximately 25% of hospitalized infants with bronchiolitis have radiographic evidence of atelectasis, and it may be difficult to distinguish between atelectasis and bacterial infiltrate or consolidation.[169] Bacterial pneumonia in infants with bronchiolitis without consolidation is unusual.[170] Antibiotic therapy may be justified in some children with bronchiolitis who require intubation and mechanical ventilation for respiratory failure.[172,173]

Although acute otitis media (AOM) in infants with bronchiolitis may be attributable to viruses, clinical features generally do not permit differentiation of viral AOM from those with a bacterial component.[174] Two studies address the frequency of AOM in patients with bronchiolitis. Andrade et al[175] prospectively identified AOM in 62% of 42 patients who presented with bronchiolitis. AOM was present in 50% on entry to the study and developed in an additional 12% within 10 days. A subsequent report[176] followed 150 children hospitalized for bronchiolitis for the development of AOM. Seventy-nine (53%) developed AOM, two-thirds within the

first 2 days of hospitalization. AOM did not influence the clinical course or laboratory findings of bronchiolitis. The current AAP guideline on AOM[177] recommends that a diagnosis of AOM should include bulging of the tympanic membrane. This is based on bulging being the best indicator for the presence of bacteria in multiple tympanocentesis studies and on 2 articles comparing antibiotic to placebo therapy that used a bulging tympanic membrane as a necessary part of the diagnosis.[178,179] New studies are needed to determine the incidence of AOM in bronchiolitis by using the new criterion of bulging of the tympanic membrane. Refer to the AOM guideline[180] for recommendations regarding the management of AOM.

NUTRITION AND HYDRATION

Key Action Statement 9

Clinicians should administer nasogastric or intravenous fluids for infants with a diagnosis of bronchiolitis who cannot maintain hydration orally (Evidence Quality: X; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 9

Aggregate evidence quality	X
Benefits	Maintaining hydration
Risk, harm, cost	Risk of infection, risk of aspiration with nasogastric tube, discomfort, hyponatremia, intravenous infiltration, overhydration
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Shared decision as to which mode is used
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

The level of respiratory distress attributable to bronchiolitis guides the indications for fluid replacement. Conversely, food intake in the previous 24 hours may be a predictor of oxygen saturation among infants with bronchiolitis. One study found that food intake at less than 50% of normal for the previous 24 hours is associated with a pulse oximetry value of <95%.[180] Infants with mild respiratory distress may require only observation, particularly if feeding remains unaffected. When the respiratory rate exceeds 60 to 70 breaths per minute, feeding may be compromised, particularly if nasal secretions are copious. There is limited evidence to suggest coordination of breathing with swallowing may be impaired among infants with bronchiolitis.[181] These infants may develop increased nasal flaring, retractions, and prolonged expiratory wheezing when fed and may be at increased risk of aspiration.[182]

One study estimated that one-third of infants hospitalized for bronchiolitis require fluid replacement.[183] One case series[184] and 2 randomized trials,[185,186] examined the comparative efficacy and safety of the intravenous and nasogastric routes for fluid replacement. A pilot trial in Israel that included 51 infants younger than 6 months demonstrated no significant differences in the duration of oxygen needed or time to full oral feeds between infants receiving intravenous 5% dextrose in normal saline solution or nasogastric breast milk or formula.[187] Infants in the intravenous group had a shorter LOS (100 vs 120 hours) but it was not statistically significant. In a larger open randomized trial including infants between 2 and 12 months of age and conducted in Australia and New Zealand, there were no significant differences in rates of admission to ICUs, need for ventilatory support, and adverse events between 381 infants assigned to nasogastric hydration and 378 infants assigned to intravenous hydration.[188] There was a difference of 4 hours in mean LOS between the intravenous group (82.2 hours) and the nasogastric group (86.2 hours) that was not statistically significant. The nasogastric route had a higher success rate of insertion than the intravenous route. Parental satisfaction scores did not differ between the intravenous and nasogastric groups. These studies suggest that infants who have difficulty feeding safely because of respiratory distress can receive either intravenous or nasogastric fluid replacement; however, more evidence is needed to increase the strength of this recommendation.

The possibility of fluid retention related to production of antidiuretic hormone has been raised in patients with bronchiolitis.[187–189] Therefore, receipt of hypotonic fluid replacement and maintenance fluids may increase the risk of iatrogenic hyponatremia in these infants. A recent meta-analysis demonstrated that among hospitalized children requiring maintenance fluids, the use of hypotonic fluids was associated with significant hyponatremia compared with isotonic fluids in older children.[190] Use of isotonic fluids, in general, appears to be safer.

PREVENTION

Key Action Statement 10a

Clinicians should not administer palivizumab to otherwise healthy

infants with a gestational age of 29 weeks, 0 days or greater (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 10a

Aggregate evidence quality	B
Benefits	Reduced pain of injections, reduced use of a medication that has shown minimal benefit, reduced adverse effects, reduced visits to health care provider with less exposure to illness
Risk, harm, cost	Minimal increase in risk of RSV hospitalization
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parents may choose to not accept palivizumab
Exclusions	Infants with chronic lung disease of prematurity and hemodynamically significant cardiac disease (as described in KAS 10b)
Strength	Recommendation
Differences of opinion	None
Notes	This KAS is harmonized with the AAP policy statement on palivizumab

Key Action Statement 10b

Clinicians should administer palivizumab during the first year of life to infants with hemodynamically significant heart disease or chronic lung disease of prematurity defined as preterm infants <32 weeks, 0 days' gestation who require >21% oxygen for at least the first 28 days of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 10b

Aggregate evidence quality	B
Benefits	Reduced risk of RSV hospitalization
Risk, harm, cost	Injection pain; increased risk of illness from increased visits to clinician office or clinic; cost; side effects from palivizumab
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parents may choose to not accept palivizumab
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None
Notes	This KAS is harmonized with the AAP policy statement on palivizumab[191,192]

Key Action Statement 10c

Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the RSV season to infants who qualify for palivizumab in the first year of life (Evidence Quality: B, Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 10c

Aggregate evidence quality	B
Benefits	Reduced risk of hospitalization; reduced admission to ICU
Risk, harm, cost	Injection pain; increased risk of illness from increased visits to clinician office or clinic; cost; adverse effects of palivizumab
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Fewer doses should be used if the bronchiolitis season ends before the completion of 5 doses; if the child is hospitalized with a breakthrough RSV, monthly prophylaxis should be discontinued
Strength	Moderate recommendation
Differences of opinion	None
Notes	This KAS is harmonized with the AAP policy statement on palivizumab[191,192]

Detailed evidence to support the policy statement on palivizumab and this palivizumab section can be found in the technical report on palivizumab.[192]

Palivizumab was licensed by the US Food and Drug Administration in June 1998 largely on the basis of results of 1 clinical trial.[193] The results of a second clinical trial among children with congenital heart disease were reported in December 2003.[194] No other prospective, randomized, placebo-controlled trials have been conducted in any subgroup. Since licensure of palivizumab, new peer-reviewed publications provide greater insight into the epidemiology of disease caused by RSV.[195–197] As a result of new data, the Bronchiolitis Guideline Committee and the Committee on Infectious Diseases have updated recommendations for use of prophylaxis.

PREMATURITY

Monthly palivizumab prophylaxis should be restricted to infants born before 29 weeks, 0 days' gestation, except for infants who qualify on the basis of congenital heart disease or chronic lung disease of prematurity. Data show that infants born at or after 29 weeks, 0 days' gestation have an RSV hospitalization rate similar to the rate of full-term infants.[11,198] Infants with a gestational age of 28 weeks, 6 days or less who will be younger than 12 months at the start of the RSV season should receive a maximum of 5 monthly doses of palivizumab or until the end of the RSV season, whichever comes first. Depending on the month of birth, fewer than 5 monthly doses

will provide protection for most infants for the duration of the season.

CONGENITAL HEART DISEASE

Despite the large number of subjects enrolled, little benefit from palivizumab prophylaxis was found in the industry-sponsored cardiac study among infants in the cyanotic group (7.9% in control group versus 5.6% in palivizumab group, or 23 fewer hospitalizations per1000 children; P = .285).[197] In the acyanotic group (11.8% vs 5.0%), there were 68 fewer RSV hospitalizations per 1000 prophylaxis recipients (P = .003).[197,199,200]

CHRONIC LUNG DISEASE OF PREMATURITY

Palivizumab prophylaxis should be administered to infants and children younger than 12 months who develop chronic lung disease of prematurity, defined as a requirement for 28 days of more than 21% oxygen beginning at birth. If a child meets these criteria and is in the first 24 months of life and continues to require supplemental oxygen, diuretic therapy, or chronic corticosteroid therapy within 6 months of the start of the RSV season, monthly prophylaxis should be administered for the remainder of the season.

NUMBER OF DOSES

Community outbreaks of RSV disease usually begin in November or December, peak in January or February, and end by late March or, at times, in April.[4] Figure 1 shows the 2011–2012 bronchiolitis season, which is typical of most years. Because 5 monthly doses will provide more than 24 weeks of protective serum palivizumab concentration, administration of more than 5 monthly doses is not recommended within the continental United States. For infants who qualify for 5 monthly doses, initiation of prophylaxis in November and continuation for a total of 5 doses will provide protection into April.[201] If prophylaxis is initiated in October, the fifth and final dose should be administered in February, and protection will last into March for most children.

SECOND YEAR OF LIFE

Because of the low risk of RSV hospitalization in the second year of life, palivizumab prophylaxis is not recommended for children in the second year of life with the following exception. Children who satisfy the definition of chronic lung disease of infancy and continue to require supplemental oxygen, chronic corticosteroid therapy, or diuretic therapy within 6 months of the onset of the second RSV season may be considered for a second season of prophylaxis.

OTHER CONDITIONS

Insufficient data are available to recommend routine use of prophylaxis in children with Down syndrome, cystic fibrosis, pulmonary abnormality, neuromuscular disease, or immune compromise.

Down Syndrome

Routine use of prophylaxis for children in the first year of life with Down syndrome is not recommended unless the child qualifies because of cardiac disease or prematurity.[202]

Cystic Fibrosis

Routine use of palivizumab prophylaxis in patients with cystic fibrosis is not recommended.[203,204] Available studies indicate the incidence of RSV hospitalization in children with cystic fibrosis is low and unlikely to be different from children without cystic fibrosis. No evidence suggests a benefit from palivizumab prophylaxis in patients with cystic fibrosis. A randomized clinical trial involving 186 children with cystic fibrosis from 40 centers reported 1 subject in each group was hospitalized because of RSV infection. Although this study was not powered for efficacy, no clinically meaningful differences in outcome were reported.[205] A survey of cystic fibrosis center directors published in 2009 noted that palivizumab prophylaxis is not the standard of care for patients with cystic fibrosis.[206] If a neonate is diagnosed with cystic fibrosis by newborn screening, RSV prophylaxis should not be administered if no other indications are present. A patient with cystic fibrosis with clinical evidence of chronic lung disease in the first year of life may be considered for prophylaxis.

Neuromuscular Disease and Pulmonary Abnormality

The risk of RSV hospitalization is not well defined in children with pulmonary abnormalities or neuromuscular disease that impairs ability to clear secretions from the lower airway because of ineffective cough, recurrent gastroesophageal tract reflux, pulmonary malformations, tracheoesophageal fistula, upper airway conditions, or conditions requiring tracheostomy. No data on the relative risk of RSV hospitalization are available for this cohort. Selected infants with disease or congenital anomaly that impairs their ability to clear secretions from the lower airway because of ineffective cough may be considered for prophylaxis during the first year of life.

Immunocompromised Children

Population-based data are not available on the incidence or severity of RSV hospitalization in children who undergo solid organ or hematopoietic stem cell transplantation, receive chemotherapy, or are immunocompromised because of other conditions. Prophylaxis may be considered for hematopoietic stem cell transplant

patients who undergo transplantation and are profoundly immunosuppressed during the RSV season.[207]

MISCELLANEOUS ISSUES

Prophylaxis is not recommended for prevention of nosocomial RSV disease in the NICU or hospital setting.[208,209]

No evidence suggests palivizumab is a cost-effective measure to prevent recurrent wheezing in children. Prophylaxis should not be administered to reduce recurrent wheezing in later years.[210,211]

Monthly prophylaxis in Alaska Native children who qualify should be determined by locally generated data regarding season onset and end.

Continuation of monthly prophylaxis for an infant or young child who experiences breakthrough RSV hospitalization is not recommended.

HAND HYGIENE

Key Action Statement 11a

All people should disinfect hands before and after direct contact with patients, after contact with inanimate objects in the direct vicinity of the patient, and after removing gloves (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 11a

Aggregate evidence quality	B
Benefits	Decreased transmission of disease
Risk, harm, cost	Possible hand irritation
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Key Action Statement 11b

All people should use alcohol-based rubs for hand decontamination when caring for children with bronchiolitis. When alcohol-based rubs are not available, individuals should wash their hands with soap and water (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 11b

Aggregate evidence quality	B
Benefits	Less hand irritation
Risk, harm, cost	If there is visible dirt on the hands, hand washing is necessary; alcohol-based rubs are not effective for *Clostridium difficile,* present a fire hazard, and have a slight increased cost
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Strong recommendation
Differences of opinion	None

Efforts should be made to decrease the spread of RSV and other causative agents of bronchiolitis in medical settings, especially in the hospital. Secretions from infected patients can be found on beds, crib railings, tabletops, and toys.[12] RSV, as well as many other viruses, can survive better on hard surfaces than on porous surfaces or hands. It can remain infectious on counter tops for ≥6 hours, on gowns or paper tissues for 20 to 30 minutes, and on skin for up to 20 minutes.[212]

It has been shown that RSV can be carried and spread to others on the hands of caregivers.[213] Studies have shown that health care workers have acquired infection by performing activities such as feeding, diaper change, and playing with the RSV-infected infant. Caregivers who had contact only with surfaces contaminated with the infants' secretions or touched inanimate objects in patients' rooms also acquired RSV. In these studies, health care workers contaminated their hands (or gloves) with RSV and inoculated their oral or conjunctival mucosa.[214] Frequent hand washing by health care workers has been shown to reduce the spread of RSV in the health care setting.[215]

The Centers for Disease Control and Prevention published an extensive review of the hand-hygiene literature and made recommendations as to indications for hand washing and hand antisepsis.[216] Among the recommendations are that hands should be disinfected before and after direct contact with every patient, after contact with inanimate objects in the direct vicinity of the patient, and before putting on and after removing gloves. If hands are not visibly soiled, an alcohol-based rub is preferred. In guidelines published in 2009, the World Health Organization also recommended alcohol-based hand-rubs as the standard for hand hygiene in health care.[217] Specifically, systematic reviews show them to remove organisms more effectively, require less time, and irritate skin less often than hand washing with soap or other antiseptic agents and water. The availability of bedside alcohol-based solutions increased compliance with hand hygiene among health care workers.[214]

When caring for hospitalized children with clinically diagnosed bronchiolitis, strict adherence to hand decontamination and use of personal protective equipment (ie, gloves and gowns) can reduce the risk of cross-infection in the health care setting.[215]

Other methods of infection control in viral bronchiolitis include education of personnel and family members, surveillance for the onset of RSV season, and wearing masks when anticipating exposure to aerosolized secretions while performing patient care activities. Programs that implement the aforementioned principles, in conjunction with effective hand decontamination and cohorting of patients, have been shown to reduce the spread of RSV in the health care setting by 39% to 50%.[218,219]

TOBACCO SMOKE

Key Action Statement 12a

Clinicians should inquire about the exposure of the infant or child to tobacco smoke when assessing infants and children for bronchiolitis (Evidence Quality: C; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 12a

Aggregate evidence quality	C
Benefits	Can identify infants and children at risk whose family may benefit from counseling, predicting risk of severe disease
Risk, harm, cost	Time to inquire
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parent may choose to deny tobacco use even though they are, in fact, users
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Key Action Statement 12b

Clinicians should counsel caregivers about exposing the infant or child to environmental tobacco smoke and smoking cessation when assessing a child for bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Action Statement Profile KAS 12b

Aggregate evidence quality	B
Benefits	Reinforces the detrimental effects of smoking, potential to decrease smoking
Risk, harm, cost	Time to counsel
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parents may choose to ignore counseling
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None
Notes	Counseling for tobacco smoke prevention should begin in the prenatal period and continue in family-centered care and at all well-infant visits

Tobacco smoke exposure increases the risk and severity of bronchiolitis. Strachan and Cook[220] first delineated the effects of environmental tobacco smoke on rates of lower respiratory tract disease in infants in a meta-analysis including 40 studies. In a more recent systematic review, Jones et al[221] found a pooled odds ratio of 2.51 (95% CI 1.96 to 3.21) for tobacco smoke exposure and bronchiolitis hospitalization among the 7 studies specific to the condition. Other investigators have consistently reported tobacco smoke exposure increases both severity of illness and risk of hospitalization for bronchiolitis.[222–225] The AAP issued a technical report on the risks of secondhand smoke in 2009. The report makes recommendations regarding effective ways to eliminate or reduce secondhand smoke exposure, including education of parents.[226]

Despite our knowledge of this important risk factor, there is evidence to suggest health care providers identify fewer than half of children exposed to tobacco smoke in the outpatient, inpatient, or ED settings.[227–229] Furthermore, there is evidence that counseling parents in these settings is well received and has a measurable impact. Rosen et al[230] performed a meta-analysis of the effects of interventions in pediatric settings on parental cessation and found a pooled risk ratio of 1.3 for cessation among the 18 studies reviewed.

In contrast to many of the other recommendations, protecting children from tobacco exposure is a recommendation that is primarily implemented outside of the clinical setting. As such, it is critical that parents are fully educated about the importance of not allowing smoking in the home and that smoke lingers on clothes and in the environment for prolonged periods.[231] It should be provided in plain language and in a respectful, culturally effective manner that is family centered, engages parents as partners in their child's health, and factors in their literacy, health literacy, and primary language needs.

BREASTFEEDING

Key Action Statement 13

Clinicians should encourage exclusive breastfeeding for at least 6 months to decrease the morbidity of respiratory infections (Evidence Quality: Grade B; Recommendation Strength: Moderate Recommendation).

Action Statement Profile KAS 13

Aggregate evidence quality	B
Benefits	May reduce the risk of bronchiolitis and other illnesses; multiple benefits of breastfeeding unrelated to bronchiolitis
Risk, harm, cost	None
Benefit-harm assessment	Benefits outweigh risks
Value judgments	None
Intentional vagueness	None
Role of patient preferences	Parents may choose to feed formula rather than breastfeed
Exclusions	None
Strength	Moderate recommendation
Notes	Education on breastfeeding should begin in the prenatal period

In 2012, the AAP presented a general policy on breastfeeding.[232] The policy statement was based on the proven benefits of breastfeeding for at least 6 months. Respiratory infections were shown to be significantly less common in breastfed children. A primary resource was a meta-analysis from the Agency for Healthcare Research and Quality that showed an overall 72% reduction in the risk of hospitalization secondary to respiratory diseases in infants who were exclusively breastfed for 4 or more months compared with those who were formula fed.[233]

The clinical evidence also supports decreased incidence and severity of illness in breastfed infants with bronchiolitis. Dornelles et al[234] concluded that the duration of exclusive breastfeeding was inversely related to the length of oxygen use and the length of hospital stay in previously healthy infants with acute bronchiolitis. In a large prospective study in Australia, Oddy et al[235] showed that breastfeeding for less than 6 months was associated with an increased risk for 2 or more medical visits and hospital admission for wheezing lower respiratory illness. In Japan, Nishimura et al[236] looked at 3 groups of RSV-positive infants defined as full, partial, or token breastfeeding. There were no significant differences in the hospitalization rate among the 3 groups; however, there were significant differences in the duration of hospitalization and the rate of requiring oxygen therapy, both favoring breastfeeding.

FAMILY EDUCATION

Key Action Statement 14

Clinicians and nurses should educate personnel and family members on evidence-based diagnosis, treatment, and prevention in bronchiolitis (Evidence Quality: C; observational studies; Recommendation Strength; Moderate Recommendation).

Action Statement Profile KAS 14

Aggregate evidence quality	C
Benefits	Decreased transmission of disease, benefits of breastfeeding, promotion of judicious use of antibiotics, risks of infant lung damage attributable to tobacco smoke
Risk, harm, cost	Time to educate properly
Benefit-harm assessment	Benefits outweigh harms
Value judgments	None
Intentional vagueness	Personnel is not specifically defined but should include all people who enter a patient's room
Role of patient preferences	None
Exclusions	None
Strength	Moderate recommendation
Differences of opinion	None

Shared decision-making with parents about diagnosis and treatment of bronchiolitis is a key tenet of patient-centered care. Despite the absence of effective therapies for viral bronchiolitis, caregiver education by clinicians may have a significant impact on care patterns in the disease. Children with bronchiolitis typically suffer from symptoms for 2 to 3 weeks, and parents often seek care in multiple settings during that time period.[237] Given that children with RSV generally shed virus for 1 to 2 weeks and from 30% to 70% of family members may become ill,[238,239] education about prevention of transmission of disease is key. Restriction of visitors to newborns during the respiratory virus season should be considered. Consistent evidence suggests that parental education is helpful in the promotion of judicious use of antibiotics and that clinicians may misinterpret parental expectations about therapy unless the subject is openly discussed.[240–242]

FUTURE RESEARCH NEEDS

- Better algorithms for predicting the course of illness
- Impact of clinical score on patient outcomes
- Evaluating different ethnic groups and varying response to treatments
- Does epinephrine alone reduce admission in outpatient settings?
- Additional studies on epinephrine in combination with dexamethasone or other corticosteroids
- Hypertonic saline studies in the outpatient setting and in in hospitals with shorter LOS
- More studies on nasogastric hydration
- More studies on tonicity of intravenous fluids

- Incidence of true AOM in bronchiolitis by using 2013 guideline definition
- More studies on deep suctioning and nasopharyngeal suctioning
- Strategies for monitoring oxygen saturation
- Use of home oxygen
- Appropriate cutoff for use of oxygen in high altitude
- Oxygen delivered by high-flow nasal cannula
- RSV vaccine and antiviral agents
- Use of palivizumab in special populations, such as cystic fibrosis, neuromuscular diseases, Down syndrome, immune deficiency
- Emphasis on parent satisfaction/patient-centered outcomes in all research (ie, not LOS as the only measure)

SUBCOMMITTEE ON BRONCHIOLITIS (OVERSIGHT BY THE COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY, 2013–2014)

Shawn L. Ralston, MD, FAAP: Chair, Pediatric Hospitalist (no financial conflicts; published research related to bronchiolitis)

Allan S. Lieberthal, MD, FAAP: Chair, General Pediatrician with Expertise in Pulmonology (no conflicts)

Brian K. Alverson, MD, FAAP: Pediatric Hospitalist, AAP Section on Hospital Medicine Representative (no conflicts)

Jill E. Baley, MD, FAAP: Neonatal-Perinatal Medicine, AAP Committee on Fetus and Newborn Representative (no conflicts)

Anne M. Gadomski, MD, MPH, FAAP: General Pediatrician and Research Scientist (no financial conflicts; published research related to bronchiolitis including Cochrane review of bronchodilators)

David W. Johnson, MD, FAAP: Pediatric Emergency Medicine Physician (no financial conflicts; published research related to bronchiolitis)

Michael J. Light, MD, FAAP: Pediatric Pulmonologist, AAP Section on Pediatric Pulmonology Representative (no conflicts)

Nizar F. Maraqa, MD, FAAP: Pediatric Infectious Disease Physician, AAP Section on Infectious Diseases Representative (no conflicts)

H. Cody Meissner, MD, FAAP: Pediatric Infectious Disease Physician, AAP Committee on Infectious Diseases Representative (no conflicts)

Eneida A. Mendonca, MD, PhD, FAAP, FACMI: Informatician/Academic Pediatric Intensive Care Physician, Partnership for Policy Implementation Representative (no conflicts)

Kieran J. Phelan, MD, MSc: General Pediatrician (no conflicts)

Joseph J. Zorc, MD, MSCE, FAAP: Pediatric Emergency Physician, AAP Section on Emergency Medicine Representative (no financial conflicts; published research related to bronchiolitis)

Danette Stanko-Lopp, MA, MPH: Methodologist, Epidemiologist (no conflicts)

Mark A. Brown, MD: Pediatric Pulmonologist, American Thoracic Society Liaison (no conflicts)

Ian Nathanson, MD, FAAP: Pediatric Pulmonologist, American College of Chest Physicians Liaison (no conflicts)

Elizabeth Rosenblum, MD: Academic Family Physician, American Academy of Family Physicians liaison (no conflicts).

Stephen Sayles, III, MD, FACEP: Emergency Medicine Physician, American College of Emergency Physicians Liaison (no conflicts)

Sinsi Hernández-Cancio, JD: Parent/Consumer Representative (no conflicts)

STAFF

Caryn Davidson, MA
Linda Walsh, MAB

REFERENCES

1. American Academy of Pediatrics Subcommittee on Diagnosis and Management of Bronchiolitis. Diagnosis and management of bronchiolitis. *Pediatrics*. 2006;118(4):1774–1793
2. Agency for Healthcare Research and Quality. Management of Bronchiolitis in Infants and Children. Evidence Report/Technology Assessment No. 69. Rockville, MD: Agency for Healthcare Research and Quality; 2003. AHRQ Publication No. 03-E014
3. Mullins JA, Lamonte AC, Bresee JS, Anderson LJ. Substantial variability in community respiratory syncytial virus season timing. *Pediatr Infect Dis J*. 2003;22(10):857–862
4. Centers for Disease Control and Prevention. Respiratory syncytial virus activity—United States, July 2011-January 2013. *MMWR Morb Mortal Wkly Rep*. 2013;62(8):141–144
5. Greenough A, Cox S, Alexander J, et al. Health care utilisation of infants with chronic lung disease, related to hospitalisation for RSV infection. *Arch Dis Child*. 2001;85(6):463–468
6. Parrott RH, Kim HW, Arrobio JO, et al. Epidemiology of respiratory syncytial virus infection in Washington, D.C. II. Infection and disease with respect to age, immunologic status, race and sex. *Am J Epidemiol*. 1973;98(4):289–300
7. Meissner HC. Selected populations at increased risk from respiratory syncytial virus infection. *Pediatr Infect Dis J*. 2003;22(suppl 2):S40–S44, discussion S44–S45
8. Shay DK, Holman RC, Roosevelt GE, Clarke MJ, Anderson LJ. Bronchiolitis-associated mortality and estimates of respiratory syncytial virus-associated deaths among US children, 1979-1997. *J Infect Dis*. 2001;183(1):16–22
9. Miller EK, Gebretsadik T, Carroll KN, et al. Viral etiologies of infant bronchiolitis, croup and upper respiratory illness during 4 consecutive years. *Pediatr Infect Dis J*. 2013;32(9):950–955
10. Hasegawa K, Tsugawa Y, Brown DF, Mansbach JM, Camargo CA Jr. Trends in bronchiolitis hospitalizations in the United States, 2000-2009. *Pediatrics*. 2013;132(1):28–36
11. Hall CB, Weinberg GA, Blumkin AK, et al. Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. *Pediatrics*. 2013;132(2). Available at: www.pediatrics.org/cgi/content/full/132/2/e341
12. Hall CB. Nosocomial respiratory syncytial virus infections: the "Cold War" has not ended. *Clin Infect Dis*. 2000;31(2):590–596
13. Stevens TP, Sinkin RA, Hall CB, Maniscalco WM, McConnochie KM. Respiratory syncytial virus and premature infants born at 32 weeks' gestation or earlier: hospitalization and economic implications of prophylaxis. *Arch Pediatr Adolesc Med*. 2000;154(1):55–61
14. American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877

15. Ricart S, Marcos MA, Sarda M, et al. Clinical risk factors are more relevant than respiratory viruses in predicting bronchiolitis severity. *Pediatr Pulmonol*. 2013;48(5):456–463
16. Shaw KN, Bell LM, Sherman NH. Outpatient assessment of infants with bronchiolitis. *Am J Dis Child*. 1991;145(2):151–155
17. Hall CB, Powell KR, MacDonald NE, et al. Respiratory syncytial viral infection in children with compromised immune function. *N Engl J Med*. 1986;315(2):77–81
18. Mansbach JM, Piedra PA, Stevenson MD, et al; MARC-30 Investigators. Prospective multicenter study of children with bronchiolitis requiring mechanical ventilation. *Pediatrics*. 2012;130(3). Available at: www.pediatrics.org/cgi/content/full/130/3/e492
19. Prescott WA Jr, Hutchinson DJ. Respiratory syncytial virus prophylaxis in special populations: is it something worth considering in cystic fibrosis and immunosuppression? *J Pediatr Pharmacol Ther*. 2011;16(2):77–86
20. Armstrong D, Grimwood K, Carlin JB, et al. Severe viral respiratory infections in infants with cystic fibrosis. *Pediatr Pulmonol*. 1998;26(6):371–379
21. Alvarez AE, Marson FA, Bertuzzo CS, Arns CW, Ribeiro JD. Epidemiological and genetic characteristics associated with the severity of acute viral bronchiolitis by respiratory syncytial virus. *J Pediatr (Rio J)*. 2013;89(6):531–543
22. Iliff A, Lee VA. Pulse rate, respiratory rate, and body temperature of children between two months and eighteen years of age. *Child Dev*. 1952;23(4):237–245
23. Rogers MC. Respiratory monitoring. In: Rogers MC, Nichols DG, eds. *Textbook of Pediatric Intensive Care*. Baltimore, MD: Williams & Wilkins; 1996:332–333
24. Berman S, Simoes EA, Lanata C. Respiratory rate and pneumonia in infancy. *Arch Dis Child*. 1991;66(1):81–84
25. Fleming S, Thompson M, Stevens R, et al. Normal ranges of heart rate and respiratory rate in children from birth to 18 years of age: a systematic review of observational studies. *Lancet*. 2011;377(9770):1011–1018
26. Bonafide CP, Brady PW, Keren R, Conway PH, Marsolo K, Daymont C. Development of heart and respiratory rate percentile curves for hospitalized children. *Pediatrics*. 2013;131(4). Available at: www.pediatrics.org/cgi/content/full/131/4/e1150
27. Margolis P, Gadomski A. The rational clinical examination. Does this infant have pneumonia? *JAMA*. 1998;279(4):308–313
28. Mahabee-Gittens EM, Grupp-Phelan J, Brody AS, et al. Identifying children with pneumonia in the emergency department. *Clin Pediatr (Phila)*. 2005;44(5):427–435
29. Brooks AM, McBride JT, McConnochie KM, Aviram M, Long C, Hall CB. Predicting deterioration in previously healthy infants hospitalized with respiratory syncytial virus infection. *Pediatrics*. 1999;104(3 pt 1):463–467
30. Neuman MI, Monuteaux MC, Scully KJ, Bachur RG. Prediction of pneumonia in a pediatric emergency department. *Pediatrics*. 2011;128(2):246–253
31. Shah S, Bachur R, Kim D, Neuman MI. Lack of predictive value of tachypnea in the diagnosis of pneumonia in children. *Pediatr Infect Dis J*. 2010;29(5):406–409
32. Mansbach JM, McAdam AJ, Clark S, et al. Prospective multicenter study of the viral etiology of bronchiolitis in the emergency department. *Acad Emerg Med*. 2008;15(2):111–118
33. Mansbach JM, Piedra PA, Teach SJ, et al; MARC-30 Investigators. Prospective multicenter study of viral etiology and hospital length of stay in children with severe bronchiolitis. *Arch Pediatr Adolesc Med*. 2012;166(8):700–706
34. Navas L, Wang E, de Carvalho V, Robinson J; Pediatric Investigators Collaborative Network on Infections in Canada. Improved outcome of respiratory syncytial virus infection in a high-risk hospitalized population of Canadian children. *J Pediatr*. 1992;121(3):348–354
35. Wang EE, Law BJ, Stephens D. Pediatric Investigators Collaborative Network on Infections in Canada (PICNIC) prospective study of risk factors and outcomes in patients hospitalized with respiratory syncytial viral lower respiratory tract infection. *J Pediatr*. 1995;126(2):212–219
36. Chan PW, Lok FY, Khatijah SB. Risk factors for hypoxemia and respiratory failure in respiratory syncytial virus bronchiolitis. *Southeast Asian J Trop Med Public Health*. 2002;33(4):806–810
37. Roback MG, Baskin MN. Failure of oxygen saturation and clinical assessment to predict which patients with bronchiolitis discharged from the emergency department will return requiring admission. *Pediatr Emerg Care*. 1997;13(1):9–11
38. Lowell DI, Lister G, Von Koss H, McCarthy P. Wheezing in infants: the response to epinephrine. *Pediatrics*. 1987;79(6):939–945
39. Destino L, Weisgerber MC, Soung P, et al. Validity of respiratory scores in bronchiolitis. *Hosp Pediatr*. 2012;2(4):202–209
40. Schroeder AR, Marmor AK, Pantell RH, Newman TB. Impact of pulse oximetry and oxygen therapy on length of stay in bronchiolitis hospitalizations. *Arch Pediatr Adolesc Med*. 2004;158(6):527–530
41. Dawson KP, Long A, Kennedy J, Mogridge N. The chest radiograph in acute bronchiolitis. *J Paediatr Child Health*. 1990;26(4):209–211
42. Schroeder AR, Mansbach JM, Stevenson M, et al. Apnea in children hospitalized with bronchiolitis. *Pediatrics*. 2013;132(5). Available at: www.pediatrics.org/cgi/content/full/132/5/e1194
43. Ralston S, Hill V. Incidence of apnea in infants hospitalized with respiratory syncytial virus bronchiolitis: a systematic review. *J Pediatr*. 2009;155(5):728–733
44. Willwerth BM, Harper MB, Greenes DS. Identifying hospitalized infants who have bronchiolitis and are at high risk for apnea. *Ann Emerg Med*. 2006;48(4):441–447
45. García CG, Bhore R, Soriano-Fallas A, et al. Risk factors in children hospitalized with RSV bronchiolitis versus non-RSV bronchiolitis. *Pediatrics*. 2010;126(6). Available at: www.pediatrics.org/cgi/content/full/126/6/e1453
46. Swingler GH, Hussey GD, Zwarenstein M. Randomised controlled trial of clinical outcome after chest radiograph in ambulatory acute lower-respiratory infection in children. *Lancet*. 1998;351(9100):404–408
47. Schuh S, Lalani A, Allen U, et al. Evaluation of the utility of radiography in acute bronchiolitis. *J Pediatr*. 2007;150(4):429–433
48. Kellner JD, Ohlsson A, Gadomski AM, Wang EE. Efficacy of bronchodilator therapy in bronchiolitis. A meta-analysis. *Arch Pediatr Adolesc Med*. 1996;150(11):1166–1172
49. Flores G, Horwitz RI. Efficacy of beta2-agonists in bronchiolitis: a reappraisal and meta-analysis. *Pediatrics*. 1997;100(2 pt 1):233–239
50. Hartling L, Wiebe N, Russell K, Patel H, Klassen TP. A meta-analysis of randomized controlled trials evaluating the efficacy of epinephrine for the treatment of acute viral bronchiolitis. *Arch Pediatr Adolesc Med*. 2003;157(10):957–964
51. King VJ, Viswanathan M, Bordley WC, et al. Pharmacologic treatment of bronchiolitis in infants and children: a systematic review. *Arch Pediatr Adolesc Med*. 2004;158(2):127–137
52. Zorc JJ, Hall CB. Bronchiolitis: recent evidence on diagnosis and management. *Pediatrics*. 2010;125(2):342–349
53. Wainwright C. Acute viral bronchiolitis in children—a very common condition with few therapeutic options. *Paediatr Respir Rev*. 2010;11(1):39–45, quiz 45

54. Walsh P, Caldwell J, McQuillan KK, Friese S, Robbins D, Rothenberg SJ. Comparison of nebulized epinephrine to albuterol in bronchiolitis. *Acad Emerg Med.* 2008;15 (4):305–313
55. Scarlett EE, Walker S, Rovitelli A, Ren CL. Tidal breathing responses to albuterol and normal saline in infants with viral bronchiolitis. *Pediatr Allergy Immunol Pulmonol.* 2012;25(4):220–225
56. Gadomski AM, Scribani MB. Bronchodilators for bronchiolitis. *Cochrane Database Syst Rev.* 2014;(6):CD001266
57. Mallol J, Barrueto L, Girardi G, et al. Use of nebulized bronchodilators in infants under 1 year of age: analysis of four forms of therapy. *Pediatr Pulmonol.* 1987;3(5):298–303
58. Lines DR, Kattampallil JS, Liston P. Efficacy of nebulized salbutamol in bronchiolitis. *Pediatr Rev Commun.* 1990;5(2):121–129
59. Alario AJ, Lewander WJ, Dennehy P, Seifer R, Mansell AL. The efficacy of nebulized metaproterenol in wheezing infants and young children. *Am J Dis Child.* 1992;146 (4):412–418
60. Chavasse RJPG, Seddon P, Bara A, McKean MC. Short acting beta2-agonists for recurrent wheeze in children under two years of age. *Cochrane Database Syst Rev.* 2009;(2):CD002873
61. Totapally BR, Demerci C, Zureikat G, Nolan B. Tidal breathing flow-volume loops in bronchiolitis in infancy: the effect of albuterol [ISRCTN47364493]. *Crit Care.* 2002;6(2):160–165
62. Levin DL, Garg A, Hall LJ, Slogic S, Jarvis JD, Leiter JC. A prospective randomized controlled blinded study of three bronchodilators in infants with respiratory syncytial virus bronchiolitis on mechanical ventilation. *Pediatr Crit Care Med.* 2008;9(6):598–604
63. Bjornson C, Russell K, Vandermeer B, Klassen TP, Johnson DW. Nebulized epinephrine for croup in children. *Cochrane Database Syst Rev.* 2013;(10):CD006619
64. Hartling L, Fernandes RM, Bialy L, et al. Steroids and bronchodilators for acute bronchiolitis in the first two years of life: systematic review and meta-analysis. *BMJ.* 2011;342:d1714
65. Wainwright C, Altamirano L, Cheney M, et al. A multicenter, randomized, double-blind, controlled trial of nebulized epinephrine in infants with acute bronchiolitis. *N Engl J Med.* 2003;349(1):27–35
66. Patel H, Gouin S, Platt RW. Randomized, double-blind, placebo-controlled trial of oral albuterol in infants with mild-to-moderate acute viral bronchiolitis. *J Pediatr.* 2003;142(5):509–514
67. Skjerven HO, Hunderi JO, Brügmann-Pieper SK, et al. Racemic adrenaline and inhalation strategies in acute bronchiolitis. *N Engl J Med.* 2013;368(24):2286–2293
68. Plint AC, Johnson DW, Patel H, et al; Pediatric Emergency Research Canada (PERC). Epinephrine and dexamethasone in children with bronchiolitis. *N Engl J Med.* 2009;360(20):2079–2089
69. Wark PA, McDonald V, Jones AP. Nebulised hypertonic saline for cystic fibrosis. *Cochrane Database Syst Rev.* 2005;(3):CD001506
70. Daviskas E, Anderson SD, Gonda I, et al. Inhalation of hypertonic saline aerosol enhances mucociliary clearance in asthmatic and healthy subjects. *Eur Respir J.* 1996;9(4):725–732
71. Sood N, Bennett WD, Zeman K, et al. Increasing concentration of inhaled saline with or without amiloride: effect on mucociliary clearance in normal subjects. *Am J Respir Crit Care Med.* 2003;167(2): 158–163
72. Mandelberg A, Amirav I. Hypertonic saline or high volume normal saline for viral bronchiolitis: mechanisms and rationale. *Pediatr Pulmonol.* 2010;45(1):36–40
73. Zhang L, Mendoza-Sassi RA, Wainwright C, Klassen TP. Nebulized hypertonic saline solution for acute bronchiolitis in infants. *Cochrane Database Syst Rev.* 2008;(4): CD006458
74. Jacobs JD, Foster M, Wan J, Pershad J. 7% Hypertonic saline in acute bronchiolitis: a randomized controlled trial. *Pediatrics.* 2014;133(1). Available at: www.pediatrics.org/cgi/content/full/133/1/e8
75. Wu S, Baker C, Lang ME, et al. Nebulized hypertonic saline for bronchiolitis: a randomized clinical trial. *JAMA Pediatr.* 2014; 168(7):657–663
76. Florin TA, Shaw KN, Kittick M, Yakscoe S, Zorc JJ. Nebulized hypertonic saline for bronchiolitis in the emergency department: a randomized clinical trial. *JAMA Pediatr.* 2014;168(7):664–670
77. Sharma BS, Gupta MK, Rafik SP. Hypertonic (3%) saline vs 0.93% saline nebulization for acute viral bronchiolitis: a randomized controlled trial. *Indian Pediatr.* 2013;50(8): 743–747
78. Silver AH. Randomized controlled trial of the efficacy of nebulized 3% saline without bronchodilators for infants admitted with bronchiolitis: preliminary data [abstr E-PAS2014:2952.685]. Paper presented at: Pediatric Academic Societies Annual Meeting; May 3–6, 2014; Vancouver, British Columbia, Canada
79. Ralston S, Hill V, Martinez M. Nebulized hypertonic saline without adjunctive bronchodilators for children with bronchiolitis. *Pediatrics.* 2010;126(3). Available at: www.pediatrics.org/cgi/content/full/126/3/e520
80. Luo Z, Liu E, Luo J, et al. Nebulized hypertonic saline/salbutamol solution treatment in hospitalized children with mild to moderate bronchiolitis. *Pediatr Int.* 2010;52(2): 199–202
81. Sarrell EM, Tal G, Witzling M, et al. Nebulized 3% hypertonic saline solution treatment in ambulatory children with viral bronchiolitis decreases symptoms. *Chest.* 2002;122(6):2015–2020
82. Rowe BH, Spooner C, Ducharme FM, Bretzlaff JA, Bota GW. Early emergency department treatment of acute asthma with systemic corticosteroids. *Cochrane Database Syst Rev.* 2001;(1):CD002178
83. Smith M, Iqbal S, Elliott TM, Everard M, Rowe BH. Corticosteroids for hospitalised children with acute asthma. *Cochrane Database Syst Rev.* 2003;(2):CD002886
84. Russell KF, Liang Y, O'Gorman K, Johnson DW, Klassen TP. Glucocorticoids for croup. *Cochrane Database Syst Rev.* 2011;(1): CD001955
85. Fernandes RM, Bialy LM, Vandermeer B, et al. Glucocorticoids for acute viral bronchiolitis in infants and young children. *Cochrane Database Syst Rev.* 2013; (6):CD004878
86. Corneli HM, Zorc JJ, Mahajan P, et al; Bronchiolitis Study Group of the Pediatric Emergency Care Applied Research Network (PECARN). A multicenter, randomized, controlled trial of dexamethasone for bronchiolitis [published correction appears in *N Engl J Med* 2008;359(18): 1972]. *N Engl J Med.* 2007;357(4):331–339
87. Frey U, von Mutius E. The challenge of managing wheezing in infants. *N Engl J Med.* 2009;360(20):2130–2133
88. Gibson PG, Powell H, Ducharme F. Long-acting beta2-agonists as an inhaled corticosteroid-sparing agent for chronic asthma in adults and children. *Cochrane Database Syst Rev.* 2005;(4):CD005076
89. Barnes PJ. Scientific rationale for using a single inhaler for asthma control. *Eur Respir J.* 2007;29(3):587–595
90. Giembycz MA, Kaur M, Leigh R, Newton R. A Holy Grail of asthma management: toward understanding how long-acting beta (2)-adrenoceptor agonists enhance the clinical efficacy of inhaled corticosteroids. *Br J Pharmacol.* 2008;153(6):1090–1104
91. Kaur M, Chivers JE, Giembycz MA, Newton R. Long-acting beta2-adrenoceptor agonists synergistically enhance glucocorticoid-dependent transcription in human airway

epithelial and smooth muscle cells. *Mol Pharmacol*. 2008;73(1):203–214

92. Holden NS, Bell MJ, Rider CF, et al. β2-Adrenoceptor agonist-induced RGS2 expression is a genomic mechanism of bronchoprotection that is enhanced by glucocorticoids. *Proc Natl Acad Sci U S A*. 2011;108(49):19713–19718
93. Schuh S, Coates AL, Binnie R, et al. Efficacy of oral dexamethasone in outpatients with acute bronchiolitis. *J Pediatr*. 2002;140(1):27–32
94. Bentur L, Shoseyov D, Feigenbaum D, Gorichovsky Y, Bibi H. Dexamethasone inhalations in RSV bronchiolitis: a double-blind, placebo-controlled study. *Acta Paediatr*. 2005;94(7):866–871
95. Kuyucu S, Unal S, Kuyucu N, Yilgor E. Additive effects of dexamethasone in nebulized salbutamol or L-epinephrine treated infants with acute bronchiolitis. *Pediatr Int*. 2004;46(5):539–544
96. Mesquita M, Castro-Rodríguez JA, Heinichen L, Fariña E, Iramain R. Single oral dose of dexamethasone in outpatients with bronchiolitis: a placebo controlled trial. *Allergol Immunopathol (Madr)*. 2009;37(2):63–67
97. Alansari K, Sakran M, Davidson BL, Ibrahim K, Alrefai M, Zakaria I. Oral dexamethasone for bronchiolitis: a randomized trial. *Pediatrics*. 2013;132(4). Available at: www.pediatrics.org/cgi/content/full/132/4/e810
98. Mallory MD, Shay DK, Garrett J, Bordley WC. Bronchiolitis management preferences and the influence of pulse oximetry and respiratory rate on the decision to admit. *Pediatrics*. 2003;111(1). Available at: www.pediatrics.org/cgi/content/full/111/1/e45
99. Corneli HM, Zorc JJ, Holubkov R, et al; Bronchiolitis Study Group for the Pediatric Emergency Care Applied Research Network. Bronchiolitis: clinical characteristics associated with hospitalization and length of stay. *Pediatr Emerg Care*. 2012;28(2):99–103
100. Unger S, Cunningham S. Effect of oxygen supplementation on length of stay for infants hospitalized with acute viral bronchiolitis. *Pediatrics*. 2008;121(3):470–475
101. Cunningham S, McMurray A. Observational study of two oxygen saturation targets for discharge in bronchiolitis. *Arch Dis Child*. 2012;97(4):361–363
102. Anaesthesia UK. Oxygen dissociation curve. Available at: http://www.anaesthesiauk.com/SearchRender.aspx?DocId=1419&Index=D%3a\dtSearch\UserData\AUK&HitCount=19&hits=4+5+d+e+23+24+37+58+59+a7+a8+14a+14b+17e+180+181+1a9+1aa+1d4 Accessed July 15, 2014
103. McBride SC, Chiang VW, Goldmann DA, Landrigan CP. Preventable adverse events in infants hospitalized with bronchiolitis. *Pediatrics*. 2005;116(3):603–608
104. Hunt CE, Corwin MJ, Lister G, et al; Collaborative Home Infant Monitoring Evaluation (CHIME) Study Group. Longitudinal assessment of hemoglobin oxygen saturation in healthy infants during the first 6 months of age. *J Pediatr*. 1999;135(5):580–586
105. Gavlak JC, Stocks J, Laverty A, et al. The Young Everest Study: preliminary report of changes in sleep and cerebral blood flow velocity during slow ascent to altitude in unacclimatised children. *Arch Dis Child*. 2013;98(5):356–362
106. O'Neil SL, Barysh N, Setear SJ. Determining school programming needs of special population groups: a study of asthmatic children. *J Sch Health*. 1985;55(6):237–239
107. Bender BG, Belleau L, Fukuhara JT, Mrazek DA, Strunk RC. Psychomotor adaptation in children with severe chronic asthma. *Pediatrics*. 1987;79(5):723–727
108. Rietveld S, Colland VT. The impact of severe asthma on schoolchildren. *J Asthma*. 1999;36(5):409–417
109. Sung V, Massie J, Hochmann MA, Carlin JB, Jamsen K, Robertson CF. Estimating inspired oxygen concentration delivered by nasal prongs in children with bronchiolitis. *J Paediatr Child Health*. 2008;44(1-2):14–18
110. Ross PA, Newth CJL, Khemani RG. Accuracy of pulse oximetry in children. *Pediatrics*. 2014;133(1):22–29
111. Hasselbalch KA. Neutralitatsregulation und reizbarkeit des atemzentrums in ihren Wirkungen auf die koklensaurespannung des Blutes. *Biochem Ztschr*. 1912;46:403–439
112. Wang EE, Milner RA, Navas L, Maj H. Observer agreement for respiratory signs and oximetry in infants hospitalized with lower respiratory infections. *Am Rev Respir Dis*. 1992;145(1):106–109
113. Rojas MX, Granados Rugeles C, Charry-Anzola LP. Oxygen therapy for lower respiratory tract infections in children between 3 months and 15 years of age. *Cochrane Database Syst Rev*. 2009;(1):CD005975
114. Mitka M. Joint commission warns of alarm fatigue: multitude of alarms from monitoring devices problematic. *JAMA*. 2013;309(22):2315–2316
115. Bowton DL, Scuderi PE, Harris L, Haponik EF. Pulse oximetry monitoring outside the intensive care unit: progress or problem? *Ann Intern Med*. 1991;115(6):450–454
116. Groothuis JR, Gutierrez KM, Lauer BA. Respiratory syncytial virus infection in children with bronchopulmonary dysplasia. *Pediatrics*. 1988;82(2):199–203
117. Voepel-Lewis T, Pechlavanidis E, Burke C, Talsma AN. Nursing surveillance moderates the relationship between staffing levels and pediatric postoperative serious adverse events: a nested case-control study. *Int J Nurs Stud*. 2013;50(7):905–913
118. Bajaj L, Turner CG, Bothner J. A randomized trial of home oxygen therapy from the emergency department for acute bronchiolitis. *Pediatrics*. 2006;117(3):633–640
119. Tie SW, Hall GL, Peter S, et al. Home oxygen for children with acute bronchiolitis. *Arch Dis Child*. 2009;94(8):641–643
120. Halstead S, Roosevelt G, Deakyne S, Bajaj L. Discharged on supplemental oxygen from an emergency department in patients with bronchiolitis. *Pediatrics*. 2012;129(3). Available at: www.pediatrics.org/cgi/content/full/129/3/e605
121. Sandweiss DR, Mundorff MB, Hill T, et al. Decreasing hospital length of stay for bronchiolitis by using an observation unit and home oxygen therapy. *JAMA Pediatr*. 2013;167(5):422–428
122. Flett KB, Breslin K, Braun PA, Hambidge SJ. Outpatient course and complications associated with home oxygen therapy for mild bronchiolitis. *Pediatrics*. 2014;133(5):769–775
123. Gauthier M, Vincent M, Morneau S, Chevalier I. Impact of home oxygen therapy on hospital stay for infants with acute bronchiolitis. *Eur J Pediatr*. 2012;171(12):1839–1844
124. Bergman AB. Pulse oximetry: good technology misapplied. *Arch Pediatr Adolesc Med*. 2004;158(6):594–595
125. Sandweiss DR, Kadish HA, Campbell KA. Outpatient management of patients with bronchiolitis discharged home on oxygen: a survey of general pediatricians. *Clin Pediatr (Phila)*. 2012;51(5):442–446
126. Dysart K, Miller TL, Wolfson MR, Shaffer TH. Research in high flow therapy: mechanisms of action. *Respir Med*. 2009;103(10):1400–1405
127. Milési C, Baleine J, Matecki S, et al. Is treatment with a high flow nasal cannula effective in acute viral bronchiolitis? A physiologic study [published correction appears in *Intensive Care Med*. 2013;39(6):1170]. *Intensive Care Med*. 2013;39(6):1088–1094

128. Arora B, Mahajan P, Zidan MA, Sethuraman U. Nasopharyngeal airway pressures in bronchiolitis patients treated with high-flow nasal cannula oxygen therapy. *Pediatr Emerg Care*. 2012;28(11):1179–1184
129. Spentzas T, Minarik M, Patters AB, Vinson B, Stidham G. Children with respiratory distress treated with high-flow nasal cannula. *J Intensive Care Med*. 2009;24(5):323–328
130. Hegde S, Prodhan P. Serious air leak syndrome complicating high-flow nasal cannula therapy: a report of 3 cases. *Pediatrics*. 2013;131(3). Available at: www.pediatrics.org/cgi/content/full/131/3/e939
131. Pham TM, O'Malley L, Mayfield S, Martin S, Schibler A. The effect of high flow nasal cannula therapy on the work of breathing in infants with bronchiolitis [published online ahead of print May 21, 2014]. *Pediatr Pulmonol*. doi:doi:10.1002/ppul.23060
132. Bressan S, Balzani M, Krauss B, Pettenazzo A, Zanconato S, Baraldi E. High-flow nasal cannula oxygen for bronchiolitis in a pediatric ward: a pilot study. *Eur J Pediatr*. 2013;172(12):1649–1656
133. Ganu SS, Gautam A, Wilkins B, Egan J. Increase in use of non-invasive ventilation for infants with severe bronchiolitis is associated with decline in intubation rates over a decade. *Intensive Care Med*. 2012;38(7):1177–1183
134. Wing R, James C, Maranda LS, Armsby CC. Use of high-flow nasal cannula support in the emergency department reduces the need for intubation in pediatric acute respiratory insufficiency. *Pediatr Emerg Care*. 2012;28(11):1117–1123
135. McKiernan C, Chua LC, Visintainer PF, Allen H. High flow nasal cannulae therapy in infants with bronchiolitis. *J Pediatr*. 2010;156(4):634–638
136. Schibler A, Pham TM, Dunster KR, et al. Reduced intubation rates for infants after introduction of high-flow nasal prong oxygen delivery. *Intensive Care Med*. 2011;37(5):847–852
137. Kelly GS, Simon HK, Sturm JJ. High-flow nasal cannula use in children with respiratory distress in the emergency department: predicting the need for subsequent intubation. *Pediatr Emerg Care*. 2013;29(8):888–892
138. Kallappa C, Hufton M, Millen G, Ninan TK. Use of high flow nasal cannula oxygen (HFNCO) in infants with bronchiolitis on a paediatric ward: a 3-year experience. *Arch Dis Child*. 2014;99(8):790–791
139. Hilliard TN, Archer N, Laura H, et al. Pilot study of vapotherm oxygen delivery in moderately severe bronchiolitis. *Arch Dis Child*. 2012;97(2):182–183
140. Roqué i Figuls M, Giné-Garriga M, Granados Rugeles C, Perrotta C. Chest physiotherapy for acute bronchiolitis in paediatric patients between 0 and 24 months old. *Cochrane Database Syst Rev*. 2012;(2):CD004873
141. Aviram M, Damri A, Yekutielli C, Bearman J, Tal A. Chest physiotherapy in acute bronchiolitis [abstract]. *Eur Respir J*. 1992;5(suppl 15):229–230
142. Webb MS, Martin JA, Cartlidge PH, Ng YK, Wright NA. Chest physiotherapy in acute bronchiolitis. *Arch Dis Child*. 1985;60(11):1078–1079
143. Nicholas KJ, Dhouieb MO, Marshal TG, Edmunds AT, Grant MB. An evaluation of chest physiotherapy in the management of acute bronchiolitis: changing clinical practice. *Physiotherapy*. 1999;85(12):669–674
144. Bohé L, Ferrero ME, Cuestas E, Polliotto L, Genoff M. Indications of conventional chest physiotherapy in acute bronchiolitis [in Spanish]. *Medicina (B Aires)*. 2004;64(3):198–200
145. De Córdoba F, Rodrigues M, Luque A, Cadrobbi C, Faria R, Solé D. Fisioterapia respiratória em lactentes com bronquiolite: realizar ou não? *Mundo Saúde*. 2008;32(2):183–188
146. Gajdos V, Katsahian S, Beydon N, et al. Effectiveness of chest physiotherapy in infants hospitalized with acute bronchiolitis: a multicenter, randomized, controlled trial. *PLoS Med*. 2010;7(9):e1000345
147. Rochat I, Leis P, Bouchardy M, et al. Chest physiotherapy using passive expiratory techniques does not reduce bronchiolitis severity: a randomised controlled trial. *Eur J Pediatr*. 2012;171(3):457–462
148. Postiaux G, Louis J, Labasse HC, et al. Evaluation of an alternative chest physiotherapy method in infants with respiratory syncytial virus bronchiolitis. *Respir Care*. 2011;56(7):989–994
149. Sánchez Bayle M, Martín Martín R, Cano Fernández J, et al. Chest physiotherapy and bronchiolitis in the hospitalised infant. Double-blind clinical trial [in Spanish]. *An Pediatr (Barc)*. 2012;77(1):5–11
150. Mussman GM, Parker MW, Statile A, Sucharew H, Brady PW. Suctioning and length of stay in infants hospitalized with bronchiolitis. *JAMA Pediatr*. 2013;167(5):414–421
151. Weisgerber MC, Lye PS, Li SH, et al. Factors predicting prolonged hospital stay for infants with bronchiolitis. *J Hosp Med*. 2011;6(5):264–270
152. Nichol KP, Cherry JD. Bacterial-viral interrelations in respiratory infections of children. *N Engl J Med*. 1967;277(13):667–672
153. Field CM, Connolly JH, Murtagh G, Slattery CM, Turkington EE. Antibiotic treatment of epidemic bronchiolitis—a double-blind trial. *BMJ*. 1966;1(5479):83–85
154. Antonow JA, Hansen K, McKinstry CA, Byington CL. Sepsis evaluations in hospitalized infants with bronchiolitis. *Pediatr Infect Dis J*. 1998;17(3):231–236
155. Friis B, Andersen P, Brenøe E, et al. Antibiotic treatment of pneumonia and bronchiolitis. A prospective randomised study. *Arch Dis Child*. 1984;59(11):1038–1045
156. Greenes DS, Harper MB. Low risk of bacteremia in febrile children with recognizable viral syndromes. *Pediatr Infect Dis J*. 1999;18(3):258–261
157. Spurling GK, Doust J, Del Mar CB, Eriksson L. Antibiotics for bronchiolitis in children. *Cochrane Database Syst Rev*. 2011;(6):CD005189
158. Ralston S, Hill V, Waters A. Occult serious bacterial infection in infants younger than 60 to 90 days with bronchiolitis: a systematic review. *Arch Pediatr Adolesc Med*. 2011;165(10):951–956
159. Purcell K, Fergie J. Lack of usefulness of an abnormal white blood cell count for predicting a concurrent serious bacterial infection in infants and young children hospitalized with respiratory syncytial virus lower respiratory tract infection. *Pediatr Infect Dis J*. 2007;26(4):311–315
160. Purcell K, Fergie J. Concurrent serious bacterial infections in 2396 infants and children hospitalized with respiratory syncytial virus lower respiratory tract infections. *Arch Pediatr Adolesc Med*. 2002;156(4):322–324
161. Purcell K, Fergie J. Concurrent serious bacterial infections in 912 infants and children hospitalized for treatment of respiratory syncytial virus lower respiratory tract infection. *Pediatr Infect Dis J*. 2004;23(3):267–269
162. Kuppermann N, Bank DE, Walton EA, Senac MO Jr, McCaslin I. Risks for bacteremia and urinary tract infections in young febrile children with bronchiolitis. *Arch Pediatr Adolesc Med*. 1997;151(12):1207–1214
163. Titus MO, Wright SW. Prevalence of serious bacterial infections in febrile infants with respiratory syncytial virus infection. *Pediatrics*. 2003;112(2):282–284
164. Melendez E, Harper MB. Utility of sepsis evaluation in infants 90 days of age or younger with fever and clinical bronchiolitis. *Pediatr Infect Dis J*. 2003;22(12):1053–1056
165. Hall CB, Powell KR, Schnabel KC, Gala CL, Pincus PH. Risk of secondary bacterial

infection in infants hospitalized with respiratory syncytial viral infection. *J Pediatr*. 1988;113(2):266–271

166. Hall CB. Respiratory syncytial virus: a continuing culprit and conundrum. *J Pediatr*. 1999;135(2 pt 2):2–7
167. Davies HD, Matlow A, Petric M, Glazier R, Wang EE. Prospective comparative study of viral, bacterial and atypical organisms identified in pneumonia and bronchiolitis in hospitalized Canadian infants. *Pediatr Infect Dis J*. 1996;15(4):371–375
168. Levine DA, Platt SL, Dayan PS, et al; Multicenter RSV-SBI Study Group of the Pediatric Emergency Medicine Collaborative Research Committee of the American Academy of Pediatrics. Risk of serious bacterial infection in young febrile infants with respiratory syncytial virus infections. *Pediatrics*. 2004;113(6):1728–1734
169. Kellner JD, Ohlsson A, Gadomski AM, Wang EE. Bronchodilators for bronchiolitis. *Cochrane Database Syst Rev*. 2000;(2):CD001266
170. Pinto LA, Pitrez PM, Luisi F, et al. Azithromycin therapy in hospitalized infants with acute bronchiolitis is not associated with better clinical outcomes: a randomized, double-blinded, and placebo-controlled clinical trial. *J Pediatr*. 2012;161(6):1104–1108
171. McCallum GB, Morris PS, Chang AB. Antibiotics for persistent cough or wheeze following acute bronchiolitis in children. *Cochrane Database Syst Rev*. 2012;(12):CD009834
172. Levin D, Tribuzio M, Green-Wrzesinki T, et al. Empiric antibiotics are justified for infants with RSV presenting with respiratory failure. *Pediatr Crit Care*. 2010;11(3):390–395
173. Thorburn K, Reddy V, Taylor N, van Saene HK. High incidence of pulmonary bacterial co-infection in children with severe respiratory syncytial virus (RSV) bronchiolitis. *Thorax*. 2006;61(7):611–615
174. Gomaa MA, Galal O, Mahmoud MS. Risk of acute otitis media in relation to acute bronchiolitis in children. *Int J Pediatr Otorhinolaryngol*. 2012;76(1):49–51
175. Andrade MA, Hoberman A, Glustein J, Paradise JL, Wald ER. Acute otitis media in children with bronchiolitis. *Pediatrics*. 1998;101(4 pt 1):617–619
176. Shazberg G, Revel-Vilk S, Shoseyov D, Ben-Ami A, Klar A, Hurvitz H. The clinical course of bronchiolitis associated with acute otitis media. *Arch Dis Child*. 2000;83(4):317–319
177. Lieberthal AS, Carroll AE, Chonmaitree T, et al. The diagnosis and management of acute otitis media [published correction appears in *Pediatrics*. 2014;133(2):346]. *Pediatrics*. 2013;131(3). Available at: www.pediatrics.org/cgi/content/full/131/3/e964
178. Hoberman A, Paradise JL, Rockette HE, et al. Treatment of acute otitis media in children under 2 years of age. *N Engl J Med*. 2011;364(2):105–115
179. Tähtinen PA, Laine MK, Huovinen P, Jalava J, Ruuskanen O, Ruohola A. A placebo-controlled trial of antimicrobial treatment for acute otitis media. *N Engl J Med*. 2011;364(2):116–126
180. Corrard F, de La Rocque F, Martin E, et al. Food intake during the previous 24 h as a percentage of usual intake: a marker of hypoxia in infants with bronchiolitis: an observational, prospective, multicenter study. *BMC Pediatr*. 2013;13:6
181. Pinnington LL, Smith CM, Ellis RE, Morton RE. Feeding efficiency and respiratory integration in infants with acute viral bronchiolitis. *J Pediatr*. 2000;137(4):523–526
182. Khoshoo V, Edell D. Previously healthy infants may have increased risk of aspiration during respiratory syncytial viral bronchiolitis. *Pediatrics*. 1999;104(6):1389–1390
183. Kennedy N, Flanagan N. Is nasogastric fluid therapy a safe alternative to the intravenous route in infants with bronchiolitis? *Arch Dis Child*. 2005;90(3):320–321
184. Sammartino L, James D, Goutzamanis J, Lines D. Nasogastric rehydration does have a role in acute paediatric bronchiolitis. *J Paediatr Child Health*. 2002;38(3):321–322
185. Kugelman A, Raibin K, Dabbah H, et al. Intravenous fluids versus gastric-tube feeding in hospitalized infants with viral bronchiolitis: a randomized, prospective pilot study. *J Pediatr*. 2013;162(3):640–642.e1
186. Oakley E, Borland M, Neutze J, et al; Paediatric Research in Emergency Departments International Collaborative (PREDICT). Nasogastric hydration versus intravenous hydration for infants with bronchiolitis: a randomised trial. *Lancet Respir Med*. 2013;1(2):113–120
187. Gozal D, Colin AA, Jaffe M, Hochberg Z. Water, electrolyte, and endocrine homeostasis in infants with bronchiolitis. *Pediatr Res*. 1990;27(2):204–209
188. van Steensel-Moll HA, Hazelzet JA, van der Voort E, Neijens HJ, Hackeng WH. Excessive secretion of antidiuretic hormone in infections with respiratory syncytial virus. *Arch Dis Child*. 1990;65(11):1237–1239
189. Rivers RP, Forsling ML, Olver RP. Inappropriate secretion of antidiuretic hormone in infants with respiratory infections. *Arch Dis Child*. 1981;56(5):358–363
190. Wang J, Xu E, Xiao Y. Isotonic versus hypotonic maintenance IV fluids in hospitalized children: a meta-analysis. *Pediatrics*. 2014;133(1):105–113
191. American Academy of Pediatrics, Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Policy statement: updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):415–420
192. American Academy of Pediatrics; Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Technical report: updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics*. 2014;134(2):e620–e638.
193. IMpact-RSV Study Group. Palivizumab, a humanized respiratory syncytial virus monoclonal antibody, reduces hospitalization from respiratory syncytial virus infection in high-risk infants. The IMpact-RSV Study Group. *Pediatrics*. 1998;102(3):531–537
194. Feltes TF, Cabalka AK, Meissner HC, et al. Palivizumab prophylaxis reduces hospitalization due to respiratory syncytial virus in young children with hemodynamically significant congenital heart disease. *J Pediatr*. 2003;143(4):532–540
195. Andabaka T, Nickerson JW, Rojas-Reyes MX, Rueda JD, Bacic VV, Barsic B. Monoclonal antibody for reducing the risk of respiratory syncytial virus infection in children. *Cochrane Database Syst Rev*. 2013;(4):CD006602
196. Wang D, Bayliss S, Meads C. Palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) bronchiolitis in high-risk infants and young children: a systematic review and additional economic modelling of subgroup analyses. *Health Technol Assess*. 2011;1(5):iii–iv, 1–124
197. Hampp C, Kauf TL, Saidi AS, Winterstein AG. Cost-effectiveness of respiratory syncytial virus prophylaxis in various indications. *Arch Pediatr Adolesc Med*. 2011;165(6):498–505
198. Hall CB, Weinberg GA, Iwane MK, et al. The burden of respiratory syncytial virus infection in young children. *N Engl J Med*. 2009;360(6):588–598
199. Dupenthaler A, Ammann RA, Gorgievski-Hrisoho M, et al. Low incidence of respiratory syncytial virus hospitalisations in haemodynamically significant congenital

heart disease. *Arch Dis Child*. 2004;89:961–965

200. Geskey JM, Thomas NJ, Brummel GL. Palivizumab in congenital heart disease: should international guidelines be revised? *Expert Opin Biol Ther*. 2007;7(11):1615–1620
201. Robbie GJ, Zhao L, Mondick J, Losonsky G, Roskos LK. Population pharmacokinetics of palivizumab, a humanized anti-respiratory syncytial virus monoclonal antibody, in adults and children. *Antimicrob Agents Chemother*. 2012;56(9):4927–4936
202. Megged O, Schlesinger Y. Down syndrome and respiratory syncytial virus infection. *Pediatr Infect Dis J*. 2010;29(7):672–673
203. Robinson KA, Odelola OA, Saldanha IJ, Mckoy NA. Palivizumab for prophylaxis against respiratory syncytial virus infection in children with cystic fibrosis. *Cochrane Database Syst Rev*. 2012;(2):CD007743
204. Winterstein AG, Eworuke E, Xu D, Schuler P. Palivizumab immunoprophylaxis effectiveness in children with cystic fibrosis. *Pediatr Pulmonol*. 2013;48(9):874–884
205. Cohen AH, Boron ML, Dingivan C. A phase IV study of the safety of palivizumab for prophylaxis of RSV disease in children with cystic fibrosis [abstract]. *American Thoracic Society Abstracts*, 2005 International Conference; 2005. p. A178
206. Giusti R. North American synagis prophylaxis survey. *Pediatr Pulmonol*. 2009;44(1):96–98
207. El Saleeby CM, Somes GW, DeVincenzo HP, Gaur AH. Risk factors for severe respiratory syncytial virus disease in children with cancer: the importance of lymphopenia and young age. *Pediatrics*. 2008;121(2):235–243
208. Berger A, Obwegeser E, Aberle SW, Langgartner M, Popow-Kraupp T. Nosocomial transmission of respiratory syncytial virus in neonatal intensive care and intermediate care units. *Pediatr Infect Dis J*. 2010;29(7):669–670
209. Ohler KH, Pham JT. Comparison of the timing of initial prophylactic palivizumab dosing on hospitalization of neonates for respiratory syncytial virus. *Am J Health Syst Pharm*. 2013;70(15):1342–1346
210. Blanken MO, Robers MM, Molenaar JM, et al. Respiratory syncytial virus and recurrent wheeze in healthy preterm infants. *N Engl J Med*. 2013;368(19):1794–1799
211. Yoshihara S, Kusuda S, Mochizuki H, Okada K, Nishima S, Simões EAF; C-CREW Investigators. Effect of palivizumab prophylaxis on subsequent recurrent wheezing in preterm infants. *Pediatrics*. 2013;132(5):811–818
212. Hall CB, Douglas RG Jr, Geiman JM. Possible transmission by fomites of respiratory syncytial virus. *J Infect Dis*. 1980;141(1):98–102
213. Sattar SA, Springthorpe VS, Tetro J, Vashon R, Keswick B. Hygienic hand antiseptics: should they not have activity and label claims against viruses? *Am J Infect Control*. 2002;30(6):355–372
214. Picheansathian W. A systematic review on the effectiveness of alcohol-based solutions for hand hygiene. *Int J Nurs Pract*. 2004;10(1):3–9
215. Hall CB. The spread of influenza and other respiratory viruses: complexities and conjectures. *Clin Infect Dis*. 2007;45(3):353–359
216. Boyce JM, Pittet D; Healthcare Infection Control Practices Advisory Committee; HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force; Society for Healthcare Epidemiology of America/Association for Professionals in Infection Control/Infectious Diseases Society of America. Guideline for Hand Hygiene in Health-Care Settings. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR Recomm Rep*. 2002;51(RR-16):1–45, quiz CE1–CE4
217. World Health Organization. Guidelines on hand hygiene in health care. Geneva, Switzerland: World Health Organization; 2009. Available at: http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf. Accessed July 15, 2014
218. Karanfil LV, Conlon M, Lykens K, et al. Reducing the rate of nosocomially transmitted respiratory syncytial virus. [published correction appears in Am J Infect Control. 1999;27(3):303] *Am J Infect Control*. 1999;27(2):91–96
219. Macartney KK, Gorelick MH, Manning ML, Hodinka RL, Bell LM. Nosocomial respiratory syncytial virus infections: the cost-effectiveness and cost-benefit of infection control. *Pediatrics*. 2000;106(3):520–526
220. Strachan DP, Cook DG. Health effects of passive smoking. 1. Parental smoking and lower respiratory illness in infancy and early childhood. *Thorax*. 1997;52(10):905–914
221. Jones LL, Hashim A, McKeever T, Cook DG, Britton J, Leonardi-Bee J. Parental and household smoking and the increased risk of bronchitis, bronchiolitis and other lower respiratory infections in infancy: systematic review and meta-analysis. *Respir Res*. 2011;12:5
222. Bradley JP, Bacharier LB, Bonfiglio J, et al. Severity of respiratory syncytial virus bronchiolitis is affected by cigarette smoke exposure and atopy. *Pediatrics*. 2005;115(1). Available at: www.pediatrics.org/cgi/content/full/115/1/e7
223. Al-Shawwa B, Al-Huniti N, Weinberger M, Abu-Hasan M. Clinical and therapeutic variables influencing hospitalisation for bronchiolitis in a community-based paediatric group practice. *Prim Care Respir J*. 2007;16(2):93–97
224. Carroll KN, Gebretsadik T, Griffin MR, et al. Maternal asthma and maternal smoking are associated with increased risk of bronchiolitis during infancy. *Pediatrics*. 2007;119(6):1104–1112
225. Semple MG, Taylor-Robinson DC, Lane S, Smyth RL. Household tobacco smoke and admission weight predict severe bronchiolitis in infants independent of deprivation: prospective cohort study. *PLoS ONE*. 2011;6(7):e22425
226. Best D; Committee on Environmental Health; Committee on Native American Child Health; Committee on Adolescence. From the American Academy of Pediatrics: Technical report—Secondhand and prenatal tobacco smoke exposure. *Pediatrics*. 2009;124(5). Available at: www.pediatrics.org/cgi/content/full/124/5/e1017
227. Wilson KM, Wesgate SC, Best D, Blumkin AK, Klein JD. Admission screening for secondhand tobacco smoke exposure. *Hosp Pediatr*. 2012;2(1):26–33
228. Mahabee-Gittens M. Smoking in parents of children with asthma and bronchiolitis in a pediatric emergency department. *Pediatr Emerg Care*. 2002;18(1):4–7
229. Dempsey DA, Meyers MJ, Oh SS, et al. Determination of tobacco smoke exposure by plasma cotinine levels in infants and children attending urban public hospital clinics. *Arch Pediatr Adolesc Med*. 2012;166(9):851–856
230. Rosen LJ, Noach MB, Winickoff JP, Hovell MF. Parental smoking cessation to protect young children: a systematic review and meta-analysis. *Pediatrics*. 2012;129(1):141–152
231. Matt GE, Quintana PJ, Destaillats H, et al. Thirdhand tobacco smoke: emerging evidence and arguments for a multidisciplinary research agenda. *Environ Health Perspect*. 2011;119(9):1218–1226
232. Section on Breastfeeding. Breastfeeding and the use of human milk. *Pediatrics*. 2012;129(3). Available at: www.pediatrics.org/cgi/content/full/129/3/e827
233. Ip S, Chung M, Raman G, et al. *Breastfeeding and Maternal and Infant Health Outcomes in Developed Countries*. Rockville,

MD: Agency for Healthcare Research and Quality; 2007

234. Dornelles CT, Piva JP, Marostica PJ. Nutritional status, breastfeeding, and evolution of infants with acute viral bronchiolitis. *J Health Popul Nutr*. 2007;25(3):336–343
235. Oddy WH, Sly PD, de Klerk NH, et al. Breast feeding and respiratory morbidity in infancy: a birth cohort study. *Arch Dis Child*. 2003;88(3):224–228
236. Nishimura T, Suzue J, Kaji H. Breastfeeding reduces the severity of respiratory syncytial virus infection among young infants: a multi-center prospective study. *Pediatr Int*. 2009;51(6):812–816
237. Petruzella FD, Gorelick MH. Duration of illness in infants with bronchiolitis evaluated in the emergency department. *Pediatrics*. 2010;126(2):285–290
238. von Linstow ML, Eugen-Olsen J, Koch A, Winther TN, Westh H, Hogh B. Excretion patterns of human metapneumovirus and respiratory syncytial virus among young children. *Eur J Med Res*. 2006;11(8):329–335
239. Sacri AS, De Serres G, Quach C, Boulianne N, Valiquette L, Skowronski DM. Transmission of acute gastroenteritis and respiratory illness from children to parents. *Pediatr Infect Dis J*. 2014;33(6):583–588
240. Taylor JA, Kwan-Gett TS, McMahon EM Jr. Effectiveness of an educational intervention in modifying parental attitudes about antibiotic usage in children. *Pediatrics*. 2003;111 (5 pt 1). Available at: www.pediatrics.org/cgi/content/full/111/5pt1/e548
241. Kuzujanakis M, Kleinman K, Rifas-Shiman S, Finkelstein JA. Correlates of parental antibiotic knowledge, demand, and reported use. *Ambul Pediatr*. 2003;3(4):203–210
242. Mangione-Smith R, McGlynn EA, Elliott MN, Krogstad P, Brook RH. The relationship between perceived parental expectations and pediatrician antimicrobial prescribing behavior. *Pediatrics*. 1999;103(4 pt 1):711–718

APPENDIX 1 SEARCH TERMS BY TOPIC

Introduction

MedLine

((“bronchiolitis”[MeSH]) OR (“respiratory syncytial viruses”[MeSH]) NOT “bronchiolitis obliterans”[All Fields])

1. and exp Natural History/
2. and exp Epidemiology/
3. and (exp economics/ or exp “costs and cost analysis”/ or exp “cost allocation”/ or exp cost-benefit analysis/ or exp “cost control”/ or exp “cost of illness”/ or exp “cost sharing”/ or exp health care costs/ or exp health expenditures/)
4. and exp Risk Factors/

Limit to English Language AND Humans AND (“all infant (birth to 23 months)” or “newborn infant (birth to 1 month)” or “infant (1 to 23 months)”)

CINAHL

(MM “Bronchiolitis+”) AND (“natural history” OR (MM “Epidemiology”) OR (MM “Costs and Cost Analysis”) OR (MM “Risk Factors”))

The Cochrane Library

Bronchiolitis AND (epidemiology OR risk factor OR cost)

Diagnosis/Severity

MedLine

exp BRONCHIOLITIS/di [Diagnosis] OR exp Bronchiolitis, Viral/di [Diagnosis]

limit to English Language AND (“all infant (birth to 23 months)” or “newborn infant (birth to 1 month)” or “infant (1 to 23 months)”)

CINAHL

(MH “Bronchiolitis/DI”)

The Cochrane Library

Bronchiolitis AND Diagnosis

*Upper Respiratory Infection Symptoms

MedLine

(exp Bronchiolitis/ OR exp Bronchiolitis, Viral/) AND exp *Respiratory Tract Infections/

Limit to English Language

Limit to “all infant (birth to 23 months)” OR “newborn infant (birth to 1 month)” OR “infant (1 to 23 months)”)

CINAHL

(MM “Bronchiolitis+”) AND (MM “Respiratory Tract Infections+”)

The Cochrane Library

Bronchiolitis AND Respiratory Infection

Inhalation Therapies

*Bronchodilators & Corticosteroids

MedLine

((“bronchiolitis”[MeSH]) OR (“respiratory syncytial viruses”[MeSH]) NOT “bronchiolitis obliterans”[All Fields])

AND (exp Receptors, Adrenergic, β-2/ OR exp Receptors, Adrenergic, β/ OR exp Receptors, Adrenergic, β-1/ OR β adrenergic*.mp. OR exp ALBUTEROL/ OR levalbuterol.mp. OR exp EPINEPHRINE/ OR exp Cholinergic Antagonists/ OR exp IPRATROPIUM/ OR exp Anti-Inflammatory Agents/ OR ics.mp. OR inhaled corticosteroid*.mp. OR exp Adrenal Cortex Hormones/ OR exp Leukotriene Antagonists/ OR montelukast.mp. OR exp Bronchodilator Agents/)

Limit to English Language AND (“all infant (birth to 23 months)” or “newborn infant (birth to 1 month)” or “infant (1 to 23 months)”)

CINAHL

(MM “Bronchiolitis+”) AND (MM “Bronchodilator Agents”)

The Cochrane Library

Bronchiolitis AND (bronchodilator OR epinephrine OR albuterol OR salbutamol OR corticosteroid OR steroid)

*Hypertonic Saline

MedLine

((“bronchiolitis”[MeSH]) OR (“respiratory syncytial viruses”[MeSH]) NOT “bronchiolitis obliterans”[All Fields])

AND (exp Saline Solution, Hypertonic/ OR (aerosolized saline.mp. OR (exp AEROSOLS/ AND exp Sodium Chloride/)) OR (exp Sodium Chloride/ AND exp “Nebulizers and Vaporizers”/) OR nebulized saline.mp.)

Limit to English Language

Limit to “all infant (birth to 23 months)” OR “newborn infant (birth to 1 month)” OR “infant (1 to 23 months)”)

CINAHL

(MM “Bronchiolitis+”) AND (MM “Saline Solution, Hypertonic”)

The Cochrane Library

Bronchiolitis AND Hypertonic Saline

Oxygen

MedLine

((“bronchiolitis”[MeSH]) OR (“respiratory syncytial viruses”[MeSH]) NOT “bronchiolitis obliterans”[All Fields])

1. AND (exp Oxygen Inhalation Therapy/ OR supplemental oxygen.mp. OR oxygen saturation.mp. OR *Oxygen/ad, st [Administration & Dosage, Standards] OR oxygen treatment.mp.)
2. AND (exp OXIMETRY/ OR oximeters.mp.) AND (exp “Reproducibility of Results”/ OR reliability.mp. OR function.mp. OR technical specifications.mp.) OR (percutaneous measurement*.mp. OR exp Blood Gas Analysis/)

Limit to English Language

Limit to “all infant (birth to 23 months)” OR “newborn infant (birth to 1 month)” OR “infant (1 to 23 months)”)

CINAHL

(MM "Bronchiolitis+") AND

((MM "Oxygen Therapy") OR (MM "Oxygen+") OR (MM "Oxygen Saturation") OR (MM "Oximetry+") OR (MM "Pulse Oximetry") OR (MM "Blood Gas Monitoring, Transcutaneous"))

The Cochrane Library

Bronchiolitis AND (oxygen OR oximetry)

Chest Physiotherapy and Suctioning

MedLine

(("bronchiolitis"[MeSH]) OR ("respiratory syncytial viruses"[MeSH]) NOT "bronchiolitis obliterans"[All Fields])

1. AND (Chest physiotherapy.mp. OR (exp Physical Therapy Techniques/ AND exp Thorax/))
2. AND (Nasal Suction.mp. OR (exp Suction/))

Limit to English Language

Limit to "all infant (birth to 23 months)" OR "newborn infant (birth to 1 month)" OR "infant (1 to 23 months)"

CINAHL

(MM "Bronchiolitis+")

1. AND ((MH "Chest Physiotherapy (Saba CCC)") OR (MH "Chest Physical Therapy+") OR (MH "Chest Physiotherapy (Iowa NIC)"))
2. AND (MH "Suctioning, Nasopharyngeal")

The Cochrane Library

Bronchiolitis AND (chest physiotherapy OR suction*)

Hydration

MedLine

(("bronchiolitis"[MeSH]) OR ("respiratory syncytial viruses"[MeSH]) NOT "bronchiolitis obliterans"[All Fields])

AND (exp Fluid Therapy/ AND (exp infusions, intravenous OR exp administration, oral))

Limit to English Language

Limit to ("all infant (birth to 23 months)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)")

CINAHL

(MM "Bronchiolitis+") AND

((MM "Fluid Therapy+") OR (MM "Hydration Control (Saba CCC)") OR (MM "Hydration (Iowa NOC)"))

The Cochrane Library

Bronchiolitis AND (hydrat* OR fluid*)

SBI and Antibacterials

MedLine

(("bronchiolitis"[MeSH]) OR ("respiratory syncytial viruses"[MeSH]) NOT "bronchiolitis obliterans"[All Fields])

AND

(exp Bacterial Infections/ OR exp Bacterial Pneumonia/ OR exp Otitis Media/ OR exp Meningitis/ OR exp *Anti-bacterial Agents/ OR exp Sepsis/ OR exp Urinary Tract Infections/ OR exp Bacteremia/ OR exp Tracheitis OR serious bacterial infection.mp.)

Limit to English Language

Limit to ("all infant (birth to 23 months)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)")

CINAHL

(MM "Bronchiolitis+") AND

((MM "Pneumonia, Bacterial+") OR (MM "Bacterial Infections+") OR (MM "Otitis Media+") OR (MM "Meningitis, Bacterial+") OR (MM "Antiinfective Agents+") OR (MM "Sepsis+") OR (MM "Urinary Tract Infections+") OR (MM "Bacteremia"))

The Cochrane Library

Bronchiolitis AND (serious bacterial infection OR sepsis OR otitis media OR meningitis OR urinary tract infection or bacteremia OR pneumonia OR antibacterial OR antimicrobial OR antibiotic)

Hand Hygiene, Tobacco, Breastfeeding, Parent Education

MedLine

(("bronchiolitis"[MeSH]) OR ("respiratory syncytial viruses"[MeSH]) NOT "bronchiolitis obliterans"[All Fields])

1. AND (exp Hand Disinfection/ OR hand decontamination.mp. OR handwashing.mp.)
2. AND exp Tobacco/
3. AND (exp Breast Feeding/ OR exp Milk, Human/ OR exp Bottle Feeding/)

Limit to English Language

Limit to ("all infant (birth to 23 months)" or "newborn infant (birth to 1 month)" or "infant (1 to 23 months)")

CINAHL

(MM "Bronchiolitis+")

1. AND (MH "Handwashing+")
2. AND (MH "Tobacco+")
3. AND (MH "Breast Feeding+" OR MH "Milk, Human+" OR MH "Bottle Feeding+")

The Cochrane Library

Bronchiolitis

1. AND (Breast Feeding OR breastfeeding)
2. AND tobacco
3. AND (hand hygiene OR handwashing OR hand decontamination)

Bronchiolitis Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — The Diagnosis, Management, and Prevention of Bronchiolitis
- *ICD-10-CM* Coding Quick Reference for Bronchiolitis
- AAP Patient Education Handout
  — *Bronchiolitis and Your Young Child*

Action Statement Summary

The Diagnosis, Management, and Prevention of Bronchiolitis

Key Action Statement 1a

Clinicians should diagnose bronchiolitis and assess disease severity on the basis of history and physical examination (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 1b

Clinicians should assess risk factors for severe disease, such as age <12 weeks, a history of prematurity, underlying cardiopulmonary disease, or immunodeficiency, when making decisions about evaluation and management of children with bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 1c

When clinicians diagnose bronchiolitis on the basis of history and physical examination, radiographic or laboratory studies should not be obtained routinely (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 2

Clinicians should not administer albuterol (or salbutamol) to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 3

Clinicians should not administer epinephrine to infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 4a

Nebulized hypertonic saline should not be administered to infants with a diagnosis of bronchiolitis in the emergency department (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 4b

Clinicians may administer nebulized hypertonic saline to infants and children hospitalized for bronchiolitis (Evidence Quality: B; Recommendation Strength: Weak Recommendation [based on randomized controlled trials with inconsistent findings]).

Key Action Statement 5

Clinicians should not administer systemic corticosteroids to infants with a diagnosis of bronchiolitis in any setting (Evidence Quality: A; Recommendation Strength: Strong Recommendation).

Key Action Statement 6a

Clinicians may choose not to administer supplemental oxygen if the oxyhemoglobin saturation exceeds 90% in infants and children with a diagnosis of bronchiolitis (Evidence Quality: D; Recommendation Strength: Weak Recommendation [based on low-level evidence and reasoning from first principles]).

Key Action Statement 6b

Clinicians may choose not to use continuous pulse oximetry for infants and children with a diagnosis of bronchiolitis (Evidence Quality: C; Recommendation Strength: Weak Recommendation [based on lower-level evidence]).

Key Action Statement 7

Clinicians should not use chest physiotherapy for infants and children with a diagnosis of bronchiolitis (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 8

Clinicians should not administer antibacterial medications to infants and children with a diagnosis of bronchiolitis unless there is a concomitant bacterial infection, or a strong suspicion of one. (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 9

Clinicians should administer nasogastric or intravenous fluids for infants with a diagnosis of bronchiolitis who cannot maintain hydration orally (Evidence Quality: X; Recommendation Strength: Strong Recommendation).

Key Action Statement 10a

Clinicians should not administer palivizumab to otherwise healthy infants with a gestational age of 29 weeks, 0 days or greater (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 10b

Clinicians should administer palivizumab during the first year of life to infants with hemodynamically significant heart disease or chronic lung disease of prematurity defined as preterm infants <32 weeks, 0 days' gestation who require >21% oxygen for at least the first 28 days of life (Evidence Quality: B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 10c

Clinicians should administer a maximum 5 monthly doses (15 mg/kg/dose) of palivizumab during the RSV season to infants who qualify for palivizumab in the first year of life (Evidence Quality: B, Recommendation Strength: Moderate Recommendation).

Key Action Statement 11a

All people should disinfect hands before and after direct contact with patients, after contact with inanimate objects in the direct vicinity of the patient, and after removing gloves (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 11b

All people should use alcohol-based rubs for hand decontamination when caring for children with bronchiolitis. When alcohol-based rubs are not available, individuals should wash their hands with soap and water (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 12a

Clinicians should inquire about the exposure of the infant or child to tobacco smoke when assessing infants and children for bronchiolitis (Evidence Quality: C; Recommendation Strength: Moderate Recommendation).

Key Action Statement 12b

Clinicians should counsel caregivers about exposing the infant or child to environmental tobacco smoke and smoking cessation when assessing a child for bronchiolitis (Evidence Quality: B; Recommendation Strength: Strong Recommendation).

Key Action Statement 13

Clinicians should encourage exclusive breastfeeding for at least 6 months to decrease the morbidity of respiratory infections (Evidence Quality: Grade B; Recommendation Strength: Moderate Recommendation).

Key Action Statement 14

Clinicians and nurses should educate personnel and family members on evidence-based diagnosis, treatment, and prevention in bronchiolitis (Evidence Quality: C; observational studies; Recommendation Strength; Moderate Recommendation).

Coding Quick Reference for Bronchiolitis
ICD-10-CM
J21.0 Acute bronchiolitis due to syncytial virus
J21.1 Acute bronchiolitis due to human metapneumovirus
J21.8 Acute bronchiolitis due to other specified organisms
J21.9 Acute bronchiolitis, unspecified

Bronchiolitis and Your Young Child

Bronchiolitis is a common respiratory illness among infants. One of its symptoms is trouble breathing, which can be scary for parents and young children. Read on for more information from the American Academy of Pediatrics about bronchiolitis, its causes, signs and symptoms, how to treat it, and how to prevent it.

What is bronchiolitis?

Bronchiolitis is an infection that causes the small breathing tubes of the lungs (bronchioles) to swell. This blocks airflow through the lungs, making it hard to breathe. It occurs most often in infants because their airways are smaller and more easily blocked than in older children. Bronchiolitis is not the same as bronchitis, which is an infection of the larger, more central airways that typically causes problems in adults.

What causes bronchiolitis?

Bronchiolitis is caused by one of several respiratory viruses such as influenza, respiratory syncytial virus (RSV), parainfluenza, and human metapneumovirus. Other viruses can also cause bronchiolitis.

Infants with RSV infection are more likely to get bronchiolitis with wheezing and difficulty breathing. Most adults and many older children with RSV infection only get a cold. RSV is spread by contact with an infected person's mucus or saliva (respiratory droplets produced during coughing or wheezing). It often spreads through families and child care centers. (See "How can you prevent your baby from getting bronchiolitis?")

What are the signs and symptoms of bronchiolitis?

Bronchiolitis often starts with signs of a cold, such as a runny nose, mild cough, and fever. After 1 or 2 days, the cough may get worse and an infant will begin to breathe faster. Your child may become dehydrated if he cannot comfortably drink fluids.

If your child shows any signs of troubled breathing or dehydration, call your child's doctor.

Signs of troubled breathing

- He may widen his nostrils and squeeze the muscles under his rib cage to try to get more air into and out of his lungs.
- When he breathes, he may grunt and tighten his stomach muscles.
- He will make a high-pitched whistling sound, called a wheeze, when he breathes out.
- He may have trouble drinking because he may have trouble sucking and swallowing.
- If it gets very hard for him to breathe, you may notice a bluish tint around his lips and fingertips. This tells you his airways are so blocked that there is not enough oxygen getting into his blood.

Signs of dehydration

- Drinking less than normal
- Dry mouth
- Crying without tears
- Urinating less often than normal

Can bronchiolitis be treated at home?

There is no specific treatment for RSV or other viruses that cause bronchiolitis. Antibiotics are not helpful because they treat illnesses caused by bacteria, not viruses. However, you can try to ease your child's symptoms.

To relieve a stuffy nose

- Thin the mucus using saline nose drops recommended by your child's doctor. Never use nonprescription nose drops that contain medicine.
- Clear your baby's nose with a suction bulb.Squeeze the bulb first. Gently put the rubber tip into one nostril, and slowly release the bulb. This suction will draw the clogged mucus out of the nose. This works best when your baby is younger than 6 months.

To relieve fever

Give your baby acetaminophen. (Follow the recommended dosage for your baby's age.) Do not give your baby aspirin because it has been associated with Reye syndrome, a disease that affects the liver and brain. Check with your child's doctor first before giving any other cold medicines.

To prevent dehydration

Make sure your baby drinks lots of fluid. She may want clear liquids rather than milk or formula. She may feed more slowly or not feel like eating because she is having trouble breathing.

Bronchiolitis and children with severe chronic illness

Bronchiolitis may cause more severe illness in children who have a chronic illness. If you think your child has bronchiolitis and she has any of the following conditions, call her doctor:

- Cystic fibrosis
- Congenital heart disease
- Chronic lung disease (seen in some infants who were on breathing machines or respirators as newborns)
- Immune deficiency disease (eg, acquired immunodeficiency syndrome [AIDS])
- Organ or bone marrow transplant
- A cancer for which she is receiving chemotherapy

How will your child's doctor treat bronchiolitis?

Your child's doctor will evaluate your child and advise you on nasal suctioning, fever control, and observation, as well as when to call back.

Some children with bronchiolitis need to be treated in a hospital for breathing problems or dehydration. Breathing problems may need to be treated with oxygen and medicine. Dehydration is treated with a special liquid diet or intravenous (IV) fluids.

In very rare cases when these treatments aren't working, an infant might have to be put on a respirator. This is usually only temporary until the infection is gone.

How can you prevent your baby from getting bronchiolitis?

The best steps you can follow to reduce the risk that your baby becomes infected with RSV or other viruses that cause bronchiolitis include

- Make sure everyone washes their hands before touching your baby.
- Keep your baby away from anyone who has a cold, fever, or runny nose.
- Avoid sharing eating utensils and drinking cups with anyone who has a cold, fever, or runny nose.

If you have questions about the treatment of bronchiolitis, call your child's doctor.

From Your Doctor

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

healthychildren.org
Powered by pediatricians. Trusted by parents. from the American Academy of Pediatrics

Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE

Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents

abstract

FREE

Over the past 3 decades, the prevalence of childhood obesity has increased dramatically in North America, ushering in a variety of health problems, including type 2 diabetes mellitus (T2DM), which previously was not typically seen until much later in life. The rapid emergence of childhood T2DM poses challenges to many physicians who find themselves generally ill-equipped to treat adult diseases encountered in children. This clinical practice guideline was developed to provide evidence-based recommendations on managing 10- to 18-year-old patients in whom T2DM has been diagnosed. The American Academy of Pediatrics (AAP) convened a Subcommittee on Management of T2DM in Children and Adolescents with the support of the American Diabetes Association, the Pediatric Endocrine Society, the American Academy of Family Physicians, and the Academy of Nutrition and Dietetics (formerly the American Dietetic Association). These groups collaborated to develop an evidence report that served as a major source of information for these practice guideline recommendations. The guideline emphasizes the use of management modalities that have been shown to affect clinical outcomes in this pediatric population. Recommendations are made for situations in which either insulin or metformin is the preferred first-line treatment of children and adolescents with T2DM. The recommendations suggest integrating lifestyle modifications (ie, diet and exercise) in concert with medication rather than as an isolated initial treatment approach. Guidelines for frequency of monitoring hemoglobin A1c (HbA1c) and finger-stick blood glucose (BG) concentrations are presented. Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendation. The clinical practice guideline underwent peer review before it was approved by the AAP. This clinical practice guideline is not intended to replace clinical judgment or establish a protocol for the care of all children with T2DM, and its recommendations may not provide the only appropriate approach to the management of children with T2DM. Providers should consult experts trained in the care of children and adolescents with T2DM when treatment goals are not met or when therapy with insulin is initiated. The AAP acknowledges that some primary care clinicians may not be confident of their ability to successfully treat T2DM in a child because of the child's age, coexisting conditions, and/or other concerns. At any point at which a clinician feels he or she is not adequately trained or is uncertain about treatment, a referral to a pediatric medical subspecialist should be made. If a diagnosis of T2DM is made by a pediatric medical subspecialist, the primary care clinician should develop a comanagement strategy with the subspecialist to ensure that the child continues to receive appropriate care consistent with a medical home model in which the pediatrician partners with parents to ensure that all health needs are met. *Pediatrics* 2013;131:364–382

Kenneth C. Copeland, MD, Janet Silverstein, MD, Kelly R. Moore, MD, Greg E. Prazar, MD, Terry Raymer, MD, CDE, Richard N. Shiffman, MD, Shelley C. Springer, MD, MBA, Vidhu V. Thaker, MD, Meaghan Anderson, MS, RD, LD, CDE, Stephen J. Spann, MD, MBA, and Susan K. Flinn, MA

KEY WORDS

diabetes, type 2 diabetes mellitus, childhood, youth, clinical practice guidelines, comanagement, management, treatment

ABBREVIATIONS

AAP—American Academy of Pediatrics
AAFP—American Academy of Family Physicians
BG—blood glucose
FDA—US Food and Drug Administration
HbA1c—hemoglobin A1c
PES—Pediatric Endocrine Society
T1DM—type 1 diabetes mellitus
T2DM—type 2 diabetes mellitus
TODAY—Treatment Options for type 2 Diabetes in Adolescents and Youth

www.pediatrics.org/cgi/doi/10.1542/peds.2012-3494

doi:10.1542/peds.2012-3494

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Key action statements are as follows:

1. Clinicians must ensure that insulin therapy is initiated for children and adolescents with T2DM who are ketotic or in diabetic ketoacidosis and in whom the distinction between types 1 and 2 diabetes mellitus is unclear and, in usual cases, should initiate insulin therapy for patients
   a. who have random venous or plasma BG concentrations ≥250 mg/dL; or
   b. whose HbA1c is >9%.

2. In all other instances, clinicians should initiate a lifestyle modification program, including nutrition and physical activity, and start metformin as first-line therapy for children and adolescents at the time of diagnosis of T2DM.

3. The committee suggests that clinicians monitor HbA1c concentrations every 3 months and intensify treatment if treatment goals for finger-stick BG and HbA1c concentrations are not being met (intensification is defined in the Definitions box).

4. The committee suggests that clinicians advise patients to monitor finger-stick BG (see Key Action Statement 4 in the guideline for further details) concentrations in patients who
   a. are taking insulin or other medications with a risk of hypoglycemia; or
   b. are initiating or changing their diabetes treatment regimen; or
   c. have not met treatment goals; or
   d. have intercurrent illnesses.

5. The committee suggests that clinicians incorporate the Academy of Nutrition and Dietetics' *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines* in their dietary or nutrition counseling of patients with T2DM at the time of diagnosis and as part of ongoing management.

6. The committee suggests that clinicians encourage children and adolescents with T2DM to engage in moderate-to-vigorous exercise for at least 60 minutes daily and to limit nonacademic "screen time" to less than 2 hours a day.

Definitions

Adolescent: an individual in various stages of maturity, generally considered to be between 12 and 18 years of age.

Childhood T2DM: disease in the child who typically

- is overweight or obese (BMI ≥85th–94th and >95th percentile for age and gender, respectively);
- has a strong family history of T2DM;
- has substantial residual insulin secretory capacity at diagnosis (reflected by normal or elevated insulin and C-peptide concentrations);
- has insidious onset of disease;
- demonstrates insulin resistance (including clinical evidence of polycystic ovarian syndrome or acanthosis nigricans);
- lacks evidence for diabetic autoimmunity (negative for autoantibodies typically associated with T1DM). These patients are more likely to have hypertension and dyslipidemia than are those with T1DM.

Clinician: any provider within his or her scope of practice; includes medical practitioners (including physicians and physician extenders), dietitians, psychologists, and nurses.
Diabetes: according to the American Diabetes Association criteria, defined as

1. HbA1c ≥6.5% (test performed in an appropriately certified laboratory); or
2. fasting (defined as no caloric intake for at least 8 hours) plasma glucose ≥126 mg/dL (7.0 mmol/L); or
3. 2-hour plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test performed as described by the World Health Organization by using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water; or
4. a random plasma glucose ≥200 mg/dL (11.1 mmol/L) with symptoms of hyperglycemia.

(In the absence of unequivocal hyperglycemia, criteria 1–3 should be confirmed by repeat testing.)

Diabetic ketoacidosis: acidosis resulting from an absolute or relative insulin deficiency, causing fat breakdown and formation of β hydroxybutyrate. Symptoms include nausea, vomiting, dehydration, Kussmaul respirations, and altered mental status.

Fasting blood glucose: blood glucose obtained before the first meal of the day and after a fast of at least 8 hours.

Glucose toxicity: The effect of high blood glucose causing both insulin resistance and impaired β-cell production of insulin.

Intensification: Increase frequency of blood glucose monitoring and adjustment of the dose and type of medication in an attempt to normalize blood glucose concentrations.

Intercurrent illnesses: Febrile illnesses or associated symptoms severe enough to cause the patient to stay home from school and/or seek medical care.

Microalbuminuria: Albumin:creatinine ratio ≥30 mg/g creatinine but <300 mg/g creatinine.

Moderate hyperglycemia: blood glucose = 180–250 mg/dL.

Moderate-to-vigorous exercise: exercise that makes the individual breathe hard and perspire and that raises his or her heart rate. An easy way to define exercise intensity for patients is the "talk test": during moderate physical activity a person can talk, but not sing. During vigorous activity, a person cannot talk without pausing to catch a breath.

Obese: BMI ≥95th percentile for age and gender.

Overweight: BMI between the 85th and 94th percentile for age and gender.

Prediabetes: Fasting plasma glucose ≥100–125 mg/dL or 2-hour glucose concentration during an oral glucose tolerance test ≥126 but <200 mg/dL or an HbA1c of 5.7% to 6.4%.

Severe hyperglycemia: blood glucose >250 mg/dL.

Thiazolidinediones (TZDs): Oral hypoglycemic agents that exert their effect at least in part by activation of the peroxisome proliferator-activated receptor γ.

Type 1 diabetes mellitus (T1DM): Diabetes secondary to autoimmune destruction of β cells resulting in absolute (complete or near complete) insulin deficiency and requiring insulin injections for management.

Type 2 diabetes mellitus (T2DM): The investigators' designation of the diagnosis was used for the purposes of the literature review. The committee acknowledges the distinction between T1DM and T2DM in this population is not always clear cut, and clinical judgment plays an important role. Typically, this diagnosis is made when hyperglycemia is secondary to insulin resistance accompanied by impaired β-cell function resulting in inadequate insulin production to compensate for the degree of insulin resistance.

Youth: used interchangeably with "adolescent" in this document.

INTRODUCTION

Over the past 3 decades, the prevalence of childhood obesity has increased dramatically in North America,[1–5] ushering in a variety of health problems, including type 2 diabetes mellitus (T2DM), which previously was not typically seen until much later in life. Currently, in the United States, up to 1 in 3 new cases of diabetes mellitus diagnosed in youth younger than 18 years is T2DM (depending on the ethnic composition of the patient population),[6,7] with a disproportionate representation in ethnic minorities[8,9] and occurring most commonly among youth between 10 and 19 years of age.[5,10] This trend is not limited to the United States but is occurring internationally[11]; it is projected that by the year 2030, an estimated 366 million people worldwide will have diabetes mellitus.[12]

The rapid emergence of childhood T2DM poses challenges to many physicians who find themselves generally ill-equipped to treat adult diseases encountered in children. Most diabetes education materials designed for pediatric patients are directed primarily to families of children with type 1 diabetes mellitus (T1DM) and emphasize insulin treatment and glucose monitoring, which may or may not be appropriate for children with

T2DM.[13,14] The National Diabetes Education Program TIP sheets (which can be ordered or downloaded from www.yourdiabetesinfo.org or ndep.nih.gov) provide guidance on healthy eating, physical activity, and dealing with T2DM in children and adolescents, but few other resources are available that are directly targeted at youth with this disease.[15] Most medications used for T2DM have been tested for safety and efficacy only in people older than 18 years, and there is scant scientific evidence for optimal management of children with T2DM.[16,17] Recognizing the scarcity of evidence-based data, this report provides a set of guidelines for the management and treatment of children with T2DM that is based on a review of current medical literature covering a period from January 1, 1990, to July 1, 2008.

Despite these limitations, the practicing physician is likely to be faced with the need to provide care for children with T2DM. Thus, the American Academy of Pediatrics (AAP), the Pediatric Endocrine Society (PES), the American Academy of Family Physicians (AAFP), American Diabetes Association, and the Academy of Nutrition and Dietetics (formerly the American Dietetic Association) partnered to develop a set of guidelines that might benefit endocrinologists and generalists, including pediatricians and family physicians alike. This clinical practice guideline may not provide the only appropriate approach to the management of children with T2DM. It is not expected to serve as a sole source of guidance in the management of children and adolescents with T2DM, nor is it intended to replace clinical judgment or establish a protocol for the care of all children with this condition. Rather, it is intended to assist clinicians in decision-making.

Primary care providers should endeavor to obtain the requisite skills to care for children and adolescents with T2DM, and should communicate and work closely with a diabetes team of subspecialists when such consultation is available, practical, and appropriate. The frequency of such consultations will vary, but should usually be obtained at diagnosis and then at least annually if possible. When treatment goals are not met, the committee encourages clinicians to consult with an expert trained in the care of children and adolescents with T2DM.[18,19] When first-line therapy (eg, metformin) fails, recommendations for intensifying therapy should be generally the same for pediatric and adult populations. The picture is constantly changing, however, as new drugs are introduced, and some drugs that initially appeared to be safe demonstrate adverse effects with wider use. Clinicians should, therefore, remain alert to new developments with regard to treatment of T2DM. Seeking the advice of an expert can help ensure that the treatment goals are appropriately set and that clinicians benefit from cutting-edge treatment information in this rapidly changing area.

The Importance of Family-Centered Diabetes Care

Family structure, support, and education help inform clinical decision-making and negotiations with the patient and family about medical preferences that affect medical decisions, independent of existing clinical recommendations. Because adherence is a major issue in any lifestyle intervention, engaging the family is critical not only to maintain needed changes in lifestyle but also to foster medication adherence.[20–22] The family's ideal role in lifestyle interventions varies, however, depending on the child's age. Behavioral interventions in younger children have shown a favorable effect. With adolescents, however, interventions based on target-age behaviors (eg, including phone or Internet-based interventions as well as face-to-face or peer-enhanced activities) appear to foster better results, at least for weight management.[23]

Success in making lifestyle changes to attain therapeutic goals requires the initial and ongoing education of the patient and the entire family about healthy nutrition and exercise. Any behavior change recommendations must establish realistic goals and take into account the families' health beliefs and behaviors. Understanding the patient and family's perception of the disease (and overweight status) before establishing a management plan is important to dispel misconceptions and promote adherence.[24] Because T2DM disproportionately affects minority populations, there is a need to ensure culturally appropriate, family-centered care along with ongoing education.[25–28] Several observational studies cite the importance of addressing cultural issues within the family.[20–22]

Restrictions in Creating This Document

In developing these guidelines, the following restrictions governed the committee's work:

- Although the importance of diabetes detection and screening of at-risk populations is acknowledged and referenced, the guidelines are restricted to patients meeting the diagnostic criteria for diabetes (eg, this document focuses on treatment postdiagnosis). Specifically, this document and its recommendations do not pertain to patients with impaired fasting plasma glucose (100–125 mg/dL) or impaired glucose tolerance (2-hour oral glucose tolerance test plasma glucose: 140–200 mg/dL) or isolated insulin resistance.
- Although it is noted that the distinction between types 1 and 2 diabetes mellitus in children may be

difficult,[29,30] these recommendations pertain specifically to patients 10 to less than 18 years of age with T2DM (as defined above).

- Although the importance of high-risk care and glycemic control in pregnancy, including pregravid glycemia, is affirmed, the evidence considered and recommendations contained in this document do not pertain to diabetes in pregnancy, including diabetes in pregnant adolescents.
- Recommended screening schedules and management tools for select comorbid conditions (hypertension, dyslipidemia, nephropathy, microalbuminuria, and depression) are provided as resources in the accompanying technical report.[31] These therapeutic recommendations were adapted from other recommended guideline documents with references, without an independent assessment of their supporting evidence.

METHODS

A systematic review was performed and is described in detail in the accompanying technical report.[31] To develop the clinical practice guideline on the management of T2DM in children and adolescents, the AAP convened the Subcommittee on Management of T2DM in Children and Adolescents with the support of the American Diabetes Association, the PES, the AAFP, and the Academy of Nutrition and Dietetics. The subcommittee was co-chaired by 2 pediatric endocrinologists preeminent in their field and included experts in general pediatrics, family medicine, nutrition, Native American health, epidemiology, and medical informatics/guideline methodology. All panel members reviewed the AAP policy on Conflict of Interest and Voluntary Disclosure and declared all potential conflicts (see conflicts statements in the Task Force member list).

These groups partnered to develop an evidence report that served as a major source of information for these practice guideline recommendations.[31] Specific clinical questions addressed in the evidence review were as follows: (1) the effectiveness of treatment modalities for T2DM in children and adolescents, (2) the efficacy of pharmaceutical therapies for treatment of children and adolescents with T2DM, (3) appropriate recommendations for screening for comorbidities typically associated with T2DM in children and adolescents, and (4) treatment recommendations for comorbidities of T2DM in children and adolescents. The accompanying technical report contains more information on comorbidities.[31]

Epidemiologic project staff searched Medline, the Cochrane Collaboration, and Embase. MESH terms used in various combinations in the search included diabetes, mellitus, type 2, type 1, treatment, prevention, diet, pediatric, T2DM, T1DM, NIDDM, metformin, lifestyle, RCT, meta-analysis, child, adolescent, therapeutics, control, adult, obese, gestational, polycystic ovary syndrome, metabolic syndrome, cardiovascular, dyslipidemia, men, and women. In addition, the Boolean operators NOT, AND, OR were included in various combinations. Articles addressing treatment of diabetes mellitus were prospectively limited to those that were published in English between January 1990 and June 2008, included abstracts, and addressed children between the ages of 120 and 215 months with an established diagnosis of T2DM. Studies in adults were considered for inclusion if >10% of the study population was 45 years of age or younger. The Medline search limits included the following: clinical trial; meta-analysis; randomized controlled trial; review; child: 6–12 years; and adolescent: 13–18 years. Additional articles were identified by review of reference lists of relevant articles and ongoing studies recommended by a technical expert advisory group. All articles were reviewed for compliance with the search limitations and appropriateness for inclusion in this document.

Initially, 199 abstracts were identified for possible inclusion, of which 52 were retained for systematic review. Results of the literature review were presented in evidence tables and published in the final evidence report. An additional literature search of Medline and the Cochrane Database of

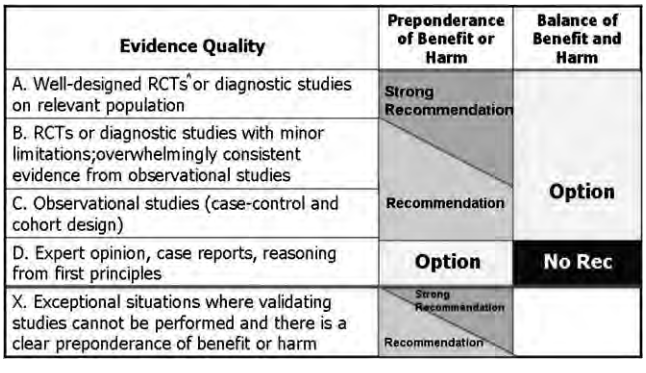


FIGURE 1

Evidence quality. Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation.[32] RCT, randomized controlled trial; Rec, recommendation.

TABLE 1 Definitions and Recommendation Implications

Statement	Definition	Implication
Strong recommendation	A *strong recommendation* in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A *recommendation* in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	*Options* define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	*No recommendation* indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

It should be noted that, because childhood T2DM is a relatively recent medical phenomenon, there is a paucity of evidence for many or most of the recommendations provided. In some cases, supporting references for a specific recommendation are provided that do not deal specifically with childhood T2DM, such as T1DM, childhood obesity, or childhood "prediabetes," or that were not included in the original comprehensive search. Committee members have made every effort to identify those references that did not affect or alter the level of evidence for specific recommendations.

Systematic Reviews was performed in July 2009 for articles discussing recommendations for screening and treatment of 5 recognized comorbidities of T2DM: cardiovascular disease, dyslipidemia, retinopathy, nephropathy, and peripheral vascular disease. Search criteria were the same as for the search on treatment of T2DM, with the inclusion of the term "type 1 diabetes mellitus." Search terms included, in various combinations, the following: diabetes, mellitus, type 2, type 1, pediatric, T2DM, T1DM, NIDDM, hyperlipidemia, retinopathy, microalbuminuria, comorbidities, screening, RCT, meta-analysis, child, and adolescent. Boolean operators and search limits mirrored those of the primary search.

An additional 336 abstracts were identified for possible inclusion, of which 26 were retained for systematic review. Results of this subsequent literature review were also presented in evidence tables and published in the final evidence report. An epidemiologist appraised the methodologic quality of the research before it was considered by the committee members.

The evidence-based approach to guideline development requires that the evidence in support of each key action statement be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement, "Classifying Recommendations for Clinical Practice Guidelines,"[32] was followed in designating levels of recommendation (see Fig 1 and Table 1).

To ensure that these recommendations can be effectively implemented, the Guidelines Review Group at Yale Center for Medical Informatics provided feedback on a late draft of these recommendations, using the GuideLine Implementability Appraisal.[33] Several potential obstacles to successful implementation were identified and resolved in the final guideline. Evidence was incorporated systematically into 6 key action statements about appropriate management facilitated by BRIDGE-Wiz software (Building Recommendations in a Developer's Guideline Editor; Yale Center for Medical Informatics).

A draft version of this clinical practice guideline underwent extensive peer review by 8 groups within the AAP, the American Diabetes Association, PES, AAFP, and the Academy of Nutrition and Dietetics. Members of the subcommittee were invited to distribute the draft to other representatives and committees within their specialty organizations. The resulting comments were reviewed by the subcommittee and incorporated into the guideline, as appropriate. All AAP guidelines are reviewed every 5 years.

KEY ACTION STATEMENTS

Key Action Statement 1

Clinicians must ensure that insulin therapy is initiated for children and adolescents with T2DM who are ketotic or in diabetic ketoacidosis and in whom the distinction between T1DM and T2DM is unclear; and, in usual cases, should initiate insulin therapy for patients:

a. who have random venous or plasma BG concentrations ≥250 mg/dL; or

b. whose HbA1c is >9%.

(Strong Recommendation: evidence quality X, validating studies cannot be performed, and C, observational studies and expert opinion; preponderance of benefit over harm.)

Action Statement Profile KAS 1

Aggregate evidence quality	X (validating studies cannot be performed)
Benefits	Avoidance of progression of diabetic ketoacidosis (DKA) and worsening metabolic acidosis; resolution of acidosis and hyperglycemia; avoidance of coma and/or death. Quicker restoration of glycemic control, potentially allowing islet β cells to "rest and recover," increasing long-term adherence to treatment; avoiding progression to DKA if T1DM. Avoiding hospitalization. Avoidance of potential risks associated with the use of other agents (eg, abdominal discomfort, bloating, loose stools with metformin; possible cardiovascular risks with sulfonylureas).
Harms/risks/cost	Potential for hypoglycemia, insulin-induced weight gain, cost, patient discomfort from injection, necessity for BG testing, more time required by the health care team for patient training.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	Extensive clinical experience of the expert panel was relied on in making this recommendation.
Role of patient preferences	Minimal.
Exclusions	None.
Intentional vagueness	None.
Strength	Strong recommendation.

The presentation of T2DM in children and adolescents varies according to the disease stage. Early in the disease, before diabetes diagnostic criteria are met, insulin resistance predominates with compensatory high insulin secretion, resulting in normoglycemia. Over time, β cells lose their ability to secrete adequate amounts of insulin to overcome insulin resistance, and hyperglycemia results. Early in this process, blood glucose (BG) concentrations may be normal much of the time and the patient likely will be asymptomatic. At this stage, the disease may only be detected by abnormal BG concentrations identified during screening. As insulin secretion declines further, the patient is likely to develop symptoms of hyperglycemia, occasionally with ketosis or frank ketoacidosis. High glucose concentrations can cause a reversible toxicity to islet β cells that contributes further to insulin deficiency. Of adolescents in whom T2DM is subsequently diagnosed, 5% to 25% present with ketoacidosis.[34]

Diabetic ketoacidosis must be treated with insulin and fluid and electrolyte replacement to prevent worsening metabolic acidosis, coma, and death. Children and adolescents with symptoms of hyperglycemia (polyuria, polydipsia, and polyphagia) who are diagnosed with diabetes mellitus should be evaluated for ketosis (serum or urine ketones) and, if positive, for ketoacidosis (venous pH), even if their phenotype and risk factor status (obesity, acanthosis nigricans, positive family history of T2DM) suggests T2DM. Patients in whom ketoacidosis is diagnosed require immediate treatment with insulin and fluid replacement in an inpatient setting under the supervision of a physician who is experienced in treating this complication.

Youth and adolescents who present with T2DM with poor glycemic control (BG concentrations ≥250 mg/dL or HbA1c >9%) but who lack evidence of ketosis or ketoacidosis may also benefit from initial treatment with insulin, at least on a short-term basis.[34] This allows for quicker restoration of glycemic control and, theoretically, may allow islet β cells to "rest and recover."[35,36] Furthermore, it has been noted that initiation of insulin may increase long-term adherence to treatment in children and adolescents with T2DM by enhancing the patient's perception of the seriousness of the disease.[7,37–40] Many patients with T2DM can be weaned gradually from insulin therapy and subsequently managed with metformin and lifestyle modification.[34]

As noted previously, in some children and adolescents with newly diagnosed diabetes mellitus, it may be difficult to distinguish between type 1 and type 2 disease (eg, an obese child presenting with ketosis).[39,41] These patients are best managed initially with insulin therapy while appropriate tests are performed to differentiate between T1DM and T2DM. The care of children and adolescents who have either newly diagnosed T2DM or undifferentiated-type diabetes and who require initial insulin treatment should be supervised by a physician experienced in treating diabetic patients with insulin.

Key Action Statement 2

In all other instances, clinicians should initiate a lifestyle modification program, including nutrition

and physical activity, and start metformin as first-line therapy for children and adolescents at the time of diagnosis of T2DM. (Strong recommendation: evidence quality B; 1 RCT showing improved outcomes with metformin versus lifestyle; preponderance of benefits over harms.)

Action Statement Profile KAS 2

Aggregate evidence quality	B (1 randomized controlled trial showing improved outcomes with metformin versus lifestyle combined with expert opinion).
Benefit	Lower HbA1c, target HbA1c sustained longer, less early deterioration of BG, less chance of weight gain, improved insulin sensitivity, improved lipid profile.
Harm (of using metformin)	Gastrointestinal adverse effects or potential for lactic acidosis and vitamin B_{12} deficiency, cost of medications, cost to administer, need for additional instruction about medication, self-monitoring blood glucose (SMBG), perceived difficulty of insulin use, possible metabolic deterioration if T1DM is misdiagnosed and treated as T2DM, potential risk of lactic acidosis in the setting of ketosis or significant dehydration. It should be noted that there have been no cases reported of vitamin B_{12} deficiency or lactic acidosis with the use of metformin in children.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	Committee members valued faster achievement of BG control over not medicating children.
Role of patient preferences	Moderate; precise implementation recommendations likely will be dictated by patient preferences regarding healthy nutrition, potential medication adverse reaction, exercise, and physical activity.
Exclusions	Although the recommendation to start metformin applies to all, certain children and adolescents with T2DM will not be able to tolerate metformin. In addition, certain older or more debilitated patients with T2DM may be restricted in the amount of moderate-to-vigorous exercise they can perform safely. Nevertheless, this recommendation applies to the vast majority of children and adolescents with T2DM.
Intentional vagueness	None.
Policy level	Strong recommendation.

Metformin as First-Line Therapy

Because of the low success rate with diet and exercise alone in pediatric patients diagnosed with T2DM, metformin should be initiated along with the promotion of lifestyle changes, unless insulin is needed to reverse glucose toxicity in the case of significant hyperglycemia or ketoacidosis (see Key Action Statement 1). Because gastrointestinal adverse effects are common with metformin therapy, the committee recommends starting the drug at a low dose of 500 mg daily, increasing by 500 mg every 1 to 2 weeks, up to an ideal and maximum dose of 2000 mg daily in divided doses.[41] It should be noted that the main gastrointestinal adverse effects (abdominal pain, bloating, loose stools) present at initiation of metformin often are transient and often disappear completely if medication is continued. Generally, doses higher than 2000 mg daily do not provide additional therapeutic benefit.[34,42,43] In addition, the use of extended-release metformin, especially with evening dosing, may be considered, although data regarding the frequency of adverse effects with this preparation are scarce. Metformin is generally better tolerated when taken with food. It is important to recognize the paucity of credible RCTs in adolescents with T2DM. The evidence to recommend initiating metformin at diagnosis along with lifestyle changes comes from 1 RCT, several observational studies, and consensus recommendations.

Lifestyle modifications (including nutrition interventions and increased physical activity) have long been the cornerstone of therapy for T2DM. Yet, medical practitioners recognize that effecting these changes is both challenging and often accompanied by regression over time to behaviors not conducive to maintaining the target range of BG concentrations. In pediatric patients, lifestyle change is most likely to be successful when a multidisciplinary approach is used and the entire family is involved. (Encouragement of healthy eating and physical exercise are discussed in Key Action Statements 5 and 6.) Unfortunately, efforts at lifestyle change often fail for a variety of reasons, including high rates of loss to follow-up; a high rate of depression in teenagers, which affects adherence; and peer pressure to participate in activities that often center on unhealthy eating.

Expert consensus is that fewer than 10% of pediatric T2DM patients will attain their BG goals through lifestyle interventions alone.[6,35,44] It is possible that the poor long-term success rates observed from lifestyle interventions stem from patients' perception that the intervention is not important because medications are not being prescribed. One might speculate that prescribing medications, particularly insulin therapy, may convey a greater degree of concern for the patient's health and the seriousness of the diagnosis, relative to that conveyed when medications are not needed, and that improved treatment adherence and follow-up may result from the use of medication. Indeed, 2 prospective observational studies revealed that treatment with

lifestyle modification alone is associated with a higher rate of loss to follow-up than that found in patients who receive medication.[45]

Before initiating treatment with metformin, a number of important considerations must be taken into account. First, it is important to determine whether the child with a new diagnosis has T1DM or T2DM, and it is critical to err on the side of caution if there is any uncertainty. The 2009 *Clinical Practice Consensus Guidelines on Type 2 Diabetes in Children and Adolescents* from the International Society for Pediatric and Adolescent Diabetes provides more information on the classification of diabetes in children and adolescents with new diagnoses.[46] If the diagnosis is unclear (as may be the case when an obese child with diabetes presents also with ketosis), the adolescent must be treated with insulin until the T2DM diagnosis is confirmed.[47] Although it is recognized that some children with newly diagnosed T2DM may respond to metformin alone, the committee believes that the presence of either ketosis or ketoacidosis dictates an absolute initial requirement for insulin replacement. (This is addressed in Key Action Statement 1.)

Although there is little debate that a child presenting with significant hyperglycemia and/or ketosis requires insulin, children presenting with more modest levels of hyperglycemia (eg, random BG of 200–249 mg/dL) or asymptomatic T2DM present additional therapeutic challenges to the clinician. In such cases, metformin alone, insulin alone, or metformin with insulin all represent reasonable options. Additional agents are likely to become reasonable options for initial pharmacologic management in the near future. Although metformin and insulin are the only antidiabetic agents currently approved by the US Food and Drug Administration (FDA) for use in children, both thiazolidinediones and incretins are occasionally used in adolescents younger than 18 years.[48]

Metformin is recommended as the initial pharmacologic agent in adolescents presenting with mild hyperglycemia and without ketonuria or severe hyperglycemia. In addition to improving hepatic insulin sensitivity, metformin has a number of practical advantages over insulin:

- Potential weight loss or weight neutrality.[37,48]
- Because of a lower risk of hypoglycemia, less frequent finger-stick BG measurements are required with metformin, compared with insulin therapy or sulfonylureas.[37,42,49–51]
- Improves insulin sensitivity and may normalize menstrual cycles in females with polycystic ovary syndrome. (Because metformin may also improve fertility in patients with polycystic ovary syndrome, contraception is indicated for sexually active patients who wish to avoid pregnancy.)
- Taking pills does not have the discomfort associated with injections.
- Less instruction time is required to start oral medication, making it is easier for busy practitioners to prescribe.
- Adolescents do not always accept injections, so oral medication might enhance adherence.[52]

Potential advantages of insulin over metformin for treatment at diabetes onset include the following:

- Metabolic control may be achieved more rapidly with insulin compared with metformin therapy.[37]
- With appropriate education and targeting the regimen to the individual, adolescents are able to accept and use insulin therapy with improved metabolic outcomes.[53]
- Insulin offers theoretical benefits of improved metabolic control while preserving β-cell function or even reversing β-cell damage.[34,35]
- Initial use of insulin therapy may convey to the patient a sense of seriousness of the disease.[7,53]

Throughout the writing of these guidelines, the authors have been following the progress of the National Institute of Diabetes and Digestive and Kidney Diseases–supported Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) trial,[54] designed to compare standard (metformin alone) therapy versus more aggressive therapy as the initial treatment of youth with recent-onset T2DM. Since the completion of these guidelines, results of the TODAY trial have become available and reveal that metformin alone is inadequate in effecting sustained glycemic control in the majority of youth with diabetes. The study also revealed that the addition of rosiglitazone to metformin is superior to metformin alone in preserving glycemic control. Direct application of these findings to clinical practice is problematic, however, because rosiglitazone is not FDA-approved for use in children, and its use, even in adults, is now severely restricted by the FDA because of serious adverse effects reported in adults. Thus, the results suggest that therapy that is more aggressive than metformin monotherapy may be required in these adolescents to prevent loss of glycemic control, but they do not provide specific guidance because it is not known whether the effect of the additional agent was specific to rosiglitazone or would be seen with the addition of other agents. Unfortunately, there are limited data for the use of other currently available oral or injected hypoglycemic agents in this age range, except for insulin. Therefore,

the writing group for these guidelines continues to recommend metformin as first-line therapy in this age group but with close monitoring for glycemic deterioration and the early addition of insulin or another pharmacologic agent if needed.

Lifestyle Modification, Including Nutrition and Physical Activity

Although lifestyle changes are considered indispensable to reaching treatment goals in diabetes, no significant data from RCTs provide information on success rates with such an approach alone.

A potential downside for initiating lifestyle changes alone at T2DM onset is potential loss of patients to follow-up and worse health outcomes. The value of lifestyle modification in the management of adolescents with T2DM is likely forthcoming after a more detailed analysis of the lifestyle intervention arm of the multicenter TODAY trial becomes available.[54] As noted previously, although it was published after this guideline was developed, the TODAY trial indicated that results from the metformin-plus-lifestyle intervention were not significantly different from either metformin alone or the metformin-plus-rosiglitazone intervention in maintaining glycemic control over time.[54]

Summary

As noted previously, metformin is a safe and effective agent for use at the time of diagnosis in conjunction with lifestyle changes. Although observational studies and expert opinion strongly support lifestyle changes as a key component of the regimen in addition to metformin, randomized trials are needed to delineate whether using lifestyle options alone is a reasonable first step in treating any select subgroups of children with T2DM.

Key Action Statement 3

The committee suggests that clinicians monitor HbA1c concentrations every 3 months and intensify treatment if treatment goals for BG and HbA1c concentrations are not being met. (Option: evidence quality D; expert opinion and studies in children with T1DM and in adults with T2DM; preponderance of benefits over harms.)

Action Statement Profile KAS 3

Aggregate evidence quality	D (expert opinion and studies in children with T1DM and in adults with T2DM; no studies have been performed in children and adolescents with T2DM).
Benefit	Diminishing the risk of progression of disease and deterioration resulting in hospitalization; prevention of microvascular complications of T2DM.
Harm	Potential for hypoglycemia from overintensifying treatment to reach HbA1c target goals; cost of frequent testing and medical consultation; possible patient discomfort.
Benefits-harms assessment	Preponderance of benefits over harms.
Value judgments	Recommendation dictated by widely accepted standards of diabetic care.
Role of patient preferences	Minimal; recommendation dictated by widely accepted standards of diabetic care.
Exclusions	None.
Intentional vagueness	Intentional vagueness in the recommendation as far as setting goals and intensifying treatment attributable to limited evidence.
Policy level	Option.

HbA1c provides a measure of glycemic control in patients with diabetes mellitus and allows an estimation of the individual's average BG over the previous 8 to 12 weeks. No RCTs have evaluated the relationship between glycemic control and the risk of developing microvascular and/or macrovascular complications in children and adolescents with T2DM. A number of studies of children with T1DM[55–57] and adults with T2DM have, however, shown a significant relationship between glycemic control (as measured by HbA1c concentration) and the risk of microvascular complications (eg, retinopathy, nephropathy, and neuropathy).[58,59] The relationship between HbA1c concentration and risk of microvascular complications appears to be curvilinear; the lower the HbA1c concentration, the lower the downstream risk of microvascular complications, with the greatest risk reduction seen at the highest HbA1c concentrations.[57]

It is generally recommended that HbA1c concentrations be measured every 3 months.[60] For adults with T1DM, the American Diabetes Association recommends target HbA1c concentrations of less than 7%; the American Association of Clinical Endocrinologists recommends target concentrations of less than 6.5%. Although HbA1c target concentrations for children and adolescents with T1DM are higher,[13] several review articles suggest target HbA1c concentrations of less than 7% for children and adolescents with T2DM.[40,61–63] The committee concurs that, ideally, target HbA1c concentration should be less than 7% but notes that specific goals must be achievable for the individual patient and that this concentration may not be applicable for all patients. For patients in whom a target concentration of less than 7% seems unattainable, individualized goals should be set, with the ultimate goal of reaching guideline target concentrations. In addition, in the absence of hypoglycemia, even lower HbA1c target concentrations can be considered on the basis of an absence of hypoglycemic events and other individual considerations.

When concentrations are found to be above the target, therapy should be intensified whenever possible, with the goal of bringing the concentration to target. Intensification activities may include, but are not limited to, increasing the frequency of clinic visits, engaging in more frequent BG monitoring, adding 1 or more antidiabetic agents, meeting with a registered dietitian and/or diabetes educator, and increasing attention to diet and exercise regimens. Patients whose HbA1c concentrations remain relatively stable may only need to be tested every 6 months. Ideally, real-time HbA1c concentrations should be available at the time of the patient's visit with the clinician to allow the physician and patient and/or parent to discuss intensification of therapy during the visit, if needed.

Key Action Statement 4

The committee suggests that clinicians advise patients to monitor finger-stick BG concentrations in those who

a. are taking insulin or other medications with a risk of hypoglycemia; or
b. are initiating or changing their diabetes treatment regimen; or
c. have not met treatment goals; or
d. have intercurrent illnesses.

(Option: evidence quality D; expert consensus. Preponderance of benefits over harms.)

Glycemic control correlates closely with the frequency of BG monitoring in adolescents with T1DM.[64,65] Although studies evaluating the efficacy of frequent BG monitoring have not been conducted in children and adolescents with T2DM, benefits have been described in insulin-treated adults with T2DM who tested their BG 4 times per day, compared with adults following a less frequent monitoring regimen.[66] These data support the value of BG monitoring in adults treated with insulin, and likely are relevant to youth with T2DM as well, especially those treated with insulin, at the onset of the disease, when treatment goals are not met, and when the treatment regimen is changed. The committee believes that current (2011) ADA recommendations for finger-stick BG monitoring apply to most youth with T2DM[67]:

- Finger-stick BG monitoring should be performed 3 or more times daily for patients using multiple insulin injections or insulin pump therapy.
- For patients using less-frequent insulin injections, noninsulin therapies, or medical nutrition therapy alone, finger-stick BG monitoring may be useful as a guide to the success of therapy.
- To achieve postprandial glucose targets, postprandial finger-stick BG monitoring may be appropriate.

Action Statement Profile KAS 4

Aggregate evidence quality	D (expert consensus).
Benefit	Potential for improved metabolic control, improved potential for prevention of hypoglycemia, decreased long-term complications.
Harm	Patient discomfort, cost of materials.
Benefits-harms assessment	Benefit over harm.
Value judgments	Despite lack of evidence, there were general committee perceptions that patient safety concerns related to insulin use or clinical status outweighed any risks from monitoring.
Role of patient preferences	Moderate to low; recommendation driven primarily by safety concerns.
Exclusions	None.
Intentional vagueness	Intentional vagueness in the recommendation about specific approaches attributable to lack of evidence and the need to individualize treatment.
Policy level	Option.

Recognizing that current practices may not always reflect optimal care, a 2004 survey of practices among members of the PES revealed that 36% of pediatric endocrinologists asked their pediatric patients with T2DM to monitor BG concentrations twice daily; 12% asked patients to do so once daily; 13% asked patients to do so 3 times per day; and 12% asked patients to do so 4 times daily.[61] The questionnaire provided to the pediatric endocrinologists did not ask about the frequency of BG monitoring in relationship to the diabetes regimen, however.

Although normoglycemia may be difficult to achieve in adolescents with T2DM, a fasting BG concentration of 70 to 130 mg/dL is a reasonable target for most. In addition, because postprandial hyperglycemia has been associated with increased risk of cardiovascular events in adults, postprandial BG testing may be valuable in select patients. BG concentrations obtained 2 hours after meals (and paired with pre-meal concentrations) provide an index of glycemic excursion, and may be useful in improving glycemic control, particularly for the patient whose fasting plasma glucose is normal but whose HbA1c is not at target.[68] Recognizing the limited evidence for benefit of FSBG testing in this population, the committee provides suggested guidance for testing frequency, tailored to the medication regimen, as follows:

BG Testing Frequency for Patients With Newly Diagnosed T2DM: Fasting, Premeal, and Bedtime Testing

The committee suggests that all patients with newly diagnosed T2DM, regardless of prescribed treatment plan, should perform finger-stick BG monitoring before meals (including a morning fasting concentration) and

at bedtime until reasonable metabolic control is achieved.[69] Once BG concentrations are at target levels, the frequency of monitoring can be modified depending on the medication used, the regimen's intensity, and the patient's metabolic control. Patients who are prone to marked hyperglycemia or hypoglycemia or who are on a therapeutic regimen associated with increased risk of hypoglycemia will require continued frequent BG testing. Expectations for frequency and timing of BG monitoring should be clearly defined through shared goal-setting between the patient and clinician. The adolescent and family members should be given a written action plan stating the medication regimen, frequency and timing of expected BG monitoring, as well as follow-up instructions.

BG Testing Frequency for Patients on Single Insulin Daily Injections and Oral Agents

Single bedtime long-acting insulin: The simplest insulin regimen consists of a single injection of long-acting insulin at bedtime (basal insulin only). The appropriateness of the insulin dose for patients using this regimen is best defined by the fasting/prebreakfast BG test. For patients on this insulin regimen, the committee suggests daily fasting BG measurements. This regimen is associated with some risk of hypoglycemia (especially overnight or fasting hypoglycemia) and may not provide adequate insulin coverage for mealtime ingestions throughout the day, as reflected by fasting BG concentrations in target, but daytime readings above target. In such cases, treatment with meglitinide (Prandin [Novo Nordisk Pharmaceuticals] or Starlix [Novartis Pharmaceuticals]) or a short-acting insulin before meals (see below) may be beneficial.

Oral agents: Once treatment goals are met, the frequency of monitoring can be decreased; however, the committee recommends some continued BG testing for all youth with T2DM, at a frequency determined within the clinical context (e.g. medication regimen, HbA1c, willingness of the patient, etc.). For example, an infrequent or intermittent monitoring schedule may be adequate when the patient is using exclusively an oral agent associated with a low risk of hypoglycemia and if HbA1c concentrations are in the ideal or non-diabetic range. A more frequent monitoring schedule should be advised during times of illness or if symptoms of hyperglycemia or hypoglycemia develop.

Oral agent plus a single injection of a long-acting insulin: Some youth with T2DM can be managed successfully with a single injection of long-acting insulin in conjunction with an oral agent. Twice a day BG monitoring (fasting plus a second BG concentration – ideally 2-hour post prandial) often is recommended, as long as HbA1c and BG concentrations remain at goal and the patient remains asymptomatic.

BG Testing Frequency for Patients Receiving Multiple Daily Insulin Injections (eg, Basal Bolus Regimens): Premeal and Bedtime Testing

Basal bolus regimens are commonly used in children and youth with T1DM and may be appropriate for some youth with T2DM as well. They are the most labor intensive, providing both basal insulin plus bolus doses of short-acting insulin at meals. Basal insulin is provided through either the use of long-acting, relatively peak-free insulin (by needle) or via an insulin pump. Bolus insulin doses are given at meal-time, using one of the rapid-acting insulin analogs. The bolus dose is calculated by using a correction algorithm for the premeal BG concentration as well as a "carb ratio," in which 1 unit of a rapid-acting insulin analog is given for "X" grams of carbohydrates ingested (see box below). When using this method, the patient must be willing and able to count the number of grams of carbohydrates in the meal and divide by the assigned "carb ratio (X)" to know how many units of insulin should be taken. In addition, the patient must always check BG concentrations before the meal to determine how much additional insulin should be given as a correction dose using an algorithm assigned by the care team if the fasting BG is not in target. Insulin pumps are based on this concept of "basal-bolus" insulin administration and have the capability of calculating a suggested bolus dosage, based on inputted grams of carbohydrates and BG concentrations. Because the BG value determines the amount of insulin to be given at each meal, the recommended testing frequency for patients on this regimen is before every meal.

Box 1 Example of Basal Bolus Insulin Regimen

If an adolescent has a BG of 250 mg/dL, is to consume a meal containing 60 g of carbohydrates, with a carbohydrate ratio of 1:10 and an assigned correction dose of 1:25>125 (with 25 being the insulin sensitivity and 125 mg/dL the target blood glucose level), the mealtime bolus dose of insulin would be as follows:

60 g/10 "carb ratio" =

6 units rapid-acting insulin for meal

plus

(250–125)/25 = 125/25 =

5 units rapid-acting insulin for correction

Thus, total bolus insulin coverage at mealtime is: **11 U** (6 + 5) of rapid-acting insulin.

Key Action Statement 5

The committee suggests that clinicians incorporate the Academy of Nutrition and Dietetics' *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines* in the nutrition counseling of patients with T2DM both at the time of diagnosis and as part of ongoing management. (Option; evidence quality D; expert opinion; preponderance of benefits over harms. Role of patient preference is dominant.)

Action Statement Profile KAS 5

Aggregate evidence quality	D (expert opinion).
Benefit	Promotes weight loss; improves insulin sensitivity; contributes to glycemic control; prevents worsening of disease; facilitates a sense of well-being; and improves cardiovascular health.
Harm	Costs of nutrition counseling; inadequate reimbursement of clinicians' time; lost opportunity costs vis-a-vis time and resources spent in other counseling activities.
Benefits-harms assessment	Benefit over harm.
Value judgments	There is a broad societal agreement on the benefits of dietary recommendations.
Role of patient preference	Dominant. Patients may have different preferences for how they wish to receive assistance in managing their weight-loss goals. Some patients may prefer a referral to a nutritionist while others might prefer accessing online sources of help. Patient preference should play a significant role in determining an appropriate weight-loss strategy.
Exclusions	None.
Intentional vagueness	Intentional vagueness in the recommendation about specific approaches attributable to lack of evidence and the need to individualize treatment.
Policy level	Option.

Consuming more calories than one uses results in weight gain and is a major contributor to the increasing incidence of T2DM in children and adolescents. Current literature is inconclusive about a single best meal plan for patients with diabetes mellitus, however, and studies specifically addressing the diet of children and adolescents with T2DM are limited. Challenges to making recommendations stem from the small sample size of these studies, limited specificity for children and adolescents, and difficulties in generalizing the data from dietary research studies to the general population.

Although evidence is lacking in children with T2DM, numerous studies have been conducted in overweight children and adolescents, because the great majority of children with T2DM are obese or overweight at diagnosis.[26] The committee suggests that clinicians encourage children and adolescents with T2DM to follow the Academy of Nutrition and Dietetics' recommendations for maintaining healthy weight to promote health and reduce obesity in this population. The committee recommends that clinicians refer patients to a registered dietitian who has expertise in the nutritional needs of youth with T2DM. Clinicians should incorporate the Academy of Nutrition and Dietetics' *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines*, which describe effective, evidence-based treatment options for weight management, summarized below (A complete list of these recommendations is accessible to health care professionals at: http://www.andevidencelibrary.com/topic.cfm?cat=4102&auth=1.)

According to the Academy of Nutrition and Dietetics' guidelines, when incorporated with lifestyle changes, balanced macronutrient diets at 900 to 1200 kcal per day are associated with both short- and long-term (eg, $\geq$ 1 year) improvements in weight status and body composition in children 6 to 12 years of age.[70] These calorie recommendations are to be incorporated with lifestyle changes, including increased activity and possibly medication. Restrictions of no less than 1200 kcal per day in adolescents 13 to 18 years old result in improved weight status and body composition as well.[71] The Diabetes Prevention Program demonstrated that participants assigned to the intensive lifestyle-intervention arm had a reduction in daily energy intake of 450 kcal and a 58% reduction in progression to diabetes at the 2.8-year follow-up.[71] At the study's end, 50% of the lifestyle-arm participants had achieved the goal weight loss of at least 7% after the 24-week curriculum and 38% showed weight loss of at least 7% at the time of their most recent visit.[72] The Academy of Nutrition and Dietetics recommends that protein-sparing, modified-fast (ketogenic) diets be restricted to children who are >120% of their ideal body weight and who have a serious medical complication that would benefit from rapid weight loss.[71] Specific recommendations are for the intervention to be short-term (typically 10 weeks) and to be conducted under the supervision of a multidisciplinary team specializing in pediatric obesity.

Regardless of the meal plan prescribed, some degree of nutrition education must be provided to maximize adherence and positive results. This education should encourage patients to follow healthy eating patterns, such as consuming 3 meals with planned snacks per day, not eating while watching television or using computers, using smaller plates to make portions appear larger, and leaving small amounts of food on the plate.[73] Common dietary recommendations to reduce calorie intake and to promote weight loss in children include the following: (1) eating regular meals and snacks; (2) reducing portion sizes; (3) choosing calorie-free beverages, except for milk; (4) limiting juice to 1 cup per day; (5) increasing consumption of fruits and vegetables; (6) consuming 3 or 4 servings of low-fat dairy products per day; (7) limiting intake of high-fat foods; (8) limiting frequency and size of snacks; and (9) reducing calories consumed in fast-food meals.[74]

Key Action Statement 6

The committee suggests that clinicians encourage children and adolescents with T2DM to engage in moderate-to-vigorous exercise for at least 60 minutes daily and to limit nonacademic screen time to less than 2 hours per day. (Option: evidence quality D, expert opinion and evidence from studies of metabolic syndrome and obesity; preponderance of benefits over harms. Role of patient preference is dominant.)

Action Statement Profile KAS 6

Aggregate evidence quality	D (expert opinion and evidence from studies of metabolic syndrome and obesity).
Benefit	Promotes weight loss; contributes to glycemic control; prevents worsening of disease; facilitates the ability to perform exercise; improves the person's sense of well-being; and fosters cardiovascular health.
Harm	Cost for patient of counseling, food, and time; costs for clinician in taking away time that could be spent on other activities; inadequate reimbursement for clinician's time.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	Broad consensus.
Role of patient preference	Dominant. Patients may seek various forms of exercise. Patient preference should play a significant role in creating an exercise plan.
Exclusions	Although certain older or more debilitated patients with T2DM may be restricted in the amount of moderate-to-vigorous exercise they can perform safely, this recommendation applies to the vast majority of children and adolescents with T2DM.
Intentional vagueness	Intentional vagueness on the sequence of follow-up contact attributable to the lack of evidence and the need to individualize care.
Policy level	Option.

Recommendations From the Academy of Nutrition and Dietetics

Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines

Recommendation	Strength
Interventions to reduce pediatric obesity should be multicomponent and include diet, physical activity, nutritional counseling, and parent or caregiver participation.	Strong
A nutrition prescription should be formulated as part of the dietary intervention in a multicomponent pediatric weight management program.	Strong
Dietary factors that may be associated with an increased risk of overweight are increased total dietary fat intake and increased intake of calorically sweetened beverages.	Strong
Dietary factors that may be associated with a decreased risk of overweight are increased fruit and vegetable intake.	Strong
A balanced macronutrient diet that contains no fewer than 900 kcal per day is recommended to improve weight status in children aged 6–12 y who are medically monitored.	Strong
A balanced macronutrient diet that contains no fewer than 1200 kcal per day is recommended to improve weight status in adolescents aged 13–18 y who are medically monitored.	Strong
Family diet behaviors that are associated with an increased risk of pediatric obesity are parental restriction of highly palatable foods, consumption of food away from home, increased meal portion size, and skipping breakfast.	Fair

Engaging in Physical Activity

Physical activity is an integral part of weight management for prevention and treatment of T2DM. Although there is a paucity of available data from children and adolescents with T2DM, several well-controlled studies performed in obese children and adolescents at risk of metabolic syndrome and T2DM provide guidelines for physical activity. (See the Resources section for tools on this subject.) A summary of the references supporting the evidence for this guideline can be found in the technical report.[31]

At present, moderate-to-vigorous exercise of at least 60 minutes daily is recommended for reduction of BMI and improved glycemic control in patients with T2DM.[75] "Moderate to

vigorous exercise" is defined as exercise that makes the individual breathe hard and perspire and that raises his or her heart rate. An easy way to define exercise intensity for patients is the "talk test"; during moderate physical activity a person can talk but not sing. During vigorous activity, a person cannot talk without pausing to catch a breath.[76]

Adherence may be improved if clinicians provide the patient with a written prescription to engage in physical activity, including a "dose" describing ideal duration, intensity, and frequency.[75] When prescribing physical exercise, clinicians are encouraged to be sensitive to the needs of children, adolescents, and their families. Routine, organized exercise may be beyond the family's logistical and/or financial means, and some families may not be able to provide structured exercise programs for their children. It is most helpful to recommend an individualized approach that can be incorporated into the daily routine, is tailored to the patients' physical abilities and preferences, and recognizes the families' circumstances.[77] For example, clinicians might recommend only daily walking, which has been shown to improve weight loss and insulin sensitivity in adults with T2DM[78] and may constitute "moderate to vigorous activity" for some children with T2DM. It is also important to recognize that the recommended 60 minutes of exercise do not have to be accomplished in 1 session but can be completed through several, shorter increments (eg, 10–15 minutes). Patients should be encouraged to identify a variety of forms of activity that can be performed both easily and frequently.[77] In addition, providers should be cognizant of the potential need to adjust the medication dosage, especially if the patient is receiving insulin, when initiating an aggressive physical activity program.

Reducing Screen Time

Screen time contributes to a sedentary lifestyle, especially when the child or adolescent eats while watching television or playing computer games. The US Department of Health and Human Services recommends that individuals limit "screen time" spent watching television and/or using computers and handheld devices to less than 2 hours per day unless the use is related to work or homework.[79] Physical activity may be gained either through structured games and sports or through everyday activities, such as walking, ideally with involvement of the parents as good role models.

Increased screen time and food intake and reduced physical activity are associated with obesity. There is good evidence that modifying these factors can help prevent T2DM by reducing the individual's rate of weight gain. The evidence profile in pediatric patients with T2DM is inadequate at this time, however. Pending new data, the committee suggests that clinicians follow the AAP Committee on Nutrition's guideline, *Prevention of Pediatric Overweight and Obesity*. The guideline recommends restricting nonacademic screen time to a maximum of 2 hours per day and discouraging the presence of video screens and television sets in children's bedrooms.[80–82] The American Medical Association's Expert Panel on Childhood Obesity has endorsed this guideline.

Valuable recommendations for enhancing patient health include the following:

- With patients and their families, jointly determining an individualized plan that includes specific goals to reduce sedentary behaviors and increase physical activity.
- Providing a written prescription for engaging in 60-plus minutes of moderate-to-vigorous physical activities per day that includes dose, timing, and duration. It is important for clinicians to be sensitive to the needs of children, adolescents, and their families in encouraging daily physical exercise. Graded duration of exercise is recommended for those youth who cannot initially be active for 60 minutes daily, and the exercise may be accomplished through several, shorter increments (eg, 10–15 minutes).
- Incorporating physical activities into children's and adolescents' daily routines. Physical activity may be gained either through structured games and sports or through everyday activities, such as walking.
- Restricting nonacademic screen time to a maximum of 2 hours per day.
- Discouraging the presence of video screens and television sets in children's bedrooms.

Conversations pertaining to the Key Action Statements should be clearly documented in the patient's medical record.

AREAS FOR FUTURE RESEARCH

As noted previously, evidence for medical interventions in children in general is scant and is especially lacking for interventions directed toward children who have developed diseases not previously seen commonly in youth, such as childhood T2DM. Recent studies such as the Search for Diabetes in Youth Study (SEARCH)—an observational multicenter study in 2096 youth with T2DM funded by the Centers for Disease Control and Prevention and the National Institute of Diabetes and Digestive and Kidney Diseases—now provide a detailed description of childhood diabetes. Subsequent trials will describe the short-term and enduring effects of specific interventions

on the progression of the disease with time.

Although it is likely that children and adolescents with T2DM have an aggressive form of diabetes, as reflected by the age of onset, future research should determine whether the associated comorbidities and complications of diabetes also are more aggressive in pediatric populations than in adults and if they are more or less responsive to therapeutic interventions. Additional research should explore whether early introduction of insulin or the use of particular oral agents will preserve β-cell function in these children, and whether recent technologic advances (such as continuous glucose monitoring and insulin pumps) will benefit this population. Additional issues that require further study include the following:

- To delineate whether using lifestyle options without medication is a reliable first step in treating selected children with T2DM.
- To determine whether BG monitoring should be recommended to all children and youth with T2DM, regardless of therapy used; what the optimal frequency of BG monitoring is for pediatric patients on the basis of treatment regimen; and which subgroups will be able to successfully maintain glycemic goals with less frequent monitoring.
- To explore the efficacy of school- and clinic-based diet and physical activity interventions to prevent and manage pediatric T2DM.
- To explore the association between increased "screen time" and reduced physical activity with respect to T2DM's risk factors.

RESOURCES

Several tools are available online to assist providers in improving patient adherence to lifestyle modifications, including examples of activities to be recommended for patients:

- The American Academy of Pediatrics:
  - www.healthychildren.org
  - www.letsmove.gov
  - Technical Report: Management of Type 2 Diabetes Mellitus in Children and Adolescents.[31]
    - Includes an overview and screening tools for a variety of comorbidities.
  - Gahagan S, Silverstein J; Committee on Native American Child Health and Section on Endocrinology. Clinical report: prevention and treatment of type 2 diabetes mellitus in children, with special emphasis on American Indian and Alaska Native Children. *Pediatrics*. 2003;112 (4):e328–e347. Available at: http://www.pediatrics.org/cgi/content/full/112/4/e328[63]
    - Fig 3 presents a screening tool for microalbumin.
  - Bright Futures: http://brightfutures.aap.org/
  - Daniels SR, Greer FR; Committee on Nutrition. Lipid screening and cardiovascular health in childhood. *Pediatrics*. 2008;122 (1):198–208. Available at:
- The American Diabetes Association: www.diabetes.org
  - Management of dyslipidemia in children and adolescents with diabetes. *Diabetes Care*. 2003;26(7):2194–2197. Available at: http://care.diabetesjournals.org/content/26/7/2194.full
- Academy of Nutrition and Dietetics:
  - http://www.eatright.org/childhoodobesity/
  - http://www.eatright.org/kids/
  - http://www.eatright.org/cps/rde/xchg/ada/hs.xsl/index.html
  - Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines: http://www.adaevidencelibrary.com/topic.cfm?cat=2721
- American Heart Association:
  - American Heart Association *Circulation*. 2006 Dec 12;114(24):2710-2738. Epub 2006 Nov 27. Review.
- Centers for Disease Control and Prevention:
  - http://www.cdc.gov/obesity/childhood/solutions.html
  - BMI and other growth charts can be downloaded and printed from the CDC Web site: http://www.cdc.gov/growthcharts.
  - Center for Epidemiologic Studies Depression Scale (CES-D): http://www.chcr.brown.edu/pcoc/cesdscale.pdf; see attachments
- *Diagnostic and Statistical Manual of Mental Disorders*. 4th ed. Washington, DC: American Psychiatric Association; 1994
- Let's Move Campaign: www.letsmove.gov
- The Reach Institute. *Guidelines for Adolescent Depression in Primary Care (GLAD-PC) Toolkit*, 2007. Contains a listing of the criteria for major depressive disorder as defined by the DSM-IV-TR. Available at: http://www.gladpc.org
- The National Heart, Lung, and Blood Institute (NHLBI) hypertension guidelines: http://www.nhlbi.nih.gov/guidelines/hypertension/child_tbl.htm
- The National Diabetes Education Program and TIP sheets (including tip sheets on youth transitioning to adulthood and adult providers, Staying Active, Eating Healthy, Ups and Downs of Diabetes, etc): www.ndep.nih.gov or www.yourdiabetesinfo.org

- National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents, The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents: *Pediatrics*. 2004;114:555–576. Available at: http://pediatrics.aappublications.org/content/114/Supplement_2/555.long
- National Initiative for Children's Healthcare Quality (NICHQ): childhood obesity section: http://www.nichq.org/childhood_obesity/index.html
- The National Institute of Child Health and Human Development (NICHD): www.NICHD.org
- President's Council on Physical Fitness and Sports: http://www.presidentschallenge.org/home_kids.aspx
- US Department of Agriculture's "My Pyramid" Web site:
  - http://www.choosemyplate.gov/
  - http://fnic.nal.usda.gov/life-cycle-nutrition/child-nutrition-and-health

SUBCOMMITTEE ON TYPE 2 DIABETES (OVERSIGHT BY THE STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT, 2008–2012)

Kenneth Claud Copeland, MD, FAAP: Co-chair—Endocrinology and Pediatric Endocrine Society Liaison (2009: Novo Nordisk, Genentech, Endo [National Advisory Groups]; 2010: Novo Nordisk [National Advisory Group]); published research related to type 2 diabetes

Janet Silverstein, MD, FAAP: Co-chair—Endocrinology and American Diabetes Association Liaison (small grants with Pfizer, Novo Nordisk, and Lilly; grant review committee for Genentech; was on an advisory committee for Sanofi Aventis, and Abbott Laboratories for a 1-time meeting); published research related to type 2 diabetes

Kelly Roberta Moore, MD, FAAP: General Pediatrics, Indian Health, AAP Committee on Native American Child Health Liaison (board member of the Merck Company Foundation Alliance to Reduce Disparities in Diabetes. Their national program office is the University of Michigan's Center for Managing Chronic Disease.)

Greg Edward Prazar, MD, FAAP: General Pediatrics (no conflicts)

Terry Raymer, MD, CDE: Family Medicine, Indian Health Service (no conflicts)

Richard N. Shiffman, MD, FAAP: Partnership for Policy Implementation Informatician, General Pediatrics (no conflicts)

Shelley C. Springer, MD, MBA, FAAP: Epidemiologist (no conflicts)

Meaghan Anderson, MS, RD, LD, CDE: Academy of Nutrition and Dietetics Liaison (formerly a Certified Pump Trainer for Animas)

Stephen J. Spann, MD, MBA, FAAFP: American Academy of Family Physicians Liaison (no conflicts)

Vidhu V. Thaker, MD, FAAP: QuIIN Liaison, General Pediatrics (no conflicts)

CONSULTANT

Susan K. Flinn, MA: Medical Writer (no conflicts)

STAFF

Caryn Davidson, MA

REFERENCES

1. Centers for Disease Control and Prevention. Data and Statistics. Obesity rates among children in the United States. Available at: www.cdc.gov/obesity/childhood/prevalence.html. Accessed August 13, 2012
2. Copeland KC, Chalmers LJ, Brown RD. Type 2 diabetes in children: oxymoron or medical metamorphosis? *Pediatr Ann*. 2005;34(9):686–697
3. Narayan KM, Boyle JP, Thompson TJ, Sorensen SW, Williamson DF. Lifetime risk for diabetes mellitus in the United States. *JAMA*. 2003;290(14):1884–1890
4. Chopra M, Galbraith S, Darnton-Hill I. A global response to a global problem: the epidemic of overnutrition. *Bull World Health Organ*. 2002;80(12):952–958
5. Liese AD, D'Agostino RB, Jr, Hamman RF, et al; SEARCH for Diabetes in Youth Study Group. The burden of diabetes mellitus among US youth: prevalence estimates from the SEARCH for Diabetes in Youth Study. *Pediatrics*. 2006;118(4):1510–1518
6. Silverstein JH, Rosenbloom AL. Type 2 diabetes in children. *Curr Diab Rep*. 2001;1(1):19–27
7. Pinhas-Hamiel O, Zeitler P. Clinical presentation and treatment of type 2 diabetes in children. *Pediatr Diabetes*. 2007;8(suppl 9):16–27
8. Dabelea D, Bell RA, D'Agostino RB Jr, et al; Writing Group for the SEARCH for Diabetes in Youth Study Group. Incidence of diabetes in youth in the United States. *JAMA*. 2007;297(24):2716–2724
9. Mayer-Davis EJ, Bell RA, Dabelea D, et al; SEARCH for Diabetes in Youth Study Group. The many faces of diabetes in American youth: type 1 and type 2 diabetes in five race and ethnic populations: the SEARCH for Diabetes in Youth Study. *Diabetes Care*. 2009;32(suppl 2):S99–S101
10. Copeland KC, Zeitler P, Geffner M, et al; TODAY Study Group. Characteristics of adolescents and youth with recent-onset type 2 diabetes: the TODAY cohort at baseline. *J Clin Endocrinol Metab*. 2011;96(1):159–167
11. Narayan KM, Williams R. Diabetes—a global problem needing global solutions. *Prim Care Diabetes*. 2009;3(1):3–4
12. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *Diabetes Care*. 2004;27(5):1047–1053
13. Silverstein J, Klingensmith G, Copeland K, et al; American Diabetes Association. Care of children and adolescents with type 1 diabetes: a statement of the American Diabetes Association. *Diabetes Care*. 2005;28(1):186–212
14. Pinhas-Hamiel O, Zeitler P. Barriers to the treatment of adolescent type 2 diabetes—a survey of provider perceptions. *Pediatr Diabetes*. 2003;4(1):24–28
15. Moore KR, McGowan MK, Donato KA, Kollipara S, Roubideaux Y. Community resources for promoting youth nutrition and physical activity. *Am J Health Educ*. 2009;40(5):298–303
16. Zeitler P, Epstein L, Grey M, et al; The TODAY Study Group. Treatment Options for type 2 diabetes mellitus in Adolescents and Youth: a study of the comparative efficacy of metformin alone or in combination with rosiglitazone or lifestyle intervention in adolescents with type 2 diabetes mellitus. *Pediatr Diabetes*. 2007;8(2):74–87
17. Kane MP, Abu-Baker A, Busch RS. The utility of oral diabetes medications in type 2

diabetes of the young. *Curr Diabetes Rev.* 2005;1(1):83–92

18. De Berardis G, Pellegrini F, Franciosi M, et al. Quality of care and outcomes in type 2 diabetes patientes. *Diabetes Care.* 2004;27 (2):398–406
19. Ziemer DC, Miller CD, Rhee MK, et al. Clinical inertia contributes to poor diabetes control in a primary care setting. *Diabetes Educ.* 2005;31(4):564–571
20. Bradshaw B. The role of the family in managing therapy in minority children with type 2 diabetes mellitus. *J Pediatr Endocrinol Metab.* 2002;15(suppl 1):547–551
21. Pinhas-Hamiel O, Standiford D, Hamiel D, Dolan LM, Cohen R, Zeitler PS. The type 2 family: a setting for development and treatment of adolescent type 2 diabetes mellitus. *Arch Pediatr Adolesc Med.* 1999; 153(10):1063–1067
22. Mulvaney SA, Schlundt DG, Mudasiru E, et al. Parent perceptions of caring for adolescents with type 2 diabetes. *Diabetes Care.* 2006;29(5):993–997
23. Summerbell CD, Ashton V, Campbell KJ, Edmunds L, Kelly S, Waters E. Interventions for treating obesity in children. *Cochrane Database Syst Rev.* 2003;(3):CD001872
24. Skinner AC, Weinberger M, Mulvaney S, Schlundt D, Rothman RL. Accuracy of perceptions of overweight and relation to self-care behaviors among adolescents with type 2 diabetes and their parents. *Diabetes Care.* 2008;31(2):227–229
25. American Diabetes Association. Type 2 diabetes in children and adolescents. *Diabetes Care.* 2000;23(3):381–389
26. Pinhas-Hamiel O, Zeitler P. Type 2 diabetes in adolescents, no longer rare. *Pediatr Rev.* 1998;19(12):434–435
27. Fagot-Campagna A, Pettitt DJ, Engelgau MM, et al. Type 2 diabetes among North American children and adolescents: an epidemiologic review and a public health perspective. *J Pediatr.* 2000;136(5):664–672
28. Rothman RL, Mulvaney S, Elasy TA, et al. Self-management behaviors, racial disparities, and glycemic control among adolescents with type 2 diabetes. *Pediatrics.* 2008;121(4). Available at: www.pediatrics.org/cgi/content/full/121/4/e912
29. Scott CR, Smith JM, Cradock MM, Pihoker C. Characteristics of youth-onset noninsulin-dependent diabetes mellitus and insulin-dependent diabetes mellitus at diagnosis. *Pediatrics.* 1997;100(1):84–91
30. Libman IM, Pietropaolo M, Arslanian SA, LaPorte RE, Becker DJ. Changing prevalence of overweight children and adolescents at onset of insulin-treated diabetes. *Diabetes Care.* 2003;26(10):2871–2875
31. Springer SC, Copeland KC, Silverstein J, et al. Technical report: management of type 2 diabetes mellitus in children and adolescents. *Pediatrics.* 2012, In press
32. American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics.* 2004;114(3):874–877
33. Shiffman RN, Dixon J, Brandt C, et al. The GuideLine Implementability Appraisal (GLIA): development of an instrument to identify obstacles to guideline implementation. *BMC Med Inform Decis Mak.* 2005;5:23
34. Gungor N, Hannon T, Libman I, Bacha F, Arslanian S. Type 2 diabetes mellitus in youth: the complete picture to date. *Pediatr Clin North Am.* 2005;52(6):1579–1609
35. Daaboul JJ, Siverstein JH. The management of type 2 diabetes in children and adolescents. *Minerva Pediatr.* 2004;56(3):255–264
36. Kadmon PM, Grupposo PA. Glycemic control with metformin or insulin therapy in adolescents with type 2 diabetes mellitus. *J Pediatr Endocrinol.* 2004;17(9):1185–1193
37. Owada M, Nitadori Y, Kitagawa T. Treatment of NIDDM in youth. *Clin Pediatr (Phila).* 1998;37(2):117–121
38. Pinhas-Hamiel O, Zeitler P. Advances in epidemiology and treatment of type 2 diabetes in children. *Adv Pediatr.* 2005;52: 223–259
39. Jones KL, Haghi M. Type 2 diabetes mellitus in children and adolescence: a primer. *Endocrinologist.* 2000;10:389–396
40. Kawahara R, Amemiya T, Yoshino M, et al. Dropout of young non-insulin-dependent diabetics from diabetic care. *Diabetes Res Clin Pract.* 1994;24(3):181–185
41. Kaufman FR. Type 2 diabetes mellitus in children and youth: a new epidemic. *J Pediatr Endocrinol Metab.* 2002;15(suppl 2): 737–744
42. Garber AJ, Duncan TG, Goodman AM, Mills DJ, Rohlf JL. Efficacy of metformin in type II diabetes: results of a double-blind, placebo-controlled, dose-response trial. *Am J Med.* 1997;103(6):491–497
43. Dabelea D, Pettitt DJ, Jones KL, Arslanian SA. Type 2 diabetes mellitus in minority children and adolescents: an emerging problem. *Endocrinol Metabo Clin North Am.* 1999;28(4):709–729
44. Miller JL, Silverstein JH. The management of type 2 diabetes mellitus in children and adolescents. *J Pediatr Endocrinol Metab.* 2005;18(2):111–123
45. Reinehr T, Schober E, Roth CL, Wiegand S, Holl R; DPV-Wiss Study Group. Type 2 diabetes in children and adolescents in a 2-year follow-up: insufficient adherence to diabetes centers. *Horm Res.* 2008;69(2):107–113
46. Rosenbloom AL, Silverstein JH, Amemiya S, Zeitler P, Klingensmith GJ. Type 2 diabetes in children and adolescents. *Pediatr Diabetes.* 2009;10(suppl 12):17–32
47. Zuhri-Yafi MI, Brosnan PG, Hardin DS. Treatment of type 2 diabetes mellitus in children and adolescents. *J Pediatr Endocrinol Metab.* 2002;15(suppl 1):541–546
48. Rapaport R, Silverstein JH, Garzarella L, Rosenbloom AL. Type 1 and type 2 diabetes mellitus in childhood in the United States: practice patterns by pediatric endocrinologists. *J Pediatr Endocrinol Metab.* 2004;17 (6):871–877
49. Glaser N, Jones KL. Non-insulin-dependent diabetes mellitus in children and adolescents. *Adv Pediatr.* 1996;43:359–396
50. Miller JL, Silverstein JH. The treatment of type 2 diabetes mellitus in youth: which therapies? *Treat Endocrinol.* 2006;5(4):201–210
51. Silverstein JH, Rosenbloom AL. Treatment of type 2 diabetes mellitus in children and adolescents. *J Pediatr Endocrinol Metab.* 2000;13(suppl 6):1403–1409
52. Dean H. Treatment of type 2 diabetes in youth: an argument for randomized controlled studies. *Paediatr Child Health (Oxford).* 1999;4(4):265–270
53. Sellers EAC, Dean HJ. Short-term insulin therapy in adolescents with type 2 diabetes mellitus. *J Pediatr Endocrinol Metab.* 2004; 17(11):1561–1564
54. Zeitler P, Hirst K, Pyle L, et al; TODAY Study Group. A clinical trial to maintain glycemic control in youth with type 2 diabetes. *N Engl J Med.* 2012;366(24):2247–2256
55. White NH, Cleary PA, Dahms W, Goldstein D, Malone J, Tamborlane WV; Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) Research Group. Beneficial effects of intensive therapy of diabetes during adolescence: outcomes after the conclusion of the Diabetes Control and Complications Trial (DCCT). *J Pediatr.* 2001;139(6):804–812
56. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med.* 1993;329(14):977–986
57. Orchard TJ, Olson JC, Erbey JR, et al. Insulin resistance-related factors, but not glycemia, predict coronary artery disease in type 1 diabetes: 10-year follow-up data from the Pittsburgh Epidemiology of Diabetes Complications Study. *Diabetes Care.* 2003;26(5):1374–1379

58. UK Prospective Diabetes Study Group. U.K. prospective diabetes study 16. Overview of 6 years' therapy of type II diabetes: a progressive disease. *Diabetes*. 1995;44(11): 1249–1258
59. Shichiri M, Kishikawa H, Ohkubo Y, Wake N. Long-term results of the Kumamoto Study on optimal diabetes control in type 2 diabetic patients. *Diabetes Care*. 2000;23 (suppl 2):B21–B29
60. Baynes JW, Bunn HF, Goldstein D, et al; National Diabetes Data Group. National Diabetes Data Group: report of the expert committee on glucosylated hemoglobin. *Diabetes Care*. 1984;7(6):602–606
61. Dabiri G, Jones K, Krebs J, et al. Benefits of rosiglitazone in children with type 2 diabetes mellitus [abstract]. *Diabetes*. 2005; A457
62. Ponder SW, Sullivan S, McBath G. Type 2 diabetes mellitus in teens. *Diabetes Spectrum*. 2000;13(2):95–119
63. Gahagan S, Silverstein J, and the American Academy of Pediatrics Committee on Native American Child Health. Prevention and treatment of type 2 diabetes mellitus in children, with special emphasis on American Indian and Alaska Native children. *Pediatrics*. 2003;112(4). Available at: www.pediatrics.org/cgi/content/full/112/4/e328
64. Levine BS, Anderson BJ, Butler DA, Antisdel JE, Brackett J, Laffel LM. Predictors of glycemic control and short-term adverse outcomes in youth with type 1 diabetes. *J Pediatr*. 2001;139(2):197–203
65. Haller MJ, Stalvey MS, Silverstein JH. Predictors of control of diabetes: monitoring may be the key. *J Pediatr*. 2004;144(5):660–661
66. Murata GH, Shah JH, Hoffman RM, et al; Diabetes Outcomes in Veterans Study (DOVES). Intensified blood glucose monitoring improves glycemic control in stable, insulin-treated veterans with type 2 diabetes: the Diabetes Outcomes in Veterans Study (DOVES). *Diabetes Care*. 2003;26(6): 1759–1763
67. American Diabetes Association. Standards of medical care in diabetes—2011. *Diabetes Care*. 2011;34(suppl 1):S11–S61
68. Hanefeld M, Fischer S, Julius U, et al. Risk factors for myocardial infarction and death in newly detected NIDDM: the Diabetes Intervention Study, 11-year follow-up. *Diabetologia*. 1996;39(12):1577–1583
69. Franciosi M, Pellegrini F, De Berardis G, et al; QuED Study Group. The impact of blood glucose self-monitoring on metabolic control and quality of life in type 2 diabetic patients: an urgent need for better educational strategies. *Diabetes Care*. 2001;24 (11):1870–1877
70. American Dietetic Association. Recommendations summary: pediatric weight management (PWM) using protein sparing modified fast diets for pediatric weight loss. Available at: www.adaevidencelibrary.com/template.cfm?template=guide_-summary&key=416. Accessed August 13, 2012
71. Knowler WC, Barrett-Connor E, Fowler SE, et al; Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med*. 2002;346(6): 393–403
72. Willi SM, Martin K, Datko FM, Brant BP. Treatment of type 2 diabetes in childhood using a very-low-calorie diet. *Diabetes Care*. 2004;27(2):348–353
73. Berry D, Urban A, Grey M. Management of type 2 diabetes in youth (part 2). *J Pediatr Health Care*. 2006;20(2):88–97
74. Loghmani ES. Nutrition therapy for overweight children and adolescents with type 2 diabetes. *Curr Diab Rep*. 2005;5(5):385–390
75. McGavock J, Sellers E, Dean H. Physical activity for the prevention and management of youth-onset type 2 diabetes mellitus: focus on cardiovascular complications. *Diab Vasc Dis Res*. 2007;4(4):305–310
76. Centers for Disease Control and Prevention. Physical activity for everyone: how much physical activity do you need? Atlanta, GA: Centers for Disease Control and Prevention; 2008. Available at: www.cdc.gov/physicalactivity/everyone/guidelines/children.html. Accessed August 13, 2012
77. Pinhas-Hamiel O, Zeitler P. A weighty problem: diagnosis and treatment of type 2 diabetes in adolescents. *Diabetes Spectrum*. 1997;10(4):292–298
78. Yamanouchi K, Shinozaki T, Chikada K, et al. Daily walking combined with diet therapy is a useful means for obese NIDDM patients not only to reduce body weight but also to improve insulin sensitivity. *Diabetes Care*. 1995;18(6):775–778
79. National Heart, Lung, and Blood Institute, US Department of Health and Human Services, National Institutes of Health. Reduce screen time. Available at: www.nhlbi.nih.gov/health/public/heart/obesity/wecan/reduce-screen-time/index.htm. Accessed August 13, 2012
80. Krebs NF, Jacobson MS; American Academy of Pediatrics Committee on Nutrition. Prevention of pediatric overweight and obesity. *Pediatrics*. 2003;112(2):424–430
81. American Academy of Pediatrics Committee on Public Education. American Academy of Pediatrics: children, adolescents, and television. *Pediatrics*. 2001;107(2):423–426
82. American Medical Association. Appendix. Expert Committee recommendations on the assessment, prevention, and treatment of child and adolescent overweight and obesity. Chicago, IL: American Medical Association; January 25, 2007. Available at: www.ama-assn.org/ama1/pub/upload/mm/433/ped_obesity_recs.pdf. Accessed August 13, 2012

ERRATA

Several inaccuracies occurred in the American Academy of Pediatrics "Clinical Practice Guideline: Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents" published in the February 2013 issue of *Pediatrics* (2013;131[2]:364–382).

On page 366 in the table of definitions, "Prediabetes" should be defined as "Fasting plasma glucose ≥100–125 mg/dL or 2-hour glucose concentration during an oral glucose tolerance test of ≥140 but <200 mg/dL or an HbA1c of 5.7% to 6.4%."

On page 378, middle column, under "Reducing Screen Time," the second sentence should read as follows: "The US Department of Health and Human Services reflects the American Academy of Pediatrics policies by recommending that individuals limit "screen time" spent watching television and/or using computers and handheld devices to <2 hours per day unless the use is related to work or homework."[79–81,83]

Also on page 378, middle column, in the second paragraph under "Reducing Screen Time," the fourth sentence should read: "Pending new data, the committee suggests that clinicians follow the policy statement 'Children, Adolescents, and Television' from the AAP Council on Communications and Media (formerly the Committee on Public Education)." The references cited in the next sentence should be 80–83.

Reference 82 should be replaced with the following reference: Barlow SE; Expert Committee. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics*. 2007;120(suppl 4):S164–S192

Finally, a new reference 83 should be added: American Academy of Pediatrics, Council on Communications and Media. Policy statement: children, adolescents, obesity, and the media. *Pediatrics*. 2011;128(1):201–208

doi:10.1542/peds.2013-0666

Diabetes Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents
- *ICD-10-CM* Coding Quick Reference for Type 2 Diabetes Mellitus
- AAP Patient Education Handout
  — *Type 2 Diabetes: Tips for Healthy Living*

Action Statement Summary

Management of Newly Diagnosed Type 2 Diabetes Mellitus (T2DM) in Children and Adolescents

Key Action Statement 1

Clinicians must ensure that insulin therapy is initiated for children and adolescents with T2DM who are ketotic or in diabetic ketoacidosis and in whom the distinction between T1DM and T2DM is unclear; and, in usual cases, should initiate insulin therapy for patients:

- who have random venous or plasma BG concentrations ≥250 mg/dL; or
- whose HbA1c is >9%.

(Strong Recommendation: evidence quality X, validating studies cannot be performed, and C, observational studies and expert opinion; preponderance of benefit over harm.)

Key Action Statement 2

In all other instances, clinicians should initiate a lifestyle modification program, including nutrition and physical activity, and start metformin as first-line therapy for children and adolescents at the time of diagnosis of T2DM. (Strong recommendation: evidence quality B; 1 RCT showing improved outcomes with metformin versus lifestyle; preponderance of benefits over harms.)

Key Action Statement 3

The committee suggests that clinicians monitor HbA1c concentrations every 3 months and intensify treatment if treatment goals for BG and HbA1c concentrations are not being met. (Option: evidence quality D; expert opinion and studies in children with T1DM and in adults with T2DM; preponderance of benefits over harms.)

Key Action Statement 4

The committee suggests that clinicians advise patients to monitor finger-stick BG concentrations in those who

- are taking insulin or other medications with a risk of hypoglycemia; or
- are initiating or changing their diabetes treatment regimen; or
- have not met treatment goals; or
- have intercurrent illnesses.

(Option: evidence quality D; expert consensus. Preponderance of benefits over harms.)

Key Action Statement 5

The committee suggests that clinicians incorporate the Academy of Nutrition and Dietetics' *Pediatric Weight Management Evidence-Based Nutrition Practice Guidelines* in the nutrition counseling of patients with T2DM both at the time of diagnosis and as part of ongoing management. (Option; evidence quality D; expert opinion; preponderance of benefits over harms. Role of patient preference is dominant.)

Key Action Statement 6

The committee suggests that clinicians encourage children and adolescents with T2DM to engage in moderate-to-vigorous exercise for at least 60 minutes daily and to limit nonacademic screen time to less than 2 hours per day. (Option: evidence quality D, expert opinion and evidence from studies of metabolic syndrome and obesity; preponderance of benefits over harms. Role of patient preference is dominant.)

Coding Quick Reference for Type 2 Diabetes Mellitus	
ICD-10-CM	
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	Type 2 diabetes mellitus without complications
E13.9	Other specified diabetes mellitus without complications
Use codes above (**E11.8–E13.9**). *ICD-10-CM* does not discern between controlled and uncontrolled.	

Type 2 Diabetes: Tips for Healthy Living

Children with type 2 diabetes can live a healthy life. If your child has been diagnosed with type 2 diabetes, your child's doctor will talk with you about the importance of lifestyle and medication in keeping your child's blood glucose (blood sugar) levels under control.

Read on for information from the American Academy of Pediatrics (AAP) about managing blood glucose and creating plans for healthy living.

What is blood glucose?

Glucose is found in the blood and is the body's main source of energy. The food your child eats is broken down by the body into glucose. Glucose is a type of sugar that gives energy to the cells in the body.

The cells need the help of insulin to take the glucose from the blood to the cells. Insulin is made by an organ called the pancreas.

In children with type 2 diabetes, the pancreas does not make enough insulin and the cells don't use the insulin very well.

Why is it important to manage blood glucose levels?

Glucose will build up in the blood if it cannot be used by the cells. High blood glucose levels can damage many parts of the body, such as the eyes, kidneys, nerves, and heart.

Your child's blood glucose levels may need to be checked on a regular schedule to make sure the levels do not get too high. Your child's doctor will tell you what your child's blood glucose level should be. You and your child will need to learn how to use a glucose meter. Blood glucose levels can be quickly and easily measured using a glucose meter. First, a lancet is used to prick the skin; then a drop of blood from your child's finger is placed on a test strip that is inserted into the meter.

Are there medicines for type 2 diabetes?

Insulin in a shot or another medicine by mouth may be prescribed by your child's doctor if needed to help control your child's blood glucose levels. If your child's doctor has prescribed a medicine, it's important that your child take it as directed. Side effects from certain medicines may include bloating or gassiness. Check with your child's doctor if you have questions.

Along with medicines, your child's doctor will suggest changes to your child's diet and encourage your child to be physically active.

Tips for healthy living

A healthy diet and staying active are especially important for children with type 2 diabetes. Your child's blood glucose levels are easier to manage when you child is at a healthy weight.

Create a plan for eating healthy

Talk with your child's doctor and registered dietitian about a meal plan that meets the needs of your child. The following tips can help you select foods that are healthy and contain a high content of nutrients (protein, vitamins, and minerals):

- Eat at least 5 servings of fruits and vegetables each day.
- Include high-fiber, whole-grain foods such as brown rice, whole-grain pasta, corns, peas, and breads and cereals at meals. Sweet potatoes are also a good choice.
- Choose lower-fat or fat-free toppings like grated low-fat parmesan cheese, salsa, herbed cottage cheese, nonfat/low-fat gravy, low-fat sour cream, low-fat salad dressing, or yogurt.
- Select lean meats such as skinless chicken and turkey, fish, lean beef cuts (round, sirloin, chuck, loin, lean ground beef—no more than 15% fat content), and lean pork cuts (tenderloin, chops, ham). Trim off all visible fat. Remove skin from cooked poultry before eating.
- Include healthy oils such as canola or olive oil in your diet. Choose margarine and vegetable oils without trans fats made from canola, corn, sunflower, soybean, or olive oils.
- Use nonstick vegetable sprays when cooking.
- Use fat-free cooking methods such as baking, broiling, grilling, poaching, or steaming when cooking meat, poultry, or fish.
- Serve vegetable- and broth-based soups, or use nonfat (skim) or low-fat (1%) milk or evaporated skim milk when making cream soups.
- Use the Nutrition Facts label on food packages to find foods with less saturated fat per serving. Pay attention to the serving size as you make choices. Remember that the percent daily values on food labels are based on portion sizes and calorie levels for adults.

Create a plan for physical activity

Physical activity, along with proper nutrition, promotes lifelong health. Following are some ideas on how to get fit:

- **Encourage your child to be active at least 1 hour a day.** Active play is the best exercise for younger children! Parents can join their children and have fun while being active too. School-aged child should participate every day in 1 hour or more of moderate to vigorous physical activity that is right for their age, is enjoyable, and involves a variety of activities.
- **Limit television watching and computer use.** The AAP discourages TV and other media use by children younger than 2 years and encourages interactive play. For older children, total entertainment screen time should be limited to less than 1 to 2 hours per day.
- **Keep an activity log.** The use of activity logs can help children and teens keep track of their exercise programs and physical activity. Online tools can be helpful.

- **Get the whole family involved.** It is a great way to spend time together. Also, children who regularly see their parents enjoying sports and physical activity are more likely to do so themselves.
- **Provide a safe environment.** Make sure your child's equipment and chosen site for the sport or activity are safe. Make sure your child's clothing is comfortable and appropriate.

For more information

National Diabetes Education Program

http://ndep.nih.gov

From your doctor

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site—www.HealthyChildren.org

Early Detection of Developmental Dysplasia of the Hip

- *Clinical Practice Guideline*

AMERICAN ACADEMY OF PEDIATRICS

Committee on Quality Improvement, Subcommittee on Developmental Dysplasia of the Hip

Clinical Practice Guideline: Early Detection of Developmental Dysplasia of the Hip

ABSTRACT. ***Developmental dysplasia of the hip*** **is the preferred term to describe the condition in which the femoral head has an abnormal relationship to the acetabulum. Developmental dysplasia of the hip includes frank dislocation (luxation), partial dislocation (subluxation), instability wherein the femoral head comes in and out of the socket, and an array of radiographic abnormalities that reflect inadequate formation of the acetabulum. Because many of these findings may not be present at birth, the term *developmental* more accurately reflects the biologic features than does the term *congenital*. The disorder is uncommon. The earlier a dislocated hip is detected, the simpler and more effective is the treatment. Despite newborn screening programs, dislocated hips continue to be diagnosed later in infancy and childhood,[1–11] in some instances delaying appropriate therapy and leading to a substantial number of malpractice claims. The objective of this guideline is to reduce the number of dislocated hips detected later in infancy and childhood. The target audience is the primary care provider. The target patient is the healthy newborn up to 18 months of age, excluding those with neuromuscular disorders, myelodysplasia, or arthrogryposis.**

ABBREVIATIONS. DDH, developmental dysplasia of the hip; AVN, avascular necrosis of the hip.

BIOLOGIC FEATURES AND NATURAL HISTORY

Understanding the developmental nature of developmental dysplasia of the hip (DDH) and the subsequent spectrum of hip abnormalities requires a knowledge of the growth and development of the hip joint.[12] Embryologically, the femoral head and acetabulum develop from the same block of primitive mesenchymal cells. A cleft develops to separate them at 7 to 8 weeks' gestation. By 11 weeks' gestation, development of the hip joint is complete. At birth, the femoral head and the acetabulum are primarily cartilaginous. The acetabulum continues to develop postnatally. The growth of the fibrocartilaginous rim (the labrum) that surrounds the bony acetabulum deepens the socket. Development of the femoral head and acetabulum are intimately related, and normal adult hip joints depend on further growth of these structures. Hip dysplasia may occur in utero, perinatally, or during infancy and childhood.

The acronym DDH includes hips that are unstable, subluxated, dislocated (luxated), and/or have malformed acetabula. A hip is *unstable* when the tight fit between the femoral head and the acetabulum is lost and the femoral head is able to move within (subluxated) or outside (dislocated) the confines of the acetabulum. A *dislocation* is a complete loss of contact of the femoral head with the acetabulum. Dislocations are divided into 2 types: teratologic and typical.[12] *Teratologic dislocations* occur early in utero and often are associated with neuromuscular disorders, such as arthrogryposis and myelodysplasia, or with various dysmorphic syndromes. The *typical dislocation* occurs in an otherwise healthy infant and may occur prenatally or postnatally.

During the immediate newborn period, laxity of the hip capsule predominates, and, if clinically significant enough, the femoral head may spontaneously dislocate and relocate. If the hip spontaneously relocates and stabilizes within a few days, subsequent hip development usually is normal. If subluxation or dislocation persists, then structural anatomic changes may develop. A deep concentric position of the femoral head in the acetabulum is necessary for normal development of the hip. When not deeply reduced (subluxated), the labrum may become everted and flattened. Because the femoral head is not reduced into the depth of the socket, the acetabulum does not grow and remodel and, therefore, becomes shallow. If the femoral head moves further out of the socket (dislocation), typically superiorly and laterally, the inferior capsule is pulled upward over the now empty socket. Muscles surrounding the hip, especially the adductors, become contracted, limiting abduction of the hip. The hip capsule constricts; once this capsular constriction narrows to less than the diameter of the femoral head, the hip can no longer be reduced by manual manipulative maneuvers, and operative reduction usually is necessary.

The hip is at risk for dislocation during 4 periods: 1) the 12th gestational week, 2) the 18th gestational week, 3) the final 4 weeks of gestation, and 4) the postnatal period. During the 12th gestational week, the hip is at risk as the fetal lower limb rotates medially. A dislocation at this time is termed teratologic. All elements of the hip joint develop abnor-

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

The Practice Guideline, "Early Detection of Developmental Dysplasia of the Hip," was reviewed by appropriate committees and sections of the American Academy of Pediatrics (AAP) including the Chapter Review Group, a focus group of office-based pediatricians representing each AAP District: Gene R. Adams, MD; Robert M. Corwin, MD; Diane Fuquay, MD; Barbara M. Harley, MD; Thomas J. Herr, MD, Chair; Kenneth E. Matthews, MD; Robert D. Mines, MD; Lawrence C. Pakula, MD; Howard B. Weinblatt, MD; and Delosa A. Young, MD. The Practice Guideline was also reviewed by relevant outside medical organizations as part of the peer review process. PEDIATRICS (ISSN 0031 4005).

mally. The hip muscles develop around the 18th gestational week. Neuromuscular problems at this time, such as myelodysplasia and arthrogryposis, also lead to teratologic dislocations. During the final 4 weeks of pregnancy, mechanical forces have a role. Conditions such as oligohydramnios or breech position predispose to DDH.[13] Breech position occurs in ~3% of births, and DDH occurs more frequently in breech presentations, reportedly in as many as 23%. The frank breech position of hip flexion and knee extension places a newborn or infant at the highest risk. Postnatally, infant positioning such as swaddling, combined with ligamentous laxity, also has a role.

The true incidence of dislocation of the hip can only be presumed. There is no "gold standard" for diagnosis during the newborn period. Physical examination, plane radiography, and ultrasonography all are fraught with false-positive and false-negative results. Arthrography (insertion of contrast medium into the hip joint) and magnetic resonance imaging, although accurate for determining the precise hip anatomy, are inappropriate methods for screening the newborn and infant.

The reported incidence of DDH is influenced by genetic and racial factors, diagnostic criteria, the experience and training of the examiner, and the age of the child at the time of the examination. Wynne-Davies[14] reported an increased risk to subsequent children in the presence of a diagnosed dislocation (6% risk with healthy parents and an affected child, 12% risk with an affected parent, and 36% risk with an affected parent and 1 affected child). DDH is not always detectable at birth, but some newborn screening surveys suggest an incidence as high as 1 in 100 newborns with evidence of instability, and 1 to 1.5 cases of dislocation per 1000 newborns. The incidence of DDH is higher in girls. Girls are especially susceptible to the maternal hormone relaxin, which may contribute to ligamentous laxity with the resultant instability of the hip. The left hip is involved 3 times as commonly as the right hip, perhaps related to the left occiput anterior positioning of most nonbreech newborns. In this position, the left hip resides posteriorly against the mother's spine, potentially limiting abduction.

PHYSICAL EXAMINATION

DDH is an evolving process, and its physical findings on clinical examination change.[12,15,16] The newborn must be relaxed and preferably examined on a firm surface. Considerable patience and skill are required. The physical examination changes as the child grows older. No signs are pathognomonic for a dislocated hip. The examiner must look for asymmetry. Indeed, bilateral dislocations are more difficult to diagnose than unilateral dislocations because symmetry is retained. Asymmetrical thigh or gluteal folds, better observed when the child is prone, apparent limb length discrepancy, and restricted motion, especially abduction, are significant, albeit not pathognomonic signs. With the infant supine and the pelvis stabilized, abduction to 75° and adduction to 30° should occur readily under normal circumstances.

The 2 maneuvers for assessing hip stability in the newborn are the Ortolani and Barlow tests. The Ortolani elicits the sensation of the dislocated hip reducing, and the Barlow detects the unstable hip dislocating from the acetabulum. The Ortolani is performed with the newborn supine and the examiner's index and middle fingers placed along the greater trochanter with the thumb placed along the inner thigh. The hip is flexed to 90° but not more, and the leg is held in neutral rotation. The hip is gently abducted while lifting the leg anteriorly. With this maneuver, a "clunk" is felt as the dislocated femoral head reduces into the acetabulum. This is a positive Ortolani sign. The Barlow provocative test is performed with the newborn positioned supine and the hips flexed to 90°. The leg is then gently adducted while posteriorly directed pressure is placed on the knee. A palpable clunk or sensation of movement is felt as the femoral head exits the acetabulum posteriorly. This is a positive Barlow sign. The Ortolani and Barlow maneuvers are performed 1 hip at a time. Little force is required for the performance of either of these tests. The goal is not to prove that the hip can be dislocated. Forceful and repeated examinations can break the seal between the labrum and the femoral head. These strongly positive signs of Ortolani and Barlow are distinguished from a large array of soft or equivocal physical findings present during the newborn period. High-pitched clicks are commonly elicited with flexion and extension and are inconsequential. A dislocatable hip has a rather distinctive clunk, whereas a subluxable hip is characterized by a feeling of looseness, a sliding movement, but without the true Ortolani and Barlow clunks. Separating true dislocations (clunks) from a feeling of instability and from benign adventitial sounds (clicks) takes practice and expertise. This guideline recognizes the broad range of physical findings present in newborns and infants and the confusion of terminology generated in the literature. By 8 to 12 weeks of age, the capsule laxity decreases, muscle tightness increases, and the Barlow and Ortolani maneuvers are no longer positive regardless of the status of the femoral head. In the 3-month-old infant, limitation of abduction is the most reliable sign associated with DDH. Other features that arouse suspicion include asymmetry of thigh folds, a positive Allis or Galeazzi sign (relative shortness of the femur with the hips and knees flexed), and discrepancy of leg lengths. These physical findings alert the examiner that abnormal relationships of the femoral head to the acetabulum (dislocation and subluxation) *may* be present.

Maldevelopments of the acetabulum alone (acetabular dysplasia) can be determined only by imaging techniques. Abnormal physical findings may be absent in an infant with acetabular dysplasia but no subluxation or dislocation. Indeed, because of the confusion, inconsistencies, and misuse of language in the literature (eg, an Ortolani sign called a click by some and a clunk by others), this guideline uses the following definitions.

- A *positive examination* result for DDH is the Barlow or Ortolani sign. This is the clunk of dislocation or reduction.
- An *equivocal examination* or *warning signs* include an array of physical findings that may be found in children with DDH, in children with another orthopaedic disorder, or in children who are completely healthy. These physical findings include asymmetric thigh or buttock creases, an apparent or true short leg, and limited abduction. These signs, used singly or in combination, serve to raise the pediatrician's index of suspicion and act as a threshold for referral. Newborn soft tissue hip clicks are not predictive of DDH[17] but may be confused with the Ortolani and Barlow clunks by some screening physicians and thereby be a reason for referral.

IMAGING

Radiographs of the pelvis and hips have historically been used to assess an infant with suspected DDH. During the first few months of life when the femoral heads are composed entirely of cartilage, radiographs have limited value. Displacement and instability may be undetectable, and evaluation of acetabular development is influenced by the infant's position at the time the radiograph is performed. By 4 to 6 months of age, radiographs become more reliable, particularly when the ossification center develops in the femoral head. Radiographs are readily available and relatively low in cost.

Real-time ultrasonography has been established as an accurate method for imaging the hip during the first few months of life.[15,18–25] With ultrasonography, the cartilage can be visualized and the hip can be viewed while assessing the stability of the hip and the morphologic features of the acetabulum. In some clinical settings, ultrasonography can provide information comparable to arthrography (direct injection of contrast into the hip joint), without the need for sedation, invasion, contrast medium, or ionizing radiation. Although the availability of equipment for ultrasonography is widespread, accurate results in hip sonography require training and experience. Although expertise in pediatric hip ultrasonography is increasing, this examination may not always be available or obtained conveniently. Ultrasonographic techniques include *static evaluation* of the morphologic features of the hip, as popularized in Europe by Graf,[26] and a *dynamic evaluation*, as developed by Harcke[20] that assesses the hip for stability of the femoral head in the socket, as well as static anatomy. Dynamic ultrasonography yields more useful information. With both techniques, there is considerable interobserver variability, especially during the first 3 weeks of life.[7,27]

Experience with ultrasonography has documented its ability to detect abnormal position, instability, and dysplasia not evident on clinical examination. Ultrasonography during the first 4 weeks of life often reveals the presence of minor degrees of instability and acetabular immaturity. Studies[7,28,29] indicate that nearly all these mild early findings, which will not be apparent on physical examination, resolve spontaneously without treatment. Newborn screening with ultrasonography has required a high frequency of reexamination and results in a large number of hips being unnecessarily treated. One study[23] demonstrates that a screening process with higher false-positive results also yields increased prevention of late cases. Ultrasonographic screening of all infants at 4 to 6 weeks of age would be expensive, requiring considerable resources. This practice is yet to be validated by clinical trial. *Consequently, the use of ultrasonography is recommended as an adjunct to the clinical evaluation*. It is the technique of choice for clarifying a physical finding, assessing a high-risk infant, and monitoring DDH as it is observed or treated. Used in this selective capacity, it can guide treatment and may prevent overtreatment.

PRETERM INFANTS

DDH may be unrecognized in prematurely born infants. When the infant has cardiorespiratory problems, the diagnosis and management are focused on providing appropriate ventilatory and cardiovascular support, and careful examination of the hips may be deferred until a later date. The most complete examination the infant receives may occur at the time of discharge from the hospital, and this single examination may not detect subluxation or dislocation. Despite the medical urgencies surrounding the preterm infant, it is critical to examine the entire child.

METHODS FOR GUIDELINE DEVELOPMENT

Our goal was to develop a practice parameter by using a process that would be based whenever possible on available evidence. The methods used a combination of expert panel, decision modeling, and evidence synthesis[30] (see the Technical Report available on *Pediatrics electronic pages* at www.pediatrics.org). The predominant methods recommended for such evidence synthesis are generally of 2 types: a *data-driven* method and a *model-driven*[31,32] method. In data-driven methods, the analyst finds the best data available and induces a conclusion from these data. A model-driven method, in contrast, begins with an effort to define the context for evidence and then searches for the data as defined by that context. Data-driven methods are useful when the quality of evidence is high. A careful review of the medical literature revealed that the published evidence about DDH did not meet the criteria for high quality. There was a paucity of randomized clinical trials.[8] We decided, therefore, to use the model-driven method.

A decision model was constructed based on the perspective of practicing clinicians and determining the best strategy for screening and diagnosis. The target child was a full-term newborn with no obvious orthopaedic abnormalities. We focused on the various options available to the pediatrician* for the detection of DDH, including screening by physical examination, screening by ultrasonography, and episodic screening during health supervision. Because

*In this guideline, the term *pediatrician* includes the range of pediatric primary care providers, eg, family practitioners and pediatric nurse practitioners.

the detection of a dislocated hip usually results in referral by the pediatrician, and because management of DDH is not in the purview of the pediatrician's care, treatment options are not included. We also included in our model a wide range of options for detecting DDH during the first year of life if the results of the newborn screen are negative.

The outcomes on which we focused were a dislocated hip at 1 year of age as the major morbidity of the disease and avascular necrosis of the hip (AVN) as the primary complication of DDH treatment. AVN is a loss of blood supply to the femoral head resulting in abnormal hip development, distortion of shape, and, in some instances, substantial morbidity. Ideally, a gold standard would be available to define DDH at any point in time. However, as noted, no gold standard exists except, perhaps, arthrography of the hip, which is an inappropriate standard for use in a detection model. Therefore, we defined outcomes in terms of the *process of care*. We reviewed the literature extensively. The purpose of the literature review was to provide the probabilities required by the decision model since there were no randomized clinical trials. The article or chapter title and the abstracts were reviewed by 2 members of the methodology team and members of the subcommittee. Articles not rejected were reviewed, and data were abstracted that would provide evidence for the probabilities required by the decision model. As part of the literature abstraction process, the evidence quality in each article was assessed. A computer-based literature search, hand review of recent publications, or examination of the reference section for other articles ("ancestor articles") identified 623 articles; 241 underwent detailed review, 118 of which provided some data. Of the 100 ancestor articles, only 17 yielded useful articles, suggesting that our accession process was complete. By traditional epidemiologic standards,[33] the quality of the evidence in this set of articles was uniformly low. There were few controlled trials and few studies of the follow-up of infants for whom the results of newborn examinations were negative. When the evidence was poor or lacking entirely, extensive discussions among members of the committee and the expert opinion of outside consultants were used to arrive at a consensus. No votes were taken. Disagreements were discussed, and consensus was achieved.

The available evidence was distilled in 3 ways. First, estimates were made of DDH at birth in infants without risk factors. These estimates constituted the baseline risk. Second, estimates were made of the rates of DDH in the children with risk factors. These numbers guide clinical actions: rates that are too high might indicate referral or different follow-up despite negative physical findings. Third, each screening strategy (pediatrician-based, orthopaedist-based, and ultrasonography-based) was scored for the estimated number of children given a diagnosis of DDH at birth, at mid-term (4–12 months of age), and at late-term (12 months of age and older) and for the estimated number of cases of AVN incurred, assuming that all children given a diagnosis of DDH would be treated. These numbers suggest the best strategy, balancing DDH detection with incurring adverse effects.

The baseline estimate of DDH based on orthopaedic screening was 11.5/1000 infants. Estimates from pediatric screening were 8.6/1000 and from ultrasonography were 25/1000. The 11.5/1000 rate translates into a rate for not-at-risk boys of 4.1/1000 boys and a rate for not-at-risk girls of 19/1000 girls. These numbers derive from the facts that the relative risk—the rate in girls divided by the rate in boys across several studies—is 4.6 and because infants are split evenly between boys and girls, so $.5 \times 4.1/1000 + .5 \times 19/1000 = 11.5/1000$.[34,35] We used these baseline rates for calculating the rates in other risk groups. Because the relative risk of DDH for children with a positive family history (first-degree relatives) is 1.7, the rate for boys with a positive family history is $1.7 \times 4.1 = 6.4/1000$ boys, and for girls with a positive family history, $1.7 \times 19 = 32/1000$ girls. Finally, the relative risk of DDH for breech presentation (of all kinds) is 6.3, so the risk for breech boys is $7.0 \times 4.1 = 29/1000$ boys and for breech girls, $7.0 \times 19 = 133/1000$ girls. These numbers are summarized in Table 1.

These numbers suggest that boys without risk or those with a family history have the lowest risk; girls without risk and boys born in a breech presentation have an intermediate risk; and girls with a positive family history, and especially girls born in a breech presentation, have the highest risks. Guidelines, considering the risk factors, should follow these risk profiles. Reports of newborn screening for DDH have included various screening techniques. In some, the screening clinician was an orthopaedist, in

TABLE 1. Relative and Absolute Risks for Finding a Positive Examination Result at Newborn Screening by Using the Ortolani and Barlow Signs

Newborn Characteristics	Relative Risk of a Positive Examination Result	Absolute Risk of a Positive Examination Result per 1000 Newborns With Risk Factors
All newborns	· · ·	11.5
Boys	1.0	4.1
Girls	4.6	19
Positive family history	1.7	
Boys	· · ·	6.4
Girls	· · ·	32
Breech presentation	7.0	
Boys	· · ·	29
Girls	· · ·	133

TABLE 2. Newborn Strategy*

Outcome	Orthopaedist PE	Pediatrician PE	Ultrasonography
DDH in newborn	12	8.6	25
DDH at ~6 mo of age	.1	.45	.28
DDH at 12 mo of age or more	.16	.33	.1
AVN at 12 mo of age	.06	.1	.1

* PE indicates physical examination. Outcome per 1000 infants initially screened.

others, a pediatrician, and in still others, a physiotherapist. In addition, screening has been performed by ultrasonography. In assessing the expected effect of each strategy, we estimated the newborn DDH rates, the mid-term DDH rates, and the late-term DDH rates for each of the 3 strategies, as shown in Table 2. We also estimated the rate of AVN for DDH treated before 2 months of age (2.5/1000 treated) and after 2 months of age (109/1000 treated). We could not distinguish the AVN rates for children treated between 2 and 12 months of age from those treated later. Table 2 gives these data. The total cases of AVN per strategy are calculated, assuming that all infants with positive examination results are treated.

Table 2 shows that a strategy using pediatricians to screen newborns would give the lowest newborn rate but the highest mid- and late-term DDH rates. To assess how much better an ultrasonography-only screening strategy would be, we could calculate a cost-effectiveness ratio. In this case, the "cost" of ultrasonographic screening is the number of "extra" newborn cases that probably include children who do not need to be treated. (The cost from AVN is the same in the 2 strategies.) By using these cases as the cost and the number of later cases averted as the effect, a ratio is obtained of 71 children treated neonatally because of a positive ultrasonographic screen for each later case averted. Because this number is high, and because the presumption of better late-term efficacy is based on a single study, we do not recommend ultrasonographic screening at this time.

RECOMMENDATIONS AND NOTES TO ALGORITHM (Fig 1)

1. **All newborns are to be screened by physical examination**. The evidence† for this recommendation is good. The expert consensus‡ is strong. Although initial screening by orthopaedists§ would be optimal (Table 2), it is doubtful that if widely practiced, such a strategy would give the same good results as those published from pediatric orthopaedic research centers. **It is recommended that screening be done by a properly trained health care provider** (eg, physician, pediatric nurse practitioner, physician assistant, or physical therapist). (Evidence for this recommendation is strong.) A number of studies performed by properly trained nonphysicians report results indistinguishable from those performed by physicians.[36] The examination after discharge from the neonatal intensive care unit should be performed as a newborn examination with appropriate screening. **Ultrasonography of all newborns is not recommended.** (Evidence is fair; consensus is strong.) Although there is indirect evidence to support the use of ultrasonographic screening of all newborns, it is not advocated because it is operator-dependent, availability is questionable, it increases the rate of treatment, and interobserver variability is high. There are probably some increased costs. We considered a strategy of "no newborn screening." This arm is politically indefensible because screening newborns is inherent in pediatrician's care. The technical report details this limb through decision analysis. Regardless of the screening method used for the newborn, DDH is detected in 1 in 5000 infants at 18 months of age.[3] The evidence and consensus for newborn screening remain strong.

Newborn Physical Examination and Treatment

2. **If a positive Ortolani or Barlow sign is found in the newborn examination, the infant should be referred to an orthopaedist**. Orthopaedic referral is recommended when the Ortolani sign is unequivocally positive (a clunk). Orthopaedic referral is not recommended for any softly positive finding in the examination (eg, hip click without dislocation). The precise time frame for the newborn to be evaluated by the orthopaedist cannot be determined from the literature. However, the literature suggests that the majority of "abnormal" physical findings of hip examinations at birth (clicks and clunks) will resolve by 2 weeks; therefore, consultation and possible initiation of treatment are recommended by that time. The data recommending that all those with a positive Ortolani sign be referred to an orthopaedist are limited, but expert panel consensus, nevertheless, was strong, because pediatricians do not have the training to take full responsibility and because true Ortolani clunks are rare and their management is more appropriately performed by the orthopaedist.

If the results of the physical examination at birth are "equivocally" positive (ie, soft click, mild asymmetry, but neither an Ortolani nor a Barlow sign is present), then a follow-up hip examination by the pediatrician in 2 weeks is recommended. (Evidence is good; consensus is strong.) The available data suggest that most clicks resolve by 2 weeks and that these "benign hip clicks" in the newborn period do

†In this guideline, evidence is listed as good, fair, or poor based on the methodologist's evaluation of the literature quality. (See the Technical Report.)

‡Opinion or consensus is listed as *strong* if opinion of the expert panel was unanimous or *mixed* if there were dissenting points of view.

§In this guideline, the term *orthopaedist* refers to an orthopaedic surgeon with expertise in pediatric orthopaedic conditions.

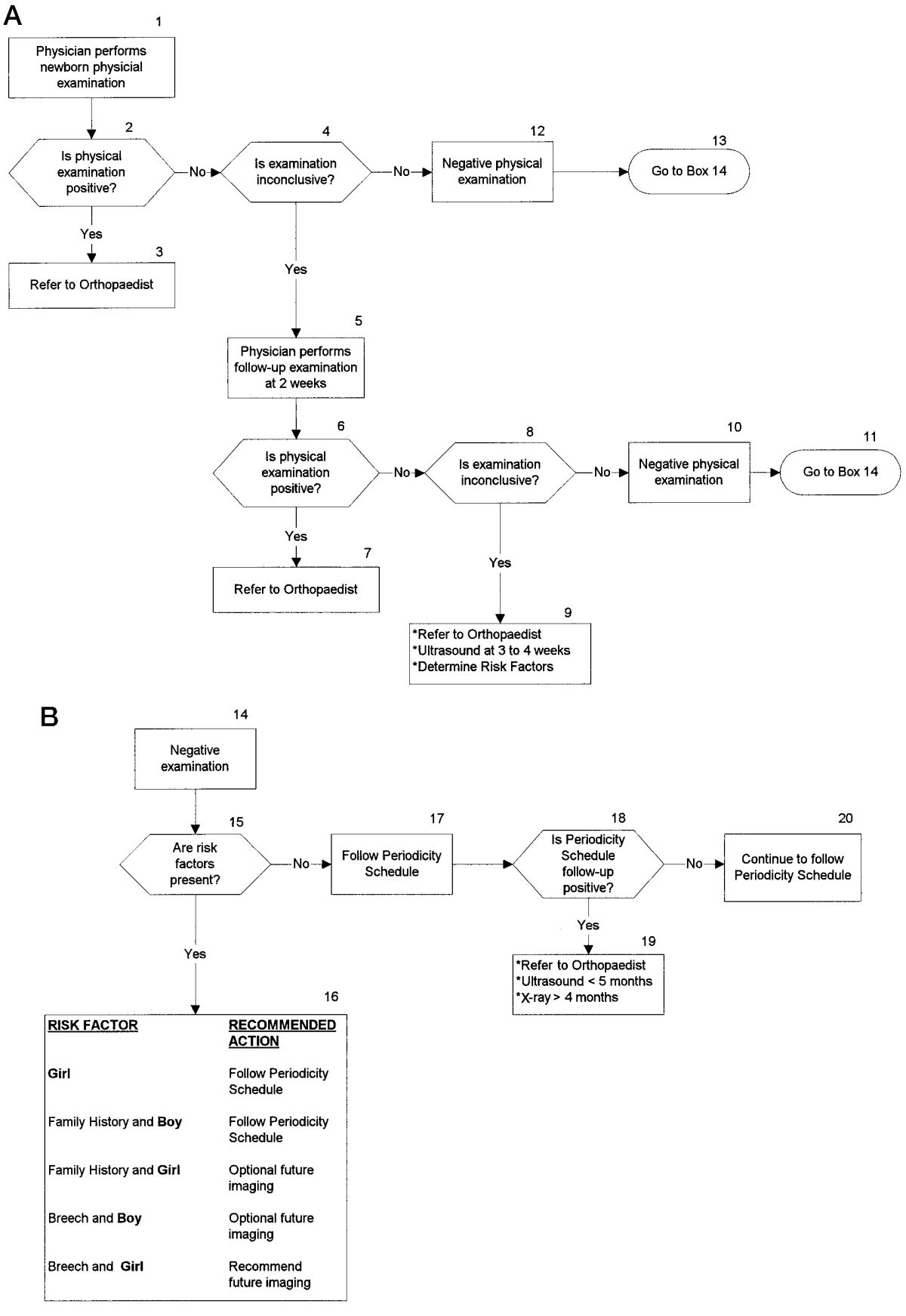


Fig 1. Screening for developmental hip dysplasia—clinical algorithm.

not lead to later hip dysplasia.[9,17,28,37] Thus, for an infant with softly positive signs, the pediatrician should reexamine the hips at 2 weeks before making referrals for orthopaedic care or ultrasonography. We recognize the concern of pediatricians about adherence to follow-up care regimens, but this concern regards all aspects of health maintenance and is not a reason to request ultrasonography or other diagnostic study of the newborn hips.

3. **If the results of the newborn physical examination are positive (ie, presence of an Ortolani or a Barlow sign), ordering an ultrasonographic examination of the newborn is not recommended**. (Evidence is poor; opinion is strong.) Treatment decisions are not influenced by the results of ultrasonography but are based on the results of the physical examination. The treating physician may use a variety of imaging studies during clinical management. **If the results of the newborn physical examination are positive, obtaining a radiograph of the newborn's pelvis and hips is not recommended** (evidence is poor; opinion is strong), because they are of limited value and do not influence treatment decisions.

The use of triple diapers when abnormal physical signs are detected during the newborn period is not recommended. (Evidence is poor; opinion is strong.) Triple diaper use is common practice despite the lack of data on the effectiveness of triple diaper use; and, in instances of frank dislocation, the use of triple diapers may delay the initiation of more appropriate treatment (such as with the Pavlik harness). Often, the primary care pediatrician may not have performed the newborn examination in the hospital. The importance of communication cannot be overemphasized, and triple diapers may aid in follow-up as a reminder that a possible abnormal physical examination finding was present in the newborn.

2-Week Examination

4. **If the results of the physical examination are positive (eg, positive Ortolani or Barlow sign) at 2 weeks, refer to an orthopaedist**. (Evidence is strong; consensus is strong.) Referral is urgent but is not an emergency. Consensus is strong that, as in the newborn, the presence of an Ortolani or Barlow sign at 2 weeks warrants referral to an orthopaedist. An Ortolani sign at 2 weeks may be a new finding or a finding that was not apparent at the time of the newborn examination.

5. **If at the 2-week examination the Ortolani and Barlow signs are absent but physical findings raise suspicions, consider referral to an orthopaedist or request ultrasonography at age 3 to 4 weeks**. Consensus is mixed about the follow-up for softly positive or equivocal findings at 2 weeks of age (eg, adventitial click, thigh asymmetry, and apparent leg length difference). Because it is necessary to confirm the status of the hip joint, the pediatrician can consider referral to an orthopaedist or for ultrasonography if the constellation of physical findings raises a high level of suspicion. However, if the physical findings are minimal, continuing follow-up by the periodicity schedule with focused hip examinations is also an option, provided risk factors are considered. (See "Recommendations" 7 and 8.)

6. **If the results of the physical examination are negative at 2 weeks, follow-up is recommended at the scheduled well-baby periodic examinations**. (Evidence is good; consensus is strong.)

7. **Risk factors**. **If the results of the newborn examination are negative (or equivocally positive), risk factors may be considered**.[13,21,38–41] Risk factors are a study of thresholds to act.[42] Table 1 gives the risk of finding a positive Ortolani or Barlow sign at the time of the initial newborn screening. If this examination is negative, the absolute risk of there being a true dislocated hip is greatly reduced. Nevertheless, the data in Table 1 may influence the pediatrician to perform confirmatory evaluations. Action will vary based on the individual clinician. The following recommendations are made (evidence is strong; opinion is strong):
   - **Girl** (newborn risk of 19/1000). When the results of the newborn examination are negative or equivocally positive, hips should be reevaluated at 2 weeks of age. If negative, continue according to the periodicity schedule; if positive, refer to an orthopaedist or for ultrasonography at 3 weeks of age.
   - **Infants with a positive family history of DDH** (newborn risk for boys of 9.4/1000 and for girls, 44/1000). When the results of the newborn examination in boys are negative or equivocally positive, hips should be reevaluated at 2 weeks of age. If negative, continue according to the periodicity schedule; if positive, refer to an orthopaedist or for ultrasonography at 3 weeks of age. In girls, the absolute risk of 44/1000 may exceed the pediatrician's threshold to act, and imaging with an ultrasonographic examination at 6 weeks of age or a radiograph of the pelvis at 4 months of age is recommended.
   - **Breech presentation** (newborn risk for boys of 26/1000 and for girls, 120/1000). **For negative or equivocally positive newborn examinations, the infant should be reevaluated at regular intervals (according to the periodicity schedule) if the examination results remain negative**. Because an absolute risk of 120/1000 (12%) probably exceeds most pediatricians' threshold to act, imaging with an ultrasonographic examination at 6 weeks of age or with a radiograph of the pelvis and hips at 4 months of age is recommended. In addition, because some reports show a high incidence of hip abnormalities detected at an older age in children born breech, this imaging strategy remains an option for all children born breech, not just girls. These hip abnormalities are, for the most part, inadequate development of the acetabulum. Acetabular dysplasia is best found by a radiographic examination at 6 months of age or older. A

suggestion of poorly formed acetabula may be observed at 6 weeks of age by ultrasonography, but the best study remains a radiograph performed closer to 6 months of age. Ultrasonographic newborn screening of all breech infants will not eliminate the possibility of later acetabular dysplasia.

8. **Periodicity**. **The hips must be examined at every well-baby visit according to the recommended periodicity schedule for well-baby examinations (2–4 days for newborns discharged in less than 48 hours after delivery, by 1 month, 2 months, 4 months, 6 months, 9 months, and 12 months of age)**. If at any time during the follow-up period DDH is suspected because of an abnormal physical examination or by a parental complaint of difficulty diapering or abnormal appearing legs, the pediatrician must confirm that the hips are stable, in the sockets, and developing normally. Confirmation can be made by a focused physical examination when the infant is calm and relaxed, by consultation with another primary care pediatrician, by consultation with an orthopaedist, by ultrasonography if the infant is younger than 5 months of age, or by radiography if the infant is older than 4 months of age. (Between 4 and 6 months of age, ultrasonography and radiography seem to be equally effective diagnostic imaging studies.)

DISCUSSION

DDH is an important term because it accurately reflects the biologic features of the disorder and the susceptibility of the hip to become dislocated at various times. Dislocated hips always will be diagnosed later in infancy and childhood because not every dislocated hip is detectable at birth, and hips continue to dislocate throughout the first year of life. Thus, this guideline requires that the pediatrician follow *a process of care for the detection of DDH*. The process recommended for early detection of DDH includes the following:

- Screen all newborns' hips by physical examination.
- Examine all infants' hips according to a periodicity schedule and follow-up until the child is an established walker.
- Record and document physical findings.
- Be aware of the changing physical examination for DDH.
- If physical findings raise suspicion of DDH, or if parental concerns suggest hip disease, confirmation is required by expert physical examination, referral to an orthopaedist, or by an age-appropriate imaging study.

When this process of care is followed, the number of dislocated hips diagnosed at 1 year of age should be minimized. However, the problem of late detection of dislocated hips will not be eliminated. The results of screening programs have indicated that 1 in 5000 children have a dislocated hip detected at 18 months of age or older.[3]

TECHNICAL REPORT

The Technical Report is available from the American Academy of Pediatrics from several sources. The Technical Report is published in full-text on *Pediatrics electronic pages*. It is also available in a compendium of practice guidelines that contains guidelines and evidence reports together. The objective was to create a recommendation to pediatricians and other primary care providers about their role as screeners for detecting DDH. The patients are a theoretical cohort of newborns. A model-based method using decision analysis was the foundation. Components of the approach include:

- Perspective: primary care provider
- Outcomes: DDH and AVN
- Preferences: expected rates of outcomes
- Model: influence diagram assessed from the subcommittee and from the methodology team with critical feedback from the subcommittee
- Evidence sources: Medline and EMBase (detailed in "Methods" section)
- Evidence quality: assessed on a custom, subjective scale, based primarily on the fit of the evidence in the decision model

The results are detailed in the "Methods" section. Based on the raw evidence and Bayesian hierarchical meta-analysis,[34,35] estimates for the incidence of DDH based on the type of screener (orthopaedist vs pediatrician); the odds ratio for DDH given risk factors of sex, family history, and breech presentation; and estimates for late detection and AVN were determined and are detailed in the "Methods" section and in Tables 1 and 2.

The decision model (reduced based on available evidence) suggests that orthopaedic screening is optimal, but because orthopaedists in the published studies and in practice would differ in pediatric expertise, the supply of pediatric orthopaedists is relatively limited, and the difference between orthopaedists and pediatricians is statistically insignificant, we conclude that pediatric screening is to be recommended. The place for ultrasonography in the screening process remains to be defined because of the limited data available regarding late diagnosis in ultrasonography screening to permit definitive recommendations.

These data could be used by others to refine the conclusion based on costs, parental preferences, or physician style. Areas for research are well defined by our model-based method. All references are in the Technical Report.

RESEARCH QUESTIONS

The quality of the literature suggests many areas for research, because there is a paucity of randomized clinical trials and case-controlled studies. The following is a list of possibilities:

1. Minimum diagnostic abilities of a screener. Although there are data for pediatricians in general, few, if any, studies evaluated the abilities of an individual examiner. What should the minimum

sensitivity and specificity be, and how should they be assessed?
2. Intercurrent screening. There were few studies on systemic processes for screening after the newborn period.[2,43,44] Although several studies assessed postneonatal DDH, the data did not specify how many examinations were performed on each child before the abnormal result was found.
3. Trade-offs. Screening always results in false-positive results, and these patients suffer the adverse effects of therapy. How many unnecessary AVNs are we—families, physicians, and society—willing to tolerate from a screening program for every appropriately treated infant in whom late DDH was averted? This assessment depends on people's values and preferences and is not strictly an epidemiologic issue.
4. Postneonatal DDH after ultrasonographic screening. Although we concluded that ultrasonographic screening did not result in fewer diagnoses of postneonatal DDH, that conclusion was based on only 1 study.[36] Further study is needed.
5. Cost-effectiveness. If ultrasonographic screening reduces the number of postneonatal DDH diagnoses, then there will be a cost trade-off between the resources spent up front to screen everyone with an expensive technology, as in the case of ultrasonography, and the resources spent later to treat an expensive adverse event, as in the case of physical examination-based screening. The level at which the cost per case of postneonatal DDH averted is no longer acceptable is a matter of social preference, not of epidemiology.

ACKNOWLEDGMENTS

We acknowledge and appreciate the help of our methodology team, Richard Hinton, MD, Paola Morello, MD, and Jeanne Santoli, MD, who diligently participated in the literature review and abstracting the articles into evidence tables, and the subcommittee on evidence analysis.

We would also like to thank Robert Sebring, PhD, for assisting in the management of this process; Bonnie Cosner for managing the workflow; and Chris Kwiat, MLS, from the American Academy of Pediatrics Bakwin Library, who performed the literature searches.

REFERENCES

1. Bjerkreim I, Hagen O, Ikonomou N, Kase T, Kristiansen T, Arseth P. Late diagnosis of developmental dislocation of the hip in Norway during the years 1980–1989. *J Pediatr Orthop B*. 1993;2:112–114
2. Clarke N, Clegg J, Al-Chalabi A. Ultrasound screening of hips at risk for CDH: failure to reduce the incidence of late cases. *J Bone Joint Surg Br*. 1989;71:9–12
3. Dezateux C, Godward C. Evaluating the national screening programme for congenital dislocation of the hip. *J Med Screen*. 1995;2:200–206
4. Hadlow V. Neonatal screening for congenital dislocation of the hip: a prospective 21-year survey. *J Bone Joint Surg Br*. 1988;70:740–743
5. Krikler S, Dwyer N. Comparison of results of two approaches to hip screening in infants. *J Bone Joint Surg Br*. 1992;74:701–703
6. Macnicol M. Results of a 25-year screening programme for neonatal hip instability. *J Bone Joint Surg Br*. 1990;72:1057–1060
7. Marks DS, Clegg J, Al-Chalabi AN. Routine ultrasound screening for neonatal hip instability: can it abolish late-presenting congenital dislocation of the hip? *J Bone Joint Surg Br*. 1994;76:534–538
8. Rosendahl K, Markestad T, Lie R. Congenital dislocation of the hip: a prospective study comparing ultrasound and clinical examination. *Acta Paediatr*. 1992;81:177–181
9. Sanfridson J, Redlund-Johnell I, Uden A. Why is congenital dislocation of the hip still missed? Analysis of 96,891 infants screened in Malmo 1956–1987. *Acta Orthop Scand*. 1991;62:87–91
10. Tredwell S, Bell H. Efficacy of neonatal hip examination. *J Pediatr Orthop*. 1981;1:61–65
11. Yngve D, Gross R. Late diagnosis of hip dislocation in infants. *J Pediatr Orthop*. 1990;10:777–779
12. Aronsson DD, Goldberg MJ, Kling TF, Roy DR. Developmental dysplasia of the hip. *Pediatrics*. 1994;94:201–212
13. Hinderaker T, Daltveit AK, Irgens LM, Uden A, Reikeras O. The impact of intra-uterine factors on neonatal hip instability: an analysis of 1,059,479 children in Norway. *Acta Orthop Scand*. 1994;65:239–242
14. Wynne-Davies R. Acetabular dysplasia and familial joint laxity: two etiological factors in congenital dislocation of the hip: a review of 589 patients and their families. *J Bone Joint Surg Br*. 1970;52:704–716
15. De Pellegrin M. Ultrasound screening for congenital dislocation of the hip: results and correlations between clinical and ultrasound findings. *Ital J Orthop Traumatol*. 1991;17:547–553
16. Stoffelen D, Urlus M, Molenaers G, Fabry G. Ultrasound, radiographs, and clinical symptoms in developmental dislocation of the hip: a study of 170 patients. *J Pediatr Orthop B*. 1995;4:194–199
17. Bond CD, Hennrikus WL, Della Maggiore E. Prospective evaluation of newborn soft tissue hip clicks with ultrasound. *J Pediatr Orthop*. 1997; 17:199–201
18. Bialik V, Wiener F, Benderly A. Ultrasonography and screening in developmental displacement of the hip. *J Pediatr Orthop B*. 1992;1:51–54
19. Castelein R, Sauter A. Ultrasound screening for congenital dysplasia of the hip in newborns: its value. *J Pediatr Orthop*. 1988;8:666–670
20. Clarke NMP, Harcke HT, McHugh P, Lee MS, Borns PF, MacEwen GP. Real-time ultrasound in the diagnosis of congenital dislocation and dysplasia of the hip. *J Bone Joint Surg Br*. 1985;67:406–412
21. Garvey M, Donoghue V, Gorman W, O'Brien N, Murphy J. Radiographic screening at four months of infants at risk for congenital hip dislocation. *J Bone Joint Surg Br*. 1992;74:704–707
22. Langer R. Ultrasonic investigation of the hip in newborns in the diagnosis of congenital hip dislocation: classification and results of a screening program. *Skeletal Radiol*. 1987;16:275–279

23. Rosendahl K, Markestad T, Lie RT. Ultrasound screening for developmental dysplasia of the hip in the neonate: the effect on treatment rate and prevalence of late cases. *Pediatrics*. 1994;94:47–52
24. Terjesen T. Ultrasound as the primary imaging method in the diagnosis of hip dysplasia in children aged <2 years. *J Pediatr Orthop B*. 1996;5: 123–128
25. Vedantam R, Bell M. Dynamic ultrasound assessment for monitoring of treatment of congenital dislocation of the hip. *J Pediatr Orthop*. 1995;15: 725–728
26. Graf R. Classification of hip joint dysplasia by means of sonography. *Arch Orthop Trauma Surg*. 1984;102:248–255
27. Berman L, Klenerman L. Ultrasound screening for hip abnormalities: preliminary findings in 1001 neonates. *Br Med J (Clin Res Ed)*. 1986;293: 719–722
28. Castelein R, Sauter A, de Vlieger M, van Linge B. Natural history of ultrasound hip abnormalities in clinically normal newborns. *J Pediatr Orthop*. 1992;12:423–427
29. Clarke N. Sonographic clarification of the problems of neonatal hip stability. *J Pediatr Orthop*. 1986;6:527–532
30. Eddy DM. The confidence profile method: a Bayesian method for assessing health technologies. *Operations Res*. 1989;37:210–228
31. Howard RA, Matheson JE. Influence diagrams. In: Matheson JE, ed. *Readings on the Principles and Applications of Decision Analysis*. Menlo Park, CA: Strategic Decisions Group; 1981:720–762
32. Nease RF, Owen DK. Use of influence diagrams to structure medical decisions. *Med Decis Making*. 1997;17:265–275
33. Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook RJ. Users' guide to the medical literature, IX: a method for grading health care recommendations. *JAMA*. 1995;274:1800–1804
34. Gelman A, Carlin JB, Stern HS, Rubin DB. *Bayesian Data Analysis*. London, UK: Chapman and Hall; 1997
35. Spiegelhalter D, Thomas A, Best N, Gilks W. *BUGS 0.5: Bayesian Inference Using Gibbs Sampling Manual, II*. Cambridge, MA: MRC Biostatistics Unit, Institute of Public Health; 1996. Available at: http://www.mrc-bsu.cam.ac.uk/bugs/software/software.html
36. Fiddian NJ, Gardiner JC. Screening for congenital dislocation of the hip by physiotherapists: results of a ten-year study. *J Bone Joint Surg Br*. 1994;76:458–459
37. Dunn P, Evans R, Thearle M, Griffiths H, Witherow P. Congenital dislocation of the hip: early and late diagnosis and management compared. *Arch Dis Child*. 1992;60:407–414
38. Holen KJ, Tegnander A, Terjesen T, Johansen OJ, Eik-Nes SH. Ultrasonographic evaluation of breech presentation as a risk factor for hip dysplasia. *Acta Paediatr*. 1996;85:225–229
39. Jones D, Powell N. Ultrasound and neonatal hip screening: a prospective study of "high risk" babies. *J Bone Joint Surg Br*. 1990;72:457–459
40. Teanby DN, Paton RW. Ultrasound screening for congenital dislocation of the hip: a limited targeted programme. *J Pediatr Orthop*. 1997;17: 202–204
41. Tonnis D, Storch K, Ulbrich H. Results of newborn screening for CDH with and without sonography and correlation of risk factors. *J Pediatr Orthop*. 1990;10:145–152
42. Pauker SG, Kassirer JP. The threshold approach to clinical decision making. *N Engl J Med*. 1980;302:1109–1117
43. Bower C, Stanley F, Morgan B, Slattery H, Stanton C. Screening for congenital dislocation of the hip by child-health nurses in western Australia. *Med J Aust*. 1989;150:61–65
44. Franchin F, Lacalendola G, Molfetta L, Mascolo V, Quagliarella L. Ultrasound for early diagnosis of hip dysplasia. *Ital J Orthop Traumatol*. 1992;18:261–269

ADDENDUM TO REFERENCES FOR THE DDH GUIDELINE

New information is generated constantly. Specific details of this report must be changed over time.

New articles (additional articles 1–7) have been published since the completion of our literature search and construction of this Guideline. These articles taken alone might seem to contradict some of the Guideline's estimates as detailed in the article and in the Technical Report. However, taken in context with the literature synthesis carried out for the construction of this Guideline, our estimates remain intact and no conclusions are obviated.

ADDITIONAL ARTICLES

1. Bialik V, Bialik GM, Blazer S, Sujov P, Wiener F, Berant M. Developmental dysplasia of the hip: a new approach to incidence. *Pediatrics*. 1999;103:93–99
2. Clegg J, Bache CE, Raut VV. Financial justification for routine ultrasound screening of the neonatal hip. *J Bone Joint Surg*. 1999;81-B:852–857
3. Holen KJ, Tegnander A, Eik-Nes SH, Terjesen T. The use of ultrasound in determining the initiation in treatment in instability of the hips in neonates. *J Bone Joint Surg*. 1999;81-B:846–851
4. Lewis K, Jones DA, Powell N. Ultrasound and neonatal hip screening: the five-year results of a prospective study in high risk babies. *J Pediatr Orthop*. 1999;19:760–762
5. Paton RW, Srinivasan MS, Shah B, Hollis S. Ultrasound screening for hips at risk in developmental dysplasia: is it worth it? *J Bone Joint Surg*. 1999;81-B:255–258
6. Sucato DJ, Johnston CE, Birch JG, Herring JA, Mack P. Outcomes of ultrasonographic hip abnormalities in clinically stable hips. *J Pediatr Orthop*. 1999;19:754–759
7. Williams PR, Jones DA, Bishay M. Avascular necrosis and the aberdeen splint in developmental dysplasia of the hip. *J Bone Joint Surg*. 1999;81-B:1023–1028

Dysplasia of the Hip Clinical Practice Guideline Quick Reference Tools

- Recommendation Summary
  — Early Detection of Developmental Dysplasia of the Hip
- *ICD-10-CM* Coding Quick Reference for Dysplasia of the Hip
- AAP Patient Education Handout
  — *Hip Dysplasia (Developmental Dysplasia of the Hip)*

Recommendation Summary

Early Detection of Developmental Dysplasia of the Hip

Recommendation 1

A. All newborns are to be screened by physical examination. (The evidence for this recommendation is good. The expert consensus is strong.)
B. It is recommended that screening be done by a properly trained health care provider (eg, physician, pediatric nurse practitioner, physician assistant, or physical therapist). (Evidence for this recommendation is strong.)
C. Ultrasonography of all newborns is not recommended. (Evidence is fair; consensus is strong.)

Recommendation 2

A. If a positive Ortolani or Barlow sign is found in the newborn examination, the infant should be referred to an orthopaedist. (The data recommending that all those with a positive Ortolani sign be referred to an orthopaedist are limited, but expert panel consensus, nevertheless, was strong….)
B. If the results of the physical examination at birth are "equivocally" positive (ie, soft click, mild asymmetry, but neither an Ortolani nor a Barlow sign is present), then a follow-up hip examination by the pediatrician in 2 weeks is recommended. (Evidence is good; consensus is strong.)

Recommendation 3

A. If the results of the newborn physical examination are positive (ie, presence of an Ortolani or a Barlow sign), ordering an ultrasonographic examination of the newborn is not recommended. (Evidence is poor; opinion is strong.)
B. If the results of the newborn physical examination are positive, obtaining a radiograph of the newborn's pelvis and hips is not recommended. (Evidence is poor; opinion is strong.)
C. The use of triple diapers when abnormal physical signs are detected during the newborn period is not recommended. (Evidence is poor; opinion is strong.)

Recommendation 4

If the results of the physical examination are positive (eg, positive Ortolani or Barlow sign) at 2 weeks, refer to an orthopaedist. (Evidence is strong; consensus is strong.)

Recommendation 5

If at the 2-week examination the Ortolani and Barlow signs are absent but physical findings raise suspicions, consider referral to an orthopaedist or request ultrasonography at age 3 to 4 weeks.

Recommendation 6

If the results of the physical examination are negative at 2 weeks, follow-up is recommended at the scheduled well-baby periodic examinations. (Evidence is good; consensus is strong.)

Recommendation 7

Risk factors. If the results of the newborn examination are negative (or equivocally positive), risk factors may be considered. The following recommendations are made (evidence is strong; opinion is strong):

A. Girl (newborn risk of 19/1000). When the results of the newborn examination are negative or equivocally positive, hips should be reevaluated at 2 weeks of age. If negative, continue according to the periodicity schedule; if positive, refer to an orthopaedist or for ultrasonography at 3 weeks of age.
B. Infants with a positive family history of DDH (newborn risk for boys of 9.4/1000 and for girls, 44/1000). When the results of the newborn examination in boys are negative or equivocally positive, hips should be reevaluated at 2 weeks of age. If negative, continue according to the periodicity schedule; if positive, refer to an orthopaedist or for ultrasonography at 3 weeks of age. In girls, the absolute risk of 44/1000 may exceed the pediatrician's threshold to act, and imaging with an ultrasonographic examination at 6 weeks of age or a radiograph of the pelvis at 4 months of age is recommended.
C. Breech presentation (newborn risk for boys of 26/1000 and for girls, 120/1000). For negative or equivocally positive newborn examinations, the infant should be reevaluated at regular intervals (according to the periodicity schedule) if the examination results remain negative.

Recommendation 8

Periodicity. The hips must be examined at every well-baby visit according to the recommended periodicity schedule for well-baby examinations (2–4 days for newborns discharged in less than 48 hours after delivery, by 1 month, 2 months, 4 months, 6 months, 9 months, and 12 months of age).

Coding Quick Reference for Dysplasia of the Hip	
ICD-10-CM	
Q65.0-	Congenital dislocation of hip, unilateral
Q65.1	Congenital dislocation of hip, bilateral
Q65.3-	Congenital partial dislocation of hip, unilateral
Q65.4	Congenital partial dislocation of hip, bilateral
Q65.6	Congenital unstable hip (Congenital dislocatable hip)
Q65.89	Other specified congenital deformities of hip

Symbol "-" requires a fifth character; **1** = right; **2** = left.

Hip Dysplasia

(Developmental Dysplasia of the Hip)

Hip dysplasia (developmental dysplasia of the hip) is a condition in which a child's upper thighbone is dislocated from the hip socket. It can be present at birth or develop during a child's first year of life.

Hip dysplasia is not always detectable at birth or even during early infancy. In spite of careful screening of children for hip dysplasia during regular well-child exams, a number of children with hip dysplasia are not diagnosed until after they are 1 year old.

Hip dysplasia is rare. However, if your baby is diagnosed with the condition, quick treatment is important.

What causes hip dysplasia?

No one is sure why hip dysplasia occurs (or why the left hip dislocates more often than the right hip). One reason may have to do with the hormones a baby is exposed to before birth. While these hormones serve to relax muscles in the pregnant mother's body, in some cases they also may cause a baby's joints to become too relaxed and prone to dislocation. This condition often corrects itself in several days, and the hip develops normally. In some cases, these dislocations cause changes in the hip anatomy that need treatment.

Who is at risk?

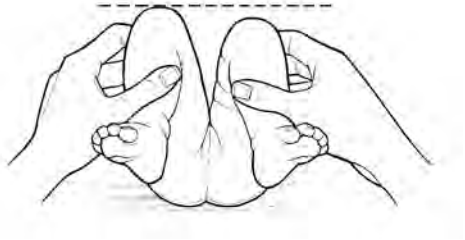
Factors that may increase the risk of hip dysplasia include

- Sex—more frequent in girls
- Family history—more likely when other family members have had hip dysplasia
- Birth position—more common in infants born in the breech position
- Birth order—firstborn children most at risk for hip dysplasia

Detecting hip dysplasia

Your pediatrician will check your newborn for hip dysplasia right after birth and at every well-child exam until your child is walking normally.

During the exam, your child's pediatrician will carefully flex and rotate your child's legs to see if the thighbones are properly positioned in the hip sockets. This does not require a great deal of force and will not hurt your baby.



Your child's pediatrician also will look for other signs that may suggest a problem, including

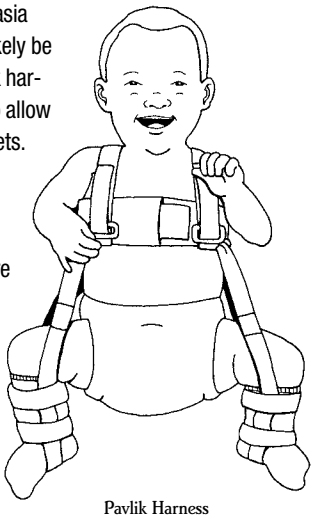
- Limited range of motion in either leg
- One leg is shorter than the other
- Thigh or buttock creases appear uneven or lopsided

If your child's pediatrician suspects a problem with your child's hip, you may be referred to an orthopedic specialist who has experience treating hip dysplasia.

Treating hip dysplasia

Early treatment is important. The sooner treatment begins, the simpler it will be. In the past parents were told to double or triple diaper their babies to keep the legs in a position where dislocation was unlikely. *This practice is not recommended.* The diapering will not prevent hip dysplasia and will only delay effective treatment. Failure to treat this condition can result in permanent disability.

If your child is diagnosed with hip dysplasia before she is 6 months old, she will most likely be treated with a soft brace (such as the Pavlik harness) that holds the legs flexed and apart to allow the thighbones to be secure in the hip sockets.



Pavlik Harness

The orthopedic consultant will tell you how long and when your baby will need to wear the brace. Your child also will be examined frequently during this time to make sure that the hips remain normal and stable.

In resistant cases or in older children, hip dysplasia may need to be treated with a combination of braces, casts, traction, or surgery. Your child will be admitted to the hospital if surgery is necessary. After surgery, your child will be placed in a hip spica cast for about 3 months. A hip spica cast is a hard cast that immobilizes the hips and keeps them in the correct position. When the cast is removed, your child will need to wear a removable hip brace for several more months.

Remember

If you have any concerns about your child's walking, talk with his pediatrician. If the cause is hip dysplasia, prompt treatment is important.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site—www.aap.org

Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures

- *Clinical Practice Guideline*

CLINICAL PRACTICE GUIDELINE

Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures

Steering Committee on Quality Improvement and Management, Subcommittee on Febrile Seizures

ABSTRACT

Febrile seizures are the most common seizure disorder in childhood, affecting 2% to 5% of children between the ages of 6 and 60 months. Simple febrile seizures are defined as brief (<15-minute) generalized seizures that occur once during a 24-hour period in a febrile child who does not have an intracranial infection, metabolic disturbance, or history of afebrile seizures. This guideline (a revision of the 1999 American Academy of Pediatrics practice parameter [now termed clinical practice guideline] "The Long-term Treatment of the Child With Simple Febrile Seizures") addresses the risks and benefits of both continuous and intermittent anticonvulsant therapy as well as the use of antipyretics in children with simple febrile seizures. It is designed to assist pediatricians by providing an analytic framework for decisions regarding possible therapeutic interventions in this patient population. It is not intended to replace clinical judgment or to establish a protocol for all patients with this disorder. Rarely will these guidelines be the only approach to this problem. *Pediatrics* 2008;121:1281–1286

www.pediatrics.org/cgi/doi/10.1542/peds.2008-0939

doi:10.1542/peds.2008-0939

Key Word
fever

Abbreviation
AAP—American Academy of Pediatrics

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

The expected outcomes of this practice guideline include:

1. optimizing practitioner understanding of the scientific basis for using or avoiding various proposed treatments for children with simple febrile seizures;
2. improving the health of children with simple febrile seizures by avoiding therapies with high potential for adverse effects and no demonstrated ability to improve children's long-term outcomes;
3. reducing costs by avoiding therapies that will not demonstrably improve children's long-term outcomes; and
4. helping the practitioner educate caregivers about the low risks associated with simple febrile seizures.

The committee determined that with the exception of a high rate of recurrence, no long-term effects of simple febrile seizures have been identified. The risk of developing epilepsy in these patients is extremely low, although slightly higher than that in the general population. No data, however, suggest that prophylactic treatment of children with simple febrile seizures would reduce the risk, because epilepsy likely is the result of genetic predisposition rather than structural damage to the brain caused by recurrent simple febrile seizures. Although antipyretics have been shown to be ineffective in preventing recurrent febrile seizures, there is evidence that continuous anticonvulsant therapy with phenobarbital, primidone, or valproic acid and intermittent therapy with diazepam are effective in reducing febrile-seizure recurrence. The potential toxicities associated with these agents, however, outweigh the relatively minor risks associated with simple febrile seizures. As such, the committee concluded that, on the basis of the risks and benefits of the effective therapies, neither continuous nor intermittent anticonvulsant therapy is recommended for children with 1 or more simple febrile seizures.

INTRODUCTION

Febrile seizures are seizures that occur in febrile children between the ages of 6 and 60 months who do not have an intracranial infection, metabolic disturbance, or history of afebrile seizures. Febrile seizures are subdivided into 2 categories: simple and complex. Simple febrile seizures last for less than 15 minutes, are generalized (without a focal component), and occur once in a 24-hour period, whereas complex febrile seizures are prolonged (>15 minutes), are focal, or occur more than once in 24 hours.[1] Despite the frequency of febrile seizures (2%–5%), there is no unanimity of opinion about management options. This clinical practice guideline addresses potential therapeutic interventions in neurologically normal children with simple febrile seizures. It is not intended for patients with complex febrile seizures and does not pertain to children with previous neurologic insults, known central nervous system abnor-

malities, or a history of afebrile seizures. This clinical practice guideline is a revision of a 1999 American Academy of Pediatrics (AAP) clinical practice parameter, "The Long-term Treatment of the Child With Simple Febrile Seizures."[2]

For a child who has experienced a simple febrile seizure, there are potentially 4 adverse outcomes that theoretically may be altered by an effective therapeutic agent: (1) decline in IQ; (2) increased risk of epilepsy; (3) risk of recurrent febrile seizures; and (4) death. Neither a decline in IQ, academic performance or neurocognitive inattention nor behavioral abnormalities have been shown to be a consequence of recurrent simple febrile seizures.[3] Ellenberg and Nelson[4] studied 431 children who experienced febrile seizures and observed no significant difference in their learning compared with sibling controls. In a similar study by Verity et al,[5] 303 children with febrile seizures were compared with control children. No difference in learning was identified, except in those children who had neurologic abnormalities before their first seizure.

The second concern, increased risk of epilepsy, is more complex. Children with simple febrile seizures have approximately the same risk of developing epilepsy by the age of 7 years as does the general population (ie, 1%).[6] However, children who have had multiple simple febrile seizures, are younger than 12 months at the time of their first febrile seizure, and have a family history of epilepsy are at higher risk, with generalized afebrile seizures developing by 25 years of age in 2.4%.[7] Despite this fact, no study has demonstrated that successful treatment of simple febrile seizures can prevent this later development of epilepsy, and there currently is no evidence that simple febrile seizures cause structural damage to the brain. Indeed, it is most likely that the increased risk of epilepsy in this population is the result of genetic predisposition.

In contrast to the slightly increased risk of developing epilepsy, children with simple febrile seizures have a high rate of recurrence. The risk varies with age. Children younger than 12 months at the time of their first simple febrile seizure have an approximately 50% probability of having recurrent febrile seizures. Children older than 12 months at the time of their first event have an approximately 30% probability of a second febrile seizure; of those who do have a second febrile seizure, 50% have a chance of having at least 1 additional recurrence.[8]

Finally, there is a theoretical risk of a child dying during a simple febrile seizure as a result of documented injury, aspiration, or cardiac arrhythmia, but to the committee's knowledge, it has never been reported.

In summary, with the exception of a high rate of recurrence, no long-term adverse effects of simple febrile seizures have been identified. Because the risks associated with simple febrile seizures, other than recurrence, are so low and because the number of children who have febrile seizures in the first few years of life is so high, to be commensurate, a proposed therapy would need to be exceedingly low in risks and adverse effects, inexpensive, and highly effective.

METHODS

To update the clinical practice guideline on the treatment of children with simple febrile seizures, the AAP reconvened the Subcommittee on Febrile Seizures. The committee was chaired by a child neurologist and consisted of a neuroepidemiologist, 2 additional child neurologists, and a practicing pediatrician. All panel members reviewed and signed the AAP voluntary disclosure and conflict-of-interest form. The guideline was reviewed by members of the AAP Steering Committee on Quality Improvement and Management; members of the AAP Sections on Neurology, Pediatric Emergency Medicine, Developmental and Behavioral Pediatrics, and Epidemiology; members of the AAP Committees on Pediatric Emergency Medicine and Medical Liability and Risk Management; members of the AAP Councils on Children With Disabilities and Community Pediatrics; and members of outside organizations including the Child Neurology Society and the American Academy of Neurology.

A comprehensive review of the evidence-based literature published since 1998 was conducted with the aim of addressing possible therapeutic interventions in the management of children with simple febrile seizures. The review focused on both the efficacy and potential adverse effects of the proposed treatments. Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendations.

The AAP established a partnership with the University of Kentucky (Lexington, KY) to develop an evidence report, which served as a major source of information for these practice-guideline recommendations. The specific issues addressed were (1) effectiveness of continuous anticonvulsant therapy in preventing recurrent febrile seizures, (2) effectiveness of intermittent anticonvulsant therapy in preventing recurrent febrile seizures, (3) effectiveness of antipyretics in preventing recurrent febrile seizures, and (4) adverse effects of either continuous or intermittent anticonvulsant therapy.

In the original practice parameter, more than 300 medical journal articles reporting studies of the natural history of simple febrile seizures or the therapy of these seizures were reviewed and abstracted.[2] An additional 65 articles were reviewed and abstracted for the update. Emphasis was placed on articles that differentiated simple febrile seizures from other types of seizures, that carefully matched treatment and control groups, and that described adherence to the drug regimen. Tables were constructed from the 65 articles that best fit these criteria. A more comprehensive review of the literature on which this report is based can be found in a forthcoming technical report (the initial technical report can be accessed at http://aappolicy.aappublications.org/cgi/content/full/pediatrics;103/6/e86). The technical report also will contain dosing information.

The evidence-based approach to guideline development requires that the evidence in support of a recommendation be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is

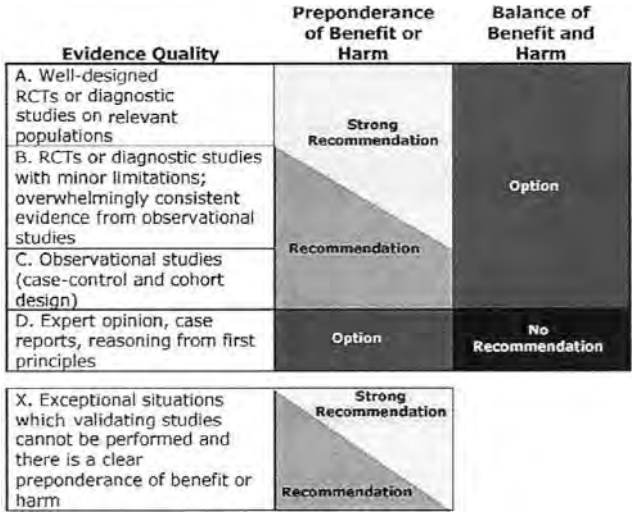


FIGURE 1
Integrating evidence-quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is conducted leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation. RCT indicates randomized, controlled trial.

anticipated when the recommendation is followed. The AAP policy statement "Classifying Recommendations for Clinical Practice Guidelines"[9] was followed in designating levels of recommendations (see Fig 1 and Table 1).

RECOMMENDATION

On the basis of the risks and benefits of the effective therapies, neither continuous nor intermittent anticonvulsant therapy is recommended for children with 1 or more simple febrile seizures.

- Aggregate evidence quality: B (randomized, controlled trials and diagnostic studies with minor limitations).
- Benefit: prevention of recurrent febrile seizures, which are not harmful and do not significantly increase the risk for development of future epilepsy.
- Harm: adverse effects including rare fatal hepatotoxicity (especially in children younger than 2 years who are also at greatest risk of febrile seizures), thrombocytopenia, weight loss and gain, gastrointestinal disturbances, and pancreatitis with valproic acid and hyperactivity, irritability, lethargy, sleep disturbances, and hypersensitivity reactions with phenobarbital; lethargy, drowsiness, and ataxia for intermittent diazepam as well as the risk of masking an evolving central nervous system infection.
- Benefits/harms assessment: preponderance of harm over benefit.
- Policy level: recommendation.

BENEFITS AND RISKS OF CONTINUOUS ANTICONVULSANT THERAPY

Phenobarbital

Phenobarbital is effective in preventing the recurrence of simple febrile seizures.[10] In a controlled double-blind study, daily therapy with phenobarbital reduced the rate of subsequent febrile seizures from 25 per 100 subjects per year to 5 per 100 subjects per year.[11] For the agent to be effective, however, it must be given daily and maintained in the therapeutic range. In a study by Farwell et al,[12] for example, children whose phenobarbital levels were in the therapeutic range had a reduction in recurrent seizures, but because noncompliance was so high, an overall benefit with phenobarbital therapy was not identified.

The adverse effects of phenobarbital include hyperactivity, irritability, lethargy, sleep disturbances, and hypersensitivity reactions. The behavioral adverse effects

TABLE 1 **Guideline Definitions for Evidence-Based Statements**

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

may occur in up to 20% to 40% of patients and may be severe enough to necessitate discontinuation of the drug.[13–16]

Primidone

Primidone, in doses of 15 to 20 mg/kg per day, has also been shown to reduce the recurrence rate of febrile seizures.[17,18] It is of interest that the derived phenobarbital level in a Minigawa and Miura study[17] was below therapeutic (16 μg/mL) in 29 of the 32 children, suggesting that primidone itself may be active in preventing seizure recurrence. As with phenobarbital, adverse effects include behavioral disturbances, irritability, and sleep disturbances.[18]

Valproic Acid

In randomized, controlled studies, only 4% of children taking valproic acid, as opposed to 35% of control subjects, had a subsequent febrile seizure. Therefore, valproic acid seems to be at least as effective in preventing recurrent simple febrile seizures as phenobarbital and significantly more effective than placebo.[19–21]

Drawbacks to therapy with valproic acid include its rare association with fatal hepatotoxicity (especially in children younger than 2 years, who are also at greatest risk of febrile seizures), thrombocytopenia, weight loss and gain, gastrointestinal disturbances, and pancreatitis. In studies in which children received valproic acid to prevent recurrence of febrile seizures, no cases of fatal hepatotoxicity were reported.[15]

Carbamazepine

Carbamazepine has not been shown to be effective in preventing the recurrence of simple febrile seizures. Antony and Hawke[13] compared children who had been treated with therapeutic levels of either phenobarbital or carbamazepine, and 47% of the children in the carbamazepine-treated group had recurrent seizures compared with only 10% of those in the phenobarbital group. In another study, Camfield et al[22] treated children (whose conditions failed to improve with phenobarbital therapy) with carbamazepine. Despite good compliance, 13 of the 16 children treated with carbamazepine had a recurrent febrile seizure within 18 months. It is theoretically possible that these excessively high rates of recurrences might have been attributable to adverse effects of carbamazepine.

Phenytoin

Phenytoin has not been shown to be effective in preventing the recurrence of simple febrile seizures, even when the agent is in the therapeutic range.[23,24] Other anticonvulsants have not been studied for the continuous treatment of simple febrile seizures.

BENEFITS AND RISKS OF INTERMITTENT ANTICONVULSANT THERAPY

Diazepam

A double-blind controlled study of patients with a history of febrile seizures demonstrated that administration of oral diazepam (given at the time of fever) could reduce the recurrence of febrile seizures. Children with a history of febrile seizures were given either oral diazepam (0.33 mg/kg, every 8 hours for 48 hours) or a placebo at the time of fever. The risk of febrile seizures per person-year was decreased 44% with diazepam.[25] In a more recent study, children with a history of febrile seizures were given oral diazepam at the time of fever and then compared with children in an untreated control group. In the oral diazepam group, there was an 11% recurrence rate compared with a 30% recurrence rate in the control group.[26] It should be noted that all children for whom diazepam was considered a failure had been noncompliant with drug administration, in part because of adverse effects of the medication.

There is also literature that demonstrates the feasibility and safety of interrupting a simple febrile seizure lasting less than 5 minutes with rectal diazepam and with both intranasal and buccal midazolam.[27,28] Although these agents are effective in terminating the seizure, it is questionable whether they have any long-term influence on outcome. In a study by Knudsen et al,[29] children were given either rectal diazepam at the time of fever or only at the onset of seizure. Twelve-year follow-up found that the long-term prognosis of the children in the 2 groups did not differ regardless of whether treatment was aimed at preventing seizures or treating them.

A potential drawback to intermittent medication is that a seizure could occur before a fever is noticed. Indeed, in several of these studies, recurrent seizures were likely attributable to failure of method rather than failure of the agent.

Adverse effects of oral and rectal diazepam[26] and both intranasal and buccal midazolam include lethargy, drowsiness, and ataxia. Respiratory depression is extremely rare, even when given by the rectal route.[28,30] Sedation caused by any of the benzodiazepines, whether administered by the oral, rectal, nasal, or buccal route, have the potential of masking an evolving central nervous system infection. If used, the child's health care professional should be contacted.

BENEFITS AND RISKS OF INTERMITTENT ANTIPYRETICS

No studies have demonstrated that antipyretics, in the absence of anticonvulsants, reduce the recurrence risk of simple febrile seizures. Camfield et al[11] treated 79 children who had had a first febrile seizure with either a placebo plus antipyretic instruction (either aspirin or acetaminophen) versus daily phenobarbital plus antipyretic instruction (either aspirin or acetaminophen). Recurrence risk was significantly lower in the phenobarbital-treated group, suggesting that antipyretic instruction, including the use of antipyretics, is ineffective in preventing febrile-seizure recurrence.

Whether antipyretics are given regularly (every 4 hours) or sporadically (contingent on a specific body-temperature elevation) does not influence outcome. Acetaminophen was either given every 4 hours or only for temperature elevations of more than 37.9°C in 104 children. The incidence of febrile episodes did not differ

significantly between the 2 groups, nor did the early recurrence of febrile seizures. The authors determined that administering prophylactic acetaminophen during febrile episodes was ineffective in preventing or reducing fever and in preventing febrile-seizure recurrence.[31]

In a randomized double-blind placebo-controlled trial, acetaminophen was administered along with low-dose oral diazepam.[32] Febrile-seizure recurrence was not reduced, compared with control groups. As with acetaminophen, ibuprofen also has been shown to be ineffective in preventing recurrence of febrile seizures.[33–35]

In general, acetaminophen and ibuprofen are considered to be safe and effective antipyretics for children. However, hepatotoxicity (with acetaminophen) and respiratory failure, metabolic acidosis, renal failure, and coma (with ibuprofen) have been reported in children after overdose or in the presence of risk factors.[36,37]

CONCLUSIONS

The subcommittee has determined that a simple febrile seizure is a benign and common event in children between the ages of 6 and 60 months. Nearly all children have an excellent prognosis. The committee concluded that although there is evidence that both continuous antiepileptic therapy with phenobarbital, primidone, or valproic acid and intermittent therapy with oral diazepam are effective in reducing the risk of recurrence, the potential toxicities associated with antiepileptic drugs outweigh the relatively minor risks associated with simple febrile seizures. As such, long-term therapy is not recommended. In situations in which parental anxiety associated with febrile seizures is severe, intermittent oral diazepam at the onset of febrile illness may be effective in preventing recurrence. Although antipyretics may improve the comfort of the child, they will not prevent febrile seizures.

REFERENCES

1. Nelson KB, Ellenberg JH. Prognosis in children with febrile seizures. *Pediatrics.* 1978;61(5):720–727
2. American Academy of Pediatrics, Committee on Quality Improvement, Subcommittee on Febrile Seizures. The long-term treatment of the child with simple febrile seizures. *Pediatrics.* 1999;103(6 pt 1):1307–1309
3. Chang YC, Guo NW, Huang CC, Wang ST, Tsai JJ. Neurocognitive attention and behavior outcome of school age children with a history of febrile convulsions: a population study. *Epilepsia.* 2000;41(4):412–420
4. Ellenberg JH, Nelson KB. Febrile seizures and later intellectual performance. *Arch Neurol.* 1978;35(1):17–21
5. Verity CM, Butler NR, Golding J. Febrile convulsions in a national cohort followed up from birth. II: medical history and intellectual ability at 5 years of age. *BMJ.* 1985;290(6478):1311–1315
6. Nelson KB, Ellenberg JH. Predictors of epilepsy in children who have experienced febrile seizures. *N Engl J Med.* 1976;295(19):1029–1033
7. Annegers JF, Hauser WA, Shirts SB, Kurland LT. Factors prognostic of unprovoked seizures after febrile convulsions. *N Engl J Med.* 1987;316(9):493–498
8. Berg AT, Shinnar S, Darefsky AS, et al. Predictors of recurrent febrile seizures: a prospective cohort study. *Arch Pediatr Adolesc Med.* 1997;151(4):371–378
9. American Academy of Pediatrics, Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics.* 2004;114(3):874–877
10. Wolf SM, Carr A, Davis DC, Davidson S, et al. The value of phenobarbital in the child who has had a single febrile seizure: a controlled prospective study. *Pediatrics.* 1977;59(3):378–385
11. Camfield PR, Camfield CS, Shapiro SH, Cummings C. The first febrile seizure: antipyretic instruction plus either phenobarbital or placebo to prevent recurrence. *J Pediatr.* 1980;97(1):16–21
12. Farwell JR, Lee JY, Hirtz DG, Sulzbacher SI, Ellenberg JH, Nelson KB. Phenobarbital for febrile seizures: effects on intelligence and on seizure recurrence [published correction appears in *N Engl J Med*. 1992;326(2):144]. *N Engl J Med.* 1990;322(6):364–369
13. Antony JH, Hawke SHB. Phenobarbital compared with carbamazepine in prevention of recurrent febrile convulsions. *Am J Dis Child.* 1983;137(9):892–895
14. Knudsen Fu, Vestermark S. Prophylactic diazepam or phenobarbitone in febrile convulsions: a prospective, controlled study. *Arch Dis Child.* 1978;53(8):660–663
15. Lee K, Melchior JC. Sodium valproate versus phenobarbital in the prophylactic treatment of febrile convulsions in childhood. *Eur J Pediatr.* 1981;137(2):151–153
16. Camfield CS, Chaplin S, Doyle AB, Shapiro SH, Cummings C, Camfield PR. Side effects of phenobarbital in toddlers: behavioral and cognitive aspects. *J Pediatr.* 1979;95(3):361–365
17. Minagawa K, Miura H. Phenobarbital, primidone and sodium valproate in the prophylaxis of febrile convulsions. *Brain Dev.* 1981;3(4):385–393
18. Herranz JL, Armijo JA, Arteaga R. Effectiveness and toxicity of phenobarbital, primidone, and sodium valproate in the pre-

vention of febrile convulsions, controlled by plasma levels. *Epilepsia.* 1984;25(1):89–95
19. Wallace SJ, Smith JA. Successful prophylaxis against febrile convulsions with valproic acid or phenobarbitone. *BMJ.* 1980; 280(6211):353–354
20. Mamelle N, Mamelle JC, Plasse JC, Revol M, Gilly R. Prevention of recurrent febrile convulsions: a randomized therapeutic assay—sodium valproate, phenobarbitone and placebo. *Neuropediatrics.* 1984;15(1):37–42
21. Ngwane E, Bower B. Continuous sodium valproate or phenobarbitone in the prevention of "simple" febrile convulsions. *Arch Dis Child.* 1980;55(3):171–174
22. Camfield PR, Camfield CS, Tibbles JA. Carbamazepine does not prevent febrile seizures in phenobarbital failures. *Neurology.* 1982;32(3):288–289
23. Bacon CJ, Hierons AM, Mucklow JC, Webb JK, Rawlins MD, Weightman D. Placebo-controlled study of phenobarbitone and phenytoin in the prophylaxis of febrile convulsions. *Lancet.* 1981;2(8247):600–604
24. Melchior JC, Buchthal F, Lennox Buchthal M. The ineffectiveness of diphenylhydantoin in preventing febrile convulsions in the age of greatest risk, under 3 years. *Epilepsia.* 1971;12(1): 55–62
25. Rosman NP, Colton T, Labazzo J, et al. A controlled trial of diazepam administered during febrile illnesses to prevent recurrence of febrile seizures. *N Engl J Med.* 1993;329(2):79–84
26. Verrotti A, Latini G, di Corcia G, et al. Intermittent oral diazepam prophylaxis in febrile convulsions: its effectiveness for febrile seizure recurrence. *Eur J Pediatr Neurol.* 2004;8(3): 131–134
27. Lahat E, Goldman M, Barr J, Bistritzer T, Berkovitch M. Comparison of intranasal midazolam with intravenous diazepam for treating febrile seizures in children: prospective randomized study. *BMJ.* 2000;321(7253):83–86
28. McIntyre J, Robertson S, Norris E, et al. Safety and efficacy of buccal midazolam versus rectal diazepam for emergency treatment of seizures in children: a randomized controlled trial. *Lancet.* 2005;366(9481):205–210
29. Knudsen FU, Paerregaard A, Andersen R, Andresen J. Long term outcome of prophylaxis for febrile convulsions. *Arch Dis Child.* 1996;74(1):13–18
30. Pellock JM, Shinnar S. Respiratory adverse events associated with diazepam rectal gel. *Neurology.* 2005;64(10):1768–1770
31. Schnaiderman D, Lahat E, Sheefer T, Aladjem M. Antipyretic effectiveness of acetaminophen in febrile seizures: ongoing prophylaxis versus sporadic usage. *Eur J Pediatr.* 1993;152(9): 747–749
32. Uhari M, Rantala H, Vainionpaa L, Kurttila R. Effect of acetaminophen and of low dose intermittent doses of diazepam on prevention of recurrences of febrile seizures. *J Pediatr.* 1995; 126(6):991–995
33. van Stuijvenberg M, Derksen-Lubsen G, Steyerberg EW, Habbema JDF, Moll HA. Randomized, controlled trial of ibuprofen syrup administered during febrile illnesses to prevent febrile seizure recurrences. *Pediatrics.* 1998;102(5). Available at: www.pediatrics.org/cgi/content/full/102/5/e51
34. van Esch A, Van Steensel-Moll HA, Steyerberg EW, Offringa M, Habbema JDF, Derksen-Lubsen G. Antipyretic efficacy of ibuprofen and acetaminophen in children with febrile seizures. *Arch Pediatr Adolesc Med.* 1995;149(6):632–637
35. van Esch A, Steyerberg EW, Moll HA, et al. A study of the efficacy of antipyretic drugs in the prevention of febrile seizure recurrence. *Ambul Child Health.* 2000;6(1):19–26
36. Easley RB, Altemeier WA. Central nervous system manifestations of an ibuprofen overdose reversed by naloxone. *Pediatr Emerg Care.* 2000;16(1):39–41
37. American Academy of Pediatrics, Committee on Drugs. Acetaminophen toxicity in children. *Pediatrics.* 2001;108(4): 1020–1024

Febrile Seizures: Guideline for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure

- *Clinical Practice Guideline*

Clinical Practice Guideline—Febrile Seizures: Guideline for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure

SUBCOMMITTEE ON FEBRILE SEIZURES

KEY WORD
seizure

ABBREVIATIONS
AAP—American Academy of Pediatrics
Hib—*Haemophilus influenzae* type b
EEG—electroencephalogram
CT—computed tomography

The recommendations in this report do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

www.pediatrics.org/cgi/doi/10.1542/peds.2010-3318

doi:10.1542/peds.2010-3318

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

abstract

FREE

OBJECTIVE: To formulate evidence-based recommendations for health care professionals about the diagnosis and evaluation of a simple febrile seizure in infants and young children 6 through 60 months of age and to revise the practice guideline published by the American Academy of Pediatrics (AAP) in 1996.

METHODS: This review included search and analysis of the medical literature published since the last version of the guideline. Physicians with expertise and experience in the fields of neurology and epilepsy, pediatrics, epidemiology, and research methodologies constituted a subcommittee of the AAP Steering Committee on Quality Improvement and Management. The steering committee and other groups within the AAP and organizations outside the AAP reviewed the guideline. The subcommittee member who reviewed the literature for the 1996 AAP practice guidelines searched for articles published since the last guideline through 2009, supplemented by articles submitted by other committee members. Results from the literature search were provided to the subcommittee members for review. Interventions of direct interest included lumbar puncture, electroencephalography, blood studies, and neuroimaging. Multiple issues were raised and discussed iteratively until consensus was reached about recommendations. The strength of evidence supporting each recommendation and the strength of the recommendation were assessed by the committee member most experienced in informatics and epidemiology and graded according to AAP policy.

CONCLUSIONS: Clinicians evaluating infants or young children after a simple febrile seizure should direct their attention toward identifying the cause of the child's fever. Meningitis should be considered in the differential diagnosis for any febrile child, and lumbar puncture should be performed if there are clinical signs or symptoms of concern. For any infant between 6 and 12 months of age who presents with a seizure and fever, a lumbar puncture is an option when the child is considered deficient in *Haemophilus influenzae* type b (Hib) or *Streptococcus pneumoniae* immunizations (ie, has not received scheduled immunizations as recommended), or when immunization status cannot be determined, because of an increased risk of bacterial meningitis. A lumbar puncture is an option for children who are pretreated with antibiotics. In general, a simple febrile seizure does not usually require further evaluation, specifically electroencephalography, blood studies, or neuroimaging. *Pediatrics* 2011;127:389–394

DEFINITION OF THE PROBLEM

This practice guideline provides recommendations for the neurodiagnostic evaluation of neurologically healthy infants and children 6 through 60 months of age who have had a simple febrile seizure and present for evaluation within 12 hours of the event. It replaces the 1996 practice parameter.[1] This practice guideline is not intended for patients who have had complex febrile seizures (prolonged, focal, and/or recurrent), and it does not pertain to children with previous neurologic insults, known central nervous system abnormalities, or history of afebrile seizures.

TARGET AUDIENCE AND PRACTICE SETTING

This practice guideline is intended for use by pediatricians, family physicians, child neurologists, neurologists, emergency physicians, nurse practitioners, and other health care providers who evaluate children for febrile seizures.

BACKGROUND

A febrile seizure is a seizure accompanied by fever (temperature $\geq$ 100.4°F or 38°C[2] by any method), without central nervous system infection, that occurs in infants and children 6 through 60 months of age. Febrile seizures occur in 2% to 5% of all children and, as such, make up the most common convulsive event in children younger than 60 months. In 1976, Nelson and Ellenberg,[3] using data from the National Collaborative Perinatal Project, further defined febrile seizures as being either simple or complex. Simple febrile seizures were defined as primary generalized seizures that lasted for less than 15 minutes and did not recur within 24 hours. Complex febrile seizures were defined as focal, prolonged ($\geq$15 minutes), and/or recurrent within 24 hours. Children who had simple febrile seizures had no evidence of increased mortality, hemiplegia, or mental retardation. During follow-up evaluation, the risk of epilepsy after a simple febrile seizure was shown to be only slightly higher than that of the general population, whereas the chief risk associated with simple febrile seizures was recurrence in one-third of the children. The authors concluded that simple febrile seizures are benign events with excellent prognoses, a conclusion reaffirmed in the 1980 consensus statement from the National Institutes of Health.[3,4]

The expected outcomes of this practice guideline include the following:

1. Optimize clinician understanding of the scientific basis for the neurodiagnostic evaluation of children with simple febrile seizures.
2. Aid the clinician in decision-making by using a structured framework.
3. Optimize evaluation of the child who has had a simple febrile seizure by detecting underlying diseases, minimizing morbidity, and reassuring anxious parents and children.
4. Reduce the costs of physician and emergency department visits, hospitalizations, and unnecessary testing.
5. Educate the clinician to understand that a simple febrile seizure usually does not require further evaluation, specifically electroencephalography, blood studies, or neuroimaging.

METHODOLOGY

To update the clinical practice guideline on the neurodiagnostic evaluation of children with simple febrile seizures,[1] the American Academy of Pediatrics (AAP) reconvened the Subcommittee on Febrile Seizures. The committee was chaired by a child neurologist and consisted of a neuroepidemiologist, 3 additional child neurologists, and a practicing pediatrician. All panel members reviewed and signed the AAP voluntary disclosure and conflict-of-interest form. No conflicts were reported. Participation in the guideline process was voluntary and not paid. The guideline was reviewed by members of the AAP Steering Committee on Quality Improvement and Management; members of the AAP Section on Administration and Practice Management, Section on Developmental and Behavioral Pediatrics, Section on Epidemiology, Section on Infectious Diseases, Section on Neurology, Section on Neurologic Surgery, Section on Pediatric Emergency Medicine, Committee on Pediatric Emergency Medicine, Committee on Practice and Ambulatory Medicine, Committee on Child Health Financing, Committee on Infectious Diseases, Committee on Medical Liability and Risk Management, Council on Children With Disabilities, and Council on Community Pediatrics; and members of outside organizations including the Child Neurology Society, the American Academy of Neurology, the American College of Emergency Physicians, and members of the Pediatric Committee of the Emergency Nurses Association.

A comprehensive review of the evidence-based literature published from 1996 to February 2009 was conducted to discover articles that addressed the diagnosis and evaluation of children with simple febrile seizures. Preference was given to population-based studies, but given the scarcity of such studies, data from hospital-based studies, groups of young children with febrile illness, and comparable groups were reviewed. Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendations.

In the original practice parameter,[1] 203 medical journal articles were reviewed and abstracted. An additional 372 articles were reviewed and abstracted for this update. Emphasis was placed on articles that differentiated simple febrile seizures from other types of seizures. Tables were constructed from the 70 articles that best fit these criteria.

The evidence-based approach to guideline development requires that the evidence in support of a recommendation be identified, appraised, and summarized and that an explicit link between

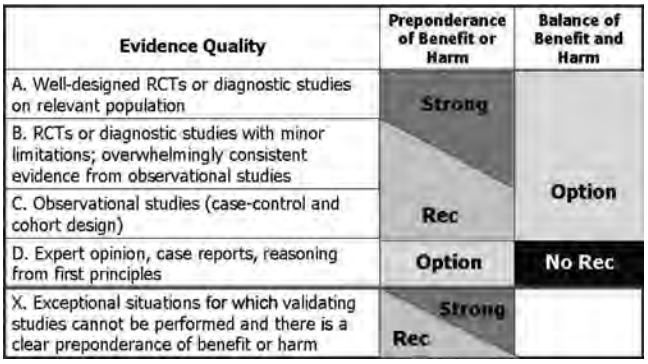


FIGURE 1
Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation. RCT indicates randomized controlled trial; Rec, recommendation.

evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement "Classifying Recommendations for Clinical Practice Guidelines"[5] was followed in designating levels of recommendations (see Fig 1).

KEY ACTION STATEMENTS

Action Statement 1

Action Statement 1a

A lumbar puncture should be performed in any child who presents with a seizure and a fever and has meningeal signs and symptoms (eg, neck stiffness, Kernig and/or Brudzinski signs) or in any child whose history or examination suggests the presence of meningitis or intracranial infection.

- Aggregate evidence level: B (overwhelming evidence from observational studies).
- Benefits: Meningeal signs and symptoms strongly suggest meningitis, which, if bacterial in etiology, will likely be fatal if left untreated.
- Harms/risks/costs: Lumbar puncture is an invasive and often painful procedure and can be costly.
- Benefits/harms assessment: Preponderance of benefit over harm.
- Value judgments: Observational data and clinical principles were used in making this judgment.
- Role of patient preferences: Although parents may not wish to have their child undergo a lumbar puncture, health care providers should explain that if meningitis is not diagnosed and treated, it could be fatal.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

Action Statement 1b

In any infant between 6 and 12 months of age who presents with a seizure and fever, a lumbar puncture is an option when the child is considered deficient in *Haemophilus influenzae* type b (Hib) or *Streptococcus pneumoniae* immunizations (ie, has not received scheduled immunizations as recommended) or when immunization status cannot be determined because of an increased risk of bacterial meningitis.

- Aggregate evidence level: D (expert opinion, case reports).
- Benefits: Meningeal signs and symptoms strongly suggest meningitis, which, if bacterial in etiology, will likely be fatal or cause significant long-term disability if left untreated.
- Harms/risks/costs: Lumbar puncture is an invasive and often painful procedure and can be costly.
- Benefits/harms assessment: Preponderance of benefit over harm.
- Value judgments: Data on the incidence of bacterial meningitis from before and after the existence of immunizations against Hib and *S pneumoniae* were used in making this recommendation.
- Role of patient preferences: Although parents may not wish their child to undergo a lumbar puncture, health care providers should explain that in the absence of complete immunizations, their child may be at risk of having fatal bacterial meningitis.
- Exclusions: This recommendation applies only to children 6 to 12 months of age. The subcommittee felt that clinicians would recognize symptoms of meningitis in children older than 12 months.
- Intentional vagueness: None.
- Policy level: Option.

Action Statement 1c

A lumbar puncture is an option in the child who presents with a seizure and fever and is pretreated with antibiotics, because antibiotic treatment can mask the signs and symptoms of meningitis.

- Aggregate evidence level: D (reasoning from clinical experience, case series).
- Benefits: Antibiotics may mask meningeal signs and symptoms but may be insufficient to eradicate meningitis; a diagnosis of meningitis, if bacterial in etiology, will likely be fatal if left untreated.
- Harms/risks/costs: Lumbar puncture is an invasive and often painful procedure and can be costly.

- Benefits/harms assessment: Preponderance of benefit over harm.
- Value judgments: Clinical experience and case series were used in making this judgment while recognizing that extensive data from studies are lacking.
- Role of patient preferences: Although parents may not wish to have their child undergo a lumbar puncture, medical providers should explain that in the presence of pretreatment with antibiotics, the signs and symptoms of meningitis may be masked. Meningitis, if untreated, can be fatal.
- Exclusions: None.
- Intentional vagueness: Data are insufficient to define the specific treatment duration necessary to mask signs and symptoms. The committee determined that the decision to perform a lumbar puncture will depend on the type and duration of antibiotics administered before the seizure and should be left to the individual clinician.
- Policy level: Option.

The committee recognizes the diversity of past and present opinions regarding the need for lumbar punctures in children younger than 12 months with a simple febrile seizure. Since the publication of the previous practice parameter,[1] however, there has been widespread immunization in the United States for 2 of the most common causes of bacterial meningitis in this age range: Hib and *S pneumoniae*. Although compliance with all scheduled immunizations as recommended does not completely eliminate the possibility of bacterial meningitis from the differential diagnosis, current data no longer support routine lumbar puncture in well-appearing, fully immunized children who present with a simple febrile seizure.[6–8] Moreover, although approximately 25% of young children with meningitis have seizures as the presenting sign of the disease, some are either obtunded or comatose when evaluated by a physician for the seizure, and the remainder most often have obvious clinical signs of meningitis (focal seizures, recurrent seizures, petechial rash, or nuchal rigidity).[9–11] Once a decision has been made to perform a lumbar puncture, then blood culture and serum glucose testing should be performed concurrently to increase the sensitivity for detecting bacteria and to determine if there is hypoglycorrhachia characteristic of bacterial meningitis, respectively.

Recent studies that evaluated the outcome of children with simple febrile seizures have included populations with a high prevalence of immunization.[7,8] Data for unimmunized or partially immunized children are lacking. Therefore, lumbar puncture is an option for young children who are considered deficient in immunizations or those in whom immunization status cannot be determined. There are also no definitive data on the outcome of children who present with a simple febrile seizure while already on antibiotics. The authors were unable to find a definition of "pretreated" in the literature, so they consulted with the AAP Committee on Infectious Diseases. Although there is no formal definition, pretreatment can be considered to include systemic antibiotic therapy by any route given within the days before the seizure. Whether pretreatment will affect the presentation and course of bacterial meningitis cannot be predicted but will depend, in part, on the antibiotic administered, the dose, the route of administration, the drug's cerebrospinal fluid penetration, and the organism causing the meningitis. Lumbar puncture is an option in any child pretreated with antibiotics before a simple febrile seizure.

Action Statement 2

An electroencephalogram (EEG) should not be performed in the evaluation of a neurologically healthy child with a simple febrile seizure.

- Aggregate evidence level: B (overwhelming evidence from observational studies).
- Benefits: One study showed a possible association with paroxysmal EEGs and a higher rate of afebrile seizures.[12]
- Harms/risks/costs: EEGs are costly and may increase parental anxiety.
- Benefits/harms assessment: Preponderance of harm over benefit.
- Value judgments: Observational data were used for this judgment.
- Role of patient preferences: Although an EEG might have limited prognostic utility in this situation, parents should be educated that the study will not alter outcome.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

There is no evidence that EEG readings performed either at the time of presentation after a simple febrile seizure or within the following month are predictive of either recurrence of febrile seizures or the development of afebrile seizures/epilepsy within the next 2 years.[13,14] There is a single study that found that a paroxysmal EEG was associated with a higher rate of afebrile seizures.[12] There is no evidence that interventions based on this test would alter outcome.

Action Statement 3

The following tests should not be performed routinely for the sole purpose of identifying the cause of a simple febrile seizure: measurement of serum electrolytes, calcium, phosphorus, magnesium, or blood glucose or complete blood cell count.

- Aggregate evidence level: B (overwhelming evidence from observational studies).
- Benefits: A complete blood cell count may identify children at risk for bacte-

remia; however, the incidence of bacteremia in febrile children younger than 24 months is the same with or without febrile seizures.

- Harms/risks/costs: Laboratory tests may be invasive and costly and provide no real benefit.
- Benefits/harms assessment: Preponderance of harm over benefit.
- Value judgments: Observational data were used for this judgment.
- Role of patient preferences: Although parents may want blood tests performed to explain the seizure, they should be reassured that blood tests should be directed toward identifying the source of their child's fever.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

There is no evidence to suggest that routine blood studies are of benefit in the evaluation of the child with a simple febrile seizure.[15–18] Although some children with febrile seizures have abnormal serum electrolyte values, their condition should be identifiable by obtaining appropriate histories and performing careful physical examinations. It should be noted that as a group, children with febrile seizures have relatively low serum sodium concentrations. As such, physicians and caregivers should avoid overhydration with hypotonic fluids.[18] Complete blood cell counts may be useful as a means of identifying young children at risk of bacteremia. It should be noted, however, that the incidence of bacteremia in children younger than 24 months with or without febrile seizures is the same. When fever is present, the decision regarding the need for laboratory testing should be directed toward identifying the source of the fever rather than as part of the routine evaluation of the seizure itself.

Action Statement 4

Neuroimaging should not be performed in the routine evaluation of the child with a simple febrile seizure.

- Aggregate evidence level: B (overwhelming evidence from observational studies).
- Benefits: Neuroimaging might provide earlier detection of fixed structural lesions, such as dysplasia, or very rarely, abscess or tumor.
- Harms/risks/costs: Neuroimaging tests are costly, computed tomography (CT) exposes children to radiation, and MRI may require sedation.
- Benefits/harms assessment: Preponderance of harm over benefit.
- Value judgments: Observational data were used for this judgment.
- Role of patient preferences: Although parents may want neuroimaging performed to explain the seizure, they should be reassured that the tests carry risks and will not alter outcome for their child.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

The literature does not support the use of skull films in evaluation of the child with a febrile seizure.[15,19] No data have been published that either support or negate the need for CT or MRI in the evaluation of children with simple febrile seizures. Data, however, show that CT scanning is associated with radiation exposure that may escalate future cancer risk. MRI is associated with risks from required sedation and high cost.[20,21] Extrapolation of data from the literature on the use of CT in neurologically healthy children who have generalized epilepsy has shown that clinically important intracranial structural abnormalities in this patient population are uncommon.[22,23]

CONCLUSIONS

Clinicians evaluating infants or young children after a simple febrile seizure should direct their attention toward identifying the cause of the child's fever. Meningitis should be considered in the differential diagnosis for any febrile child, and lumbar puncture should be performed if the child is ill-appearing or if there are clinical signs or symptoms of concern. A lumbar puncture is an option in a child 6 to 12 months of age who is deficient in Hib and *S pneumoniae* immunizations or for whom immunization status is unknown. A lumbar puncture is an option in children who have been pretreated with antibiotics. In general, a simple febrile seizure does not usually require further evaluation, specifically EEGs, blood studies, or neuroimaging.

SUBCOMMITTEE ON FEBRILE SEIZURES, 2002–2010

Patricia K. Duffner, MD (neurology, no conflicts)
Peter H. Berman, MD (neurology, no conflicts)
Robert J. Baumann, MD (neuroepidemiology, no conflicts)
Paul Graham Fisher, MD (neurology, no conflicts)
John L. Green, MD (general pediatrics, no conflicts)
Sanford Schneider, MD (neurology, no conflicts)

STAFF

Caryn Davidson, MA

OVERSIGHT BY THE STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT, 2009–2011

REFERENCES

1. American Academy of Pediatrics, Provisional Committee on Quality Improvement and Subcommittee on Febrile Seizures. Practice parameter: the neurodiagnostic evaluation of a child with a first simple febrile seizure. *Pediatrics*. 1996;97(5):769–772; discussion 773–775
2. Michael Marcy S, Kohl KS, Dagan R, et al; Brighton Collaboration Fever Working Group. Fever as an adverse event following immunization: case definition and guidelines of data collection, analysis, and presentation. *Vaccine*. 2004;22(5–6):551–556
3. Nelson KB, Ellenberg JH. Predictors of epilepsy in children who have experienced febrile seizures. *N Engl J Med*. 1976;295(19):1029–1033
4. Consensus statement: febrile seizures—long-term management of children with fever-associated seizures. *Pediatrics*. 1980;66(6):1009–1012
5. American Academy of Pediatrics, Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877
6. Trainor JL, Hampers LC, Krug SE, Listernick R. Children with first-time simple febrile seizures are at low risk of serious bacterial illness. *Acad Emerg Med*. 2001;8(8):781–787
7. Shaked O, Peña BM, Linares MY, Baker RL. Simple febrile seizures: are the AAP guidelines regarding lumbar puncture being followed? *Pediatr Emerg Care*. 2009;25(1):8–11
8. Kimia AA, Capraro AJ, Hummel D, Johnston P, Harper MB. Utility of lumbar puncture for first simple febrile seizure among children 6 to 18 months of age. *Pediatrics*. 2009;123(1):6–12
9. Warden CR, Zibulewsky J, Mace S, Gold C, Gausche-Hill M. Evaluation and management of febrile seizures in the out-of-hospital and emergency department settings. *Ann Emerg Med*. 2003;41(2):215–222
10. Rutter N, Smales OR. Role of routine investigations in children presenting with their first febrile convulsion. *Arch Dis Child*. 1977;52(3):188–191
11. Green SM, Rothrock SG, Clem KJ, Zurcher RF, Mellick L. Can seizures be the sole manifestation of meningitis in febrile children? *Pediatrics*. 1993;92(4):527–534
12. Kuturec M, Emoto SE, Sofijanov N, et al. Febrile seizures: is the EEG a useful predictor of recurrences? *Clin Pediatr (Phila)*. 1997;36(1):31–36
13. Frantzen E, Lennox-Buchthal M, Nygaard A. Longitudinal EEG and clinical study of children with febrile convulsions. *Electroencephalogr Clin Neurophysiol*. 1968;24(3):197–212
14. Thorn I. The significance of electroencephalography in febrile convulsions. In: Akimoto H, Kazamatsuri H, Seino M, Ward A, eds. *Advances in Epileptology: XIIIth International Epilepsy Symposium*. New York, NY: Raven Press; 1982:93–95
15. Jaffe M, Bar-Joseph G, Tirosh E. Fever and convulsions: indications for laboratory investigations. *Pediatrics*. 1981;67(5):729–731
16. Gerber MA, Berliner BC. The child with a "simple" febrile seizure: appropriate diagnostic evaluation. *Am J Dis Child*. 1981;135(5):431–443
17. Heijbel J, Blom S, Bergfors PG. Simple febrile convulsions: a prospective incidence study and an evaluation of investigations initially needed. *Neuropadiatrie*. 1980;11(1):45–56
18. Thoman JE, Duffner PK, Shucard JL. Do serum sodium levels predict febrile seizure recurrence within 24 hours? *Pediatr Neurol*. 2004;31(5):342–344
19. Nealis GT, McFadden SW, Ames RA, Ouellette EM. Routine skull roentgenograms in the management of simple febrile seizures. *J Pediatr*. 1977;90(4):595–596
20. Stein SC, Hurst RW, Sonnad SS. Meta-analysis of cranial CT scans in children: a mathematical model to predict radiation-induced tumors associated with radiation exposure that may escalate future cancer risk. *Pediatr Neurosurg*. 2008;44(6):448–457
21. Brenner DJ, Hall EJ. Computed tomography: an increasing source of radiation exposure. *N Engl J Med*. 2007;357(22):2277–2284
22. Yang PJ, Berger PE, Cohen ME, Duffner PK. Computed tomography and childhood seizure disorders. *Neurology*. 1979;29(8):1084–1088
23. Bachman DS, Hodges FJ, Freeman JM. Computerized axial tomography in chronic seizure disorders of childhood. *Pediatrics*. 1976;58(6):828–832

Febrile Seizures Clinical Practice Guidelines Quick Reference Tools

- Recommendation Summaries
  - — Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures
  - — Febrile Seizures: Guideline for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure
- *ICD-10-CM* Coding Quick Reference for Febrile Seizures
- AAP Patient Education Handout
  - — *Febrile Seizures*

Recommendation Summaries

Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child With Simple Febrile Seizures

On the basis of the risks and benefits of the effective therapies, neither continuous nor intermittent anticonvulsant therapy is recommended for children with 1 or more simple febrile seizures.

- Aggregate evidence quality: B (randomized, controlled trials and diagnostic studies with minor limitations).
- Benefit: prevention of recurrent febrile seizures, which are not harmful and do not significantly increase the risk for development of future epilepsy.
- Harm: adverse effects including rare fatal hepatotoxicity (especially in children younger than 2 years who are also at greatest risk of febrile seizures), thrombocytopenia, weight loss and gain, gastrointestinal disturbances, and pancreatitis with valproic acid and hyperactivity, irritability, lethargy, sleep disturbances, and hypersensitivity reactions with phenobarbital; lethargy, drowsiness, and ataxia for intermittent diazepam as well as the risk of masking an evolving central nervous system infection.
- Benefits/harms assessment: preponderance of harm over benefit.
- Policy level: recommendation.

Febrile Seizures: Guideline for the Neurodiagnostic Evaluation of the Child With a Simple Febrile Seizure

Action Statement 1a

A lumbar puncture should be performed in any child who presents with a seizure and a fever and has meningeal signs and symptoms (eg, neck stiffness, Kernig and/or Brudzinski signs) or in any child whose history or examination suggests the presence of meningitis or intracranial infection.

Action Statement 1b

In any infant between 6 and 12 months of age who presents with a seizure and fever, a lumbar puncture is an option when the child is considered deficient in *Haemophilus influenzae* type b (Hib) or *Streptococcus pneumoniae* immunizations (ie, has not received scheduled immunizations as recommended) or when immunization status cannot be determined because of an increased risk of bacterial meningitis.

Action Statement 1c

A lumbar puncture is an option in the child who presents with a seizure and fever and is pretreated with antibiotics, because antibiotic treatment can mask the signs and symptoms of meningitis.

Action Statement 2

An electroencephalogram (EEG) should not be performed in the evaluation of a neurologically healthy child with a simple febrile seizure.

Action Statement 3

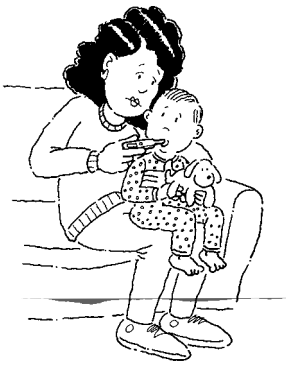
The following tests should not be performed routinely for the sole purpose of identifying the cause of a simple febrile seizure: measurement of serum electrolytes, calcium, phosphorus, magnesium, or blood glucose or complete blood cell count.

Action Statement 4

Neuroimaging should not be performed in the routine evaluation of the child with a simple febrile seizure.

Coding Quick Reference for Febrile Seizures
ICD-10-CM
R56.00 Simple febrile convulsions
R56.01 Complex febrile convulsions

Febrile Seizures



In some children, fevers can trigger seizures. Febrile seizures occur in 2% to 5% of all children between the ages of 6 months and 5 years. Seizures, sometimes called "fits" or "spells," are frightening, but they usually are harmless. Read on for information from the American Academy of Pediatrics that will help you understand febrile seizures and what happens if your child has one.

What is a febrile seizure?

A febrile seizure usually happens during the first few hours of a fever. The child may look strange for a few moments, then stiffen, twitch, and roll his eyes. He will be unresponsive for a short time, his breathing will be disturbed, and his skin may appear a little darker than usual. After the seizure, the child quickly returns to normal. Seizures usually last less than 1 minute but, although uncommon, can last for up to 15 minutes.

Febrile seizures rarely happen more than once within a 24-hour period. Other kinds of seizures (ones that are not caused by fever) last longer, can affect only one part of the body, and may occur repeatedly.

What do I do if my child has a febrile seizure?

If your child has a febrile seizure, act immediately to prevent injury.

- Place her on the floor or bed away from any hard or sharp objects.
- Turn her head to the side so that any saliva or vomit can drain from her mouth.
- Do not put anything into her mouth; she will not swallow her tongue.
- Call your child's doctor.
- If the seizure does not stop after 5 minutes, call 911 or your local emergency number.

Will my child have more seizures?

Febrile seizures tend to run in families. The risk of having seizures with other episodes of fever depends on the age of your child. Children younger than 1 year of age at the time of their first seizure have about a 50% chance of having another febrile seizure. Children older than 1 year of age at the time of their first seizure have only a 30% chance of having a second febrile seizure.

Will my child get epilepsy?

Epilepsy is a term used for multiple and recurrent seizures. Epileptic seizures are not caused by fever. Children with a history of febrile seizures are at only a slightly higher risk of developing epilepsy by age 7 than children who have not had febrile seizures.

Are febrile seizures dangerous?

While febrile seizures may be very scary, they are harmless to the child. Febrile seizures do not cause brain damage, nervous system problems, paralysis, intellectual disability (formerly called mental retardation), or death.

How are febrile seizures treated?

If your child has a febrile seizure, call your child's doctor right away. He or she will want to examine your child in order to determine the cause of your child's fever. It is more important to determine and treat the cause of the fever rather than the seizure. A spinal tap may be done to be sure your child does not have a serious infection like meningitis, especially if your child is younger than 1 year of age.

In general, doctors do not recommend treatment of a simple febrile seizure with preventive medicines. However, this should be discussed with your child's doctor. In cases of prolonged or repeated seizures, the recommendation may be different.

Medicines like acetaminophen and ibuprofen can help lower a fever, but they do not prevent febrile seizures. Your child's doctor will talk with you about the best ways to take care of your child's fever.

If your child has had a febrile seizure, do not fear the worst. These types of seizures are not dangerous to your child and do not cause long-term health problems. If you have concerns about this issue or anything related to your child's health, talk with your child's doctor.

From your doctor

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site — www.HealthyChildren.org

Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*

See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents

Joseph T. Flynn, MD, MS, FAAP,[a] David C. Kaelber, MD, PhD, MPH, FAAP, FACP, FACMI,[b] Carissa M. Baker-Smith, MD, MS, MPH, FAAP, FAHA,[c] Douglas Blowey, MD,[d] Aaron E. Carroll, MD, MS, FAAP,[e] Stephen R. Daniels, MD, PhD, FAAP,[f] Sarah D. de Ferranti, MD, MPH, FAAP,[g] Janis M. Dionne, MD, FRCPC,[h] Bonita Falkner, MD,[i] Susan K. Flinn, MA,[j] Samuel S. Gidding, MD,[k] Celeste Goodwin,[l] Michael G. Leu, MD, MS, MHS, FAAP,[m] Makia E. Powers, MD, MPH, FAAP,[n] Corinna Rea, MD, MPH, FAAP,[o] Joshua Samuels, MD, MPH, FAAP,[p] Madeline Simasek, MD, MSCP, FAAP,[q] Vidhu V. Thaker, MD, FAAP,[r] Elaine M. Urbina, MD, MS, FAAP,[s] SUBCOMMITTEE ON SCREENING AND MANAGEMENT OF HIGH BLOOD PRESSURE IN CHILDREN

abstract

FREE

These pediatric hypertension guidelines are an update to the 2004 "Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents." Significant changes in these guidelines include (1) the replacement of the term "prehypertension" with the term "elevated blood pressure," (2) new normative pediatric blood pressure (BP) tables based on normal-weight children, (3) a simplified screening table for identifying BPs needing further evaluation, (4) a simplified BP classification in adolescents ≥13 years of age that aligns with the forthcoming American Heart Association and American College of Cardiology adult BP guidelines, (5) a more limited recommendation to perform screening BP measurements only at preventive care visits, (6) streamlined recommendations on the initial evaluation and management of abnormal BPs, (7) an expanded role for ambulatory BP monitoring in the diagnosis and management of pediatric hypertension, and (8) revised recommendations on when to perform echocardiography in the evaluation of newly diagnosed hypertensive pediatric patients (generally only before medication initiation), along with a revised definition of left ventricular hypertrophy. These guidelines include 30 Key Action Statements and 27 additional recommendations derived from a comprehensive review of almost 15 000 published articles between January 2004 and July 2016. Each Key Action Statement includes level of evidence, benefit-harm relationship, and strength of recommendation. This clinical practice guideline, endorsed by the American Heart Association, is intended to foster a patient- and family-centered approach to care, reduce unnecessary and costly medical interventions, improve patient diagnoses and outcomes, support implementation, and provide direction for future research.

[a]Dr. Robert O. Hickman Endowed Chair in Pediatric Nephrology, Division of Nephrology, Department of Pediatrics, University of Washington and Seattle Children's Hospital, Seattle, Washington; [b]Departments of Pediatrics, Internal Medicine, Population and Quantitative Health Sciences, Center for Clinical Informatics Research and Education, Case Western Reserve University and MetroHealth System, Cleveland, Ohio; [c]Division of Pediatric Cardiology, School of Medicine, University of Maryland, Baltimore, Maryland; [d]Children's Mercy Hospital, University of Missouri-Kansas City and Children's Mercy Integrated Care Solutions, Kansas City, Missouri; [e]Department of Pediatrics, School of Medicine, Indiana University, Bloomington, Indiana; [f]Department of Pediatrics, School of Medicine, University of Colorado-Denver and Pediatrician in Chief, Children's Hospital Colorado, Aurora, Colorado; [g]Director, Preventive Cardiology Clinic, Boston Children's Hospital, Department of Pediatrics, Harvard Medical School, Boston, Massachusetts; [h]Division of Nephrology, Department of Pediatrics, University of British Columbia and British Columbia Children's Hospital, Vancouver, British Columbia, Canada; Departments of [i]Medicine and Pediatrics, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania; [j]Consultant, American Academy of Pediatrics, Washington, District of Columbia; [k]Cardiology Division Head, Nemours Cardiac Center, Alfred I. duPont Hospital for Children, Wilmington, Delaware; [l]National Pediatric Blood Pressure Awareness Foundation, Prairieville, Louisiana; Departments of [m]Pediatrics and Biomedical Informatics and Medical Education, University of Washington, University of Washington Medicine and Information Technology Services, and Seattle Children's Hospital,

To cite: Flynn JT, Kaelber DC, Baker-Smith CM, et al. Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents. *Pediatrics.* 2017;140(3):e20171904

1. INTRODUCTION

1. Scope of the Clinical Practice Guideline

Interest in childhood hypertension (HTN) has increased since the 2004 publication of the "Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents" (Fourth Report).[1] Recognizing ongoing evidence gaps and the need for an updated, thorough review of the relevant literature, the American Academy of Pediatrics (AAP) and its Council on Quality Improvement and Patient Safety developed this practice guideline to provide an update on topics relevant to the diagnosis, evaluation, and management of pediatric HTN. It is primarily directed at clinicians caring for children and adolescents in the outpatient setting. This guideline is endorsed by the American Heart Association.

When it was not possible to identify sufficient evidence, recommendations are based on the consensus opinion of the expert members of the Screening and Management of High Blood Pressure in Children Clinical Practice Guideline Subcommittee (henceforth, "the subcommittee"). The subcommittee intends to regularly update this guideline as new evidence becomes available. Implementation tools for this guideline are available on the AAP Web site (https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/coqips/Pages/Implementation-Guide.aspx).

1.1 Methodology

The subcommittee was co-chaired by a pediatric nephrologist and a general pediatrician and consisted of 17 members, including a parent representative. All subcommittee members were asked to disclose relevant financial or proprietary conflicts of interest for members or their family members at the start of and throughout the guideline preparation process. Potential conflicts of interest were addressed and resolved by the AAP. A detailed list of subcommittee members and affiliations can be found in the Consortium section at the end of this article. A listing of subcommittee members with conflicts of interest will be included in the forthcoming technical report.

The subcommittee epidemiologist created a detailed content outline, which was reviewed and approved by the subcommittee. The outline contained a list of primary and secondary topics generated to guide a thorough literature search and meet the goal of providing an up-to-date systemic review of the literature pertaining to the diagnosis, management, and treatment of pediatric HTN as well as the prevalence of pediatric HTN and its associated comorbidities.

Of the topics covered in the outline, ~80% were researched by using a Patient, Intervention/Indicator, Comparison, Outcome, and Time (PICOT) format to address the following key questions:

1. How should systemic HTN (eg, primary HTN, renovascular HTN, white coat hypertension [WCH], and masked hypertension [MH]) in children be diagnosed, and what is the optimal approach to diagnosing HTN in children and adolescents?
2. What is the recommended workup for pediatric HTN? How do we best identify the underlying etiologies of secondary HTN in children?
3. What is the optimal goal systolic blood pressure (SBP) and/or diastolic blood pressure (DBP) for children and adolescents?
4. In children 0 to 18 years of age, how does treatment with lifestyle versus antihypertensive agents influence indirect measures of cardiovascular disease (CVD) risk, such as carotid intimamedia thickness (cIMT), flow-mediated dilation (FMD), left ventricular hypertrophy (LVH), and other markers of vascular dysfunction?

To address these key questions, a systematic search and review of literature was performed. The initial search included articles published between the publication of the Fourth Report (January 2004) and August 2015. The process used to conduct the systematic review was consistent with the recommendations of the Institute of Medicine for systematic reviews.[2]

For the topics not researched by using the PICOT format, separate searches were conducted. Not all topics (eg, economic aspects of pediatric HTN) were appropriate for the PICOT format. A third and final search was conducted at the time the Key Action Statements (KASs) were generated to identify any additional relevant articles published between August 2015 and July 2016. (See Table 1 for a complete list of KASs.)

A detailed description of the methodology used to conduct the literature search and systematic review for this clinical practice guideline will be included in the forthcoming technical report. In brief, reference selection involved a multistep process. First, 2 subcommittee members reviewed the titles and abstracts of references identified for each key question. The epidemiologist provided a deciding vote when required. Next, 2 subcommittee members and the epidemiologist conducted full-text reviews of the selected articles. Although many subcommittee members have extensively published articles on topics covered in this guideline, articles were not preferentially selected on the basis of authorship.

Articles selected at this stage were mapped back to the relevant main topic in the outline. Subcommittee members were then assigned to

TABLE 1 Summary of KASs for Screening and Management of High BP in Children and Adolescents

KAS	Evidence Quality, Strength of Recommendation
1. BP should be measured annually in children and adolescents ≥3 y of age.	C, moderate
2. BP should be checked in all children and adolescents ≥3 y of age at every health care encounter if they have obesity, are taking medications known to increase BP, have renal disease, a history of aortic arch obstruction or coarctation, or diabetes.	C, moderate
3. Trained health care professionals in the office setting should make a diagnosis of HTN if a child or adolescent has auscultatory-confirmed BP readings ≥95th percentile at 3 different visits.	C, moderate
4. Organizations with EHRs used in an office setting should consider including flags for abnormal BP values, both when the values are being entered and when they are being viewed.	C, weak
5. Oscillometric devices may be used for BP screening in children and adolescents. When doing so, providers should use a device that has been validated in the pediatric age group. If elevated BP is suspected on the basis of oscillometric readings, confirmatory measurements should be obtained by auscultation.	B, strong
6. ABPM should be performed for confirmation of HTN in children and adolescents with office BP measurements in the elevated BP category for 1 year or more or with stage 1 HTN over 3 clinic visits.	C, moderate
7. Routine performance of ABPM should be strongly considered in children and adolescents with high-risk conditions (see Table 12) to assess HTN severity and determine if abnormal circadian BP patterns are present, which may indicate increased risk for target organ damage.	B, moderate
8. ABPM should be performed by using a standardized approach (see Table 13) with monitors that have been validated in a pediatric population, and studies should be interpreted by using pediatric normative data.	C, moderate
9. Children and adolescents with suspected WCH should undergo ABPM. Diagnosis is based on the presence of mean SBP and DBP <95th percentile and SBP and DBP load <25%.	B, strong
10. Home BP monitoring should not be used to diagnose HTN, MH, or WCH but may be a useful adjunct to office and ambulatory BP measurement after HTN has been diagnosed.	C, moderate
11. Children and adolescents ≥6 y of age do not require an extensive evaluation for secondary causes of HTN if they have a positive family history of HTN, are overweight or obese, and/or do not have history or physical examination findings (Table 14) suggestive of a secondary cause of HTN.	C, moderate
12. Children and adolescents who have undergone coarctation repair should undergo ABPM for the detection of HTN (including MH).	B, strong
13. In children and adolescents being evaluated for high BP, the provider should obtain a perinatal history, appropriate nutritional history, physical activity history, psychosocial history, and family history and perform a physical examination to identify findings suggestive of secondary causes of HTN.	B, strong
14. Clinicians should not perform electrocardiography in hypertensive children and adolescents being evaluated for LVH.	B, strong
15-1. It is recommended that echocardiography be performed to assess for cardiac target organ damage (LV mass, geometry, and function) at the time of consideration of pharmacologic treatment of HTN.	C, moderate
15-2. LVH should be defined as LV mass >51 g/$m^{2.7}$ (boys and girls) for children and adolescents older than age 8 y and defined by LV mass >115 g/BSA for boys and LV mass >95 g/BSA for girls.	
15-3. Repeat echocardiography may be performed to monitor improvement or progression of target organ damage at 6- to 12-mo intervals. Indications to repeat echocardiography include persistent HTN despite treatment, concentric LV hypertrophy, or reduced LV ejection fraction.	
15-4. In patients without LV target organ injury at initial echocardiographic assessment, repeat echocardiography at yearly intervals may be considered in those with stage 2 HTN, secondary HTN, or chronic stage 1 HTN incompletely treated (noncompliance or drug resistance) to assess for the development of worsening LV target organ injury.	
16. Doppler renal ultrasonography may be used as a noninvasive screening study for the evaluation of possible RAS in normal-wt children and adolescents ≥8 y of age who are suspected of having renovascular HTN and who will cooperate with the procedure.	C, moderate
17. In children and adolescents suspected of having RAS, either CTA or MRA may be performed as noninvasive imaging studies. Nuclear renography is less useful in pediatrics and should generally be avoided.	D, weak
18. Routine testing for MA is not recommended for children and adolescents with primary HTN.	C, moderate
19. In children and adolescents diagnosed with HTN, the treatment goal with nonpharmacologic and pharmacologic therapy should be a reduction in SBP and DBP to <90th percentile and <130/80 mm Hg in adolescents ≥ 13 years old.	C, moderate
20. At the time of diagnosis of elevated BP or HTN in a child or adolescent, clinicians should provide advice on the DASH diet and recommend moderate to vigorous physical activity at least 3 to 5 d per week (30–60 min per session) to help reduce BP.	C, weak
21. In hypertensive children and adolescents who have failed lifestyle modifications (particularly those who have LV hypertrophy on echocardiography, symptomatic HTN, or stage 2 HTN without a clearly modifiable factor [eg, obesity]), clinicians should initiate pharmacologic treatment with an ACE inhibitor, ARB, long-acting calcium channel blocker, or thiazide diuretic.	B, moderate
22. ABPM may be used to assess treatment effectiveness in children and adolescents with HTN, especially when clinic and/or home BP measurements indicate insufficient BP response to treatment.	B, moderate
23-1. Children and adolescents with CKD should be evaluated for HTN at each medical encounter.	B, strong
23-2. Children or adolescents with both CKD and HTN should be treated to lower 24-hr MAP <50th percentile by ABPM.	
23-3. Regardless of apparent control of BP with office measures, children and adolescents with CKD and a history of HTN should have BP assessed by ABPM at least yearly to screen for MH.	
24. Children and adolescents with CKD and HTN should be evaluated for proteinuria.	B, strong
25. Children and adolescents with CKD, HTN, and proteinuria should be treated with an ACE inhibitor or ARB.	B, strong

TABLE 1 Continued

KAS	Evidence Quality, Strength of Recommendation
26. Children and adolescents with T1DM or T2DM should be evaluated for HTN at each medical encounter and treated if BP ≥95th percentile or >130/80 mm Hg in adolescents ≥13 y of age.	C, moderate
27. In children and adolescents with acute severe HTN and life-threatening symptoms, immediate treatment with short-acting antihypertensive medication should be initiated, and BP should be reduced by no more than 25% of the planned reduction over the first 8 h.	Expert opinion, D, weak
28. Children and adolescents with HTN may participate in competitive sports once hypertensive target organ effects and cardiovascular risk have been assessed.	C, moderate
29. Children and adolescents with HTN should receive treatment to lower BP below stage 2 thresholds before participation in competitive sports.	C, moderate
30. Adolescents with elevated BP or HTN (whether they are receiving antihypertensive treatment) should typically have their care transitioned to an appropriate adult care provider by 22 y of age (recognizing that there may be individual cases in which this upper age limit is exceeded, particularly in the case of youth with special health care needs). There should be a transfer of information regarding HTN etiology and past manifestations and complications of the patient's HTN.	X, strong

writing teams that evaluated the evidence quality for selected topics and generated appropriate KASs in accordance with an AAP grading matrix (see Fig 1 and the detailed discussion in the forthcoming technical report).[3] Special working groups were created to address 2 specific topics for which evidence was lacking and expert opinion was required to generate KASs, "Definition of HTN" and "Definition of LVH." References for any topics not covered by the key questions were selected on the basis of additional literature searches and reviewed by the epidemiologist and subcommittee members assigned to the topic. When applicable, searches were conducted by using the PICOT format .

In addition to the 30 KASs listed above, this guideline also contains 27 additional recommendations that are based on the consensus expert opinion of the subcommittee members. These recommendations, along with their locations in the document, are listed in Table 2.

2. EPIDEMIOLOGY AND CLINICAL SIGNIFICANCE

2.1 Prevalence of HTN in Children

Information on the prevalence of high blood pressure (BP) in children is largely derived from data from the NHANES and typically is based on a single BP measurement session. These surveys, conducted since 1988, indicate that there has been an increase in the prevalence of childhood high BP, including both HTN and elevated BP.[4,5] High BP is consistently greater in boys (15%–19%) than in girls (7%–12%). The prevalence of high BP is higher among Hispanic and non-Hispanic African American children compared with non-Hispanic white children, with higher rates among adolescents than among younger children.[6]

However, in a clinical setting and with repeated BP measurements, the prevalence of confirmed HTN is lower in part because of inherent BP variability as well as an adjustment to the experience of having BP measured (also known as the accommodation effect). Therefore, the actual prevalence of clinical HTN in children and adolescents is ~3.5%.[7,8] The prevalence of persistently elevated BP (formerly termed "prehypertension," including BP values from the 90th to 94th percentiles or between 120/80 and 130/80 mm Hg in adolescents) is also ~2.2% to 3.5%, with higher rates among children and adolescents who have overweight and obesity.[7,9]

Data on BP tracking from childhood to adulthood demonstrate that higher BP in childhood correlates with higher BP in adulthood and the onset of HTN in young adulthood. The strength of the tracking relationship is stronger in older children and adolescents.[10] Trajectory data on BP (including repeat measurements from early childhood into midadulthood) confirm the association of elevated BP in adolescence with HTN in early adulthood[11] and that normal BP in childhood is associated with a lack of HTN in midadulthood.[11]

2.2 Awareness, Treatment, and Control of HTN in Children

Of the 32.6% of US adults who have HTN, almost half (17.2%) are not aware they have HTN; even among those who are aware of their condition, only approximately half (54.1%) have controlled BP.[12] Unfortunately, there are no large studies in which researchers have systematically studied BP awareness or control in youth, although an analysis of prescribing patterns from a nationwide prescription drug provider found an increase in the number of prescriptions written for high BP in youth from 2004 to 2007.[13]

The SEARCH for Diabetes in Youth study found that only 7.4% of youth with type 1 diabetes mellitus (T1DM) and 31.9% of youth with type 2 diabetes mellitus (T2DM) demonstrated knowledge of their BP status.[14] Even after becoming aware of the diagnosis, only 57.1% of patients with T1DM and 40.6% of patients with T2DM achieved good BP control.[14] The HEALTHY Primary Prevention Trial of Risk Factors for

TABLE 2 Additional Consensus Opinion Recommendations and Text Locations

Recommendation	CPG Section(s)
1. Follow the revised classification scheme in Table 3 for childhood BP levels, including the use of the term "elevated BP," the new definition of stage 2 HTN, and the use of similar BP levels as adults for adolescents ≥13 y of age.	3.1
2. Use simplified BP tables (Table 4) to screen for BP values that may require further evaluation by a clinician.	3.2a
3. Use reference data on neonatal BP from ref 80 to identify elevated BP values in neonates up to 44 wk postmenstrual age and BP curves from the 1987 Second Task Force report to identify elevated BP values in infants 1–12 mo of age.	3.3
4. Use the standardized technique for measuring BP by auscultation described in Table 7 and Fig 2 (including appropriate cuff size, extremity, and patient positioning) to obtain accurate BP values.	4.1
5. If the initial BP at an office visit is elevated, as described in Fig 3, obtain 2 additional BP measurements at the same visit and average them; use the averaged auscultatory BP measurement to determine the patient's BP category.	4.1
6. Oscillometric devices are used to measure BP in infants and toddlers until they are able to cooperate with auscultatory BP. Follow the same rules for BP measurement technique and cuff size as for older children.	4.1a
7. Measure BP at every health care encounter in children <3 y of age if they have an underlying condition listed in Table 9 that increases their risk for HTN.	4.2
8. After a patient's BP has been categorized, follow Table 11 for when to obtain repeat BP readings, institute lifestyle changes, or proceed to a workup for HTN.	4.3
9. When an oscillometric BP reading is elevated, obtain repeat readings, discard the first reading, and average subsequent readings to approximate auscultatory BP.	4.5
10. Wrist and forearm BP measurements should not be used in children and adolescents for the diagnosis or management of HTN.	4.6
11. Use ABPM to evaluate high-risk patients (those with obesity, CKD, or repaired aortic coarctation) for potential MH.	4.7a, 4.8
12. Routine use of BP readings obtained in the school setting is not recommended for diagnosis of HTN in children and adolescents.	4.10
13. Use the history and physical examination to identify possible underlying causes of HTN, such as heart disease, kidney disease, renovascular disease, endocrine HTN (Table 15), drug-induced HTN (Table 8), and OSAS-associated HTN (Table 18).	5.2–5.4, 5.7, 9.2
14. Suspect monogenic HTN in patients with a family history of early-onset HTN, hypokalemia, suppressed plasma renin, or an elevated ARR.	5.8
15. Obtain laboratory studies listed in Table 10 to evaluate for underlying secondary causes of HTN when indicated.	6.4
16. Routine use of vascular imaging, such as carotid intimal-media measurements or PWV measurements, is not recommended in the evaluation of HTN in children and adolescents.	6.7
17. Suspect renovascular HTN in selected children and adolescents with stage 2 HTN, significant diastolic HTN, discrepant kidney sizes on ultrasound, hypokalemia on screening laboratories, or an epigastric and/or upper abdominal bruit on physical examination.	6.8a
18. Routine measurement of serum UA is not recommended for children and adolescents with elevated BP.	6.9
19. Offer intensive weight-loss programs to hypertensive children and adolescents with obesity; consider using MI as an adjunct to the treatment of obesity.	7.2c
20. Follow-up children and adolescents treated with antihypertensive medications every 4–6 wk until BP is controlled, then extend the interval. Follow-up every 3–6 mo is appropriate for patients treated with lifestyle modification only.	7.3c
21. Evaluate and treat children and adolescents with apparent treatment-resistant HTN in a similar manner to that recommended for adults with resistant HTN.	7.4
22. Treat hypertensive children and adolescents with dyslipidemia according to current, existing pediatric lipid guidelines.	9.1
23. Use ABPM to evaluate for potential HTN in children and adolescents with known or suspected OSAS.	9.2
24. Racial, ethnic, and sex differences need not be considered in the evaluation and management of children and adolescents with HTN.	10
25. Use ABPM to evaluate BP in pediatric heart- and kidney-transplant recipients.	11.3

Type 2 Diabetes in Middle-School Youth, which examined a school-based intervention designed to reduce cardiovascular (CV) risk among middle school students, found the prevalence of stage 1 or 2 HTN to be ~9.5%.[15] There was no significant reduction in HTN in the control group after the intervention; the intervention group saw a reduction in the prevalence of HTN of ~1%, leaving 8.5% with BP still above the ideal range.

Researchers in a number of small, single-center studies have evaluated BP control in children and adolescents with HTN. One study found that lifestyle change and medications produced adequate BP control in 46 of 65 youth (70%) with HTN.[16] Another study in which researchers used ambulatory blood pressure monitoring (ABPM) to assess BP control among a group of 38 children (of whom 84% had chronic kidney disease [CKD]) found that only 13 children (34%) achieved adequate BP control even among those who received more than 1 drug.[17] A similar study found that additional drugs did increase rates of BP control in children with CKD, however.[18]

2.3 Prevalence of HTN Among Children With Various Chronic Conditions

It is well recognized that HTN rates are higher in children with certain chronic conditions, including children with obesity, sleep-disordered breathing (SDB), CKD, and those born preterm. These are described below.

2.3a Children With Obesity

HTN prevalence ranges from 3.8% to 24.8% in youth with overweight and obesity. Rates of HTN increase in a graded fashion with increasing adiposity.[19–24] Similar relationships are seen between HTN and increasing waist circumference.[4,25,26] Systematic reviews of 63 studies on BMI[27] and 61 studies on various measures

TABLE 2 Continued

Recommendation	CPG Section(s)
26. Reasonable strategies for HTN prevention include the maintenance of a normal BMI, consuming a DASH-type diet, avoidance of excessive sodium consumption, and regular vigorous physical activity.	13.2
27. Provide education about HTN to patients and their parents to improve patient involvement in their care and better achieve therapeutic goals.	15.2, 15.3

Based on the expert opinion of the subcommittee members (level of evidence = D; strength of recommendations = weak). CPG, clinical practice guideline.

of abdominal adiposity[28] have shown associations between these conditions and HTN. Obesity is also associated with a lack of circadian variability of BP,[29,30] with up to 50% of children who have obesity not experiencing the expected nocturnal BP dip.[31–33]

Studies have shown that childhood obesity is also related to the development of future HTN.[22] Elevated BMI as early as infancy is associated with higher future BP.[34] This risk appears to increase with obesity severity; there is a fourfold increase in BP among those with severe obesity (BMI >99th percentile) versus a twofold increase in those with obesity (BMI 95th–98th percentiles) compared with normal-weight children and adolescents.[35]

Collectively, the results of these cross-sectional and longitudinal studies firmly establish an increasing prevalence of HTN with increasing BMI percentile. The study results also underscore the importance of monitoring BP in all children with overweight and/or obesity at every clinical encounter.

Obesity in children with HTN may be accompanied by additional cardiometabolic risk factors (eg, dyslipidemia and disordered glucose metabolism)[36,37] that may have their own effects on BP or may represent comorbid conditions arising from the same adverse lifestyle behaviors.[25,38] Some argue that the presence of multiple risk factors, including obesity and HTN, leads to far greater increases in CV risk than is explained by the individual risk factors alone. Although this phenomenon has been hard to demonstrate definitively, the Strong Heart Study did show that American Indian adolescents with multiple cardiometabolic risk factors had a higher prevalence of LVH (43.2% vs 11.7%), left atrial dilation (63.1% vs 21.9%; $P < .001$), and reduced LV systolic and diastolic function compared with those without multiple cardiometabolic risk factors.[39] Notably, both obesity and HTN were drivers of these CV abnormalities, with obesity being a stronger determinant of cardiac abnormalities than HTN (odds ratio, 4.17 vs 1.03).

2.3b Children With SDB

SDB occurs on a spectrum that includes (1) primary snoring, (2) sleep fragmentation, and (3) obstructive sleep apnea syndrome (OSAS). Researchers in numerous studies have identified an association between SDB and HTN in the pediatric population.[40–42] Studies suggest that children who sleep 7 hours or less per night are at increased risk for HTN.[43] Small studies of youth with sleep disorders have found the prevalence of high BP to range between 3.6% and 14%.[40,41] The more severe the OSAS, the more likely a child is to have HTN.[44,45] Even inadequate duration of sleep and poor-quality sleep have been associated with elevated BP.[43]

2.3c Children With CKD

There are well-established pathophysiologic links between childhood HTN and CKD. Certain forms of CKD can lead to HTN, and untreated HTN can lead to CKD in adults, although evidence for the latter in pediatric patients is lacking. Among children and adolescents with CKD, ~50% are known to be hypertensive.[46–48] In children and adolescents with end-stage renal disease (either those on dialysis or after transplant), ~48% to 79% are hypertensive, with 20% to 70% having uncontrolled HTN.[49–53] Almost 20% of pediatric HTN may be attributable to CKD.[54]

2.3d Children With History of Prematurity

Abnormal birth history—including preterm birth and low birth weight—has been identified as a risk factor for HTN and other CVD in adults[55]; only low birth weight has been associated with elevated BP in the pediatric age range.[56] One retrospective cohort study showed a prevalence of HTN of 7.3% among 3 year olds who were born preterm.[57] Researchers in another retrospective case series noted a high prevalence of HTN in older children with a history of preterm birth.[58] It also appears that preterm birth may result in abnormal circadian BP patterns in childhood.[59] These data are intriguing but limited. Further study is needed to determine how often preterm birth results in childhood HTN.

2.4 Importance of Diagnosing HTN in Children and Adolescents

Numerous studies have shown that elevated BP in childhood increases the risk for adult HTN and metabolic syndrome.[10,60–62] Youth with higher BP levels in childhood are also more likely to have persistent HTN as adults.[60,63] One recent study found that adolescents with elevated BP progressed to HTN at a rate of 7% per year, and elevated BMI predicted sustained BP elevations.[64] In addition, young patients with HTN are likely to experience accelerated vascular aging. Both autopsy[65] and imaging studies[66] have demonstrated BP-related CV damage in youth. These intermediate markers of CVD (eg, increased LV mass,[67] cIMT,[68] and

pulse wave velocity [PWV][69]) are known to predict CV events in adults, making it crucial to diagnose and treat HTN early.

Eighty million US adults (1 in 3) have HTN, which is a major contributor to CVD.[12] Key contributors to CV health have been identified by the American Heart Association (AHA) as "Life's Simple 7," including 4 ideal health behaviors (not smoking, normal BMI, physical activity at goal levels, and a healthy diet) and 3 ideal health factors (untreated, normal total cholesterol; normal fasting blood glucose; and normal untreated BP, defined in childhood as ≤90th percentile or <120/80 mm Hg). Notably, elevated BP is the least common abnormal health factor in children and adolescents[70]; 89% of youth (ages 12–19 years) are in the ideal BP category.[6]

Given the prevalence of known key contributors in youth (ie, tobacco exposure, obesity, inactivity, and nonideal diet[12,71]), adult CVD likely has its origins in childhood. One-third of US adolescents report having tried a cigarette in the past 30 days.[72] Almost half (40%–48%) of teenagers have elevated BMI, and the rates of severe obesity (BMI >99th percentile) continue to climb, particularly in girls and adolescents.[73–75] Physical activity measured by accelerometry shows less than half of school-aged boys and only one-third of school-aged girls meet the goal for ideal physical activity levels.[72] More than 80% of youth 12 to 19 years of age have a poor diet (as defined by AHA metrics for ideal CV health); only ~10% eat adequate fruits and vegetables, and only ~15% consume <1500 mg per day of sodium, both of which are key dietary determinants of HTN.[76]

Finally, measuring BP at routine well-child visits enables the early detection of primary HTN as well as the detection of asymptomatic HTN secondary to another underlying disorder. Early detection of HTN is vital given the greater relative prevalence of secondary causes of HTN in children compared with adults.

TABLE 3 Updated Definitions of BP Categories and Stages

For Children Aged 1–13 y	For Children Aged ≥13 y
Normal BP: <90th percentile	Normal BP: <120/<80 mm Hg
Elevated BP: ≥90th percentile to <95th percentile or 120/80 mm Hg to <95th percentile (whichever is lower)	Elevated BP: 120/<80 to 129/<80 mm Hg
Stage 1 HTN: ≥95th percentile to <95th percentile + 12 mmHg, or 130/80 to 139/89 mm Hg (whichever is lower)	Stage 1 HTN: 130/80 to 139/89 mm Hg
Stage 2 HTN: ≥95th percentile + 12 mm Hg, or ≥140/90 mm Hg (whichever is lower)	Stage 2 HTN: ≥140/90 mm Hg

3. DEFINITION OF HTN

3.1 Definition of HTN (1–18 Years of Age)

Given the lack of outcome data, the current definition of HTN in children and adolescents is based on the normative distribution of BP in healthy children.[1] Because it is a major determinant of BP in growing children, height has been incorporated into the normative data since the publication of the 1996 Working Group Report.[1] BP levels should be interpreted on the basis of sex, age, and height to avoid misclassification of children who are either extremely tall or extremely short. It should be noted that the normative data were collected by using an auscultatory technique,[1] which may provide different values than measurement obtained by using oscillometric devices or from ABPM.

In the Fourth Report, "normal blood pressure" was defined as SBP and DBP values <90th percentile (on the basis of age, sex, and height percentiles). For the preadolescent, "prehypertension" was defined as SBP and/or DBP ≥90th percentile and <95th percentile (on the basis of age, sex, and height tables). For adolescents, "prehypertension" was defined as BP ≥120/80 mm Hg to <95th percentile, or ≥90th and <95th percentile, whichever was lower. HTN was defined as average clinic measured SBP and/or DBP ≥95th percentile (on the basis of age, sex, and height percentiles) and was further classified as stage 1 or stage 2 HTN.

There are still no data to identify a specific level of BP in childhood that leads to adverse CV outcomes in adulthood. Therefore, the subcommittee decided to maintain a statistical definition for childhood HTN. The staging criteria have been revised for stage 1 and stage 2 HTN for ease of implementation compared with the Fourth Report. For children ≥13 years of age, this staging scheme will seamlessly interface with the 2017 AHA and American College of Cardiology (ACC) adult HTN guideline.* Additionally, the term "prehypertension" has been replaced by the term "elevated blood pressure," to be consistent with the AHA and ACC guideline and convey the importance of lifestyle measures to prevent the development of HTN (see Table 3).

3.2 New BP Tables

New normative BP tables based on normal-weight children are included with these guidelines (see Tables 4 and 5). Similar to the tables in the

*Whelton PK, Carey RM, Aranow WS, et al. ACC/AHA/APPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation and managament of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension*. 2017, In press.

Fourth Report,[1] they include SBP and DBP values arranged by age, sex, and height (and height percentile). These values are based on auscultatory measurements obtained from ~50 000 children and adolescents. A new feature in these tables is that the BP values are categorized according to the scheme presented in Table 3 as normal (50th percentile), elevated BP (>90th percentile), stage 1 HTN (≥95th percentile), and stage 2 HTN (≥95th percentile + 12 mm Hg). Additionally, actual heights in centimeters and inches are provided.

Unlike the tables in the Fourth Report,[1] the BP values in these tables do not include children and adolescents with overweight and obesity (ie, those with a BMI ≥85th percentile); therefore, they represent normative BP values for normal-weight youth. The decision to create these new tables was based on evidence of the strong association of both overweight and obesity with elevated BP and HTN. Including patients with overweight and obesity in normative BP tables was thought to create bias. The practical effect of this change is that the BP values in Tables 4 and 5 are several millimeters of mercury lower than in the similar tables in the Fourth Report.[1] These tables are based on the same population data excluding participants with overweight and obesity, and the same methods used in the Fourth Report.[1] The methods and results have been published elsewhere.[77] For researchers and others interested in the equations used to calculate the tables' BP values, detailed methodology and the Statistical Analysis System (SAS) code can be found at: http://sites.google.com/a/channing.harvard.edu/bernardrosner/pediatric-blood-press/childhood-blood-pressure.

There are slight differences between the actual percentile-based values in these tables and the cut-points in Table 3, particularly for teenagers ≥13 years of age. Clinicians should understand that the scheme in Table 3 was chosen to align with the new adult guideline and facilitate the management of older adolescents with high BP. The percentile-based values in Tables 4 and 5 are provided to aid researchers and others interested in a more precise classification of BP.

3.2a. Simplified BP Table

This guideline includes a new, simplified table for initial BP screening (see Table 6) based on the 90th percentile BP for age and sex for children at the 5th percentile of height, which gives the values in the table a negative predictive value of >99%.[78] This simplified table is designed as a screening tool only for the identification of children and adolescents who need further evaluation of their BP starting with repeat BP measurements. It should not be used to diagnose elevated BP or HTN by itself. To diagnose elevated BP or HTN, it is important to locate the actual cutoffs in the complete BP tables because the SBP and DBP cutoffs may be as much as 9 mm Hg higher depending on a child's age and length or height. A typical-use case for this simplified table is for nursing staff to quickly identify BP that may need further evaluation by a clinician. For adolescents ≥13 years of age, a threshold of 120/80 mm Hg is used in the simplified table regardless of sex to align with adult guidelines for the detection of elevated BP.

3.3 Definition of HTN in the Neonate and Infant (0–1 Year of Age)

Although a reasonably strict definition of HTN has been developed for older children, it is more difficult to define HTN in neonates given the well-known changes in BP that occur during the first few weeks of life.[79] These BP changes can be significant in preterm infants, in whom BP depends on a variety of factors, including postmenstrual age, birth weight, and maternal conditions.[80]

In an attempt to develop a more standardized approach to the HTN definition in preterm and term neonates, Dionne et al[79] compiled available data on neonatal BP and generated a summary table of BP values, including values for the 95th and 99th percentiles for infants from 26 to 44 weeks' postmenstrual age. The authors proposed that by using these values, a similar approach to that used to identify older children with elevated BP can be followed in neonates, even in those who are born preterm.

At present, no alternative data have been developed, and no outcome data are available on the consequences of high BP in this population; thus, it is reasonable to use these compiled BP values in the assessment of elevated BP in newborn infants. Of note, the 1987 "Report of the Second Task Force on Blood Pressure Control in Children" published curves of normative BP values in older infants up to 1 year of age.[81] These normative values should continue to be used given the lack of more contemporary data for this age group.

4. MEASUREMENT OF BP

4.1 BP Measurement Technique

BP in childhood may vary considerably between visits and even during the same visit. There are many potential etiologies for isolated elevated BP in children and adolescents, including such factors as anxiety and recent caffeine intake.[82] BP generally decreases with repeated measurements during a single visit,[83] although the variability may not be large enough to affect BP classification.[84] BP measurements can also vary across visits[64,85]; one study in adolescents found that only 56% of the sample had the same HTN stage on 3 different occasions.[8] Therefore, it is important to obtain multiple measurements over time before diagnosing HTN.

TABLE 4 BP Levels for Boys by Age and Height Percentile

Age (y)	BP Percentile	SBP (mm Hg)							DBP (mm Hg)						
		Height Percentile or Measured Height							Height Percentile or Measured Height						
		5%	10%	25%	50%	75%	90%	95%	5%	10%	25%	50%	75%	90%	95%
1	Height (in)	30.4	30.8	31.6	32.4	33.3	34.1	34.6	30.4	30.8	31.6	32.4	33.3	34.1	34.6
	Height (cm)	77.2	78.3	80.2	82.4	84.6	86.7	87.9	77.2	78.3	80.2	82.4	84.6	86.7	87.9
	50th	85	85	86	86	87	88	88	40	40	40	41	41	42	42
	90th	98	99	99	100	100	101	101	52	52	53	53	54	54	54
	95th	102	102	103	103	104	105	105	54	54	55	55	56	57	57
	95th + 12 mm Hg	114	114	115	115	116	117	117	66	66	67	67	68	69	69
2	Height (in)	33.9	34.4	35.3	36.3	37.3	38.2	38.8	33.9	34.4	35.3	36.3	37.3	38.2	38.8
	Height (cm)	86.1	87.4	89.6	92.1	94.7	97.1	98.5	86.1	87.4	89.6	92.1	94.7	97.1	98.5
	50th	87	87	88	89	89	90	91	43	43	44	44	45	46	46
	90th	100	100	101	102	103	103	104	55	55	56	56	57	58	58
	95th	104	105	105	106	107	107	108	57	58	58	59	60	61	61
	95th + 12 mm Hg	116	117	117	118	119	119	120	69	70	70	71	72	73	73
3	Height (in)	36.4	37	37.9	39	40.1	41.1	41.7	36.4	37	37.9	39	40.1	41.1	41.7
	Height (cm)	92.5	93.9	96.3	99	101.8	104.3	105.8	92.5	93.9	96.3	99	101.8	104.3	105.8
	50th	88	89	89	90	91	92	92	45	46	46	47	48	49	49
	90th	101	102	102	103	104	105	105	58	58	59	59	60	61	61
	95th	106	106	107	107	108	109	109	60	61	61	62	63	64	64
	95th + 12 mm Hg	118	118	119	119	120	121	121	72	73	73	74	75	76	76
4	Height (in)	38.8	39.4	40.5	41.7	42.9	43.9	44.5	38.8	39.4	40.5	41.7	42.9	43.9	44.5
	Height (cm)	98.5	100.2	102.9	105.9	108.9	111.5	113.2	98.5	100.2	102.9	105.9	108.9	111.5	113.2
	50th	90	90	91	92	93	94	94	48	49	49	50	51	52	52
	90th	102	103	104	105	105	106	107	60	61	62	62	63	64	64
	95th	107	107	108	108	109	110	110	63	64	65	66	67	67	68
	95th + 12 mm Hg	119	119	120	120	121	122	122	75	76	77	78	79	79	80
5	Height (in)	41.1	41.8	43.0	44.3	45.5	46.7	47.4	41.1	41.8	43.0	44.3	45.5	46.7	47.4
	Height (cm)	104.4	106.2	109.1	112.4	115.7	118.6	120.3	104.4	106.2	109.1	112.4	115.7	118.6	120.3
	50th	91	92	93	94	95	96	96	51	51	52	53	54	55	55
	90th	103	104	105	106	107	108	108	63	64	65	65	66	67	67
	95th	107	108	109	109	110	111	112	66	67	68	69	70	70	71
	95th + 12 mm Hg	119	120	121	121	122	123	124	78	79	80	81	82	82	83
6	Height (in)	43.4	44.2	45.4	46.8	48.2	49.4	50.2	43.4	44.2	45.4	46.8	48.2	49.4	50.2
	Height (cm)	110.3	112.2	115.3	118.9	122.4	125.6	127.5	110.3	112.2	115.3	118.9	122.4	125.6	127.5
	50th	93	93	94	95	96	97	98	54	54	55	56	57	57	58
	90th	105	105	106	107	109	110	110	66	66	67	68	68	69	69
	95th	108	109	110	111	112	113	114	69	70	70	71	72	72	73
	95th + 12 mm Hg	120	121	122	123	124	125	126	81	82	82	83	84	84	85
7	Height (in)	45.7	46.5	47.8	49.3	50.8	52.1	52.9	45.7	46.5	47.8	49.3	50.8	52.1	52.9
	Height (cm)	116.1	118	121.4	125.1	128.9	132.4	134.5	116.1	118	121.4	125.1	128.9	132.4	134.5
	50th	94	94	95	97	98	98	99	56	56	57	58	58	59	59
	90th	106	107	108	109	110	111	111	68	68	69	70	70	71	71
	95th	110	110	111	112	114	115	116	71	71	72	73	73	74	74
	95th + 12 mm Hg	122	122	123	124	126	127	128	83	83	84	85	85	86	86

TABLE 4 Continued

Age (y)	BP Percentile	SBP (mm Hg)							DBP (mm Hg)						
		Height Percentile or Measured Height							Height Percentile or Measured Height						
		5%	10%	25%	50%	75%	90%	95%	5%	10%	25%	50%	75%	90%	95%
8	Height (in)	47.8	48.6	50	51.6	53.2	54.6	55.5	47.8	48.6	50	51.6	53.2	54.6	55.5
	Height (cm)	121.4	123.5	127	131	135.1	138.8	141	121.4	123.5	127	131	135.1	138.8	141
	50th	95	96	97	98	99	99	100	57	57	58	59	59	60	60
	90th	107	108	109	110	111	112	112	69	70	70	71	72	72	73
	95th	111	112	112	114	115	116	117	72	73	73	74	75	75	75
	95th + 12 mm Hg	123	124	124	126	127	128	129	84	85	85	86	87	87	87
9	Height (in)	49.6	50.5	52	53.7	55.4	56.9	57.9	49.6	50.5	52	53.7	55.4	56.9	57.9
	Height (cm)	126	128.3	132.1	136.3	140.7	144.7	147.1	126	128.3	132.1	136.3	140.7	144.7	147.1
	50th	96	97	98	99	100	101	101	57	58	59	60	61	62	62
	90th	107	108	109	110	112	113	114	70	71	72	73	74	74	74
	95th	112	112	113	115	116	118	119	74	74	75	76	76	77	77
	95th + 12 mm Hg	124	124	125	127	128	130	131	86	86	87	88	88	89	89
10	Height (in)	51.3	52.2	53.8	55.6	57.4	59.1	60.1	51.3	52.2	53.8	55.6	57.4	59.1	60.1
	Height (cm)	130.2	132.7	136.7	141.3	145.9	150.1	152.7	130.2	132.7	136.7	141.3	145.9	150.1	152.7
	50th	97	98	99	100	101	102	103	59	60	61	62	63	63	64
	90th	108	109	111	112	113	115	116	72	73	74	74	75	75	76
	95th	112	113	114	116	118	120	121	76	76	77	77	78	78	78
	95th + 12 mm Hg	124	125	126	128	130	132	133	88	88	89	89	90	90	90
11	Height (in)	53	54	55.7	57.6	59.6	61.3	62.4	53	54	55.7	57.6	59.6	61.3	62.4
	Height (cm)	134.7	137.3	141.5	146.4	151.3	155.8	158.6	134.7	137.3	141.5	146.4	151.3	155.8	158.6
	50th	99	99	101	102	103	104	106	61	61	62	63	63	63	63
	90th	110	111	112	114	116	117	118	74	74	75	75	75	76	76
	95th	114	114	116	118	120	123	124	77	78	78	78	78	78	78
	95th + 12 mm Hg	126	126	128	130	132	135	136	89	90	90	90	90	90	90
12	Height (in)	55.2	56.3	58.1	60.1	62.2	64	65.2	55.2	56.3	58.1	60.1	62.2	64	65.2
	Height (cm)	140.3	143	147.5	152.7	157.9	162.6	165.5	140.3	143	147.5	152.7	157.9	162.6	165.5
	50th	101	101	102	104	106	108	109	61	62	62	62	62	63	63
	90th	113	114	115	117	119	121	122	75	75	75	75	75	76	76
	95th	116	117	118	121	124	126	128	78	78	78	78	78	79	79
	95th + 12 mm Hg	128	129	130	133	136	138	140	90	90	90	90	90	91	91
13	Height (in)	57.9	59.1	61	63.1	65.2	67.1	68.3	57.9	59.1	61	63.1	65.2	67.1	68.3
	Height (cm)	147	150	154.9	160.3	165.7	170.5	173.4	147	150	154.9	160.3	165.7	170.5	173.4
	50th	103	104	105	108	110	111	112	61	60	61	62	63	64	65
	90th	115	116	118	121	124	126	126	74	74	74	75	76	77	77
	95th	119	120	122	125	128	130	131	78	78	78	78	80	81	81
	95th + 12 mm Hg	131	132	134	137	140	142	143	90	90	90	90	92	93	93
14	Height (in)	60.6	61.8	63.8	65.9	68.0	69.8	70.9	60.6	61.8	63.8	65.9	68.0	69.8	70.9
	Height (cm)	153.8	156.9	162	167.5	172.7	177.4	180.1	153.8	156.9	162	167.5	172.7	177.4	180.1
	50th	105	106	109	111	112	113	113	60	60	62	64	65	66	67
	90th	119	120	123	126	127	128	129	74	74	75	77	78	79	80
	95th	123	125	127	130	132	133	134	77	78	79	81	82	83	84
	95th + 12 mm Hg	135	137	139	142	144	145	146	89	90	91	93	94	95	96

TABLE 4 Continued

Age (y)	BP Percentile	SBP (mm Hg)							DBP (mm Hg)						
		Height Percentile or Measured Height							Height Percentile or Measured Height						
		5%	10%	25%	50%	75%	90%	95%	5%	10%	25%	50%	75%	90%	95%
15	Height (in)	62.6	63.8	65.7	67.8	69.8	71.5	72.5	62.6	63.8	65.7	67.8	69.8	71.5	72.5
	Height (cm)	159	162	166.9	172.2	177.2	181.6	184.2	159	162	166.9	172.2	177.2	181.6	184.2
	50th	108	110	112	113	114	114	114	61	62	64	65	66	67	68
	90th	123	124	126	128	129	130	130	75	76	78	79	80	81	81
	95th	127	129	131	132	134	135	135	78	79	81	83	84	85	85
	95th + 12 mm Hg	139	141	143	144	146	147	147	90	91	93	95	96	97	97
16	Height (in)	63.8	64.9	66.8	68.8	70.7	72.4	73.4	63.8	64.9	66.8	68.8	70.7	72.4	73.4
	Height (cm)	162.1	165	169.6	174.6	179.5	183.8	186.4	162.1	165	169.6	174.6	179.5	183.8	186.4
	50th	111	112	114	115	115	116	116	63	64	66	67	68	69	69
	90th	126	127	128	129	131	131	132	77	78	79	80	81	82	82
	95th	130	131	133	134	135	136	137	80	81	83	84	85	86	86
	95th + 12 mm Hg	142	143	145	146	147	148	149	92	93	95	96	97	98	98
17	Height (in)	64.5	65.5	67.3	69.2	71.1	72.8	73.8	64.5	65.5	67.3	69.2	71.1	72.8	73.8
	Height (cm)	163.8	166.5	170.9	175.8	180.7	184.9	187.5	163.8	166.5	170.9	175.8	180.7	184.9	187.5
	50th	114	115	116	117	117	118	118	65	66	67	68	69	70	70
	90th	128	129	130	131	132	133	134	78	79	80	81	82	82	83
	95th	132	133	134	135	137	138	138	81	82	84	85	86	86	87
	95th + 12 mm Hg	144	145	146	147	149	150	150	93	94	96	97	98	98	99

Use percentile values to stage BP readings according to the scheme in Table 3 (elevated BP: ≥90th percentile; stage 1 HTN: ≥95th percentile; and stage 2 HTN: ≥95th percentile + 12 mm Hg). The 50th, 90th, and 95th percentiles were derived by using quantile regression on the basis of normal-weight children (BMI <85th percentile).[77]

TABLE 5 BP Levels for Girls by Age and Height Percentile

Age (y)	BP Percentile	SBP (mm Hg)							DBP (mm Hg)						
		Height Percentile or Measured Height							Height Percentile or Measured Height						
		5%	10%	25%	50%	75%	90%	95%	5%	10%	25%	50%	75%	90%	95%
1	Height (in)	29.7	30.2	30.9	31.8	32.7	33.4	33.9	29.7	30.2	30.9	31.8	32.7	33.4	33.9
	Height (cm)	75.4	76.6	78.6	80.8	83	84.9	86.1	75.4	76.6	78.6	80.8	83	84.9	86.1
	50th	84	85	86	86	87	88	88	41	42	42	43	44	45	46
	90th	98	99	99	100	101	102	102	54	55	56	56	57	58	58
	95th	101	102	102	103	104	105	105	59	59	60	60	61	62	62
	95th + 12 mm Hg	113	114	114	115	116	117	117	71	71	72	72	73	74	74
2	Height (in)	33.4	34	34.9	35.9	36.9	37.8	38.4	33.4	34	34.9	35.9	36.9	37.8	38.4
	Height (cm)	84.9	86.3	88.6	91.1	93.7	96	97.4	84.9	86.3	88.6	91.1	93.7	96	97.4
	50th	87	87	88	89	90	91	91	45	46	47	48	49	50	51
	90th	101	101	102	103	104	105	106	58	58	59	60	61	62	62
	95th	104	105	106	106	107	108	109	62	63	63	64	65	66	66
	95th + 12 mm Hg	116	117	118	118	119	120	121	74	75	75	76	77	78	78
3	Height (in)	35.8	36.4	37.3	38.4	39.6	40.6	41.2	35.8	36.4	37.3	38.4	39.6	40.6	41.2
	Height (cm)	91	92.4	94.9	97.6	100.5	103.1	104.6	91	92.4	94.9	97.6	100.5	103.1	104.6
	50th	88	89	89	90	91	92	93	48	48	49	50	51	53	53
	90th	102	103	104	104	105	106	107	60	61	61	62	63	64	65
	95th	106	106	107	108	109	110	110	64	65	65	66	67	68	69
	95th + 12 mm Hg	118	118	119	120	121	122	122	76	77	77	78	79	80	81
4	Height (in)	38.3	38.9	39.9	41.1	42.4	43.5	44.2	38.3	38.9	39.9	41.1	42.4	43.5	44.2
	Height (cm)	97.2	98.8	101.4	104.5	107.6	110.5	112.2	97.2	98.8	101.4	104.5	107.6	110.5	112.2
	50th	89	90	91	92	93	94	94	50	51	51	53	54	55	55
	90th	103	104	105	106	107	108	108	62	63	64	65	66	67	67
	95th	107	108	109	109	110	111	112	66	67	68	69	70	70	71
	95th + 12 mm Hg	119	120	121	121	122	123	124	78	79	80	81	82	82	83
5	Height (in)	40.8	41.5	42.6	43.9	45.2	46.5	47.3	40.8	41.5	42.6	43.9	45.2	46.5	47.3
	Height (cm)	103.6	105.3	108.2	111.5	114.9	118.1	120	103.6	105.3	108.2	111.5	114.9	118.1	120
	50th	90	91	92	93	94	95	96	52	52	53	55	56	57	57
	90th	104	105	106	107	108	109	110	64	65	66	67	68	69	70
	95th	108	109	109	110	111	112	113	68	69	70	71	72	73	73
	95th + 12 mm Hg	120	121	121	122	123	124	125	80	81	82	83	84	85	85
6	Height (in)	43.3	44	45.2	46.6	48.1	49.4	50.3	43.3	44	45.2	46.6	48.1	49.4	50.3
	Height (cm)	110	111.8	114.9	118.4	122.1	125.6	127.7	110	111.8	114.9	118.4	122.1	125.6	127.7
	50th	92	92	93	94	96	97	97	54	54	55	56	57	58	59
	90th	105	106	107	108	109	110	111	67	67	68	69	70	71	71
	95th	109	109	110	111	112	113	114	70	71	72	72	73	74	74
	95th + 12 mm Hg	121	121	122	123	124	125	126	82	83	84	84	85	86	86
7	Height (in)	45.6	46.4	47.7	49.2	50.7	52.1	53	45.6	46.4	47.7	49.2	50.7	52.1	53
	Height (cm)	115.9	117.8	121.1	124.9	128.8	132.5	134.7	115.9	117.8	121.1	124.9	128.8	132.5	134.7
	50th	92	93	94	95	97	98	99	55	55	56	57	58	59	60
	90th	106	106	107	109	110	111	112	68	68	69	70	71	72	72
	95th	109	110	111	112	113	114	115	72	72	73	73	74	74	75
	95th + 12 mm Hg	121	122	123	124	125	126	127	84	84	85	85	86	86	87

TABLE 5 Continued

Age (y)	BP Percentile	SBP (mm Hg)							DBP (mm Hg)						
		Height Percentile or Measured Height							Height Percentile or Measured Height						
		5%	10%	25%	50%	75%	90%	95%	5%	10%	25%	50%	75%	90%	95%
8	Height (in)	47.6	48.4	49.8	51.4	53	54.5	55.5	47.6	48.4	49.8	51.4	53	54.5	55.5
	Height (cm)	121	123	126.5	130.6	134.7	138.5	140.9	121	123	126.5	130.6	134.7	138.5	140.9
	50th	93	94	95	97	98	99	100	56	56	57	59	60	61	61
	90th	107	107	108	110	111	112	113	69	70	71	72	72	73	73
	95th	110	111	112	113	115	116	117	72	73	74	74	75	75	75
	95th + 12 mm Hg	122	123	124	125	127	128	129	84	85	86	86	87	87	87
9	Height (in)	49.3	50.2	51.7	53.4	55.1	56.7	57.7	49.3	50.2	51.7	53.4	55.1	56.7	57.7
	Height (cm)	125.3	127.6	131.3	135.6	140.1	144.1	146.6	125.3	127.6	131.3	135.6	140.1	144.1	146.6
	50th	95	95	97	98	99	100	101	57	58	59	60	60	61	61
	90th	108	108	109	111	112	113	114	71	71	72	73	73	73	73
	95th	112	112	113	114	116	117	118	74	74	75	75	75	75	75
	95th + 12 mm Hg	124	124	125	126	128	129	130	86	86	87	87	87	87	87
10	Height (in)	51.1	52	53.7	55.5	57.4	59.1	60.2	51.1	52	53.7	55.5	57.4	59.1	60.2
	Height (cm)	129.7	132.2	136.3	141	145.8	150.2	152.8	129.7	132.2	136.3	141	145.8	150.2	152.8
	50th	96	97	98	99	101	102	103	58	59	59	60	61	61	62
	90th	109	110	111	112	113	115	116	72	73	73	73	73	73	73
	95th	113	114	114	116	117	119	120	75	75	76	76	76	76	76
	95th + 12 mm Hg	125	126	126	128	129	131	132	87	87	88	88	88	88	88
11	Height (in)	53.4	54.5	56.2	58.2	60.2	61.9	63	53.4	54.5	56.2	58.2	60.2	61.9	63
	Height (cm)	135.6	138.3	142.8	147.8	152.8	157.3	160	135.6	138.3	142.8	147.8	152.8	157.3	160
	50th	98	99	101	102	104	105	106	60	60	60	61	62	63	64
	90th	111	112	113	114	116	118	120	74	74	74	74	74	75	75
	95th	115	116	117	118	120	123	124	76	77	77	77	77	77	77
	95th + 12 mm Hg	127	128	129	130	132	135	136	88	89	89	89	89	89	89
12	Height (in)	56.2	57.3	59	60.9	62.8	64.5	65.5	56.2	57.3	59	60.9	62.8	64.5	65.5
	Height (cm)	142.8	145.5	149.9	154.8	159.6	163.8	166.4	142.8	145.5	149.9	154.8	159.6	163.8	166.4
	50th	102	102	104	105	107	108	108	61	61	61	62	64	65	65
	90th	114	115	116	118	120	122	122	75	75	75	75	76	76	76
	95th	118	119	120	122	124	125	126	78	78	78	78	79	79	79
	95th + 12 mm Hg	130	131	132	134	136	137	138	90	90	90	90	91	91	91
13	Height (in)	58.3	59.3	60.9	62.7	64.5	66.1	67	58.3	59.3	60.9	62.7	64.5	66.1	67
	Height (cm)	148.1	150.6	154.7	159.2	163.7	167.8	170.2	148.1	150.6	154.7	159.2	163.7	167.8	170.2
	50th	104	105	106	107	108	108	109	62	62	63	64	65	65	66
	90th	116	117	119	121	122	123	123	75	75	75	76	76	76	76
	95th	121	122	123	124	126	126	127	79	79	79	79	80	80	81
	95th + 12 mm Hg	133	134	135	136	138	138	139	91	91	91	91	92	92	93
14	Height (in)	59.3	60.2	61.8	63.5	65.2	66.8	67.7	59.3	60.2	61.8	63.5	65.2	66.8	67.7
	Height (cm)	150.6	153	156.9	161.3	165.7	169.7	172.1	150.6	153	156.9	161.3	165.7	169.7	172.1
	50th	105	106	107	108	109	109	109	63	63	64	65	66	66	66
	90th	118	118	120	122	123	123	123	76	76	76	76	77	77	77
	95th	123	123	124	125	126	127	127	80	80	80	80	81	81	82
	95th + 12 mm Hg	135	135	136	137	138	139	139	92	92	92	92	93	93	94

TABLE 5 Continued

Age (y)	BP Percentile	SBP (mm Hg)							DBP (mm Hg)						
		Height Percentile or Measured Height							Height Percentile or Measured Height						
		5%	10%	25%	50%	75%	90%	95%	5%	10%	25%	50%	75%	90%	95%
15	Height (in)	59.7	60.6	62.2	63.9	65.6	67.2	68.1	59.7	60.6	62.2	63.9	65.6	67.2	68.1
	Height (cm)	151.7	154	157.9	162.3	166.7	170.6	173	151.7	154	157.9	162.3	166.7	170.6	173
	50th	105	106	107	108	109	109	109	64	64	64	65	66	67	67
	90th	118	119	121	122	123	123	124	76	76	76	77	77	78	78
	95th	124	124	125	126	127	127	128	80	80	80	81	82	82	82
	95th + 12 mm Hg	136	136	137	138	139	139	140	92	92	92	93	94	94	94
16	Height (in)	59.9	60.8	62.4	64.1	65.8	67.3	68.3	59.9	60.8	62.4	64.1	65.8	67.3	68.3
	Height (cm)	152.1	154.5	158.4	162.8	167.1	171.1	173.4	152.1	154.5	158.4	162.8	167.1	171.1	173.4
	50th	106	107	108	109	109	110	110	64	64	65	66	66	67	67
	90th	119	120	122	123	124	124	124	76	76	76	77	78	78	78
	95th	124	125	125	127	127	128	128	80	80	80	81	82	82	82
	95th + 12 mm Hg	136	137	137	139	139	140	140	92	92	92	93	94	94	94
17	Height (in)	60.0	60.9	62.5	64.2	65.9	67.4	68.4	60.0	60.9	62.5	64.2	65.9	67.4	68.4
	Height (cm)	152.4	154.7	158.7	163.0	167.4	171.3	173.7	152.4	154.7	158.7	163.0	167.4	171.3	173.7
	50th	107	108	109	110	110	110	111	64	64	65	66	66	66	67
	90th	120	121	123	124	124	125	125	76	76	77	77	78	78	78
	95th	125	125	126	127	128	128	128	80	80	80	81	82	82	82
	95th + 12 mm Hg	137	137	138	139	140	140	140	92	92	92	93	94	94	94

Use percentile values to stage BP readings according to the scheme in Table 3 (elevated BP: ≥90th percentile; stage 1 HTN: ≥95th percentile; and stage 2 HTN: ≥95th percentile + 12 mm Hg). The 50th, 90th, and 95th percentiles were derived by using quantile regression on the basis of normal-weight children (BMI <85th percentile).[77]

The initial BP measurement may be oscillometric (on a calibrated machine that has been validated for use in the pediatric population) or auscultatory (by using a mercury or aneroid sphygmomanometer[86,87]). (Validation status for oscillometric BP devices, including whether they are validated in the pediatric age group, can be checked at www.dableducational.org.) BP should be measured in the right arm by using standard measurement practices unless the child has atypical aortic arch anatomy, such as right aortic arch and aortic coarctation or left aortic arch with aberrant right subclavian artery (see Table 7). Other important aspects of proper BP measurement are illustrated in an AAP video available at http://youtu.be/JLzkNBpqwi0. Care should be taken that providers follow an accurate and consistent measurement technique.[88,89]

An appropriately sized cuff should be used for accurate BP measurement.[83] Researchers in 3 studies in the United Kingdom and 1 in Brazil documented the lack of availability of an appropriately sized cuff in both the inpatient and outpatient settings.[91–94] Pediatric offices should have access to a wide range of cuff sizes, including a thigh cuff for use in children and adolescents with severe obesity. For children in whom the appropriate cuff size is difficult to determine, the midarm circumference (measured as the midpoint between the acromion of the scapula and olecranon of the elbow, with the shoulder in a neutral position and the elbow flexed to 90°[86,95,96]) should be obtained for an accurate determination of the correct cuff size (see Fig 2 and Table 7).[95]

If the initial BP is elevated (≥90th percentile), providers should perform 2 additional oscillometric or auscultatory BP measurements at the same visit and average them. If using auscultation, this averaged measurement is used to determine the child's BP category (ie, normal,

TABLE 6 Screening BP Values Requiring Further Evaluation

Age, y	BP, mm Hg			
	Boys		Girls	
	Systolic	DBP	Systolic	DBP
1	98	52	98	54
2	100	55	101	58
3	101	58	102	60
4	102	60	103	62
5	103	63	104	64
6	105	66	105	67
7	106	68	106	68
8	107	69	107	69
9	107	70	108	71
10	108	72	109	72
11	110	74	111	74
12	113	75	114	75
≥13	120	80	120	80

elevated BP, stage 1 HTN, or stage 2 HTN). If the averaged oscillometric reading is ≥90th percentile, 2 auscultatory measurements should be taken and averaged to define the BP category (see Fig 3).

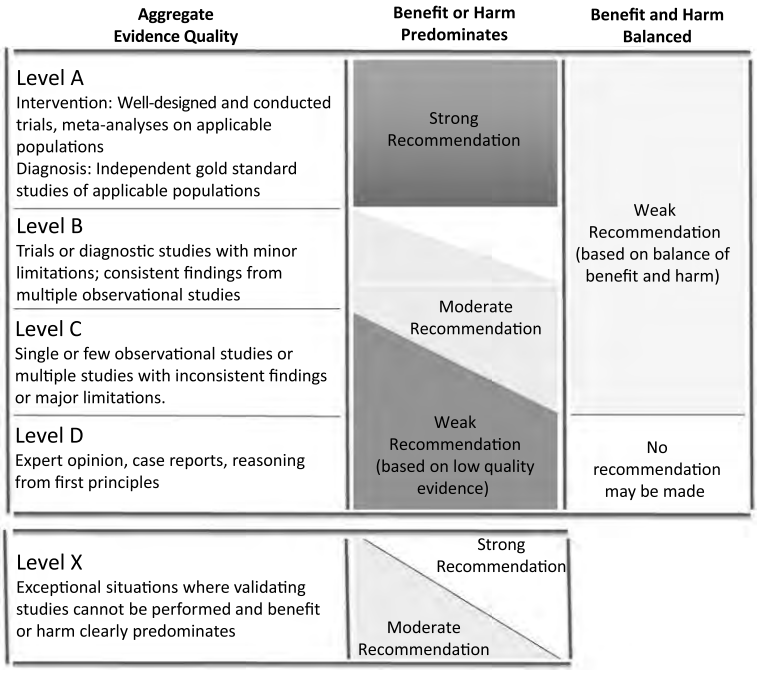


FIGURE 1
AAP grading matrix.

4.1a Measurement of BP in the Neonate

Multiple methods are available for the measurement of BP in hospitalized neonates, including direct intra-arterial measurements using indwelling catheters as well as indirect measurements using the oscillometric technique. In the office, however, the oscillometric technique typically is used at least until the infant is able to cooperate with manual BP determination (which also depends on the ability of the individual measuring the BP to obtain auscultatory BP in infants and toddlers). Normative values for neonatal and infant BP have generally been determined in the right upper arm with the infant supine, and a similar approach should be followed in the outpatient setting.

As with older children, proper cuff size is important in obtaining accurate BP readings in neonates. The cuff bladder length should encircle 80% to 100% of the arm circumference; a cuff bladder with a width-to-arm circumference ratio of 0.45 to 0.55 is recommended.[79,97,98] Offices that will be obtaining BP measurements in neonates need to have a variety of cuff sizes available. In addition, the oscillometric device used should be validated in neonates and programmed to have an initial inflation value appropriate for infants (generally ≤120 mm Hg). Auscultation becomes technically feasible once the infant's upper arm is large enough for the smallest cuff available for auscultatory devices. Measurements are best taken when the infant is in a calm state; multiple readings may be needed if the first

TABLE 7 Best BP Measurement Practices

1. The child should be seated in a quiet room for 3–5 min before measurement, with the back supported and feet uncrossed on the floor.
2. BP should be measured in the right arm for consistency, for comparison with standard tables, and to avoid a falsely low reading from the left arm in the case of coarctation of the aorta. The arm should be at heart level,[90] supported, and uncovered above the cuff. The patient and observer should not speak while the measurement is being taken.
3. The correct cuff size should be used. The bladder length should be 80%–100% of the circumference of the arm, and the width should be at least 40%.
4. For an auscultatory BP, the bell of the stethoscope should be placed over the brachial artery in the antecubital fossa, and the lower end of the cuff should be 2–3 cm above the antecubital fossa. The cuff should be inflated to 20–30 mm Hg above the point at which the radial pulse disappears. Overinflation should be avoided. The cuff should be deflated at a rate of 2–3 mm Hg per second. The first (phase I Korotkoff) and last (phase V Korotkoff) audible sounds should be taken as SBP and DBP. If the Korotkoff sounds are heard to 0 mm Hg, the point at which the sound is muffled (phase IV Korotkoff) should be taken as the DBP, or the measurement repeated with less pressure applied over the brachial artery. The measurement should be read to the nearest 2 mm Hg.
5. To measure BP in the legs, the patient should be in the prone position, if possible. An appropriately sized cuff should be placed midthigh and the stethoscope placed over the popliteal artery. The SBP in the legs is usually 10%–20% higher than the brachial artery pressure.

Adapted from Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Circulation*. 2005;111(5):697–716.

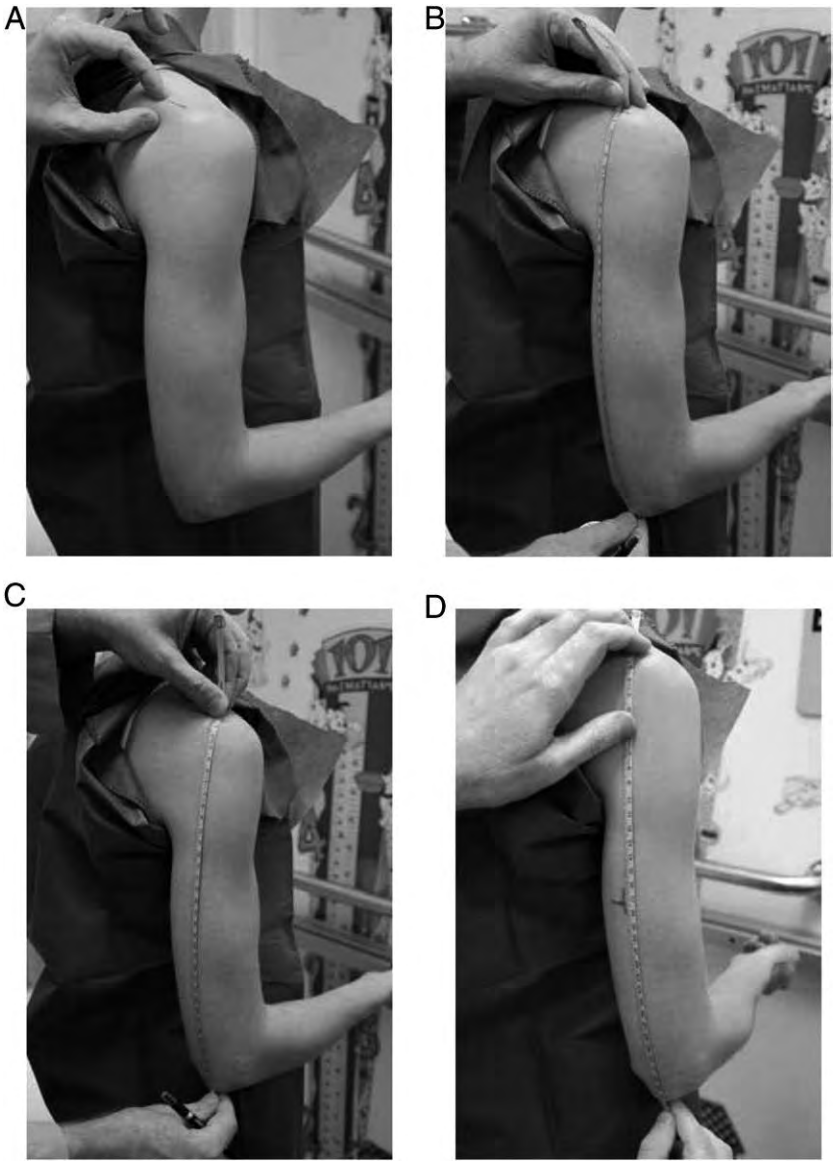


FIGURE 2
Determination of proper BP cuff size.[95] A, Marking spine extending from acromion process. B, Correct tape placement for upper arm length. C, Incorrect tape placement for upper arm length. D, Marking upper arm length midpoint.

reading is elevated, similar to the technique recommended for older children.[99,100]

4.2 BP Measurement Frequency

It remains unclear what age is optimal to begin routine BP measurement in children, although available data suggest that prevention and intervention efforts should begin at a young age.[10,60,101–106] The subcommittee believes that the recommendation to measure BP in the ambulatory setting beginning at 3 years of age should remain unchanged.[1] For otherwise healthy children, however, BP need only be measured annually rather than during every health care encounter.

Some children should have BP measured at every health encounter, specifically those with obesity (BMI ≥95 percentile),[5,27,107–109] renal disease,[46] diabetes,[110,111] aortic arch obstruction or coarctation, or those who are taking medications known to increase BP (see Table 8 and the "Secondary Causes: Medication-related" section of this guideline).[112,113]

Children younger than 3 years should have BP measurements taken at well-child care visits if they are at increased risk for developing HTN (see Table 9).[1]

Key Action Statement 1

BP should be measured annually in children and adolescents ≥3 years of age (grade C, moderate recommendation).

Key Action Statement 2

BP should be checked in all children and adolescents ≥3 years of age at every health care encounter if they have obesity, are taking medications known to increase BP, have renal disease, a history of aortic arch obstruction or coarctation, or diabetes (see Table 9) (grade C, moderate recommendation).

4.3 Patient Management on the Basis of Office BP

4.3a Normal BP

If BP is normal or normalizes after repeat readings (ie, BP <90th percentile), then no additional action is needed. Practitioners should measure the BP at the next routine well-child care visit.

4.3b Elevated BP

1. If the BP reading is at the elevated BP level (Table 3), lifestyle interventions should be recommended (ie, healthy diet, sleep, and physical activity); the measurement should be repeated in 6 months by auscultation. Nutrition and/or weight management referral should be considered as appropriate;
2. If BP remains at the elevated BP level after 6 months, upper and lower extremity BP should be checked (right arm, left arm, and 1 leg), lifestyle counseling should be repeated, and BP should be

Key Action Statement 1. BP should be measured annually in children and adolescents ≥3 years of age (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Early detection of asymptomatic HTN; prevention of short- and long-term HTN-related morbidity
Risks, harm, cost	Overtesting, misclassification, unnecessary treatment, discomfort from BP measurement procedure, time involved in measuring BP
Benefit–harm assessment	Benefit of annual BP measurement exceeds potential harm
Intentional vagueness	None
Role of patient preferences	Increased visit time, discomfort of cuff
Exclusions	None
Strength	Moderate recommendation
Key references	10,60,102,103

Key Action Statement 2. BP should be checked in all children and adolescents ≥3 years of age at every health care encounter if they have obesity, are taking medications known to increase BP, have renal disease, a history of aortic arch obstruction or coarctation, or diabetes (see Table 9) (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Early detection of HTN and prevention of CV morbidity in predisposed children and adolescents
Risks, harm, cost	Time for and difficulty of conducting measurements
Benefit–harm assessment	Benefits exceed harm
Intentional vagueness	Frequency of evaluation
Role of patient preferences	Increased visit time, discomfort of cuff
Exclusions	Children and adolescents who are not at increased risk for HTN
Strength	Moderate recommendation
Key references	27,46,107,110–112

rechecked in 6 months (ie, at the next well-child care visit) by auscultation;

3. If BP continues at the elevated BP level after 12 months (eg, after 3 auscultatory measurements), ABPM should be ordered (if available), and diagnostic evaluation should be conducted (see Table 10 for a list of screening tests and the populations in which they should be performed). Consider subspecialty referral (ie, cardiology or nephrology) (see Table 11); and
4. If BP normalizes at any point, return to annual BP screening at well-child care visits.

4.3c Stage 1 HTN

1. If the BP reading is at the stage 1 HTN level (Table 3) and the patient is asymptomatic, provide lifestyle counseling and recheck the BP in 1 to 2 weeks by auscultation;
2. If the BP reading is still at the stage 1 level, upper and lower extremity BP should be checked (right arm, left arm, and 1 leg), and BP should be rechecked in 3 months by auscultation. Nutrition and/or weight management referral should be considered as appropriate; and
3. If BP continues to be at the stage 1 HTN level after 3 visits, ABPM should be ordered (if available), diagnostic evaluation should be conducted, and treatment should be initiated. Subspecialty referral should be considered (see Table 11).

4.3d Stage 2 HTN

1. If the BP reading is at the stage 2 HTN level (Table 3), upper and lower extremity BP should be checked (right arm, left arm, and 1 leg), lifestyle recommendations given, and the BP measurement should be repeated within 1 week. Alternatively, the patient could be referred to subspecialty care within 1 week;
2. If the BP reading is still at the stage 2 HTN level when repeated, then diagnostic evaluation, including ABPM, should be conducted and treatment should be initiated, or the patient should

TABLE 8 Common Pharmacologic Agents Associated With Elevated BP in Children

Over-the-counter drugs	Decongestants
	Caffeine
	Nonsteroidal anti-inflammatory drugs
	Alternative therapies, herbal and nutritional supplements
Prescription drugs	Stimulants for attention-deficit/hyperactivity disorder
	Hormonal contraception
	Steroids
	Tricyclic antidepressants
Illicit drugs	Amphetamines
	Cocaine

Adapted from the Fourth Report.[1]

TABLE 9 Conditions Under Which Children Younger Than 3 Years Should Have BP Measured

History of prematurity <32 week's gestation or small for gestational age, very low birth weight, other neonatal complications requiring intensive care, umbilical artery line
Congenital heart disease (repaired or unrepaired)
Recurrent urinary tract infections, hematuria, or proteinuria
Known renal disease or urologic malformations
Family history of congenital renal disease
Solid-organ transplant
Malignancy or bone marrow transplant
Treatment with drugs known to raise BP
Other systemic illnesses associated with HTN (neurofibromatosis, tuberous sclerosis, sickle cell disease,[114] etc)
Evidence of elevated intracranial pressure

Adapted from Table 3 in the Fourth Report.[1]

Key Action Statement 3. Trained health care professionals in the office setting should make a diagnosis of HTN if a child or adolescent has auscultatory-confirmed BP readings ≥95th percentile on 3 different visits (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Early detection of HTN; prevention of CV morbidity in predisposed children and adolescents; identification of secondary causes of HTN
Risks, harm, cost	Overtesting, misclassification, unnecessary treatment, discomfort from BP measurement, time involved in taking BP
Benefit–harm assessment	Benefits of repeated BP measurement exceeds potential harm
Intentional vagueness	None
Role of patient preferences	Families may have varying levels of concern about elevated BP readings and may request evaluation on a different time line
Exclusions	None
Strength	Moderate recommendation
Key references	8,84,85

be referred to subspecialty care within 1 week (see Table 11); and

3. If the BP reading is at the stage 2 HTN level and the patient is symptomatic, or the BP is >30 mm Hg above the 95th percentile (or >180/120 mm Hg in an adolescent), refer to an immediate source of care, such as an emergency department (ED).

Key Action Statement 3

Trained health care professionals in the office setting should make a diagnosis of HTN if a child or adolescent has auscultatory-confirmed BP readings ≥95th percentile on 3 different visits (grade C, moderate recommendation).

4.4 Use of Electronic Health Records

Studies have demonstrated that primary care providers frequently fail to measure BP and often underdiagnose HTN.[85,115,116] One analysis using nationally representative survey data found that providers measured BP at only 67% of preventive visits for children 3 to 18 years of age. Older children and children with overweight or obesity were more likely to be screened.[117] In a large cohort study of 14 187 children, 507 patients met the criteria for HTN, but only 131 (26%) had the diagnosis documented in their electronic health records (EHRs). Elevated BP was only recognized in 11% of cases.[7]

It is likely that the low rates of screening and diagnosis of pediatric HTN are related, at least in part, to the need to use detailed reference tables incorporating age, sex, and height to classify BP levels.[118] Studies have shown that using health information technology can increase adherence to clinical guidelines and improve practitioner performance.[119–121] In fact, applying decision support in conjunction with an EHR in adult populations has also been associated with improved BP screening, recognition, medication prescribing, and control; pediatric data are limited, however.[122–125] Some studies failed to show improvement in BP screening or control,[122,126] but given the inherent complexity in the interpretation of pediatric BP measurements, EHRs should be designed to flag abnormal values both at the time of measurement and on entry into the EHR.

Key Action Statement 4. Organizations with EHRs used in an office setting should consider including flags for abnormal BP values both when the values are being entered and when they are being viewed (grade C, weak recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Improved rate of screening and recognition of elevated BP
Risks, harm, cost	Cost of EHR development, alert fatigue
Benefit–harm assessment	Benefit of EHR flagging of elevated BP outweighs harm from development cost and potential for alert fatigue
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Weak recommendation (because of a lack of pediatric data)
Key references	7,117,120,125

Key Action Statement 4

Organizations with EHRs used in an office setting should consider including flags for abnormal BP values both when the values are being entered and when they are being viewed (grade C, weak recommendation).

4.5 Oscillometric Versus Auscultatory (Manual) BP Measurement

Although pediatric normative BP data are based on auscultatory measurements, oscillometric BP devices have become commonplace in health care settings.[127] Ease of use, a lack of digit preference, and automation are all perceived benefits of using oscillometric devices. Unlike auscultatory measurement, however, oscillometric devices measure the oscillations transmitted from disrupted arterial flow by using the cuff as a transducer to determine mean arterial pressure (MAP). Rather than directly measuring any pressure that correlates to SBP or DBP, the device uses a proprietary algorithm to calculate these values from the directly measured MAP.[127] Because the algorithms vary for different brands of oscillometric devices, there is no standard oscillometric BP.[128]

Researchers in several studies have evaluated the accuracy of oscillometric devices[127,129–134] and compared auscultatory and

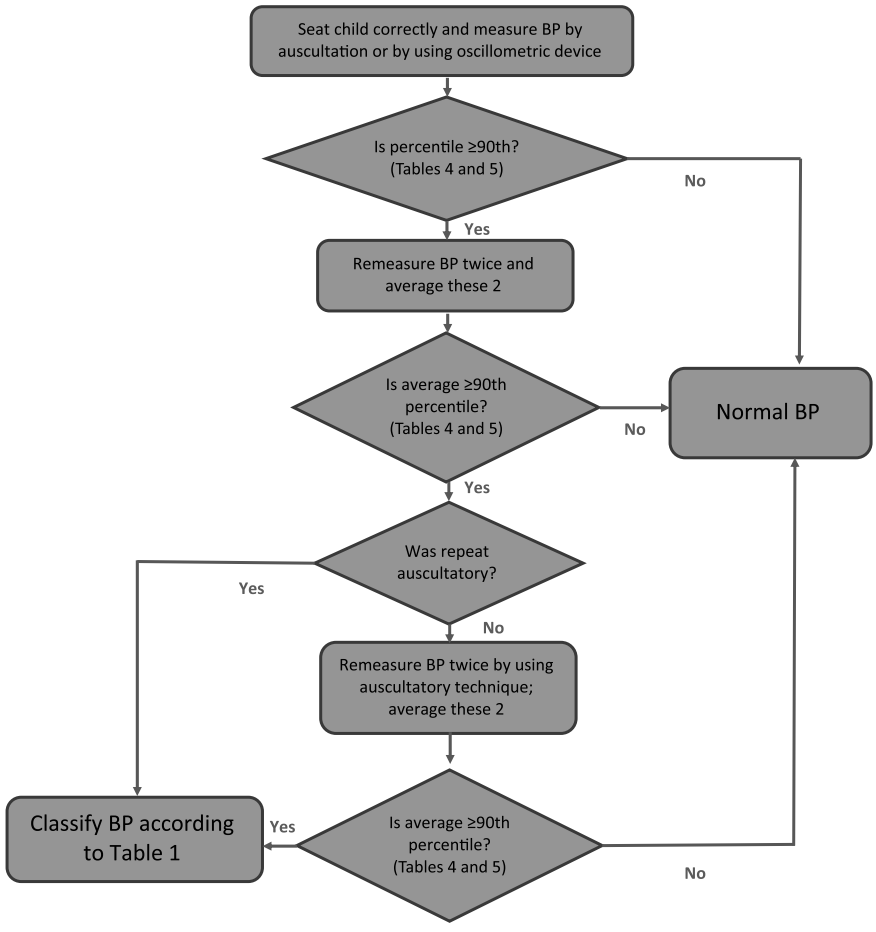


FIGURE 3
Modified BP measurement algorithm.

oscillometric readings' ability to predict target organ damage.[135] These studies demonstrated that oscillometric devices systematically overestimate SBP and DBP compared with values obtained by auscultation.[129,133] BP status potentially can be misclassified because of the different values obtained by these 2 methods, which may be magnified in the office setting.[86,88,129] Target organ damage (such as increased LV mass and elevated PWV) was best predicted by BPs obtained by auscultation.[135]

A major issue with oscillometric devices is that there appears to be great within-visit variation with inaccurately high readings obtained on initial measurement.[136] An elevated initial oscillometric reading should be ignored and repeat measures averaged to approximate values obtained by auscultation.

TABLE 10 Screening Tests and Relevant Populations

Patient Population	Screening Tests
All patients	Urinalysis
	Chemistry panel, including electrolytes, blood urea nitrogen, and creatinine
	Lipid profile (fasting or nonfasting to include high-density lipoproteina and total cholesterol)
	Renal ultrasonography in those <6 y of age or those with abnormal urinalysis or renal function
In the obese (BMI >95th percentile) child or adolescent, in addition to the above	Hemoglobin A1c (accepted screen for diabetes)
	Aspartate transaminase and alanine transaminase (screen for fatty liver)
	Fasting lipid panel (screen for dyslipidemia)
Optional tests to be obtained on the basis of history, physical examination, and initial studies	Fasting serum glucose for those at high risk for diabetes mellitus
	Thyroid-stimulating hormone
	Drug screen
	Sleep study (if loud snoring, daytime sleepiness, or reported history of apnea)
	Complete blood count, especially in those with growth delay or abnormal renal function

Adapted from Wiesen J, Adkins M, Fortune S, et al. Evaluation of pediatric patients with mild-to-moderate hypertension: yield of diagnostic testing. *Pediatrics*. 2008;122(5). Available at: www.pediatrics.org/cgi/content/full/122/5/e988.

Key Action Statement 5
Oscillometric devices may be used for BP screening in children

TABLE 11 Patient Evaluation and Management According to BP Level

BP Category (See Table 3)	BP Screening Schedule	Lifestyle Counseling (Weight and Nutrition)	Check Upper and Lower Extremity BP	ABPM[a]	Diagnostic Evaluation[b]	Initiate Treatment[c]	Consider Subspecialty Referral
Normal	Annual	X	—	—	—	—	—
Elevated BP	Initial measurement	X	—	—	—	—	—
	Second measurement: repeat in 6 mo	X	X	—	—	—	—
	Third measurement: repeat in 6 mo	X	—	X	X	—	X
Stage 1 HTN	Initial measurement	X	—	—	—	—	—
	Second measurement: repeat in 1–2 wk	X	X	—	—	—	—
	Third measurement: repeat in 3 mo	X	—	X	X	X	X
Stage 2 HTN[d]	Initial measurement	X	X	—	—	—	—
	Second measurement: repeat, refer to specialty care within 1 wk	X	—	X	X	X	X

X, recommended intervention; —, not applicable.
[a] ABPM is done to confirm HTN before initiating a diagnostic evaluation.
[b] See Table 15 for recommended studies.
[c] Treatment may be initiated by a primary care provider or subspecialist.
[d] If the patient is symptomatic or BP is >30 mm Hg above the 95th percentile (or >180/120 mm Hg in an adolescent), send to an ED.

and adolescents. When doing so, providers should use a device that has been validated in the pediatric age group. If elevated BP is suspected on the basis of oscillometric readings, confirmatory measurements should be obtained by auscultation (grade B, strong recommendation).

4.6 Forearm and/or Wrist BP Measurement

Wrist monitors have several potential advantages when compared with arm devices. They are smaller; they can be placed more easily; and, because wrist diameter is less affected by BMI, they do not need to be modified for patients with obesity.[83,137] Several studies in adults have found excellent reproducibility of wrist BP measurements, equivalence to readings obtained by mercury sphygmomanometers or ABPM, and better correlation with left ventricular mass index (LVMI) than systolic office BP.[138,139]

Although many wrist devices have been validated in adults,[140–142] some studies have shown greater variation and decreased accuracy in the resulting measurements.[143–146] These negative outcomes may possibly result from differences in the number of measurements taken,[139] the position of the wrist in relation to the heart,[147] flexion or extension of the wrist during measurement,[148] or differences in pulse pressure.[149] Technologies are being developed to help standardize wrist position.[150,151]

Few studies using wrist monitors have been conducted in children. One study in adolescents compared a wrist digital monitor with a mercury sphygmomanometer and found high agreement between systolic measurements but lower agreement for diastolic measurements, which was clinically relevant.[152] Researchers in 2 small studies conducted in PICUs compared wrist monitors with indwelling arterial lines and found good agreement between the 2 measurement modalities.[153,154] No large comparative studies or formal validation studies of wrist monitors have been conducted in children, however. Because of limited data, the use of wrist and forearm monitors is not recommended in the diagnosis or

Key Action Statement 5. Oscillometric devices may be used for BP screening in children and adolescents. When doing so, providers should use a device that has been validated in the pediatric age group. If elevated BP is suspected on the basis of oscillometric readings, confirmatory measurements should be obtained by auscultation (grade B, strong recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Use of auscultatory readings prevents potential misclassification of patients as hypertensive because of inaccuracy of oscillometric devices
Risks, harm, cost	Auscultation requires more training and experience and has flaws such as digit preference
Benefit–harm assessment	Benefit exceeds harm
Intentional vagueness	None
Role of patient preferences	Patients may prefer the convenience of oscillometric monitors
Exclusions	None
Strength	Strong recommendation
Key references	86,88,128–136

TABLE 12 High-Risk Conditions for Which ABPM May Be Useful

Condition	Rationale
Secondary HTN	Severe ambulatory HTN or nocturnal HTN indicates higher likelihood of secondary HTN[161,167]
CKD or structural renal abnormalities	Evaluate for MH or nocturnal HTN,[168–172] better control delays progression of renal disease[173]
T1DM and T2DM	Evaluate for abnormal ABPM patterns,[174,175] better BP control delays the development of MA[176–178]
Solid-organ transplant	Evaluate for MH or nocturnal HTN, better control BP[179–188]
Obesity	Evaluate for WCH and MH[23,189–192]
OSAS	Evaluate for nondipping and accentuated morning BP surge[43,46,193,194]
Aortic coarctation (repaired)	Evaluate for sustained HTN and MH[58,112,113]
Genetic syndromes associated with HTN (neurofibromatosis, Turner syndrome, Williams syndrome, coarctation of the aorta)	HTN associated with increased arterial stiffness may only be manifest with activity during ABPM[58,195]
Treated hypertensive patients	Confirm 24-h BP control[155]
Patient born prematurely	Evaluate for nondipping[196]
Research, clinical trials	To reduce sample size[197]

TABLE 13 Recommended Procedures for the Application of ABPM

Procedure	Recommendation
Device	Should be validated by the Association for the Advancement of Medical Instrumentation or the British Hypertension Society for use in children
	May be oscillometric or auscultatory
Application	Trained personnel should apply the monitor
	Correct cuff size should be selected
	Right and left arm and a lower extremity BP should be obtained to rule out coarctation of the aorta
	Use nondominant arm unless there is large difference in size between the left arm and right arm, then apply to the arm with the higher BP
	Take readings every 15–20 min during the day and every 20–30 min at night
	Compare (calibrate) the device to resting BP measured by the same technique (oscillometric or auscultatory)
	Record time of medications, activity, and sleep
Assessment	A physician who is familiar with pediatric ABPM should interpret the results
	Interpret only recordings of adequate quality. Minimum of 1 reading per hour, 40–50 for a full day, 65%–75% of all possible recordings
	Edit outliers by inspecting for biologic plausibility, edit out calibration measures
	Calculate mean BP, BP load (% of readings above threshold), and dipping (% decline in BP from wake to sleep)
	Interpret with pediatric ABPM normal data by sex and height
	Use AHA staging schema[155]
	Consider interpretation of 24-h, daytime, and nighttime MAP, especially in patients with CKD[173,198]

Adapted from Flynn JT, Daniels SR, Hayman LL, et al; American Heart Association Atherosclerosis, Hypertension and Obesity in Youth Committee of the Council on Cardiovascular Disease in the Young. Update: ambulatory blood pressure monitoring in children and adolescents: a scientific statement from the American Heart Association. *Hypertension*. 2014;63(5):1116–1135.

management of HTN in children and adolescents at this time.

4.7 ABPM

An ambulatory BP monitor consists of a BP cuff attached to a box slightly larger than a cell phone, which records BP periodically (usually every 20–30 minutes) throughout the day and night; these data are later downloaded to a computer for analysis.[155]

ABPM has been recommended by the US Preventive Services Task Force for the confirmation of HTN in adults before starting treatment.[156] Although a growing number of pediatric providers have access to ABPM, there are still gaps in access and knowledge regarding the optimal application of ABPM to the evaluation of children's BP.[155,157] For example, there are currently no reference data for children whose height is <120 cm. Because no outcome data exist linking ABPM data from childhood to hard CV events in adulthood, recommendations either rely largely on surrogate outcome markers or are extrapolated from adult studies.

However, sufficient data exist to demonstrate that ABPM is more accurate for the diagnosis of HTN than clinic-measured BP,[158,159] is more predictive of future BP,[160] and can assist in the detection of secondary HTN.[161] Furthermore, increased LVMI and LVH correlate more strongly with ABPM parameters than casual BP.[162–166] In addition, ABPM is more reproducible than casual or home BP measurements.[159] For these reasons, the routine application of ABPM is recommended, when available, as indicated below (see also Tables 12 and 13). Obtaining ABPM may require referral to a specialist.

Key Action Statement 6

ABPM should be performed for the confirmation of HTN in children

and adolescents with office BP measurements in the elevated BP category for 1 year or more or with stage 1 HTN over 3 clinic visits (grade C, moderate recommendation).

For technical reasons, ABPM may need to be limited to children ≥5 years of age who can tolerate the procedure and those for whom reference data are available.

Key Action Statement 7

The routine performance of ABPM should be strongly considered in children and adolescents with high-risk conditions (see Table 12) to assess HTN severity and determine if abnormal circadian BP patterns are present, which may indicate increased risk for target organ damage (grade B, moderate recommendation).

Key Action Statement 8

ABPM should be performed by using a standardized approach (see Table 13) with monitors that have been validated in a pediatric population, and studies should be interpreted by using pediatric normative data (grade C, moderate recommendation).

4.7a Masked Hypertension

MH occurs when patients have normal office BP but elevated BP on ABPM, and it has been found in 5.8% of unselected children studied by ABPM.[199] There is growing evidence that compared with those with normal 24-hour BP, these patients have significant risk for end organ hypertensive damage.[200,203] Patients who are at risk of MH include patients with obesity and secondary forms of HTN, such as CKD or repaired aortic coarctation. MH is particularly prevalent in patients with CKD[48] and is associated with target organ damage.[203] Children with CKD should be periodically evaluated using ABPM for MH as part of routine CKD management.[201,204–206]

4.7b White Coat Hypertension

WCH is defined as BP ≥95th percentile in the office or clinical setting but <95th percentile outside of the office or clinical setting. WCH is diagnosed by ABPM when the mean SBP and DBP are <95th percentile and SBP and DBP load are <25%; load is defined as the percentage of valid ambulatory BP measurements above a set threshold value (eg, 95th percentile) for age, sex, and height.[155,156,206] It is estimated that up to half of children who are evaluated for elevated office BP have WCH.[207,208]

In adults, compared with normotension, WCH is associated with only a slightly increased risk of adverse outcomes but at a much lower risk compared with those with established HTN.[209] Most (but not all) studies suggest that WCH is not associated with increased LV mass.[200,207,210] Although the distinction between WCH and true HTN is important, abnormal BP response to exercise and increased LVM has been found to occur in children with WCH.[207] Furthermore, the identification of WCH may reduce costs by reducing the number of additional tests performed and decreasing the number of children who are exposed to antihypertensive medications.[208] Children and adolescents with WCH should have screening BP measured at regular well-child care visits with consideration of a repeat ABPM in 1 to 2 years.

Key Action Statement 9

Children and adolescents with suspected WCH should undergo ABPM. Diagnosis is based on the presence of mean SBP and DBP <95th percentile and SBP and DBP load <25% (grade B, strong recommendation).

4.8 Measurement in Children With Obesity

Accurate BP measurement can be challenging in individuals with obesity. [23,211,212] Elevated BMI in children and adolescents is associated with an increase in the midarm circumference,[96] requiring the use of a larger cuff to obtain accurate BP measurements.[83] During NHANES 2007–2010, among children 9 to 11 years of age with obesity, one-third of boys and one-quarter of girls required an adult BP cuff, and a fraction required a large adult cuff or an adult thigh cuff for an accurate measurement of BP.[213] Researchers in studies of adults have also noted the influence of the conical upper arm shape on BP measurements in people with obesity.[214,215] ABPM is a valuable tool in the diagnosis of HTN in children with obesity because of the discrepancies between casual and

Key Action Statement 6. ABPM should be performed for the confirmation of HTN in children and adolescents with office BP measurements in the elevated BP category for 1 year or more or with stage 1 HTN over 3 clinic visits (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Avoids unnecessarily exposing youth with WCH to extensive diagnostic testing or medication
Risks, harm, cost	Risk of discomfort to patient. Some insurance plans may not reimburse for the test
Benefit–harm assessment	The risk of ABPM is lower than the risk of unnecessary treatment. The use of ABPM has also been shown to be more cost-effective than other approaches to diagnosing HTN
Intentional vagueness	None
Role of patient preferences	Some patients may prefer repeat office or home measurements to ABPM
Exclusions	None
Strength	Moderate recommendation
Key references	23,155,158,159

Key Action Statement 7. The routine performance of ABPM should be strongly considered in children and adolescents with high-risk conditions (see Table 12) to assess HTN severity and determine if abnormal circadian BP patterns are present, which may indicate increased risk for target organ damage (grade B, moderate recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Improved 24-h control of BP improves outcomes. Recognition of MH or nocturnal HTN might lead to therapeutic changes that will limit end organ damage
Risks, harm, cost	Risk of discomfort to patient. Some insurance plans may not reimburse for the test. The risk of diagnosing and labeling a patient as having MH or nocturnal HTN might lead to increased anxiety and cost of evaluation
Benefit–harm assessment	The risk of ABPM is much lower than the risk of inadequate treatment
Intentional vagueness	Frequency at which normal or abnormal ABPM should be repeated is not known
Role of patient preferences	Some patients may prefer repeat office or home measurements to ABPM
Exclusions	None
Strength	Moderate recommendation
Key references	47,155,199–202

Key Action Statement 8. ABPM should be performed by using a standardized approach (see Table 13) with monitors that have been validated in a pediatric population, and studies should be interpreted by using pediatric normative data (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Validated monitors applied and interpreted correctly will provide the most accurate results
Risks, harm, cost	Risk of discomfort to patient. Some insurance plans may not reimburse for the test. Monitors validated in the pediatric population and expertise in reading pediatric ABPM may not be universally available
Benefit–harm assessment	There is substantial evidence showing incorrect application or interpretation reduces the accuracy of results
Intentional vagueness	None
Role of patient preferences	Some patients may prefer repeat office or home measurements to ABPM
Exclusions	None
Strength	Moderate recommendation
Key references	155

ambulatory BP[23,33] and the higher prevalence of MH.[26,29,155,216,217]

4.9. At-Home Measurement

Home measurement (or self-monitoring) of BP has advantages over both office and ambulatory monitoring, including convenience and the ability to obtain repeated measurements over time.[83,218] Furthermore, automated devices with memory capacity are straightforward to use and avoid potential problems, such as observer bias, inaccurate reporting, and terminal digit preference (ie, overreporting of certain digits, like 0, as the terminal digit in recording BP).[219,220]

Numerous studies have shown that it is feasible for families to conduct repeated measurements at home.[221–223] Home BP measurements appear to be more reproducible than those conducted in the office, likely because of the familiarity of the home environment and greater comfort with repeated measurements.[159,223,224] Inaccuracies occur when measurements obtained at home are either excluded or inappropriately recorded.[219] Inconsistencies in home, office, and ambulatory BP measurements seem to be influenced by both age and HTN status, with ABPM tending to be higher than home BP measurements in children.[222,225–227] Home BP measurements show no consistent pattern when compared with office measurements.[228–230]

There are several practical concerns with the use of home BP measurement, however. The only normative data available are from the relatively small Arsakeion School study.[231] In addition, only a few automated devices have been validated for use in the pediatric population, and available cuff sizes for them are limited. Furthermore, there is no consensus regarding how many home measurements across what period of time are needed to evaluate BP.

Key Action Statement 10

Home BP monitoring should not be used to diagnose HTN, MH, or WCH but may be a useful adjunct to office and ambulatory BP measurement after HTN has been diagnosed (grade C, moderate recommendation).

4.10 School Measurement and the Role of School-Based Health Professionals

There is limited evidence to support school-based measurement of children's BP.[8,232] Observational studies demonstrate that school measurements can be reliable[233] and that longitudinal follow-up is feasible.[8,232,234] Available data do not distinguish between the efficacy of school-based screening programs in which measurements are obtained by trained clinical personnel (not a school nurse) versus measurements obtained by the school nurse. Because of insufficient evidence and a lack of established protocols, the routine use of school-based measurements to diagnose HTN cannot be recommended. However, school-based BP measurement can be a useful tool to identify children who require formal evaluation as well as a helpful adjunct in the monitoring of diagnosed HTN. Note: School-based health clinics are considered part of

Key Action Statement 9. Children and adolescents with suspected WCH should undergo ABPM. Diagnosis is based on the presence of mean SBP and DBP <95th percentile and SBP and DBP load <25% (grade B, strong recommendation).

Aggregate Evidence Quality	Grade B (Evidence Level A in Adults)
Benefits	Improved diagnosis of WCH and the benefit of fewer additional laboratory tests and/or treatment of primary HTN. Costs might be reduced if the treatment of those misdiagnosed as hypertensive is prevented
Risks, harm, cost	Additional costs; costs may not be covered by insurance companies. The ambulatory BP monitor is uncomfortable for some patients
Benefit–harm assessment	Benefit exceeds risk
Intentional vagueness	None
Role of patient preferences	Important; some patients may not want to undergo ABPM. Benefits of the procedure should be reviewed with families to assist in decision-making
Exclusions	None
Strength	Strong recommendation
Key references	206

Key Action Statement 10. Home BP monitoring should not be used to diagnose HTN, MH, or WCH but may be a useful adjunct to office and ambulatory BP measurement after HTN has been diagnosed (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Convenient, cost-effective, widely available, can be used over time
Risks, harm, cost	Risk of inaccurate diagnosis. Unclear what norms or schedule should be used. Few validated devices in children, and cuff sizes are limited
Benefit–harm assessment	Benefits outweigh harm when used as an adjunctive measurement technique
Intentional vagueness	None
Role of patient preferences	Patients may find home BP more convenient and accessible than office or ambulatory BP
Exclusions	None
Strength	Moderate recommendation
Key references	159,221–225,227,230

systems of pediatric primary care, and these comments would not apply to them.

5. PRIMARY AND SECONDARY CAUSES OF HTN

5.1 Primary HTN

Primary HTN is now the predominant diagnosis for hypertensive children and adolescents seen in referral centers in the United States,[235,236] although single-center studies from outside the United States still find primary HTN to be uncommon.[237] Although prospective, multicenter studies are generally lacking, at least one large study in which researchers used insurance claims data confirmed that primary HTN is significantly more common than secondary HTN among American youth.[238]

General characteristics of children with primary HTN include older age (≥6 years),[239,240] positive family history (in a parent and/or grandparent) of HTN,[236,237,240] and overweight and/or obesity.[16,236,237,239] Severity of BP elevation has not differed significantly between children with primary and secondary HTN in some studies,[235,237] but DBP elevation appears to be more predictive of secondary HTN,[239,240] whereas systolic HTN appears to be more predictive of primary HTN.[236,239]

Key Action Statement 11

Children and adolescents ≥6 years of age do not require an extensive evaluation for secondary causes of HTN if they have a positive family history of HTN, are overweight or obese, and/or do not have history or physical examination findings (Table 14) suggestive of a secondary cause of HTN (grade C, moderate recommendation).

5.2 Secondary Causes: Renal and/or Renovascular

Renal disease and renovascular disease are among the most common secondary causes of HTN in children. Renal parenchymal disease and renal structural abnormalities accounted for 34% to 79% of patients with secondary HTN in 3 retrospective, single-center case series, and renovascular disease was present in 12% to 13%.[101,240,241] The literature suggests that renal disease is a more common cause of HTN in younger children.[239] Renal disorders (including vascular problems) accounted for 63% to 74% of children <6 years of age who were enrolled in 3 recent clinical trials of angiotensin receptor blockers (ARBs).[239,242–244] No increased frequency was seen in younger patients in a recent single-center case series, however.[101] It is appropriate to have a high index of suspicion for renal and renovascular disease in hypertensive pediatric patients, particularly in those <6 years of age.

5.3 Secondary Causes: Cardiac, Including Aortic Coarctation

Coarctation of the aorta is a congenital abnormality of the aortic arch characterized by discrete narrowing of the aortic arch, generally at the level of the aortic isthmus. It is usually associated with HTN and right arm BP that is 20 mm Hg (or more) greater than the lower extremity BP. Repair in infants is often surgical; adolescents may be treated with angioplasty or stenting. Long-segment narrowing of the abdominal aorta can also cause HTN and should be considered in children with refractory

Key Action Statement 11. Children and adolescents ≥6 years of age do not require an extensive evaluation for secondary causes of HTN if they have a positive family history of HTN, are overweight or obese, and/or do not have history or physical examination findings (Table 14) suggestive of a secondary cause of HTN (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Avoidance of unnecessary diagnostic evaluation
Risks, harm, cost	Potential to miss some children with secondary HTN
Benefit–harm assessment	Benefit equals harm
Intentional vagueness	Not applicable
Role of patient preferences	Some families may want further testing performed
Exclusions	Hypertensive children <6 y of age
Strength	Moderate recommendation
Key references	16,129,235–240

HTN and a gradient between the upper and lower extremities in which the upper extremity SBP exceeds the lower extremity SBP by 20 mm Hg.[245] Of note, children with abdominal aortic obstruction may have neurofibromatosis, Williams syndrome, Alagille syndrome, or Takayasu arteritis.

Patients with coarctation can remain hypertensive or develop HTN even after early and successful repair, with reported prevalence varying from 17% to 77%.[112] HTN can be a manifestation of recoarctation. Recoarctation in repaired patients should be assessed for by using 4 extremity BP measurements and echocardiography. HTN can also occur without recoarctation.[246] The prevalence of HTN increases over time after successful coarctation repair.[112]

Routine office BP measurement alone is often insufficient for diagnosing HTN after coarctation repair.[113,246] Children who have undergone coarctation repair may have normal in-office BP but high BP out of the office, which is consistent with MH.[58,112] Of children with a history of aortic coarctation, ~45% have MH at ~1 to 14 years after coarctation repair.[58,113] Children with a history of repaired aortic coarctation and normal in-office BP are at risk for LVH,[58] HTN, and MH.[58,112]

ABPM has emerged as the gold standard for diagnosing HTN among individuals who have undergone coarctation repair, and it is likely more useful than casual BP.[58,245–247] Screening is recommended as a part of usual care on an annual basis beginning, at most, 12 years after coarctation repair. Earlier screening may be considered on the basis of risk factors and clinician discretion.

Key Action Statement 12

Children and adolescents who have undergone coarctation repair should undergo ABPM for the detection of HTN (including MH) (grade B, strong recommendation).

5.4 Secondary Causes: Endocrine HTN

HTN resulting from hormonal excess accounts for a relatively small proportion of children with secondary HTN. Although rare (with a prevalence ranging from 0.05% to 6% in children[101,237,239,240]), an accurate diagnosis of endocrine HTN provides the clinician with a unique treatment opportunity to render a surgical cure or achieve a dramatic response with pharmacologic therapy.[248] Known endocrine causes with associated molecular defects (when known) are summarized in Table 15.

5.5 Secondary Causes: Environmental Exposures

Several environmental exposures have been associated with higher childhood BP, although most studies are limited to small case series. Among the most prominent are lead, cadmium, mercury, and phthalates.

- Lead: Long-term exposure to lead in adults has been associated with higher BP in population studies[295,296] and in studies of industrial workers with high lead exposure,[297] although findings have not been consistent.[298] At least 1 cross-sectional study of 122 children demonstrated that children with higher blood lead concentrations had higher BP; lower socioeconomic status was also seen in this group, which may have confounded the BP results.[299] Furthermore, in a randomized study of lead-exposed children, those who received chelation with succimer did not have lower BP than in those who received a placebo.[300]
- Cadmium: Environmental cadmium exposure has been linked to higher BP levels and the development of HTN in adults, particularly among women.[296,301–303] Although cross-sectional studies have

Key Action Statement 12. Children and adolescents who have undergone coarctation repair should undergo ABPM for the detection of HTN (including MH) (grade B, strong recommendation).

Aggregate Evidence Quality	Grade B (Aggregate Level of Evidence Equals B, Given 3 Studies With Similar Findings)
Benefits	Early detection of HTN
Risks, harm, cost	Additional costs related to the placement of ABPM
Benefit–harm assessment	Benefits exceed harms
Intentional vagueness	Frequency of measurement. Because the development of HTN after coarctation repair is influenced by many factors, the ideal onset of screening for HTN (including MH) is unknown
Role of patient preferences	None
Exclusions	Individuals with a history of residual aortic arch obstruction
Strength	Strong recommendation
Key references	58,112,113

TABLE 14 Examples of Physical Examination Findings and History Suggestive of Secondary HTN or Related to End Organ Damage Secondary to HTN

Body System	Finding, History	Possible Etiology
Vital signs	Tachycardia	Hyperthyroidism
		PCC
		Neuroblastoma
	Decreased lower extremity pulses; drop in BP from upper to lower extremities	Coarctation of the aorta
Eyes	Proptosis	Hyperthyroidism
	Retinal changes[a]	Severe HTN, more likely to be associated with secondary HTN
Ear, nose, throat	Adenotonsillar hypertrophy	SDB
	History of snoring	Sleep apnea
Height, weight	Growth retardation	Chronic renal failure
	Obesity (high BMI)	Cushing syndrome
	Truncal obesity	Insulin resistance syndrome
Head, neck	Elfin facies	Williams syndrome
	Moon facies	Cushing syndrome
	Thyromegaly, goiter	Hyperthyroidism
	Webbed neck	Turner syndrome
Skin	Pallor, flushing, diaphoresis	PCC
	Acne, hirsutism, striae	Cushing syndrome
		Anabolic steroid abuse
	Café-au-lait spots	Neurofibromatosis
	Adenoma sebaceum	Tuberous sclerosis
	Malar rash	Systemic lupus
	Acanthosis nigricans	T2DM
Hematologic	Pallor	Renal disease
	Sickle cell anemia	
Chest, cardiac	Chest pain	Heart disease
	Palpitations	
	Exertional dyspnea	
	Widely spaced nipples	Turner syndrome
	Heart murmur	Coarctation of the aorta
	Friction rub	Systemic lupus (pericarditis)
		Collagen vascular disease
	Apical heave[a]	LVH
Abdomen	Abdominal mass	Wilms tumor
		Neuroblastoma
		PCC
	Epigastric, flank bruit	RAS
	Palpable kidneys	Polycystic kidney disease
		Hydronephrosis
		Multicystic dysplastic kidney
Genitourinary	Ambiguous or virilized genitalia	Congenital adrenal hyperplasia
	Urinary tract infection	Renal disease
	Vesicoureteral reflux	
	Hematuria, edema, fatigue	
	Abdominal trauma	
Extremities	Joint swelling	Systemic lupus
		Collagen vascular disease
	Muscle weakness	Hyperaldosteronism
		Liddle syndrome
Neurologic, metabolic	Hypokalemia, headache, dizziness, polyuria, nocturia	Reninoma
	Muscle weakness, hypokalemia	Monogenic HTN (Liddle syndrome, GRA, AME)

AME, apparent mineralocorticoid excess; GRA, glucocorticoid-remediable aldosteronism. Adapted from Flynn JT. Evaluation and management of hypertension in childhood. *Prog Pediatr Cardiol.* 2001;12(2):177–188; National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. *Pediatrics.* 2004;114(2):555–576.
[a] Findings that may be indicative of end organ damage related to HTN.

confirmed potential nephrotoxicity of cadmium in children,[304] no definite effect on BP has been demonstrated.[304,305]

- Mercury: Mercury is a known nephrotoxin, particularly in its elemental form.[306,307] Severe mercury intoxication has been linked to acute HTN in children in several case reports; patients' symptoms may resemble those seen in patients with pheochromocytoma (PCC).[308–310]
- Phthalates: Antenatal and childhood exposure to phthalates has recently been associated with higher childhood BP[311–313] but not with the development of overt HTN. Specific metabolites of these ubiquitous chemicals may have differential effects on BP,[313] indicating that much more detailed study is needed to completely understand the effect of such exposure.

5.6 Secondary Causes: Neurofibromatosis

Neurofibromatosis type 1 (NF-1) (also known as Von Recklinghausen disease) is a rare autosomal dominant disorder characterized by distinct clinical examination findings. These include the following: cafe-au-lait macules, neurofibromas, Lisch nodules of the iris, axillary freckling, optic nerve gliomas, and distinctive bone lesions. Patients with NF-1 have several unique and potential secondary causes of HTN, most commonly renal artery stenosis (RAS); coarctation of the aorta, middle aortic syndrome, and PCC are also well described.[314–319]

Additionally, an increased incidence of idiopathic HTN has been documented in patients with NF-1, as high as 6.1% in a recent pediatric case series, which is a much greater incidence than in the general population.[320] PCC has also been well described in patients with NF-1, although exact incidences are difficult

TABLE 15 Endocrine Causes of HTN

Name of Disorder	Genetic Mutation	Mode of Inheritance	Clinical Feature(s)	Biochemical Mechanism and Notes	Ref No(s).
Catecholamine excess					
PCC, paraganglioma	VHL (49%)	De novo, AD	HTN	Diagnostic test: fractionated plasma[a] and/or urine metanephrines and normetanephrines	248–254
	SDHB (15%)		Palpitations, headache, sweating		
	SDHD (10%)		Abdominal mass		
	RET		Incidental radiographic finding		
			Family screening		
Mineralocorticoid excess					
Specific etiologies addressed below		Screening test: ARR: PAC, PRA preferably obtained between 8:00 and 10:00 AM			255,256
Consider if:					
Early onset HTN					
Potassium level abnormalities					
Family history of primary aldosteronism					
Resistant HTN					
Congenital adrenal hyperplasia					
11β–hydroxylase deficiency	CYP11B1 (loss of function)	AR	HTN	Elevated levels of DOC, 11-deoxycortisol, androstenedione, testosterone, and DHEAS	257–259
			Hypokalemia	Higher prevalence in Moroccan Jews	
			Acne, hirsutism, and virilization in girls		
			Pseudoprecocious puberty in boys		
			11% of congenital adrenal hyperplasia		
17-α hydroxylase deficiency	CYP17 (loss of function)	AR	HTN and hypokalemia	Elevated DOC and corticosterone	260–262
			Low aldosterone and renin	Decreased androstenedione, testosterone and DHEAS	
			Undervirilized boys, sexual infantilism in girls	Prominent in Dutch Mennonites	
			<1% of congenital adrenal hyperplasia		
Familial hyperaldosteronism					
Type 1	Hybrid CYP11B1 and CYP11B2 (11β-hydroxylase–aldosterone synthase, gain of function)	AD	Young subjects with PA	Excessive, ACTH-regulated aldosterone production	263,264
			Family history of young strokes	Prescription with low-dose dexamethasone	
				May add low-dose spironolactone, calcium channel blocker, or potassium supplementation	
Type 2	Unknown, possibly 7p22	AD (prevalence varies from 1.2% to 6%)	PA in the patient with an affected first-degree relative	Excessive autonomous aldosterone production	265–267
			Unresponsive to dexamethasone		
			May have adrenal adenoma or bilateral adrenal hyperplasia		
Type 3	KCNJ5 G-protein potassium channel (loss of function)	AD	Early onset severe HTN in the first family described	Mutation leads to loss of potassium+ sensitivity causing sodium+ influx that activates Ca^{++} channels, leading to aldosterone synthesis	268–270
			Milder phenotypes also seen		
Type 4	CACNA1D coding for calcium channel (gain of function)	AD	PA and HTN age <10 y	Increased Ca^{++} channel sensitivity causing increased aldosterone synthesis	271,272
			Variable developmental abnormalities		
Other genetic causes					

TABLE 15 Continued

Name of Disorder	Genetic Mutation	Mode of Inheritance	Clinical Feature(s)	Biochemical Mechanism and Notes	Ref No(s).
Carney complex	PRKAR1A	AD	Skin pigmentation Pituitary and other tumors	Rare familial cause	273,274
McCune Albright syndrome	GNAS, α-subunit	Somatic	Cutaneous pigmentation Fibrous dysplasia	Tumors in the breast, thyroid, pituitary gland, or testicles may be present	275,276
Primary glucocorticoid resistance (Chrousos syndrome)	NR3C1 (loss of function glucocorticoid receptor)	AD	HTN Ambiguous genitalia Precocious puberty Androgen excess, menstrual abnormalities or infertility in women	Loss of function of glucocorticoid receptor	277–279
Apparent mineralocorticoid excess	HSD11B2 (loss of function)	AR	HTN Hypokalemia Low birth weight Failure to thrive Polyuria, polydipsia	Reduced or absent activity of 11 β-HSD2: cortisol gains access to MR Mimicked by licorice toxicity	280,281
Liddle syndrome	SCNN1B β-subunit–SCNN1G γ-subunit (activating mutation)		Severe HTN Hypokalemia Metabolic alkalosis Muscle weakness	Constitutive activation of the epithelial sodium channel causing salt retention and volume expansion	282,283
Geller syndrome	MCR (mineralocorticoid-d receptor, activating mutation)	AD	Onset of HTN <20 y Exacerbated by pregnancy	Constitutive activation of MR Also activated by progesterone	284
Pseudohypo-aldosteronism type 2 (Gordon syndrome)	WNK1,4; KLHL3; CUL3; SPAK (activating mutation)	AD	Short stature Hyperkalemic and hyperchloremic metabolic acidosis Borderline HTN	Increased activity of sodium chloride cotransporter causing salt retention and volume expansion	285–287
Glucocorticoid excess					
Cushing syndrome, adrenocortical carcinoma, iatrogenic excess	To be discovered	—	HTN Other signs of Cushing syndrome	Likely attributable to increased DOC, sensitivity to vasoconstriction, cardiac output, activation of RAS	288–290
Other endocrine abnormalities					
Hyperthyroidism	To be discovered	—	Tachycardia HTN Tremors Other signs of hyperthyroidism	Mechanism increased cardiac output, stroke volume, and decreased peripheral resistance Initial prescription with β blockers	291,292
Hyperparathyroidism	—	—	Hypercalcemia Other signs of hyperparathyroidism	Mechanism unknown, may not remit after treatment of hyperparathyroidism	293,294

ACTH, adrenocorticotropic hormone; AD, autosomal dominant; AR, autosomal recessive; DHEAS, dehydroepiandrosterone sulfate; DOC, deoxycortisol; MR, magnetic resonance; PA, primary hyperaldosteronism; PAC, plasma aldosterone concentration; RAS, renin angiotensin system; —, not applicable.

[a] influenced by posture, specialized center preferred.

to determine, and patients may not have classic symptoms of PCC.[321,322]

Vascular causes of HTN and PCC all require specific treatment and follow-up, so maintaining a high index of suspicion for these disorders is important in evaluating hypertensive children and adolescents with NF-1.

5.7 Secondary Causes: Medication Related

Many over-the-counter drugs, prescription medications, alternative therapies (ie, herbal and nutritional supplements), dietary products, and recreational drugs can increase BP. Common prescription medications associated with a rise in BP include oral contraceptives,[323–325] central nervous system stimulants,[326] and corticosteroids.[1,327] When a child has elevated BP measurements, the practitioner should inquire about the intake of pharmacologic agents (see Table 8).

Usually, the BP elevation is mild and reversible on discontinuation of the medication, but a significant increase in BP can occasionally occur with higher doses or as an idiosyncratic response. Over-the-counter cold medications that contain decongestants (eg, pseudoephedrine and phenylpropanolamine) may cause a mild increase in BP with the recommended dosing, but severe HTN has been observed as an idiosyncratic response with appropriate dosing as well as with excessive doses.

Nonsteroidal anti-inflammatory drugs may antagonize the BP-lowering effect of antihypertensive medications (specifically, angiotensin-converting enzyme [ACE] inhibitors) but do not appear to have an impact on BP in those without HTN. The commonly used supplement ephedra (ma haung) likely contains some amount of ephedrine and caffeine that can cause an unpredictable rise in BP. Recreational drugs associated with HTN include stimulants (eg, cocaine and amphetamine derivatives) and anabolic steroids.

5.8 Monogenic HTN

Monogenic forms of HTN are uncommon, although the exact incidence is unknown. In a study of select hypertensive children without a known etiology, genetic testing for familial hyperaldosteronism type I (FH-I), or glucocorticoid-remediable aldosteronism, confirmed responsible genetic mutations in 3% of the population.[263]

Other monogenic forms of HTN in children include Liddle syndrome, pseudohypoaldosteronism type II (Gordon syndrome), apparent mineralocorticoid excess, familial glucocorticoid resistance, mineralocorticoid receptor activating mutation, and congenital adrenal hyperplasia (see "Secondary Causes: Endocrine Causes of Hypertension").[328] All manifest as HTN with suppressed plasma renin activity (PRA) and increased sodium absorption in the distal tubule. Other features may include serum potassium abnormalities, metabolic acid-base disturbances, and abnormal plasma aldosterone concentrations, although the clinical presentations can be highly variable.[263,328,329] In the study of FH-I, all affected children had suppressed PRA and an aldosterone to renin ratio (ARR) (ng/dL and ng/M1 per hour, respectively) of >10; the authors suggest that an ARR >10 is an indication to perform genetic testing in a hypertensive child.[263] Monogenic forms of HTN should be suspected in hypertensive children with a suppressed PRA or elevated ARR, especially if there is a family history of early-onset HTN.

6. DIAGNOSTIC EVALUATION

6.1 Patient Evaluation

As with any medical condition, appropriate diagnostic evaluation is a critical component in the evaluation of a patient with suspected HTN. Evaluation focuses on determining possible causes of and/or comorbidities associated with HTN. Evaluation, as is detailed in the following sections, should include appropriate patient history, family history, physical examination, laboratory evaluation, and imaging.

6.2 History

The first step in the evaluation of the child or adolescent with elevated BP is to obtain a history. The various components of the history include the perinatal history, past medical history, nutritional history, activity history, and psychosocial history. Each is discussed in the following sections.

6.2a Perinatal History

As discussed, perinatal factors such as maternal HTN and low birth weight have been shown to influence later BP, even in childhood.[56,330] Additionally, a high incidence of preterm birth among hypertensive children has recently been reported in 1 large case series.[101] Thus, it is appropriate to obtain a history of pertinent prenatal information, including maternal pregnancy complications; gestational age; birth weight; and, if pertinent, complications occurring in the neonatal nursery and/or ICU. It is also appropriate to document pertinent procedures, such as umbilical catheter placement.

6.2b Nutritional History

High sodium intake has been linked to childhood HTN and increased LVMI and is the focus of several population health campaigns.[4,331] In NHANES 2003–2008, among children 8 to 18 years of age (n = 6235), higher sodium intake (as assessed by dietary recall) was associated with a twofold increase in the combined outcome of elevated BP or HTN. The effect was threefold among participants with obesity.[332] Limited data suggest

the same effect is seen in younger children.[333] One study found that high intake of total fat and saturated fat, as well as adiposity and central obesity, were also predictors of SBP.[334–336]

Nutrition history is an important part of the patient assessment because it may identify dietary contributors to HTN and detect areas in which lifestyle modification may be appropriate. The important components to discuss include salt intake (including salt added in the kitchen and at the table and sodium hidden in processed and fast food), consumption of high-fat foods, and consumption of sugary beverages.[337,338] Infrequent consumption of fruits, vegetables, and low-fat dairy products should also be identified.

6.2c Physical Activity History

A detailed history of physical activity and inactivity is an integral part of the patient assessment, not only to understand contributors to the development of HTN but also to direct lifestyle modification counseling as an important part of management.[339–344]

6.2d Psychosocial History

Providers should obtain a psychosocial history in children and adolescents with suspected or confirmed HTN. Adverse experiences both prenatally[345] and during childhood (including maltreatment, early onset depression, and anxiety) are associated with adult-onset HTN.[346,347] The identification of stress may suggest a diagnosis of WCH. The psychosocial history should include questions about feelings of depression and anxiety, bullying, and body perceptions. The latter is particularly important for patients with overweight or obesity because ~70% of these children report having bullying and body perception concerns.[348] Starting at 11 years of age, the psychosocial history should include questions about smoking,[349,350] alcohol, and other drug use.[351]

6.2e Family History

Taking and updating the family history is a quick and easy way to risk-stratify pediatric patients with an increased risk for HTN. It is important to update the family history for HTN over the course of the pediatric patient's lifetime in the practice (typically until 18–21 years of age) because first- and second-degree relatives may develop HTN during this time. All too often, the diagnosis of HTN in the pediatric patient stimulates the collection of a detailed family history of HTN, sometimes even years after the pediatric patient has had elevated BP, instead of the other way around.[352]

6.3 Physical Examination

A complete physical examination may provide clues to potential secondary causes of HTN and assess possible hypertensive end organ damage. The child's height, weight, calculated BMI, and percentiles for age should be determined at the start of the physical examination. Poor growth may indicate an underlying chronic illness.

At the second visit with confirmed elevated BP or stage 1 HTN or the first visit with confirmed stage 2 HTN, BP should be measured in both arms and in a leg. Normally, BP is 10 to 20 mm Hg higher in the legs than the arms. If the leg BP is lower than the arm BP, or if femoral pulses are weak or absent, coarctation of the aorta may be present. Obesity alone is an insufficient explanation for diminished femoral pulses in the presence of high BP.

The remainder of the physical examination should pursue clues found in the history and should focus on body systems and findings that may indicate secondary HTN and/or end organ damage related to HTN. Table 14 lists important physical examination findings in hypertensive children.[353] These are examples of history and physical findings and do not represent all possible history and physical examination findings. The physical examination in hypertensive children is frequently normal except for the BP elevation.

Key Action Statement 13

In children and adolescents being evaluated for high BP, the provider should obtain a perinatal history, appropriate nutritional history, physical activity history, psychosocial history, and family history and perform a physical examination to identify findings suggestive of secondary causes of HTN (grade B, strong recommendation).

6.4 Laboratory Evaluation

The purpose of the laboratory evaluation is to identify underlying secondary causes of HTN (eg, renal or endocrine disease) that would require specific treatment guided by a subspecialist. In general, such testing includes a basic set of screening tests and additional, specific tests; the latter are selected on the basis of clues obtained from the history and physical examination and/or the results of the initial screening tests.[354] Table 10 provides a list of screening tests and the populations in which they should be performed.

6.5 Electrocardiography

Approximately one-half of adolescents with HTN have undergone electrocardiography at least once as an assessment for LVH.[355] Unlike echocardiography, electrocardiography takes little time and is a relatively low-cost test. Electrocardiography has high specificity but poor sensitivity for identifying children and adolescents with LVH.[356–358] The positive predictive value of electrocardiography to identify LVH is extremely low.[359]

Key Action Statement 14

Clinicians should not perform electrocardiography in hypertensive

Key Action Statement 13. In children and adolescents being evaluated for high BP, the provider should obtain a perinatal history, appropriate nutritional history, physical activity history, psychosocial history, and family history and perform a physical examination to identify findings suggestive of secondary causes of HTN (grade B, strong recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Identify personal risk factors for HTN
Risks, harm, cost	None
Benefit–harm assessment	Identification of personal risk factors is useful in the assessment of childhood HTN
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Children with normal BP
Strength	Strong recommendation
Key references	56,330

children and adolescents being evaluated for LVH (grade B, strong recommendation).

6.6 Imaging Evaluation, Echocardiography: Detection of Target Organ Damage

Echocardiography was identified in the Fourth Report as a tool to measure left ventricular (LV) target organ injury related to HTN in children.[1] The basis for this assessment is as follows: (1) the relationship of LV mass to BP,[361] (2) the independent and strong relationship of LVH to adverse CVD outcomes in adults,[362–364] and (3) that a significant percentage of children and adolescents with HTN demonstrate the degree of LVH associated with adverse outcomes in adults.[365–367] Antihypertensive treatment reduces LVH. Observational data suggest that the regression of LVH independently predicts outcomes in adults.[368]

The best-studied measures of LV target organ injury are measures of LV structure (LV mass and the relationship of LV wall thickness or mass to LV cavity volume) and systolic function (LV ejection fraction). LV structure is usually stratified into 4 groups on the basis of LV mass (normal or hypertrophied) and relative LV wall thickness (normal or increased). These 4 are as follows: (1) normal geometry with normal LV mass and wall thickness, (2) concentric geometry with normal LV mass and increased LV wall thickness, (3) eccentric LVH with increased LV mass and normal LV wall thickness, and (4) concentric LVH with both increased LV mass and increased relative wall thickness.[369,370]

Key Action Statement 14. Clinicians should not perform electrocardiography in hypertensive children and adolescents being evaluated for LVH (grade B, strong recommendation).

Aggregate Evidence Quality	Grade B (Aggregate of Level of Evidence Equals B Because of Multiple Level of Evidence C References With Similar Findings)
Benefits	Electrocardiography is less expensive than echocardiography or other imaging modalities for identifying LVH
Risks, harm, cost	Electrocardiography has a low sensitivity for detecting LVH
Benefit–harm assessment	The risk of concluding that a child with HTN does not have LVH on the basis of a normal electrocardiogram means that a diagnosis of end organ injury is potentially missed
Intentional vagueness	None
Role of patient preferences	Patients and families may prefer electrocardiography because of cost and convenience, but the sensitivity of the test is poor
Exclusions	None
Strength	Strong recommendation
Key references	1,355–360

The American Society of Echocardiography recommendations should be followed with regard to image acquisition and LV measurement for calculating LV ejection fraction, mass, and relative wall thickness.[369,371] LV ejection fraction may be significantly decreased in severe or acute onset HTN with associated congestive heart failure.[1] Rarely, LV ejection fraction may be mildly depressed in chronic HTN.

Because the heart increases in size in relation to body size, indexing LV mass is required.[361] Indexing LV mass is particularly important in infants and younger children because of their rapid growth.[372,373] Physical training increases LV mass in a healthful manner. Lean body mass is more strongly associated with LV mass than fat mass.[370] Because body composition is not routinely measured clinically, surrogate formulae for indexing are required. It is unclear whether expected values for LV mass should be derived from reference populations of normal weight and normotensive children or should include normotensive children who have overweight or obesity. The best method for indexing LV mass in children is an area of active investigation.

For this document, the following definitions for LV target organ injury have been chosen regarding hypertrophy, relative wall thickness, and ejection fraction. These definitions are based on published guidelines from the American Society of Echocardiography and associations of thresholds for indexed LV mass with adverse outcomes in adults[362,363,369]:

- LVH is defined as LV mass >51 g/$m^{2.7}$ or LV mass >115 g per body surface area (BSA) for boys and LV mass >95 g/BSA for girls. (Note that the values for LVH are well above the 95th percentile for distributions of LV mass in children and adolescents.[369] The clinical significance of values between the

95th percentile of a population-based distribution and these thresholds is uncertain[372]);

- An LV relative wall thickness >0.42 cm indicates concentric geometry. LV wall thickness >1.4 cm is abnormal[373]; and
- Decreased LV ejection fraction is a value <53%.

There are a number of additional evidence gaps related to the echocardiographic assessment of LV target organ injury. The value of LV mass assessment in risk reclassification independent of conventional risk assessment has not been established in adults.[364] The costs and benefits of incorporation of echocardiography into HTN care has not been assessed. Quality control regarding reproducibility of measurements across laboratories may be suboptimal.[374] The most accurate method to measure LV mass (M-mode; two-dimensional; or, in the near future, three-dimensional techniques) requires further research.

Key Action Statement 15

1. It is recommended that echocardiography be performed to assess for cardiac target organ damage (LV mass, geometry, and function) at the time of consideration of pharmacologic treatment of HTN;
2. LVH should be defined as LV mass >51 g/m$^{2.7}$ (boys and girls) for children and adolescents older than 8 years and defined by LV mass >115 g/BSA for boys and LV mass >95 g/BSA for girls;
3. Repeat echocardiography may be performed to monitor improvement or progression of target organ damage at 6- to 12-month intervals. Indications to repeat echocardiography include persistent HTN despite treatment, concentric LV hypertrophy, or reduced LV ejection fraction; and
4. In patients without LV target organ injury at initial echocardiographic assessment, repeat echocardiography at yearly intervals may be considered in those with stage 2 HTN, secondary HTN, or chronic stage 1 HTN incompletely treated (noncompliance or drug resistance) to assess for the development of worsening LV target organ injury (grade C, moderate recommendation).

TABLE 16 DASH Diet Recommendations

Food	Servings per Day
Fruits and vegetables	4–5
Low-fat milk products	≥2
Whole grains	6
Fish, poultry, and lean red meats	≤2
Legumes and nuts	1
Oils and fats	2–3
Added sugar and sweets (including sweetened beverages)	≤1
Dietary sodium	<2300 mg per d

Adapted from Barnes TL, Crandell JL, Bell RA, Mayer-Davis EJ, Dabelea D, Liese AD. Change in DASH diet score and cardiovascular risk factors in youth with type 1 and type 2 diabetes mellitus: the SEARCH for Diabetes in Youth study. *Nutr Diabetes.* 2013;3:e91; US Department of Health and Human Services, US Department of Agriculture. Appendix 7. Nutritional goals for age-sex groups based on dietary reference intakes and dietary guidelines recommendations. In: *2015-2020 Dietary Guidelines for Americans.* Washington, DC: US Department of Health and Human Services, US Department of Agriculture; 2015; and Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents; National Heart, Lung, and Blood Institute. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report. *Pediatrics.* 2011;128 (suppl 5): S213–S256.

6.7 Vascular Structure and Function

Emerging data demonstrate an association of higher levels of BP in youth with adverse changes in measures of vascular structure and function, including ultrasonography of the cIMT, PWV, a robust measure of central arterial stiffness[66] that is related to hard CV events in adults

Key Action Statement 15. It is recommended that echocardiography be performed to assess for cardiac target organ damage (LV mass, geometry, and function) at the time of consideration of pharmacologic treatment of HTN;

LVH should be defined as LV mass >51 g/m2.7 (boys and girls) for children and adolescents older than 8 years and defined by LV mass >115 g/BSA for boys and LV mass >95 g/BSA for girls;

Repeat echocardiography may be performed to monitor improvement or progression of target organ damage at 6- to 12-month intervals. Indications to repeat echocardiography include persistent HTN despite treatment, concentric LV hypertrophy, or reduced LV ejection fraction; and

In patients without LV target organ injury at initial echocardiographic assessment, repeat echocardiography at yearly intervals may be considered in those with stage 2 HTN, secondary HTN, or chronic stage 1 HTN incompletely treated (noncompliance or drug resistance) to assess for the development of worsening LV target organ injury (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Severe LV target organ damage can only be identified with LV imaging. May improve risk stratification
Risks, harm, cost	Adds cost; improvement in outcomes from incorporating echocardiography into clinical care is not established
Benefit–harm assessment	Benefits exceed harms
Intentional vagueness	None
Role of patient preferences	Patients may elect to not to have the study
Exclusions	None
Strength	Moderate recommendation
Key references	361,363,364,367–369

(eg, stroke, myocardial infarction, etc),[69] and FMD, which assesses endothelial function and describes the ability of the endothelium to release nitric oxide in response to stress.[375]

Although there are multiple large studies of PWV in youth,[376–381] they all suffer from notable limitations, primarily the lack of racial and ethnic diversity and differences in measurement devices and protocols. Researchers in the largest study of PWV in youth to date (N = 6576) only evaluated 10 and 11 year olds and measured only carotid-radial PWV across the arm; this measure has not been linked to CV events in adults.[382] Researchers in one large study of FMD performed in youth (N = 5809) only included 10- to 11-year-old children in England.[382] The largest set of data for cIMT included 1155 European youth who were 6 to 18 years of age.[383] No racial and ethnic breakdown was provided for this study. The wide heterogeneity in the methods for cIMT measurement hinders the pooling of data. For instance, researchers in the aforementioned article only measured common carotid,[383] although the bulb and internal carotid are the sites of earliest atherosclerotic disease.[384]

Many studies have had significant issues related to methodology. For example, carotid-femoral PWV is not measured identically with different devices and is not equivalent to other measures of PWV, such as brachial-femoral PWV.[385,386] No direct comparisons have been made between carotid-femoral and brachial-ankle PWV, methods in which brachial-ankle PWV provide values considerably higher than carotid-femoral PWV.[378] The brachial-ankle PWV measures stiffness along both a central elastic artery (aorta) and the medium muscular arteries of the leg.

Therefore, insufficient normative data are available to define clinically actionable cut-points between normal and abnormal for these vascular parameters. The routine measurement of vascular structure and function to stratify risk in hypertensive youth cannot be recommended at this time.

6.8 Imaging for Renovascular Disease

There are no evidence-based criteria for the identification of children and adolescents who may be more likely to have RAS. Some experts will do a more extensive evaluation for RAS in children and adolescents with stage 2 HTN, those with significant diastolic HTN (especially on ABPM), those with HTN and hypokalemia on screening laboratories, and those with a notable size discrepancy between the kidneys on standard ultrasound imaging. Bruits over the renal arteries are also suggestive of RAS but are not always present. Consultation with a subspecialist is recommended to help decide which patients warrant further investigation and to aid in the selection of the appropriate imaging modality.

6.8a Renal Ultrasonography

The utility of Doppler renal ultrasonography as a noninvasive screening study for the identification of RAS in children and adolescents has been examined in at least 2 recent case series; sensitivity has been reported to be 64% to 90%, with a specificity of 68% to 70%.[387,388] In another study that included both children and adults, sensitivity and specificity for the detection of renal artery stenoses was 75% and 89%, respectively.[389] Factors that may affect the accuracy of Doppler ultrasonography include patient cooperation, the technician's experience, the age of the child, and the child's BMI. Best results are obtained in older (≥8 years),[388] nonobese (BMI ≤85th percentile), cooperative children and adolescents who are examined in a facility with extensive pediatric vascular imaging experience. Doppler ultrasonography should probably not be obtained in patients who do not meet these criteria or in facilities that lack appropriate pediatric experience.

Key Action Statement 16

Doppler renal ultrasonography may be used as a noninvasive screening study for the evaluation of possible RAS in normal-weight children and adolescents ≥8 years of age who are suspected of having renovascular HTN and who will cooperate with the procedure (grade C, moderate recommendation).

6.8b Computed Tomographic Angiography, Magnetic Resonance Angiography, and Renography

Other noninvasive imaging studies that have been assessed for their ability to identify RAS include computed tomographic angiography (CTA), magnetic resonance angiography (MRA), and nuclear medicine studies. Each of these

Key Action Statement 16. Doppler renal ultrasonography may be used as a noninvasive screening study for the evaluation of possible RAS in normal-weight children and adolescents ≥8 years of age who are suspected of having renovascular HTN and who will cooperate with the procedure (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Avoidance of complications of invasive procedure (angiography) or radiation from traditional or computed tomography angiography
Risks, harm, cost	Potential false-positive or false-negative results
Benefit–harm assessment	Potential for avoidance of an invasive procedure outweighs risk of false-negative or false-positive results
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Children and adolescents without suspected renovascular HTN
Strength	Moderate recommendation
Key references	387–390

TABLE 17 Dosing Recommendations for the Initial Prescription of Antihypertensive Drugs for Outpatient Management of Chronic HTN

Drug	Age	Initial Dose	Maximal Dose	Dosing Interval	Formulations
ACE inhibitors					
Contraindications: pregnancy, angioedema					
Common adverse effects: cough, headache, dizziness, asthenia					
Severe adverse effects: hyperkalemia, acute kidney injury, angioedema, fetal toxicity					
Benazepril	≥6 y[a]	0.2 mg/kg per d (up to 10 mg per d)	0.6 mg/kg per d (up to 40 mg per d)	Daily	Tablet: 5, 10, 20, 40 mg (generic) Extemporaneous liquid: 2 mg/mL
Captopril	Infants	0.05 mg/kg per dose	6 mg/kg per d	Daily to 4 times a day	Tablet: 12.5, 25, 50, 100 mg (generic)
	Children	0.5 mg/kg per dose	6 mg/kg per d	Three times a day	Extemporaneous liquid: 1 mg/mL
Enalapril	≥1 mo[a]	0.08 mg/kg per d (up to 5 mg per d)	0.6 mg/kg per d (up to 40 mg per d)	Daily to twice a day	Tablet: 2.5, 5, 10, 20 mg (generic) Solution: 1 mg/mL
Fosinopril	≥6 y <50 kg	0.1 mg/kg per d (up to 5 mg per d)	40 mg per d	Daily	Tablet: 10, 20, 40 mg (generic)
	≥50 kg[a]	5 mg per d	40 mg per d		
Lisinopril	≥6 y[a]	0.07 mg/kg per d (up to 5 mg per d)	0.6 mg/kg per d (up to 40 mg per d)	Daily	Tablet: 2.5, 5, 10, 20, 30, 40 mg (generic) Solution: 1 mg/mL
Ramipril	—	1.6 mg/m^2 per d	6 mg/m^2 per d	Daily	Capsule: 1.25, 2.5, 5 10 mg (generic)
Quinapril	—	5 mg per d	80 mg per d	Daily	Tablet: 5, 10, 20, 40 mg (generic)
ARBs					
Contraindications: pregnancy					
Common adverse effects: headache, dizziness					
Severe adverse effects: hyperkalemia, acute kidney injury, fetal toxicity					
Candesartan	1–5 y[a]	0.02 mg/kg per d (up to 4 mg per d)	0.4 mg/kg per d (up to 16 mg per d)	Daily to twice a day	Tablet: 4, 8, 16, 32 mg
	≥6 y[a]				Extemporaneous liquid: 1 mg/mL
	<50 kg	4 mg per d	16 mg per d		
	≥50 kg	8 mg per d	32 mg per d		
Irbesartan	6–12 y	75 mg per d	150 mg per d	Daily	Tablet: 75, 150, 300 mg (generic)
	≥13	150 mg per d	300 mg per d		
Losartan	≥6 y[a]	0.7 mg/kg (up to 50 mg)	1.4 mg/kg (up to 100 mg)	Daily	Tablet: 25, 50 100 (generic) Extemporaneous liquid: 2.5 mg/mL
Olmesartan	≥6 y[a]	—	—	Daily	Tablet: 5, 20, 40 mg
	<35 kg	10 mg	20 mg		Extemporaneous liquid: 2 mg/mL
	≥35 kg	20 mg	40 mg		
Valsartan	≥6 y[a]	1.3 mg/kg (up to 40 mg)	2.7 mg/kg (up to 160 mg)	Daily	Tablet: 40, 80, 160, 320 mg (generic) Extemporaneous liquid: 4 mg/mL
Thiazide diuretics					
Contraindications: anuria					
Common adverse effects: dizziness, hypokalemia					
Severe adverse effects: cardiac dysrhythmias, cholestatic jaundice, new onset diabetes mellitus, pancreatitis					
Chlorthalidone	Child	0.3 mg/kg	2 mg/k per d (50 mg)	Daily	Tablet: 25, 50, 100 mg (generic)
Chlorothiazide	Child[a]	10 mg/kg per d	20 mg/kg per d (up to 375 mg per d)	Daily to twice a day	Tablet: 250, 500 mg (generic) Suspension: 250/5 mL Extemporaneous liquid: 1 mg/mL
Hydrochlorothiazide	Child[a]	1 mg/kg per d	2 mg/kg per d (up to 37.5 mg per d)	Daily to twice a day	Tablet: 12.5, 25, 50 mg

TABLE 17 Continued

Drug	Age	Initial Dose	Maximal Dose	Dosing Interval	Formulations
Calcium channel blockers					
Contraindications: hypersensitivity to CCBs					
Common adverse effects: flushing, peripheral edema, dizziness					
Severe adverse effects: angioedema					
Amlodipine	1–5 y	0.1 mg/kg	0.6 mg/kg (up to 5 mg per d)	Daily	Tablet: 2.5, 5,10 mg
	≥6 y[a]	2.5 mg	10 mg		Extemporaneous liquid: 1 mg/mL
Felodipine	≥6 y	2.5 mg	10 mg	Daily	Tablet (extended release): 2.5,10 mg (generic)
Isradipine	Child	0.05–0.1 mg/kg	0.6 mg/kg (up to 10 mg per d)	Capsule: twice daily to 3 times a day; extended-release tablet: daily	Capsule: 2.5, 5 mg Extended-release tablet: 5, 10 mg
Nifedipine extended release	Child	0.2–0.5 mg/kg per d	3 mg/kg/d (up to 120 mg per d)	Daily to twice a day	Tablet (extended-release): 30, 60, 90 mg (generic)

—, not applicable.
[a] FDA pediatric labeling.

has been compared with the gold standard, renal arteriography. CTA and MRA have generally been found to be acceptable as noninvasive imaging modalities for the identification of hemodynamically significant vascular stenosis. One study that included both pediatric and adult patients showed that the sensitivity and specificity for the detection of RAS was 94% and 93% for CTA and 90% and 94% for MRA, respectively.[389]

Unfortunately, studies of either technique that include only pediatric patients are limited at best for CTA and are nonexistent for MRA. Despite this, expert opinion holds that either modality may be used for noninvasive screening for suspected RAS, but neither is a substitute for angiography.[390] CTA typically involves significant radiation exposure, and MRA generally requires sedation or anesthesia in young children, which are factors that must be considered when deciding to use one of these modalities.

Nuclear renography is based on the principle that after the administration of an agent affecting the renin-angiotensin-aldosterone system (RAAS), there will be reduced blood flow to a kidney or kidney segment affected by hemodynamically significant RAS. Such reduced blood flow can be detected by a comparison of perfusion before and after the administration of the RAAS agent. Limited pediatric nuclear renography studies exist that show variable sensitivity and specificity, ranging from 48% to 85.7% and 73% to 92.3%, respectively.[391–393] The utility of nuclear renography may be less in children then adults because children with RAS often have more complicated vascular abnormalities than adults.[394] Given these issues, nuclear renography has generally been abandoned as a screening test for RAS in children and adolescents.[390]

Key Action Statement 17

In children and adolescents suspected of having RAS, either CTA or MRA may be performed as a noninvasive imaging study. Nuclear renography is less useful in pediatrics and should generally be avoided (grade D, weak recommendation).

6.9 Uric Acid

Cross-sectional data have suggested a relationship between elevated serum uric acid (UA) levels and HTN. Two recent studies of adolescents included in NHANES 1999–2000 and a small study conducted in Italy found that elevated UA levels were associated with higher BP.[395–397] In the Italian study and in another US study of youth with obesity and HTN,[397,398] elevated UA was also associated with other markers of CV risk. These findings suggest that the measurement of UA levels may best be viewed as 1 component of CV risk assessment, especially in those with obesity.

A causative role for elevated UA in the development of childhood HTN has not been definitively established, although recent studies suggest that it may be on the causal pathway. A longitudinal study in which researchers followed a group of children for an average of 12 years demonstrated that childhood UA levels were associated with adult BP levels even after controlling for baseline BP.[399] A few small, single-center clinical trials have also shown that lowering UA can decrease BP levels, and increased UA levels blunt the efficacy of lifestyle modifications on BP control.[400–404] No large-scale, multicenter study has yet been conducted to confirm these preliminary findings. Hence, there is currently not sufficient evidence to support the routine measurement of serum UA in the evaluation and management of children with elevated BP.

6.10 Microalbuminuria

Microalbuminuria (MA), which should be differentiated from proteinuria in CKD, has been shown to be a marker of HTN-related kidney injury and a predictor of CVD in adults.[405–408] MA has been shown to be effectively reduced via the use of ARBs and ACE inhibitors in adults. Lowering the degree of MA in adults has been associated with decreased CVD risk.

In contrast, data to support a clear relationship between HTN and MA in pediatric patients with primary HTN are limited.[408–410] A single, retrospective study of children with primary HTN and WCH found that 20% of the former had MA versus 0% of the latter.[411] MA appears to be a nonspecific finding in children that can occur in the absence of HTN; it can occur in children who have obesity, insulin resistance, diabetes, dyslipidemia, and even in those who have recently participated in vigorous physical activity.[412] The previously mentioned study by Seeman et al[411] did not control for these potential confounders.

Limited, single-center data suggest that a reduction in the degree of MA, more than a reduction in BMI or SBP, is associated with a decrease in LVMI. In particular, researchers in this single-center, nonrandomized, prospective study of 64 hypertensive children without kidney disease who were 11 to 19 years of age evaluated the children at baseline and after 12 months of combination ACE and hydrochlorothiazide (N = 59) or ACE, hydrochlorothiazide, and ARB therapy (N = 5). Results found that lowering MA in children is associated with a regression of LVH.[413] Given the single-center design and lack of a control group, however, the applicability of these findings to the general population of children with primary HTN is unknown.

Key Action Statement 18

Routine testing for MA is not recommended for children and adolescents with primary HTN (grade C, moderate recommendation).

7. TREATMENT

7.1 Overall Goals

The overall goals for the treatment of HTN in children and adolescents, including both primary and secondary HTN, include achieving a BP level that not only reduces the risk for target organ damage in childhood but also reduces the risk for HTN and related CVD in adulthood. Several studies have shown that currently available treatment options can even reverse target organ damage in hypertensive youth.[105,414,415]

The previous recommendations for HTN treatment target in children without CKD or diabetes were SBP and DBP <95th percentile. Since that recommendation was made, evidence has emerged that markers of target organ damage, such as increased LVMI, can be detected among some

Key Action Statement 17. In children and adolescents suspected of having RAS, either CTA or MRA may be performed as a noninvasive imaging study. Nuclear renography is less useful in pediatrics and should generally be avoided (grade D, weak recommendation).

Aggregate Evidence Quality	Grade D
Benefits	Avoidance of complications of an invasive procedure (angiography)
Risks, harm, cost	Potential false-positive or false-negative results
Benefit–harm assessment	Potential for avoidance of an invasive procedure outweighs risk of false-negative or false-positive results
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Children and adolescents without suspected RAS
Strength	Weak recommendation; pediatric data are limited
Key references	389,390

Key Action Statement 18. Routine testing for MA is not recommended for children and adolescents with primary HTN (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Avoid improper detection of MA in children with HTN. Detection of MA is strongly influenced by other factors, such as recent participation in rigorous physical activity, obesity, insulin resistance and diabetes. Hence, there is no clear benefit for testing for MA in the absence of other known comorbidities
Risks, harm, cost	No known risks given a lack of clear association between MA and primary HTN in children
Benefit–harm assessment	Limited data to support any real benefit for screening children for MA
Intentional vagueness	Screening of children with primary HTN versus screening of children with single kidney or CKD and HTN
Role of patient preferences	Unknown
Exclusions	None
Strength	Moderate recommendation
Key references	408,410,411,413

children with BP >90th percentile (or >120/80 mm Hg) but <95th percentile.[66,416,417] Longitudinal studies on BP from childhood to adulthood that include indirect measures of CV injury indicate that the risk for subsequent CVD in early adulthood increases as the BP level in adolescence exceeds 120/80 mm Hg.[11,103,418] In addition, there is some evidence that targeting a BP <90th percentile results in reductions in LVMI and prevalence of LVH.[104] Therefore, an optimal BP level to be achieved with treatment of childhood HTN is <90th percentile or <130/80 mm Hg, whichever is lower.

Treatment and management options are discussed below, including lifestyle modifications and pharmacologic therapy to achieve optimal BP levels in children and adolescents with HTN.

Key Action Statement 19

In children and adolescents diagnosed with HTN, the treatment goal with nonpharmacologic and pharmacologic therapy should be a reduction in SBP and DBP to <90th percentile and <130/80 mm Hg in adolescents ≥ 13 years old (grade C, moderate recommendation).

7.2 Lifestyle and Nonpharmacologic Interventions

Lifestyle interventions are recommended to lower BP. There is good evidence from studies in adults showing that nutritional interventions lower BP,[419] including clinical trials demonstrating that reducing dietary sodium results in lower BP and CV mortality,[338] and a diet high in olive oil polyphenols lowers BP.[420] Studies of hypertensive youth suggest that the relationship between diet, physical activity, and BP in childhood is similar to that observed in adults.

Key Action Statement 19. In children and adolescents diagnosed with HTN, the treatment goal with nonpharmacologic and pharmacologic therapy should be a reduction in SBP and DBP to <90th percentile and <130/80 mm Hg in adolescents ≥ 13 years old (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Lower risk of childhood target organ damage, lower risk of adulthood HTN and CVD
Risk, harm, cost	Risk of drug adverse effects and polypharmacy
Benefit–harm assessment	Preponderance of benefit
Intentional vagueness	None
Role of patient preferences	Patient may have preference for nonpharmacologic or pharmacologic treatment
Exclusions	None
Strength	Moderate recommendation
Key references	11,66,103,104,416–418

7.2a Diet

The Dietary Approaches to Stop Hypertension (DASH) approach and specific elements of that diet have been the primary dietary strategy tested in the literature. These elements include a diet that is high in fruits, vegetables, low-fat milk products, whole grains, fish, poultry, nuts, and lean red meats; it also includes a limited intake of sugar and sweets along with lower sodium intake (see Table 16). Cross-sectional studies demonstrate associations between elements of the DASH diet and BP. For example, population-based data from NHANES show correlations between dietary sodium and BP in childhood and elevated BP and HTN, particularly in people with excess weight.[332]

A high intake of fruits, vegetables, and legumes (ie, a plant-strong diet) is associated with lower BP.[421] A lack of fruit consumption in childhood has been linked to increases in cIMT in young adulthood in the Young Finns study.[422] Higher intake of low-fat dairy products has been associated with lower BP in childhood.[423]

Longitudinal, observational, and interventional data also support relationships between diet and BP in youth. The National Heart Lung and Blood Institute's Growth and Health Study, which followed 2185 girls over 10 years, demonstrated that consuming ≥2 servings of dairy and ≥3 servings of fruits and vegetables daily was associated with lower BP in childhood and a 36% lower risk of high BP by young adulthood.[424] Similar associations have been demonstrated in children and adolescents with diabetes.[425] Moreover, an improvement in diet

led to lower BP in some studies of adolescents with elevated BP,[426] youth with overweight,[427] girls with metabolic syndrome,[428] and youth with T2DM.[429] However, consuming a healthier diet may increase costs.[430]

7.2b Physical Activity

Observational data support a relationship between physical activity and lower BP, although the data are scant.[339] Interventional data demonstrate increasing physical activity leads to lower BP. A review of 9 studies of physical activity interventions in children and adolescents with obesity suggested that 40 minutes of moderate to vigorous, aerobic physical activity at least 3 to 5 days per week improved SBP by an average of 6.6 mm Hg and prevented vascular dysfunction.[340] A number of subsequent, additional studies with small sample sizes support a benefit of physical activity on BP.[341] A more recent analysis of 12 randomized controlled trials including 1266 subjects found reductions of 1% and 3% for resting SBP and DBP, respectively. These results did not reach statistical significance, however, and the authors suggested that longer studies with larger sample sizes are needed.[344] Any type of exercise, whether it's aerobic training, resistance training, or combined training, appears to be beneficial[342] (see "HTN and the Athlete").

Programs that combine diet and physical activity can have a beneficial effect on SBP, as is shown in several studies designed to prevent childhood obesity and address cardiometabolic risk.[431]

Key Action Statement 20

At the time of diagnosis of elevated BP or HTN in a child or adolescent, clinicians should provide advice on the DASH diet and recommend moderate to vigorous physical activity at least 3 to 5 days per week (30–60 minutes per session) to help reduce BP (grade C, weak recommendation).

TABLE 18 OSAS Symptoms and Signs

History of frequent snoring (≥3 nights per week)
Labored breathing during sleep
Gasps, snorting noises, observed episodes of apnea
Sleep enuresis (especially secondary enuresis)
Sleeping in a seated position or with the neck hyperextended
Cyanosis
Headaches on awakening
Daytime sleepiness
Attention-deficit/hyperactivity disorder
Learning problems
Physical examination
Underweight or overweight
Tonsillar hypertrophy
Adenoidal facies
Micrognathia, retrognathia
High-arched palate
Failure to thrive
HTN

Adapted from Marcus CL, Brooks LJ, Draper KA, et al; American Academy of Pediatrics. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. 2012;130(3). Available at: www.pediatrics.org/cgi/content/full/130/3/e714.

7.2c Weight Loss and Related CV Risk Factors

As is true for children and adolescents with isolated HTN, a DASH diet[426,432] and vigorous physical activity[431] are recommended in pediatric patients with multiple obesity-related risk factors as part of intensive weight-loss therapy.[433,434] Motivational interviewing (MI) is a tool recommended for pediatricians' use by the AAP Expert Committee Statement on Obesity.[435] MI may be a useful counseling tool to use in combination with other behavioral techniques to address overweight and obesity in children.[436] Studies in hypertensive adults support the use of MI to improve adherence to antihypertensive medications[437] and decrease SBP.[436] Although there are no trials investigating the use of MI in the care of hypertensive youth, a number of studies have shown that MI can be used successfully to address or prevent childhood obesity by promoting physical activity and dietary changes.[438–441] However, other studies have been less promising.[442,443] In addition to the standard lifestyle approaches, intensive weight-loss therapy

Key Action Statement 20. At the time of diagnosis of elevated BP or HTN in a child or adolescent, clinicians should provide advice on the DASH diet and recommend moderate to vigorous physical activity at least 3 to 5 days per week (30–60 minutes per session) to help reduce BP (grade C, weak recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Potential to reduce BP
Risk, harm, cost	No or low potential for harm. Following a healthier diet may increase costs to patients and families
Benefit–harm assessment	Potential benefit outweighs lack of harm and minimal cost
Intentional vagueness	None
Role of patient preferences	Level of caregiver and patient concern may influence adoption of the DASH diet and physical activity. Patients may also have preferences around the use of a medication. These factors may influence the efficacy of lifestyle change
Exclusions	None
Strength	Weak recommendation
Key references	332,339–342,424–431

involving regular patient and/or family contact and at least 1 hour of moderate to vigorous physical activity on a daily basis should be offered to children and adolescents with obesity and HTN.[444]

7.2d Stress Reduction

Complimentary medicine interventions have shown some promise in studies in normotensive children and adolescents and in those with elevated BP. Breathing-awareness meditation, a component of the Mindfulness-Based Stress Reduction Program at the University of Massachusetts Memorial Medical Center,[445] led to a reduction in daytime, nighttime, and 24-hour SBP (3–4 mm Hg) and DPB (1 mm Hg) in normotensive African American adolescents and African American adolescents with elevated BP.[446] Another study of transcendental meditation showed no significant BP effect but did lead to a decrease in LVM in African American adolescents with elevated BP.[447] Scant data suggest yoga may also be helpful.[448]

7.3 Pharmacologic Treatment

Children who remain hypertensive despite a trial of lifestyle modifications or who have symptomatic HTN, stage 2 HTN without a clearly modifiable factor (eg, obesity), or any stage of HTN associated with CKD or diabetes mellitus therapy should be initiated with a single medication at the low end of the dosing range (see Table 17). Depending on repeated BP measurements, the dose of the initial medication can be increased every 2 to 4 weeks until BP is controlled (eg, <90th percentile), the maximal dose is reached, or adverse effects occur. Although the dose can be titrated every 2 to 4 weeks using home BP measurements, the patient should be seen every 4 to 6 weeks until BP has normalized. If BP is not controlled with a single agent, a second agent can be added to the regimen and titrated as with the initial drug. Because of the salt and water retention that occurs with many antihypertensive medications, a thiazide diuretic is often the preferred second agent.

Lifestyle modifications should be continued in children requiring pharmacologic therapy. An ongoing emphasis on a healthy, plant-strong diet rich in fruits and vegetables; reduced sodium intake; and increased exercise can improve the effectiveness of antihypertensive medications. The use of a combination product as initial treatment has been studied only for bisoprolol and hydrochlorothiazide,[449] so the routine use of combination products to initiate treatment in children cannot be recommended. Once BP control has been achieved, a combination product can be considered as a means to improve adherence and reduce cost if the dose and formulation are appropriate.

7.3a Pharmacologic Treatment and Pediatric Exclusivity Studies

Studies completed in hypertensive children show that antihypertensive drugs decrease BP with few adverse effects.[173,202,242–244,450–467] There are few studies in children in which researchers compare different antihypertensive agents.[453] These studies do not show clinically significant differences in the degree of BP lowering between agents. There are no clinical trials in children that have CV end points as outcomes. Long-term studies on the safety of antihypertensive medications in children and their impact on future CVD are limited.[455]

Because of legislative acts that provide incentives and mandates for drug manufacturers to complete pediatric assessments,[468] most of the newer antihypertensive medications have undergone some degree of efficacy and safety evaluation. Antihypertensive drugs without patent protection have not been, and are unlikely to be, studied in children despite their continued widespread use.[238]

7.3b Pharmacologic Treatment: Choice of Agent

Pharmacologic treatment of HTN in children and adolescents should be initiated with an ACE inhibitor, ARB,[469] long-acting calcium channel blocker, or a thiazide diuretic. Because African American children may not have as robust a response to ACE inhibitors,[470,471] a higher initial dose for the ACE inhibitor may be considered; alternatively, therapy may be initiated with a thiazide diuretic or long-acting calcium channel blocker. In view of the expanded adverse effect profile and lack of association in adults with improved outcomes compared with other agents, β-blockers are not recommended as initial treatment in children. ACE inhibitors and ARBs are contraindicated in pregnancy because these agents can cause injury and death to the developing fetus. Adolescents of childbearing potential should be informed of the potential risks of these agents on the developing fetus; alternative medications (eg, calcium channel blocker, β-blocker) can be considered when appropriate.

In children with HTN and CKD, proteinuria, or diabetes mellitus, an ACE inhibitor or ARB is recommended as the initial antihypertensive agent unless there is an absolute contraindication. Other antihypertensive medications (eg, α-blockers, β-blockers, combination α- and β-blockers, centrally acting agents, potassium-sparing diuretics, and direct vasodilators) should be reserved for children who are not responsive to 2 or more of the preferred agents (see "Treatment in CKD").

Key Action Statement 21

In hypertensive children and adolescents who have failed lifestyle modifications (particularly those

TABLE 19 Oral and Intravenous Antihypertensive Medications for Acute Severe HTN

		Useful for Severely Hypertensive Patients With Life-Threatening Symptoms		
Drug	Class	Dose	Route	Comments
Esmolol	β-adrenergic blocker	100–500 mcg/kg per min	Intravenous infusion	Short acting, constant infusion preferred. May cause profound bradycardia
Hydralazine	Direct vasodilator	0.1–0.2 mg/kg per dose up to 0.4 mg/kg per dose	Intravenous, intramuscular	Causes tachycardia Give every 4 h when given intravenous bolus
Labetalol	α- and β-adrenergic blocker	Bolus: 0.20–1.0 mg/kg per dose up to 40 mg per dose Infusion: 0.25–3.0 mg/kg per h	Intravenous bolus or infusion	Asthma and overt heart failure are relative contraindications
Nicardipine	Calcium channel blocker	Bolus: 30 mcg/kg up to 2 mg per dose Infusion: 0.5–4 mcg/kg per min	Intravenous bolus or infusion	May cause reflex tachycardia. Increases cyclosporine and tacrolimus levels
Sodium nitroprusside	Direct vasodilator	Starting: 0–3 mcg/kg per min Maximum: 10 mcg/kg per min	Intravenous infusion	Monitor cyanide levels with prolonged (>72 h) use or in renal failure; or coadminister with sodium thiosulfate
		Useful for Severely Hypertensive Patients With Less Significant Symptoms		
Clonidine	Central α-agonist	2–5 mcg/kg per dose up to 10 mcg/kg per dose given every 6–8 h	Oral	Adverse effects include dry mouth and drowsiness
Fenoldopam	Dopamine receptor agonist	0.2–0.5 mcg/kg per min up to 0.8 mcg/kg per min	Intravenous infusion	Higher doses worsen tachycardia without further reducing BP
Hydralazine	Direct vasodilator	0.25 mg/kg per dose up to 25 mg per dose given every 6–8 h	Oral	Half-life varies with genetically determined acetylation rates
Isradipine	Calcium channel blocker	0.05–0.1 mg/kg per dose up to 5 mg per dose given every 6–8 h	Oral	Exaggerated decrease in BP can be seen in patients receiving azole antifungal agents
Minoxidil	Direct vasodilator	0.1–0.2 mg/kg per dose up to 10 mg per dose given Q 8–12 h	Oral	Most potent oral vasodilator, long acting

who have LV hypertrophy on echocardiography, symptomatic HTN, or stage 2 HTN without a clearly modifiable factor [eg, obesity]), clinicians should initiate pharmacologic treatment with an ACE inhibitor, ARB, long-acting calcium channel blocker, or thiazide diuretic (grade B, moderate recommendation).

7.3c Treatment: Follow-Up and Monitoring

Treatment of a child or adolescent with HTN requires ongoing monitoring because goal BP can be difficult to achieve.[472] If the decision has been made to initiate treatment with medication, the patient should be seen frequently (every 4–6 weeks) for dose adjustments and/or addition of a second or third agent until goal BP has been achieved (see the preceding section). After that, the frequency of visits can be extended to every 3 to 4 months.

If the decision has been made to proceed with lifestyle changes only, then follow-up visits can occur at longer intervals (every 3–6 months) so that adherence to lifestyle change can be reinforced and the need for initiation of medication can be reassessed.

In patients treated with antihypertensive medications, home BP measurement is frequently used to get a better assessment of BP control (see "At-Home Measurement"). Repeat ABPM may also be used to assess BP control and is especially important in patients with CKD (see "Treatment: Use of ABPM and Assessment").

At each follow-up visit, the patient should be assessed for adherence to prescribed therapy and for any adverse effects of the prescribed medication; such assessment may include laboratory testing depending on the medication (for example, electrolyte monitoring if the patient is on a diuretic). It is also important to continually reinforce adherence

Key Action Statement 21. In hypertensive children and adolescents who have failed lifestyle modifications (particularly those who have LV hypertrophy on echocardiography, symptomatic HTN, or stage 2 HTN without a clearly modifiable factor [eg, obesity]), clinicians should initiate pharmacologic treatment with an ACE inhibitor, ARB, long-acting calcium channel blocker, or thiazide diuretic (grade B, moderate recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Potential prevention of progressive CVD; regression or avoidance of target organ damage; resolution of hypertensive symptoms; improved cognition; avoidance of worsening HTN; potential avoidance of stroke, heart failure, coronary artery disease, kidney failure
Risks, harm, cost	Potential for hypotension, financial cost, chronic medication treatment, adverse medication effects, impact on insurability (health and life)
Benefit–harm assessment	Preponderance of benefits over harms
Intentional vagueness	None
Role of patient preferences	The choice of which antihypertensive medication to use should be made in close discussion with the patient and parent regarding risk, benefits, and adverse effects
Exclusions	None
Strength	Moderate recommendation
Key references	452,455,467

to lifestyle changes because effective treatment will depend on the combination of effects from both medication and lifestyle measures. Finally, known hypertensive target organ damage (such as LVH) should be reassessed according to the recommendations in "Imaging Evaluation, Echocardiography: Coarctation of the Aorta and Detection of Target Organ Damage."

7.3d Treatment: Use of ABPM to Assess Treatment

ABPM can be an objective method to evaluate treatment effect during antihypertensive drug therapy. Data obtained in a multicenter, single-blind, crossover study in which hypertensive children received a placebo or no treatment demonstrated no change in ABPM after receiving the placebo.[473] A report from a single center found that among hypertensive children receiving antihypertensive drugs, BP data from ABPM resulted in medication changes in 63% of patients.[474] Another study of 38 hypertensive children used ABPM to evaluate the effectiveness of antihypertensive therapy (nonpharmacologic and pharmacologic). After 1 year of treatment, ABPM results indicated that treatment-goal BP was achieved in only one-third of children with HTN.[17]

Key Action Statement 22

ABPM may be used to assess treatment effectiveness in children and adolescents with HTN, especially when clinic and/or home BP measurements indicate insufficient BP response to treatment (grade B, moderate recommendation).

7.4 Treatment-Resistant HTN

Resistant HTN in adults is defined as persistently elevated BP despite treatment with 3 or more antihypertensive agents of different classes. All of these drugs should be prescribed at maximally effective doses, and at least 1 should be a diuretic. Key to the identification of patients with true resistant HTN is correct office BP measurement, confirmation of adherence to current therapy, and confirmation of treatment resistance by ABPM.

The treatment of patients with resistant HTN includes dietary sodium restriction, the elimination of substances known to elevate BP, the identification of previously undiagnosed secondary causes of HTN, the optimization of current therapy, and the addition of additional agents as needed.[475] Recent clinical trial data suggest that an aldosterone receptor antagonist (such as spironolactone) is the optimal additional agent in adults with resistant HTN; it helps address volume excess as well as untreated hyperaldosteronism, which is common in adult patients with true resistant HTN.[476,477]

At present, there are no data on whether true treatment-resistant HTN exists in pediatric patients. Evaluation and management strategies similar to those proven effective in adults with resistant HTN would be reasonable in children and adolescents who present with apparent treatment resistance.

Key Action Statement 22. ABPM may be used to assess treatment effectiveness in children and adolescents with HTN, especially when clinic and/or home BP measurements indicate insufficient BP response to treatment (grade B, moderate recommendation).

Aggregate Evidence Quality	Grade B
Benefits	ABPM results can guide adjustment in medication. ABPM can facilitate achieving treatment-goal BP levels
Risks, harm, cost	Inconvenience and patient annoyance in wearing an ABPM monitor. Cost of ABPM monitors
Benefit–harm assessment	Overall benefit
Intentional vagueness	None
Role of patient preferences	Patients may choose not to wear the ambulatory BP monitor repeatedly, which may necessitate alternative approaches to evaluate treatment efficacy
Exclusions	Uncomplicated HTN with satisfactory BP control
Strength	Moderate recommendation
Key references	17,474,475

8. TREATMENT IN SPECIAL POPULATIONS

8.1 Treatment in Patients With CKD and Proteinuria

8.1a CKD

Children and adolescents with CKD often present with or develop HTN.[478] HTN is a known risk factor for the progression of kidney disease in adults and children.[173,479,480] Evidence suggests that the treatment of HTN in children with CKD might slow the progression of or reverse end organ damage.[173,415] When evaluated by 24-hour ABPM, children and adolescents with CKD often have poor BP control even if BP measured in the clinic appears to be normal.[48] MH is associated with end organ damage, such as LVH.[203,481] Threshold values that define HTN are not different in children with CKD, although there is some evidence that lower treatment goals might improve outcomes.

In the European Effect of Strict Blood Pressure Control and ACE-Inhibition on Progression of Chronic Renal Failure in Pediatric Patients study, researchers randomly assigned children with CKD to standard antihypertensive therapy (with a treatment goal of 24-hour MAP <90th percentile by ABPM) or to intensive BP control (24-hour MAP <50th percentile by ABPM). The study demonstrated fewer composite CKD outcomes in children with the lower BP target.[173] Recent adult data from the Systolic Blood Pressure Intervention Trial suggest lower BP targets may be beneficial in preventing other, adverse CV outcomes as well.[482]

Key Action Statement 23

1. Children and adolescents with CKD should be evaluated for HTN at each medical encounter;
2. Children or adolescents with both CKD and HTN should be treated to lower 24-hour MAP to <50th percentile by ABPM; and
3. Regardless of apparent control of BP with office measures, children and adolescents with CKD and a history of HTN should have BP assessed by ABPM at least yearly to screen for MH (grade B; strong recommendation).

8.1b Proteinuria

Proteinuric renal disease is often associated with HTN and a rapid decline in glomerular filtration.[483] Studies in both adults and children have indicated that both BP control and a reduction in proteinuria are beneficial for preserving renal function. Researchers in multiple studies have evaluated the utility of RAAS blockade therapy in patients with CKD and HTN.[452,464,465,484–487] These medications have been shown to benefit both BP and proteinuria.

The benefit of such therapies may not be sustained, however.[173,488] The Effect of Strict Blood Pressure Control and ACE-Inhibition on Progression of Chronic Renal Failure in Pediatric Patients study demonstrated an initial 50% reduction in proteinuria in children with CKD after treatment with ramipril but with a rebound effect after 36 months.[450,464,488] This study also showed that BP reduction with a ramipril-based antihypertensive regimen improved renal outcomes. In children with HTN related to underlying CKD, the assessment of proteinuria and institution of RAAS blockade therapy appears to have important prognostic implications.

Key Action Statement 24

Children and adolescents with CKD and HTN should be evaluated for proteinuria (grade B, strong recommendation).

Key Action Statement 25

Children and adolescents with CKD, HTN, and proteinuria should be treated with an ACE inhibitor or ARB (grade B, strong recommendation).

Key Action Statement 23. Children and adolescents with CKD should be evaluated for HTN at each medical encounter;

Children or adolescents with both CKD and HTN should be treated to lower 24-hour MAP to <50th percentile by ABPM; and

Regardless of apparent control of BP with office measures, children and adolescents with CKD and a history of HTN should have BP assessed by ABPM at least yearly to screen for MH (grade B; strong recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Control of BP in children and adolescents with CKD has been shown to decrease CKD progression and lead to resolution of LVH
Risks, harm, cost	Cost of ABPM and BP control, both financial and nonfinancial
Benefit–harm assessment	Benefits of BP control in patients with CKD outweigh treatment risks
Intentional vagueness	Threshold
Role of patient preferences	Patients may not want to wear the ambulatory BP monitor repeatedly, which should lead to detailed counseling regarding the benefits of this procedure in CKD
Exclusions	None
Strength	Strong recommendation
Key references	47,173,203,415,480–483

8.2. Treatment in Patients With Diabetes

Based on the Fourth Report criteria for the diagnosis of HTN,[1] between 4% and 16% of children and adolescents with T1DM are found to have HTN.[14,489–491] In the SEARCH study of 3691 youth between the ages of 3 and 17 years, elevated BP was documented in 6% of children with T1DM, with the highest prevalence in Asian Pacific Islander and American Indian children followed by African American and Hispanic children and those with

higher glycosylated hemoglobin A1c levels.[14] An office-based study in Australia found much higher rates (16%) and a positive correlation with BMI.[490] BP >130/90 mm Hg has been associated with a more-than-fourfold increase in the relative risk of coronary artery disease and mortality at 10-year follow-up of individuals with T1DM.[492]

The prevalence of HTN is higher in youth with T2DM compared with T1DM, ranging from 12% at baseline (*N* = 699) in the Treatment Options for Type 2 Diabetes in Adolescents and Youth study[493] to 31% (*N* = 598) in the Pediatric Diabetes Consortium Type 2 Diabetes Clinic Registry.[494] BP and arterial stiffness in cohort studies have correlated with BMI, male sex, African American race, and age of onset of diabetes.[14,494,495] Unlike T1DM, HTN in T2DM is not correlated with glycosylated hemoglobin A1c levels or glycemic failure, and it develops early in the course of the disease.[496] It is also associated with rapid onset of adverse cardiac changes[111,497] and may not respond to diet changes.[425] The concurrence of obesity and T2DM compounds the risks for target end organ damage.[111,498]

Empirical evidence shows a poor awareness of HTN in youth with T1DM and T2DM.[14] Additionally, only a fraction of children with HTN and diabetes were found to be on pharmacologic therapy[14,490,498,499] despite treatment recommendations from the American Diabetes Association,[499] the International Society for Pediatric and Adolescent Diabetes,[500] AHA,[110] and the National Heart, Lung, and Blood Institute.[501]

Key Action Statement 26

Children and adolescents with T1DM or T2DM should be evaluated for HTN at each medical encounter and treated if BP is ≥95th percentile or >130/80 mm Hg in adolescents ≥13 years of age (grade C, moderate recommendation).

9. COMORBIDITIES

9.1 Comorbidities: Dyslipidemia

Children and adolescents with HTN are at increased risk for lipid disorders attributable to the "common soil" phenomenon,[502] in which poor diet, inactivity, and obesity contribute to both disorders. Some observational pediatric data confirm this association.[503–506] Furthermore, both HTN and dyslipidemias are associated with subclinical atherosclerosis[206] and are risk factors for future CVD.[503] Screening is recommended to identify those at increased risk for early atherosclerosis.[503] Treatment of lipid disorders identified in the setting of HTN should follow existing pediatric lipid guidelines with lifestyle advice, including weight loss and pharmacotherapy, as necessary.[503]

9.2 Comorbidities: OSAS

Children with snoring, daytime sleepiness (in adolescents), or hyperactivity (in younger children) may have OSAS and consequent HTN.[507] The more severe the OSAS, the more likely a child is to have elevated BP[44,45] (see Table 18). Children with moderate to severe OSAS are at increased risk for HTN. However, it is not known whether OSAS treatment with continuous positive airway pressure results in improved BP in all children.[44] Furthermore, adenotonsillectomy may not result in BP improvement in all children with OSAS. In particular, children who have obesity and OSAS may be less likely to experience a lowering of BP after an adenotonsillectomy.[508]

Therefore, children with signs of OSAS (eg, daytime fatigue, snoring, hyperactivity, etc) should undergo evaluation for elevated BP regardless of treatment status. Given that both nighttime and daytime BP is affected by OSAS, the use of ABPM is the recommended method for assessing the BP of children with suspected OSAS.

9.3 Comorbidities: Cognitive Impairment

Data from studies conducted in adults suggest that the central nervous system is a target organ that can be affected by HTN.[419] Preliminary studies suggest that this is true in children as well. Hypertensive children score lower on tests of neurocognition and on parental reports of executive function compared with normotensive controls.[509,510] Adams et al[511] found an increased prevalence of learning disabilities in children with primary HTN compared with normotensive controls. The postulated mechanism for these findings is impaired cerebrovascular reactivity.[512–515] At the present time, these findings do not have specific clinical implications with respect to the diagnostic evaluation of childhood HTN, although they underscore the importance of early detection and treatment.

Key Action Statement 24. Children and adolescents with CKD and HTN should be evaluated for proteinuria (grade B, strong recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Detection of proteinuria among children with CKD and HTN may foster early detection and treatment of children at risk for more advanced renal disease
Risks, harm, cost	Additional testing
Benefit–harm assessment	Benefit of detection of a higher-risk group exceeds the risk of testing
Intentional vagueness	Whether to screen children with HTN without CKD for proteinuria
Role of patient preferences	None
Exclusions	Children without CKD
Strength	Strong recommendation
Key references	47,484

Key Action Statement 25. Children and adolescents with CKD, HTN, and proteinuria should be treated with an ACE inhibitor or ARB (grade B, strong recommendation).

Aggregate Evidence Quality	Grade B
Benefits	ACE inhibitor and ARB therapy has been shown in the short-term to be effective in reducing urine proteinuria
Risks, harm, cost	Positive effect on urine protein concentrations after the receipt of an ACE inhibitor may not be sustained over time
Benefit–harm assessment	Treatment with an ACE inhibitor or ARB may lower the rate of progression of renal disease even if the effect is not sustained in the long-term
Intentional vagueness	Whether to aggressively treat the BP so that it is <90th percentile
Role of patient preferences	Patients may have concerns about the choice of medication, which should be addressed
Exclusions	Children without CKD
Strength	Strong recommendation
Key references	173,464,465,485,487,488

Key Action Statement 26. Children and adolescents with T1DM or T2DM should be evaluated for HTN at each medical encounter and treated if BP is ≥95th percentile or >130/80 mm Hg in adolescents ≥13 years of age (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Early detection and treatment of HTN in children with T1DM and T2DM may reduce future CV and kidney disease
Risks, harm, cost	Risk of drug adverse effects and polypharmacy
Benefit–harm assessment	Preponderance of benefit
Intentional vagueness	None
Role of patient preferences	Family concerns about additional testing and/or medication may need to be addressed
Exclusions	None
Strength	Weak to moderate recommendation
Key references	14,110,111,494

10. SEX, RACIAL, AND ETHNIC DIFFERENCES IN BP AND MEDICATION CHOICE

BP differences between various ethnic groups are well described in the adult population.[216,516] Large, cross-sectional studies have demonstrated that, per capita, minority ethnic groups have both a higher prevalence of HTN and more significant end organ damage and outcomes.[517,518] Although a growing body of evidence indicates that racial and ethnic differences in BP appear during adolescence,[519–521] the cause of these differences and when they develop in childhood are yet to be fully determined. The risk of HTN correlates more with obesity status than with ethnicity or race, although there may be some interaction.[216] At this time, although limited data suggest that there may be a racial difference in response to ACE inhibitors in the pediatric age group,[471] the strength of available evidence is insufficient to recommend using racial, sex, or ethnic factors to inform the evaluation or management of HTN in children.

11. SPECIAL POPULATIONS AND SITUATIONS

11.1 Acute Severe HTN

There is a lack of robust evidence to guide the evaluation and management of children and adolescents with acute presentations of severe HTN. Thus, much of what is known is derived from studies conducted in adults, including medication choice.[522] The evidence base has been enhanced somewhat over the past decade by the publication of several pediatric clinical trials and case series of antihypertensive agents that can be used to treat such patients.[465,523–530]

Although children and adolescents can become symptomatic from HTN at lesser degrees of BP elevation, in general, patients who present with acute severe HTN will have BP elevation well above the stage 2 HTN threshold. In a study of 55 children presenting to a pediatric ED in Taiwan with hypertensive crisis, 96% had SBP greater than that of stage 2 HTN, and 76% had DBP greater than that of stage 2 HTN.[531] The major clinical issue in such children is that this level of BP elevation may produce acute target organ effects, including encephalopathy, acute kidney injury, and congestive heart failure. Clinicians should be concerned about the development of these complications when a child's BP increases 30 mm Hg or more above the 95th percentile.

Although a few children with primary HTN may present with features of acute severe HTN,[532] the vast majority will have an underlying secondary cause of HTN.[532,533] Thus, for patients who present with acute severe HTN, an evaluation for secondary causes is appropriate and should be conducted expediently. Additionally, target organ effects should be assessed with renal function, echocardiography, and central nervous system imaging, among others.

Given the potential for the development of potentially life-threatening complications, expert opinion holds that children and adolescents who present with acute severe HTN require immediate treatment with short-acting antihypertensive medications that may abort such sequelae.[533,534] Treatment may be initiated with oral agents if the patient is able to tolerate oral therapy and if

TABLE 20 Comparison of HTN Screening Strategies

Dimension	Option A (Clinic BP Alone)	Option B (Clinic BP Confirmed by ABPM)	Option C (ABPM Only)	Preferred Option	Assumptions Made
Population: 170 cardiology, nephrology referred patients; analyzed at single-patient level	Auscultatory or oscillatory BP >95%	Auscultatory or oscillatory BP >90% then ABPM	Patients referred to provider who only used ABPM	—	—
Operational factors					
Percent adherence to care (goal of 80%)	Assumes 100%	Assumes 100%	Assumes 100%	—	—
Care delivery team effects	Baseline	Additional work to arrange or interpret confirmatory ABPM	Additional work to arrange and interpret ABPM for all patients	—	Assumes ABPM can be arranged and interpreted correctly
Patient, family effects	Baseline	Less desirable to have more visits; more desirable to have better accuracy		Family opinion depends on family's values	—
Benefits					
Clinical significance	Baseline	If HTN, treatment improves long-term outcome	If HTN, treatment improves long-term outcome	C	WCH estimated at 35%, ABPM results in fewer false-positive screening results
Cost of options					
Visit, diagnosis costs (annual estimated cost for 1 patient)	$1860 for visits and laboratory tests	$1330 for visits, ABPM, and laboratory tests	$1880 for visits, ABPM, and laboratory tests	B	—
Costs from complications, adverse events, nonoptimal treatment					
Likelihood of nonoptimal treatment	60% undiagnosed patients; 35% of those diagnosed with WCH	30% undiagnosed patients	All patients correctly diagnosed; fewer complications	C	Assumes treatment benefit for correctly diagnosed HTN has no complications
Costs of nonoptimal treatment	Increased mortality for not treating undiagnosed HTN; inconvenience of treatment of patients with WCH	Increased mortality for not treating undiagnosed HTN	All patients correctly diagnosed who are treated	C	—

—, none.

life-threatening complications have not yet developed. Intravenous agents are indicated when oral therapy is not possible because of the patient's clinical status or when a severe complication has developed (such as congestive heart failure) that warrants a more controlled BP reduction. In such situations, the BP should be reduced by no more than 25% of the planned reduction over the first 8 hours, with the remainder of the planned reduction over the next 12 to 24 hours.[533,534] The ultimate short-term BP goal in such patients should generally be around the 95th percentile. Table 19 lists suggested doses for oral and intravenous antihypertensive medications that may be used to treat patients with acute severe HTN.

Key Action Statement 27

In children and adolescents with acute severe HTN and life-threatening symptoms, immediate treatment with short-acting antihypertensive medication should be initiated, and BP should be reduced by no more than 25% of the planned reduction over the first 8 hours (grade expert opinion D, weak recommendation).

11.2 HTN and the Athlete

Sports participation and increased physical activity should be encouraged in children with HTN. In adults, physical fitness is associated with lower all-cause mortality.[536] Although meta-analyses and randomized controlled trials consistently show lower BP after exercise training in adults,[535] the results are less robust in children.[340] On the basis of this evidence, sports participation should improve BP over time. Additionally, there is evidence that exercise itself has a beneficial effect on cardiac structure in adolescents.[537]

The athlete interested in participating in competitive sports

and/or intense training presents a special circumstance. Existing guidelines present conflicting recommendations.[1,538] Although increased LV wall dimension may be a consequence of athletic training,[360] recommendations from AHA and ACC include the following: (1) limiting competitive athletic participation among athletes with LVH beyond that seen with athlete's heart until BP is normalized by appropriate antihypertensive drug therapy, and (2) restricting athletes with stage 2 HTN (even among those without evidence of target organ injury) from participating in high-static sports (eg, weight lifting, boxing, and wrestling) until HTN is controlled with either lifestyle modification or drug therapy.[539]

The AAP policy statement "Athletic Participation by Children and Adolescents Who Have Systemic Hypertension" recommends that children with stage 2 HTN be restricted from high-static sports (classes IIIA to IIIC) in the absence of end organ damage, including LVH or concomitant heart disease, until their BP is in the normal range after lifestyle modification and/or drug therapy.[538] It is further recommended that athletes be promptly referred and evaluated by a qualified pediatric medical subspecialist within 1 week if they are asymptomatic or immediately if they are symptomatic. The subcommittee agrees with these recommendations.

It should be acknowledged that there are no data linking the presence of HTN to sudden death related to sports participation in children, although many cases of sudden death are of unknown etiology. That said, athletes identified as hypertensive (eg, during preparticipation sports screening) should undergo appropriate evaluation as outlined above. For athletes with more severe HTN (stage 2 or greater), treatment should be initiated before sports participation.

Key Action Statement 28

Children and adolescents with HTN may participate in competitive sports once hypertensive target organ effects and risk have been assessed (grade C, moderate recommendation).

Key Action Statement 29

Children and adolescents with HTN should receive treatment to lower BP below stage 2 thresholds before participating in competitive sports (grade C, weak recommendation).

11.3 HTN and the Posttransplant Patient

HTN is common in children after solid-organ transplants, with prevalence rates ranging from 50% to 90%.[179,180,540,541] Contributing factors include the use of steroids, calcineurin inhibitors, and mTOR (mammalian target of rapamycin) inhibitors. In patients with renal transplants, the presence of native kidneys, CKD, and transplant glomerulopathy are additional risk factors for HTN. HTN rates are higher by 24-hour ABPM compared with clinic BP measurements because these populations commonly have MH and nocturnal HTN.[179–183,542] Control of HTN in renal-transplant patients has been improved with the use of annual ABPM.[184,185] Therefore, ABPM should be used to identify and monitor nocturnal BP abnormalities and MH in pediatric kidney and heart-transplant recipients. The use of home BP assessment may provide a comparable alternative to ABPM for BP assessment after transplant as well.[186]

The management of identified HTN in the pediatric transplant patient can be challenging. Rates of control of HTN in renal-transplant patients generally range from 33% to 55%.[180,187] In studies by Seeman et al,[188] intensified antihypertensive treatment in pediatric renal-transplant recipients improved nocturnal SBP and significantly reduced proteinuria.[543] Children in these studies who achieved normotension had stable graft function, whereas those who remained hypertensive at 2 years had a progression of renal disease.[544]

Antihypertensive medications have rarely been systematically studied in this population. There is limited evidence that ACE inhibitors and ARBs may be superior to other agents in achieving BP control and improving long-term graft survival in renal-transplant patients.[185,543,544] However, the combination of ACE inhibitors and ARBs in renal-transplant patients has been associated with acidosis and hyperkalemia and is not recommended.[545]

Key Action Statement 27. In children and adolescents with acute severe HTN and life-threatening symptoms, immediate treatment with short-acting antihypertensive medication should be initiated, and BP should be reduced by no more than 25% of the planned reduction over the first 8 hours (grade expert opinion D, weak recommendation).

Aggregate Evidence Quality	Expert Opinion, D
Benefits	Avoidance of complications caused by rapid BP reduction
Risks, harm, cost	Severe BP elevation may persist
Benefit–harm assessment	Benefit outweighs harm
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Patients without acute severe HTN and life-threatening symptoms
Strength	Weak recommendation because of expert opinion
Key references	240,533,535

12. LIFETIME HTN TREATMENT AND TRANSITION TO ADULTHOOD

For adolescents with HTN requiring ongoing treatment, the

Key Action Statement 28. Children and adolescents with HTN may participate in competitive sports once hypertensive target organ effects and risk have been assessed (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Aerobic exercise improves CVD risk factors in children and adolescents with HTN
Risks, harm, cost	Unknown, but theoretical risk related to a rise in BP with strenuous exercise may exist
Benefit–harm assessment	The benefits of exercise likely outweigh the potential risk in the vast majority of children and adolescents with HTN
Intentional vagueness	None
Role of patient preferences	Families may have different opinions about sports participation in children with HTN
Exclusions	None
Strength	Moderate recommendation
Key references	341,360,538,540,541

Key Action Statement 29. Children and adolescents with HTN should receive treatment to lower BP below stage 2 thresholds before participating in competitive sports (grade C, weak recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Aerobic exercise improves CVD risk factors in children and adolescents with HTN
Risks, harm, cost	Unknown, but theoretical risk related to a rise in BP with strenuous exercise may exist
Benefit–harm assessment	The benefits of exercise likely outweigh the potential risk in the vast majority of children and adolescents with HTN
Intentional vagueness	None
Role of patient preferences	None
Exclusions	None
Strength	Weak recommendation
Key references	341,360,538,540,541

transition from pediatric care to an adult provider is essential.[546] HTN definition and treatment recommendations in this guideline are generally consistent with the forthcoming adult HTN treatment guideline, so diagnosis and treatment should not typically change with transition.

Key Action Statement 30

Adolescents with elevated BP or HTN (whether they are receiving antihypertensive treatment) should typically have their care transitioned to an appropriate adult care provider by 22 years of age (recognizing that there may be individual cases in which this upper age limit is exceeded, particularly in the case of youth with special health care needs). There should be a transfer of information regarding HTN etiology and past manifestations and complications of the patient's HTN (grade X, strong recommendation).

13. PREVENTION OF HTN

13.1 Importance of Preventing HTN

BP levels tend to increase with time even after adult height is reached. The rate of progression to frank HTN in a study of more than 12 000 Japanese adults (20–35 years of age at baseline, followed for 9 years) was 36.5% and was greater with higher baseline BP category.[548] The rate of progression may also be accelerated in African American individuals. Similarly, both the Bogalusa Heart[63] and Fels Longitudinal[60] studies have clearly demonstrated that the risk of HTN in early adulthood is dependent on childhood BP, with greater numbers of elevated BP measurements in childhood conferring an increased risk of adult HTN.

Because the tracking of BP levels in children has also been well documented,[10] it is not surprising that analyses of the National Childhood BP database found 7% of adolescents with elevated BP per year progressed to true hypertensive BP levels. Of note, initial BMI and change in BMI were major determinants of the development of HTN.[22] Therefore, in both children and adults, efforts (discussed below) should be made to prevent progression to sustained HTN and to avoid the development of hypertensive CV diseases.

13.2 Strategies for Prevention

One of the largest trials of preventing progression to HTN in adults, the Trial of Preventing Hypertension study, proved that 2 years of treatment with candesartan reduced the number of subjects with elevated BP from developing stage 1 HTN even after the drug was withdrawn.[547] However, no similar study has been conducted in youth; for this reason, prevention efforts to date have focused on lifestyle modification, especially dietary intervention,[426] exercise,[549] and treatment of obesity.[550] The best evidence for the potential of such prevention strategies comes from epidemiologic evidence for risk factors for the development of HTN or from studies focused on the treatment of established HTN. These risk factors include positive family history, obesity, a high-sodium diet, the absence of a DASH-type diet, larger amounts of

Key Action Statement 30. Adolescents with elevated BP or HTN (whether they are receiving antihypertensive treatment) should typically have their care transitioned to an appropriate adult care provider by 22 years of age (recognizing that there may be individual cases in which this upper age limit is exceeded, particularly in the case of youth with special health care needs). There should be a transfer of information regarding HTN etiology and past manifestations and complications of the patient's HTN (grade X, strong recommendation).

Aggregate Evidence Quality	Grade X
Benefits	Provides continuity of care for patients
Risks, harm, cost	None
Benefit–harm assessment	No risk
Intentional vagueness	None
Role of patient preferences	Patient can pick adult care provider
Exclusions	None
Strength	Strong recommendation
Key references	547

sedentary time, and possibly other dietary factors.[551–553]

Because family history is immutable, it is difficult to build a preventive strategy around it. However, a positive family history of HTN should suggest the need for closer BP monitoring to detect HTN if it occurs.

Appropriate energy balance with calories eaten balanced by calories expended in physical activity is important. This is the best strategy to maintain an appropriate BMI percentile for age and sex and to avoid the development of obesity.[554] From a broader dietary perspective, a DASH-type diet (ie, high in fruits, vegetables, whole grains, and low-fat dairy, with decreased intake of foods high in saturated fat or sugar) may be beneficial (see Table 16).[423,427] Avoiding high-sodium foods may prove helpful in preventing HTN, particularly for individuals who are more sensitive to dietary sodium intake.[555]

Adhering to recommendations for 60 minutes a day of moderate to vigorous physical activity can be important to maintaining an appropriate weight and may be independently helpful to maintaining a lower BP.[344] The achievement of normal sleep habits and avoidance of tobacco products are also reasonable strategies to reduce CV risk.

These preventive strategies can be implemented as part of routine primary health care for children and adolescents.

14. CHALLENGES IN THE IMPLEMENTATION OF PEDIATRIC HTN GUIDELINES

Many studies have shown that physicians fail to meet benchmarks with respect to screening, especially universal screening for high BP in children.[7,115] Although the reasons for this failure likely vary from practice to practice, a number of common challenges can be identified.

The first challenge is determining how to identify every child in a clinic who merits a BP measurement. This could be accomplished through flags in an EHR, documentation rules for specific patients, and/or clinic protocols.

The second challenge is establishing a local clinic protocol for measuring BP correctly on the basis of the algorithms in this guideline. It is important to determine the optimal approach on the basis of the available equipment, the skills of clinic personnel, and the clinic's throughput needs.

The third challenge is for clinic personnel to be aware of what to do with high BP measurements when they occur. Knowing when to counsel patients, order tests or laboratory work, and reach out for help is essential. Making this part of standard practice so every child follows the prescribed pathway may be challenging.

The final diagnosis of HTN also relies on a number of sequential visits. Ensuring that patients return for all of these visits and are not lost to follow-up may require new clinic processes or mechanisms. Information technology may help remind providers to schedule these visits and remind patients to attend these visits; even with that assistance, however, completing all the visits may be difficult for some patients.

In addition, family medicine physicians and general pediatricians may face challenges in having normative pediatric BP values available for use at all times. Although adult BP cutoffs are easy to memorize, pediatric BP percentile cutoffs are greatly dependent on age and height. The BP tables in this guideline provide cutoffs to use for the proper diagnosis of HTN; their availability will simplify the recognition of abnormal BP values.

The AAP Education in Quality Improvement for Pediatric Practice module on HTN identification and management[556] and its accompanying implementation guide[557] should be of assistance to practitioners who wish to improve their approach to identifying and managing childhood HTN. This module is currently being updated to incorporate the new recommendations in this guideline.

15. OTHER TOPICS

15.1 Economic Impact of BP Management

Researchers in a small number of studies have examined the potential economic impacts related to pediatric BP management.[208,558,559] Wang et al[558] estimated both the effectiveness and cost-effectiveness of 3 screening strategies and interventions to normalize pediatric BP based on the literature and through a simulation of children (n = 4 017 821). The 3 screening strategies included the following: (1) no screening; (2) selected screening and treatment, as well as "treating everyone" (ie, with population-wide interventions, such as targeted programs for overweight adolescents [eg, weight-loss programs, exercise programs, and salt-reduction programs]); and (3) nontargeted programs for exercise and salt reduction.

The simulation suggested that these various strategies could reduce mortality, with a modest expected survival benefit of 0.5 to 8.6 days. The researchers also examined quality-adjusted life-years (QALYs) and the cost per QALY. Only 1 intervention, a nontargeted salt-reduction campaign, had a negative cost per QALY. This intervention and the other 2 described in that article support the concept that population-wide interventions may be the most cost-effective way to improve CV health. The article has serious limitations, however, including the fact that population-wide interventions for exercise and the reduction of sodium intake have not, thus far, been effective.

The accurate determination of those who actually have HTN (as opposed to WCH) is fundamental to providing sound care to patients. Researchers in two studies examined the effects of using ABPM in the diagnosis of HTN.[208,559] Davis et al[559] compared 3 HTN screening strategies; these options are summarized in the following value-analysis framework (see Table 20).[560] It appears that the implementation of ABPM for all patients is not ensured. The next best option, screening clinic BP with ABPM, is most likely to be implementable and has significant clinical benefit given the high prevalence of WCH.

Swartz et al[208] conducted a retrospective review of 267 children with elevated clinic BP measurements referred for ABPM. Of the 126 patients who received ABPM, 46% had WCH, 49% had stage 1 HTN, and 5% had stage 2 HTN. This is consistent with the concept that screening with clinic BP alone results in high numbers of false-positive results for HTN. The diagnosis of HTN in this study resulted in an additional $3420 for evaluation (includes clinic visit, facility fee, laboratory testing, renal ultrasound, and echocardiography) vs $1265 (includes clinic visit, facility fee, and ABPM). This suggests that ABPM is cost-effective because of the reduction of unnecessary testing in patients with WCH.

When examining these costs, the availability of ABPM, and the availability of practitioners who are skilled in pediatric interpretation, the most cost-effective and implementable screening solution is to measure clinic BP and confirm elevated readings by ABPM.

15.2 Patient Perspective and Pediatric HTN

Children and adolescents are not just patients; they are active participants in their health management. If children and adolescents lack a clear understanding of what is happening inside their bodies, they will not be able to make informed choices in their daily activities. Better choices lead to better decisions executed in self-care. For clear judgments to be made, there needs to be open communication between physicians and families, a provision of appropriate education on optimal HTN management, and a strong partnership assembled within a multidisciplinary health care team including physicians, advanced practice providers, dietitians, nurses, and medical and clinical assistants.

It is important for physicians to be mindful that children and adolescents want, and need, to be involved in their medical care. Pediatric HTN patients are likely to feel excluded when clinicians or other providers speak to their parents instead of including them in the conversation. When patients are neither included in the discussion nor encouraged to ask questions, their anxiety can increase, thus worsening their HTN. Keeping an open line of communication is important and is best done by using a team approach consisting of the patient, the family, health care support staff, and physicians. With practical education on HTN management provided in easily understandable terms, the patients will be more likely to apply the concepts presented to them. Education is important and should be given in a way that is appropriate for young children and their families to understand. Education should consist of suitable medication dosing, a proper diet and level of activity, the identification of symptoms, and appropriate BP monitoring (including cuff size).

15.3 Parental Perspective and Pediatric HTN

Parents play a key role in the management and care of their children's health. Parents and physicians should act as a cohesive unit to foster the best results. It

is vital for physicians to provide concise information in plain language and do so using a team approach. This will facilitate parents having a clear understanding of the required tests, medications, follow-ups, and outcomes.

Patient Perspective, by Matthew Goodwin

"I am not just a 13 year old, I am a teenager who has lived with hypertension, renal disease, and midaortic syndrome since I was 4 years old. I have experienced surgeries, extended hospitalizations, daily medications, procedures, tests, continued blood pressure monitoring, lifestyle changes, and dietary restrictions. Hypertension is a part of my everyday life. It will always be a component of me. I had to learn the effects of hypertension at a young age. I knew what would happen to me if I ate too much salt or did not fully hydrate, thus I became watchful. I did this so I could efficiently communicate with my physicians any changes I physically felt or any symptoms that were new or different regarding my illness. This has allowed me, my family, and my doctors to work effectively as one unit. I am grateful for my doctors listening to me as a person and not as a kid."

Parents of children with hypertensive issues can encounter 1 or more specialists in addition to their pediatric clinician. This can prove to be overwhelming, frightening, and may fill the parent with anxiety. Taking these things into account and creating unified partners, built with the physician and family, will encourage the family to be more involved in the patient's health management. Plain language in a team approach will yield the most positive outcomes for the patient.

Understanding the family and patient's perception of HTN and any underlying disease that may be contributing to it is important to resolve any misconceptions and encourage adherence to the physician's recommendations. To attain therapeutic goals, proper education must be provided to the family as a whole. This education should include proper medication dosages, recommended sodium intake, any dietary changes, exercise expectations, and any other behavioral changes. It is equally important to stress to the family the short- and long-term effects of HTN if it is not properly managed. Parents with younger children will carry the ultimate burden of daily decisions as it applies to medications, food choices, and activity. Parents of older adolescents will partner with the children to encourage the right choices. Education as a family unit is important for everyone involved to understand the consequences.

A family-based approach is important for all pediatric diseases but plays a particular role in conditions that are substantially influenced by lifestyle behaviors. This has been shown in several pediatric populations, including those with T2DM and obesity.[561–565]

16. EVIDENCE GAPS AND PROPOSED FUTURE DIRECTIONS

In general, the pediatric HTN literature is not as robust as the adult HTN literature. The reasons for this are many, but the 2 most important are as follows: (1) the lower prevalence of HTN in childhood compared with adults, and (2) the lack of adverse CV events (myocardial infarction, stroke, and death) attributable to HTN in young patients. These factors make it difficult to conduct the types of clinical trials that are needed to produce high-quality evidence. For example, no large pediatric cohort has ever been assembled to answer the question of whether routine BP measurement in childhood is useful to prevent adult CVD.[566] Given this, other types of evidence, such as from cross-sectional and observational cohort studies, must be examined to guide practice.[567]

From the standpoint of the primary care provider, the most significant evidence gaps relate to whether diagnosing elevated BP and HTN in children and adolescents truly has long-term health consequences, whether antihypertensive medications should be used in a child or adolescent with elevated BP, and what medications should be preferentially used. These evidence gaps have been alluded to previously in this document.

Other important evidence gaps should be highlighted, including the following:

- Is there a specific BP level in childhood that predicts adverse outcomes, and can a single number (or numbers) be used to define HTN, as in adults?
- Can and should ABPM ever replace auscultation in the diagnosis of childhood HTN?
- Are the currently used, normative standards for ABPM appropriate, or are new normative data needed?[568]
- What is the best diagnostic evaluation to confidently exclude secondary causes of HTN?
- Are other assessments of hypertensive target organ damage (such as urine MA or vascular studies) better than echocardiography?
- How confident can we be that a child or teenager with elevated BP

will have HTN and/or CVD disease as an adult?

Some of these questions may eventually be answered by research that is currently in progress, such as further analysis of the International Childhood Cardiovascular Cohort Consortium[569] and the promising Adult Hypertension Onset in Youth study, which seeks to better define the level of BP in childhood that predicts the development of hypertensive target organ damage.[570] Other studies will need to be performed in children and adolescents to fill in the remaining gaps, including more rigorous validation studies of automated BP devices in the pediatric population, expanded trials of lifestyle interventions, further comparative trials of antihypertensive medications, and studies of the clinical applicability of hypertensive target organ assessments.

Furthermore, and perhaps more crucially, there needs to be prospective assessment of the recommendations made in this document with regular updates based on new evidence as it is generated (generally, per AAP policy, these occur approximately every 5 years). With such ongoing reassessment and revision, it is hoped that this document and its future revisions will come to be viewed as an effective guide to practice and will improve the care of the young patients who are entrusted to us.

Implementation tools for this guideline are available on the AAP Web site (https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/coqips/Pages/Implementation-Guide.aspx).

AUTHORS

Joseph T. Flynn, MD, MS, FAAP
David C. Kaelber, MD, PhD, MPH, FAAP, FACP, FACMI
Carissa M. Baker-Smith, MD, MS, MPH, FAAP, FAHA
Douglas Blowey, MD
Aaron E. Carroll, MD, MS, FAAP
Stephen R. Daniels, MD, PhD, FAAP
Sarah D. de Ferranti, MD, MPH, FAAP
Janis M. Dionne, MD, FRCPC
Susan K. Flinn, MA
Bonita Falkner, MD
Samuel S. Gidding, MD
Celeste Goodwin
Michael G. Leu, MD, MS, MHS, FAAP
Makia E. Powers, MD, MPH, FAAP
Corinna Rea, MD, MPH, FAAP
Joshua Samuels, MD, MPH, FAAP
Madeline Simasek, MD, MSCP, FAAP
Vidhu V. Thaker, MD, FAAP
Elaine M. Urbina, MD, MS, FAAP

SUBCOMMITTEE ON SCREENING AND MANAGEMENT OF HIGH BLOOD PRESSURE IN CHILDREN (OVERSIGHT BY THE COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY)†

Joseph T. Flynn, MD, MS, FAAP, Co-chair, Section on Nephrology
David Kaelber, MD, MPH, PhD, FAAP, Co-chair, Section on Medicine-Pediatrcs, Council on Clinical Information Technology
Carissa M. Baker-Smith, MD, MS, MPH, Epidemiologist and Methodologist
Aaron Carroll, MD, MS, FAAP, Partnership for Policy Implementation
Stephen R. Daniels, MD, PhD, FAAP, Committee on Nutrition
Sarah D. de Ferranti, MD, MPH, FAAP, Committee on Cardiology and Cardiac Surgery
Michael G. Leu, MD, MS, MHS, FAAP, Council on Quality Improvement and Patient Safety
Makia Powers, MD, MPH, FAAP, Committee on Adolescence
Corinna Rea, MD, MPH, FAAP, Section on Early Career Physicians
Joshua Samuels, MD, MPH, FAAP, Section on Nephrology
Madeline Simasek, MD, FAAP, Quality Improvement Innovation Networks
Vidhu Thaker, MD, FAAP, Section on Obesity

LIAISONS

Douglas Blowey, MD, *American Society of Pediatric Nephrology*
Janis Dionne, MD, FRCPC, *Canadian Association of Paediatric Nephrologists*
Bonita Falkner, MD, *International Pediatric Hypertension Association*
Samuel Gidding, MD, *American College of Cardiology, American Heart Association*
Celeste Goodwin, *National Pediatric Blood Pressure Awareness Foundation*
Elaine Urbina, MD, FAAP, *American Heart Association AHOY Committee*

MEDICAL WRITER

Susan K. Flinn, MA

STAFF

Kymika Okechukwu, MPA, Manager, Evidence-Based Practice Initiatives

ABBREVIATIONS

AAP: American Academy of Pediatrics
ABPM: ambulatory blood pressure monitoring
ACC: American College of Cardiology
ACE: angiotensin-converting enzyme
AHA: American Heart Association
ARB: angiotensin receptor blocker
ARR: aldosterone to renin ratio
BP: blood pressure
BSA: body surface area
cIMT: carotid intimamedia thickness
CKD: chronic kidney disease
CTA: computed tomographic angiography
CV: cardiovascular
CVD: cardiovascular disease
DASH: Dietary Approaches to Stop Hypertension
DBP: diastolic blood pressure
ED: emergency department
EHR: electronic health record
FMD: flow-mediated dilation
HTN: hypertension
LVH: left ventricular hypertrophy
LVMI: left ventricular mass index
MA: microalbuminuria
MAP: mean arterial pressure
MH: masked hypertension
MI: motivational interviewing
MRA: magnetic resonance angiography
NF-1: neurofibromatosis type 1
OSAS: obstructive sleep apnea syndrome
PCC: pheochromocytoma
PICOT: Patient, Intervention/Indicator, Comparison, Outcome, and Time
PRA: plasma renin activity
PWV: pulse wave velocity
QALY: quality-adjusted life-year
RAAS: renin-angiotensin-aldosterone system
RAS: renal artery stenosis
SBP: systolic blood pressure
SDB: sleep-disordered breathing
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus
UA: uric acid
WCH: white coat hypertension

Seattle, Washington; [n]Department of Pediatrics, School of Medicine, Morehouse College, Atlanta, Georgia; [o]Associate Director, General Academic Pediatric Fellowship, Staff Physician, Boston's Children's Hospital Primary Care at Longwood, Instructor, Harvard Medical School, Boston, Massachusetts; Departments of [p]Pediatrics and Internal Medicine, McGovern Medical School, University of Texas, Houston, Texas; [q]Pediatric Education, University of Pittsburgh Medical Center Shadyside Family Medicine Residency, Clinical Associate Professor of Pediatrics, Children's Hospital of Pittsburgh of University of Pittsburgh Medical Center, and School of Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania; [r]Division of Molecular Genetics, Department of Pediatrics, Columbia University Medical Center, New York, New York; and [s]Preventive Cardiology, Cincinnati Children's Hospital Medical Center, Department of Pediatrics, University of Cincinnati, Cincinnati, Ohio

Drs Flynn and Kaelber served as the specialty and primary care chairs of the Subcommittee and had lead roles in developing the framework for the guidelines and coordinating the overall guideline development; Dr Baker-Smith served as the epidemiologist and led the evidence review and synthesis; Ms. Flinn compiled the first draft of the manuscript and coordinated manuscript revisions; All other authors were significantly involved in all aspects of the guideline creation including initial scoping, literature review and synthesis, draft manuscript creation and manuscript review; and all authors approved the final manuscript as submitted.

Endorsed by the American Heart Association.

DOI: https://doi.org/10.1542/peds.2017-1904

Address correspondence to Joseph T Flynn. Email: joseph.flynn@seattlechildrens.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated that they have no financial relationships relevant to this article to disclose.

FUNDING: The American Academy of Pediatrics provided funding to cover travel costs for subcommittee members to attend subcommittee meetings, to pay for the epidemiologist (Dr Baker-Smith) and consultant (Susan Flynn), and to produce the revised normative blood pressure tables.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated that they have no potential conflicts of interest to disclose.

REFERENCES

1. National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. *Pediatrics*. 2004;114(2, suppl 4th Report):555–576
2. Institute of Medicine, Committee on Standards for Systematic Reviews of Comparative Effectiveness Research. In: Eden J, Levit L, Berg A, Morton S, eds. *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: National Academies Press; 2011
3. American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877
4. Rosner B, Cook NR, Daniels S, Falkner B. Childhood blood pressure trends and risk factors for high blood pressure: the NHANES experience 1988-2008. *Hypertension*. 2013;62(2):247–254
5. Din-Dzietham R, Liu Y, Bielo MV, Shamsa F. High blood pressure trends in children and adolescents in national surveys, 1963 to 2002. *Circulation*. 2007;116(13):1488–1496
6. Kit BK, Kuklina E, Carroll MD, Ostchega Y, Freedman DS, Ogden CL. Prevalence of and trends in dyslipidemia and blood pressure among US children and adolescents, 1999-2012. *JAMA Pediatr*. 2015;169(3):272–279
7. Hansen ML, Gunn PW, Kaelber DC. Underdiagnosis of hypertension in children and adolescents. *JAMA*. 2007;298(8):874–879
8. McNiece KL, Poffenbarger TS, Turner JL, Franco KD, Sorof JM, Portman RJ. Prevalence of hypertension and pre-hypertension among adolescents. *J Pediatr*. 2007;150(6):640–644, 644.e1
9. Chiolero A, Cachat F, Burnier M, Paccaud F, Bovet P. Prevalence of hypertension in schoolchildren based on repeated measurements and association with overweight. *J Hypertens*. 2007;25(11):2209–2217
10. Chen X, Wang Y. Tracking of blood pressure from childhood to adulthood: a systematic review and meta-regression analysis. *Circulation*. 2008;117(25):3171–3180
11. Theodore RF, Broadbent J, Nagin D, et al. Childhood to early-midlife systolic blood pressure trajectories: early-life predictors, effect modifiers, and adult cardiovascular outcomes. *Hypertension*. 2015;66(6):1108–1115
12. Mozaffarian D, Benjamin EJ, Go AS, et al; Writing Group Members; American Heart Association Statistics Committee; Stroke Statistics Subcommittee. Executive summary: heart disease and stroke statistics—2016 update: a report from the American Heart Association. *Circulation*. 2016;133(4):447–454
13. Liberman JN, Berger JE, Lewis M. Prevalence of antihypertensive, antidiabetic, and dyslipidemic prescription medication use among children and adolescents. *Arch Pediatr Adolesc Med*. 2009;163(4):357–364
14. Rodriguez BL, Dabelea D, Liese AD, et al; SEARCH Study Group. Prevalence and correlates of elevated blood pressure in youth with diabetes mellitus: the

SEARCH for diabetes in youth study. *J Pediatr*. 2010;157(2):245–251.e1

15. Willi SM, Hirst K, Jago R, et al; HEALTHY Study Group. Cardiovascular risk factors in multi-ethnic middle school students: the HEALTHY primary prevention trial. *Pediatr Obes*. 2012;7(3):230–239
16. DiPietro A, Kees-Folts D, DesHarnais S, Camacho F, Wassner SJ. Primary hypertension at a single center: treatment, time to control, and extended follow-up. *Pediatr Nephrol*. 2009;24(12):2421–2428
17. Seeman T, Gilík J. Long-term control of ambulatory hypertension in children: improving with time but still not achieving new blood pressure goals. *Am J Hypertens*. 2013;26(7):939–945
18. Foglia CF, von Vigier RO, Fossali E, et al. A simplified antihypertensive drug regimen does not ameliorate control of childhood hypertension. *J Hum Hypertens*. 2005;19(8):653–654
19. Sorof J, Daniels S. Obesity hypertension in children: a problem of epidemic proportions. *Hypertension*. 2002;40(4):441–447
20. Sorof JM, Lai D, Turner J, Poffenbarger T, Portman RJ. Overweight, ethnicity, and the prevalence of hypertension in school-aged children. *Pediatrics*. 2004;113(3, pt 1):475–482
21. Koebnick C, Black MH, Wu J, et al. High blood pressure in overweight and obese youth: implications for screening. *J Clin Hypertens (Greenwich)*. 2013;15(11):793–805
22. Falkner B, Gidding SS, Ramirez-Garnica G, Wiltrout SA, West D, Rappaport EB. The relationship of body mass index and blood pressure in primary care pediatric patients. *J Pediatr*. 2006;148(2):195–200
23. Lurbe E, Invitti C, Torro I, et al. The impact of the degree of obesity on the discrepancies between office and ambulatory blood pressure values in youth [published correction appears in *J Hypertens*. 2007;25(1):258]. *J Hypertens*. 2006;24(8):1557–1564
24. Skinner AC, Perrin EM, Moss LA, Skelton JA. Cardiometabolic risks and severity of obesity in children and young adults. *N Engl J Med*. 2015;373(14):1307–1317
25. Zhang T, Zhang H, Li S, et al. Impact of adiposity on incident hypertension is modified by insulin resistance in adults: longitudinal observation from the Bogalusa Heart Study. *Hypertension*. 2016;67(1):56–62
26. So H-K, Yip GW-K, Choi K-C, et al; Hong Kong ABP Working Group. Association between waist circumference and childhood-masked hypertension: a community-based study. *J Paediatr Child Health*. 2016;52(4):385–390
27. Friedemann C, Heneghan C, Mahtani K, Thompson M, Perera R, Ward AM. Cardiovascular disease risk in healthy children and its association with body mass index: systematic review and meta-analysis. *BMJ*. 2012;345:e4759
28. Kelishadi R, Mirmoghtadaee P, Najafi H, Keikha M. Systematic review on the association of abdominal obesity in children and adolescents with cardio-metabolic risk factors. *J Res Med Sci*. 2015;20(3):294–307
29. Török K, Pálfi A, Szelényi Z, Molnár D. Circadian variability of blood pressure in obese children. *Nutr Metab Cardiovasc Dis*. 2008;18(6):429–435
30. Framme J, Dangardt F, Mårild S, Osika W, Währborg P, Friberg P. 24-h systolic blood pressure and heart rate recordings in lean and obese adolescents. *Clin Physiol Funct Imaging*. 2006;26(4):235–239
31. Wasterstål M, Marcus C. Association between nocturnal blood pressure dipping and insulin metabolism in obese adolescents. *Int J Obes*. 2010;34(3):472–477
32. Wasterstål M, Hedvall Kallerman P, Hagman E, Ek AE, Rössner SM, Marcus C. Nocturnal blood pressure non-dipping is prevalent in severely obese, prepubertal and early pubertal children. *Acta Paediatr*. 2014;103(2):225–230
33. Macumber IR, Weiss NS, Halbach SM, Hanevold CD, Flynn JT. The association of pediatric obesity with nocturnal non-dipping on 24-hour ambulatory blood pressure monitoring. *Am J Hypertens*. 2016;29(5):647–652
34. Perng W, Rifas-Shiman SL, Kramer MS, et al. Early weight gain, linear growth, and mid-childhood blood pressure: a prospective study in project viva. *Hypertension*. 2016;67(2):301–308
35. Parker ED, Sinaiko AR, Kharbanda EO, et al. Change in weight status and development of hypertension. *Pediatrics*. 2016;137(3):e20151662
36. Yip J, Facchini FS, Reaven GM. Resistance to insulin-mediated glucose disposal as a predictor of cardiovascular disease. *J Clin Endocrinol Metab*. 1998;83(8):2773–2776
37. Kashyap SR, Defronzo RA. The insulin resistance syndrome: physiological considerations. *Diab Vasc Dis Res*. 2007;4(1):13–19
38. Lurbe E, Torro I, Aguilar F, et al. Added impact of obesity and insulin resistance in nocturnal blood pressure elevation in children and adolescents. *Hypertension*. 2008;51(3):635–641
39. Chinali M, de Simone G, Roman MJ, et al. Cardiac markers of pre-clinical disease in adolescents with the metabolic syndrome: the strong heart study. *J Am Coll Cardiol*. 2008;52(11):932–938
40. Archbold KH, Vasquez MM, Goodwin JL, Quan SF. Effects of sleep patterns and obesity on increases in blood pressure in a 5-year period: report from the Tucson Children's Assessment of Sleep Apnea Study. *J Pediatr*. 2012;161(1):26–30
41. Javaheri S, Storfer-Isser A, Rosen CL, Redline S. Sleep quality and elevated blood pressure in adolescents. *Circulation*. 2008;118(10):1034–1040
42. Hartzell K, Avis K, Lozano D, Feig D. Obstructive sleep apnea and periodic limb movement disorder in a population of children with hypertension and/or nocturnal nondipping blood pressures. *J Am Soc Hypertens*. 2016;10(2):101–107
43. Au CT, Ho CK, Wing YK, Lam HS, Li AM. Acute and chronic effects of sleep duration on blood pressure. *Pediatrics*. 2014;133(1). Available at: www.pediatrics.org/cgi/content/full/133/1/e64
44. Li AM, Au CT, Ng C, Lam HS, Ho CKW, Wing YK. A 4-year prospective follow-up study of childhood OSA

and its association with BP. *Chest*. 2014;145(6):1255–1263

45. Li AM, Au CT, Sung RY, et al. Ambulatory blood pressure in children with obstructive sleep apnoea: a community based study. *Thorax*. 2008;63(9):803–809
46. Flynn JT, Mitsnefes M, Pierce C, et al; Chronic Kidney Disease in Children Study Group. Blood pressure in children with chronic kidney disease: a report from the Chronic Kidney Disease in Children study. *Hypertension*. 2008;52(4):631–637
47. Samuels J, Ng D, Flynn JT, et al; Chronic Kidney Disease in Children Study Group. Ambulatory blood pressure patterns in children with chronic kidney disease. *Hypertension*. 2012;60(1):43–50
48. Shatat IF, Flynn JT. Hypertension in children with chronic kidney disease. *Adv Chronic Kidney Dis*. 2005;12(4):378–384
49. Chavers BM, Solid CA, Daniels FX, et al. Hypertension in pediatric long-term hemodialysis patients in the United States. *Clin J Am Soc Nephrol*. 2009;4(8):1363–1369
50. Seeman T. Hypertension after renal transplantation. *Pediatr Nephrol*. 2009;24(5):959–972
51. Tkaczyk M, Nowicki M, Bałasz-Chmielewska I, et al. Hypertension in dialysed children: the prevalence and therapeutic approach in Poland–a nationwide survey. *Nephrol Dial Transplant*. 2006;21(3):736–742
52. Kramer AM, van Stralen KJ, Jager KJ, et al. Demographics of blood pressure and hypertension in children on renal replacement therapy in Europe. *Kidney Int*. 2011;80(10):1092–1098
53. Halbach SM, Martz K, Mattoo T, Flynn J. Predictors of blood pressure and its control in pediatric patients receiving dialysis. *J Pediatr*. 2012;160(4):621–625.e1
54. Kaelber DC. IBM explorys cohort discovery tool. Available at: www.ibm.com/watson/health/explorys. Accessed February 3, 2017
55. Barker DJ. The fetal and infant origins of adult disease. *BMJ*. 1990;301(6761):1111
56. Edvardsson VO, Steinthorsdottir SD, Eliasdottir SB, Indridason OS, Palsson R. Birth weight and childhood blood pressure. *Curr Hypertens Rep*. 2012;14(6):596–602
57. Mhanna MJ, Iqbal AM, Kaelber DC. Weight gain and hypertension at three years of age and older in extremely low birth weight infants. *J Neonatal Perinatal Med*. 2015;8(4):363–369
58. Di Salvo G, Castaldi B, Baldini L, et al. Masked hypertension in young patients after successful aortic coarctation repair: impact on left ventricular geometry and function. *J Hum Hypertens*. 2011;25(12):739–745
59. Bayrakci US, Schaefer F, Duzova A, Yigit S, Bakkaloglu A. Abnormal circadian blood pressure regulation in children born preterm. *J Pediatr*. 2007;151(4):399–403
60. Sun SS, Grave GD, Siervogel RM, Pickoff AA, Arslanian SS, Daniels SR. Systolic blood pressure in childhood predicts hypertension and metabolic syndrome later in life. *Pediatrics*. 2007;119(2):237–246
61. Juhola J, Oikonen M, Magnussen CG, et al. Childhood physical, environmental, and genetic predictors of adult hypertension: the cardiovascular risk in young Finns study. *Circulation*. 2012;126(4):402–409
62. Juhola J, Magnussen CG, Viikari JS, et al. Tracking of serum lipid levels, blood pressure, and body mass index from childhood to adulthood: the Cardiovascular Risk in Young Finns Study. *J Pediatr*. 2011;159(4):584–590
63. Bao W, Threefoot SA, Srinivasan SR, Berenson GS. Essential hypertension predicted by tracking of elevated blood pressure from childhood to adulthood: the Bogalusa Heart Study. *Am J Hypertens*. 1995;8(7):657–665
64. Falkner B, Gidding SS, Portman R, Rosner B. Blood pressure variability and classification of prehypertension and hypertension in adolescence. *Pediatrics*. 2008;122(2):238–242
65. Tracy RE, Newman WP III, Wattigney WA, Srinivasan SR, Strong JP, Berenson GS. Histologic features of atherosclerosis and hypertension from autopsies of young individuals in a defined geographic population: the Bogalusa Heart Study. *Atherosclerosis*. 1995;116(2):163–179
66. Urbina EM, Khoury PR, McCoy C, Daniels SR, Kimball TR, Dolan LM. Cardiac and vascular consequences of pre-hypertension in youth. *J Clin Hypertens (Greenwich)*. 2011;13(5):332–342
67. de Simone G, Devereux RB, Daniels SR, Koren MJ, Meyer RA, Laragh JH. Effect of growth on variability of left ventricular mass: assessment of allometric signals in adults and children and their capacity to predict cardiovascular risk. *J Am Coll Cardiol*. 1995;25(5):1056–1062
68. O'Leary DH, Polak JF, Kronmal RA, Manolio TA, Burke GL, Wolfson SK Jr; Cardiovascular Health Study Collaborative Research Group. Carotid-artery intima and media thickness as a risk factor for myocardial infarction and stroke in older adults. *N Engl J Med*. 1999;340(1):14–22
69. Mitchell GF, Hwang SJ, Vasan RS, et al. Arterial stiffness and cardiovascular events: the Framingham Heart Study. *Circulation*. 2010;121(4):505–511
70. Lloyd-Jones DM, Hong Y, Labarthe D, et al; American Heart Association Strategic Planning Task Force and Statistics Committee. Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association's strategic impact goal through 2020 and beyond. *Circulation*. 2010;121(4):586–613
71. Ning H, Labarthe DR, Shay CM, et al. Status of cardiovascular health in US children up to 11 years of age: the National Health and Nutrition Examination Surveys 2003-2010. *Circ Cardiovasc Qual Outcomes*. 2015;8(2):164–171
72. Steinberger J, Daniels SR, Hagberg N, et al; American Heart Association Atherosclerosis, Hypertension, and Obesity in the Young Committee of the Council on Cardiovascular Disease in the Young; Council on Cardiovascular and Stroke Nursing; Council on Epidemiology and Prevention; Council on Functional Genomics and Translational Biology; Stroke Council. Cardiovascular health promotion in children: challenges and opportunities for 2020 and beyond: a

scientific statement from the American Heart Association. *Circulation*. 2016;134(12):e236–e255

73. Ogden CL, Carroll MD, Lawman HG, et al. Trends in obesity prevalence among children and adolescents in the United States, 1988-1994 through 2013-2014. *JAMA*. 2016;315(21):2292–2299
74. Skinner AC, Perrin EM, Skelton JA. Prevalence of obesity and severe obesity in US children, 1999-2014. *Obesity (Silver Spring)*. 2016;24(5):1116–1123
75. Skinner AC, Skelton JA. Prevalence and trends in obesity and severe obesity among children in the United States, 1999-2012. *JAMA Pediatr*. 2014;168(6):561–566
76. Shay CM, Ning H, Daniels SR, Rooks CR, Gidding SS, Lloyd-Jones DM. Status of cardiovascular health in US adolescents: prevalence estimates from the National Health and Nutrition Examination Surveys (NHANES) 2005-2010. *Circulation*. 2013;127(13):1369–1376
77. Rosner B, Cook N, Portman R, Daniels S, Falkner B. Determination of blood pressure percentiles in normal-weight children: some methodological issues. *Am J Epidemiol*. 2008;167(6):653–666
78. Kaelber DC, Pickett F. Simple table to identify children and adolescents needing further evaluation of blood pressure. *Pediatrics*. 2009;123(6). Available at: www.pediatrics.org/cgi/content/full/123/6/e972
79. Dionne JM, Abitbol CL, Flynn JT. Hypertension in infancy: diagnosis, management and outcome [published correction appears in *Pediatr Nephrol*. 2012;27(1):159-60]. *Pediatr Nephrol*. 2012;27(1):17–32
80. Kent AL, Chaudhari T. Determinants of neonatal blood pressure. *Curr Hypertens Rep*. 2013;15(5):426–432
81. Report of the second task force on blood pressure control in children–1987. Task force on blood pressure control in children. National Heart, Lung, and Blood Institute, Bethesda, Maryland. *Pediatrics*. 1987;79(1):1–25
82. Savoca MR, MacKey ML, Evans CD, Wilson M, Ludwig DA, Harshfield GA. Association of ambulatory blood pressure and dietary caffeine in adolescents. *Am J Hypertens*. 2005;18(1):116–120
83. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Circulation*. 2005;111(5):697–716
84. Becton LJ, Egan BM, Hailpern SM, Shatat IF. Blood pressure reclassification in adolescents based on repeat clinic blood pressure measurements. *J Clin Hypertens (Greenwich)*. 2013;15(10):717–722
85. Daley MF, Sinaiko AR, Reifler LM, et al. Patterns of care and persistence after incident elevated blood pressure. *Pediatrics*. 2013;132(2). Available at: www.pediatrics.org/cgi/content/full/132/2/e349
86. Ostchega Y, Prineas RJ, Nwankwo T, Zipf G. Assessing blood pressure accuracy of an aneroid sphygmomanometer in a national survey environment. *Am J Hypertens*. 2011;24(3):322–327
87. Ma Y, Temprosa M, Fowler S, et al; Diabetes Prevention Program Research Group. Evaluating the accuracy of an aneroid sphygmomanometer in a clinical trial setting. *Am J Hypertens*. 2009;22(3):263–266
88. Podoll A, Grenier M, Croix B, Feig DI. Inaccuracy in pediatric outpatient blood pressure measurement. *Pediatrics*. 2007;119(3). Available at: www.pediatrics.org/cgi/content/full/119/3/e538
89. Mourad A, Carney S. Arm position and blood pressure: an audit. *Intern Med J*. 2004;34(5):290–291
90. Mourad A, Carney S, Gillies A, Jones B, Nanra R, Trevillian P. Arm position and blood pressure: a risk factor for hypertension? *J Hum Hypertens*. 2003;17(6):389–395
91. Zaheer S, Watson L, Webb NJ. Unmet needs in the measurement of blood pressure in primary care. *Arch Dis Child*. 2014;99(5):463–464
92. Veiga EV, Arcuri EAM, Cloutier L, Santos JL. Blood pressure measurement: arm circumference and cuff size availability. *Rev Lat Am Enfermagem*. 2009;17(4):455–461
93. Thomas M, Radford T, Dasgupta I. Unvalidated blood pressure devices with small cuffs are being used in hospitals. *BMJ*. 2001;323(7309):398
94. Burke MJ, Towers HM, O'Malley K, Fitzgerald DJ, O'Brien ET. Sphygmomanometers in hospital and family practice: problems and recommendations. *Br Med J (Clin Res Ed)*. 1982;285(6340):469–471
95. Centers for Disease Control and Prevention. National Health and Nutrition Examination Survey (NHANES) Anthropometry Procedures Manual. Available at: https://www.cdc.gov/nchs/data/nhanes/nhanes_07_08/manual_an.pdf. Published January 2013. Accessed May 9, 2016
96. Prineas RJ, Ostchega Y, Carroll M, Dillon C, McDowell M. US demographic trends in mid-arm circumference and recommended blood pressure cuffs for children and adolescents: data from the National Health and Nutrition Examination Survey 1988-2004. *Blood Press Monit*. 2007;12(2):75–80
97. Kimble KJ, Darnall RA Jr, Yelderman M, Ariagno RL, Ream AK. An automated oscillometric technique for estimating mean arterial pressure in critically ill newborns. *Anesthesiology*. 1981;54(5):423–425
98. Sonesson SE, Broberger U. Arterial blood pressure in the very low birthweight neonate. Evaluation of an automatic oscillometric technique. *Acta Paediatr Scand*. 1987;76(2):338–341
99. Duncan AF, Rosenfeld CR, Morgan JS, Ahmad N, Heyne RJ. Interrater reliability and effect of state on blood pressure measurements in infants 1 to 3 years of age. *Pediatrics*. 2008;122(3). Available at: www.pediatrics.org/cgi/content/full/122/3/e590
100. Nwankwo MU, Lorenz JM, Gardiner JC. A standard protocol for blood pressure measurement in the newborn. *Pediatrics*. 1997;99(6). Available at: www.pediatrics.org/cgi/content/full/99/6/e10

101. Gupta-Malhotra M, Banker A, Shete S, et al. Essential hypertension vs. secondary hypertension among children. *Am J Hypertens*. 2015;28(1):73–80

102. Kelly RK, Thomson R, Smith KJ, Dwyer T, Venn A, Magnussen CG. Factors affecting tracking of blood pressure from childhood to adulthood: the Childhood Determinants of Adult Health Study. *J Pediatr*. 2015;167(6):1422–1428.e2

103. Juhola J, Magnussen CG, Berenson GS, et al. Combined effects of child and adult elevated blood pressure on subclinical atherosclerosis: the International Childhood Cardiovascular Cohort Consortium. *Circulation*. 2013;128(3):217–224

104. Sladowska-Kozłowska J, Litwin M, Niemirska A, Wierzbicka A, Wawer ZT, Janas R. Change in left ventricular geometry during antihypertensive treatment in children with primary hypertension. *Pediatr Nephrol*. 2011;26(12):2201–2209

105. Litwin M, Niemirska A, Sladowska-Kozlowska J, et al. Regression of target organ damage in children and adolescents with primary hypertension. *Pediatr Nephrol*. 2010;25(12):2489–2499

106. Meyer AA, Kundt G, Lenschow U, Schuff-Werner P, Kienast W. Improvement of early vascular changes and cardiovascular risk factors in obese children after a six-month exercise program. *J Am Coll Cardiol*. 2006;48(9):1865–1870

107. Juonala M, Magnussen CG, Berenson GS, et al. Childhood adiposity, adult adiposity, and cardiovascular risk factors. *N Engl J Med*. 2011;365(20):1876–1885

108. Lo JC, Chandra M, Sinaiko A, et al. Severe obesity in children: prevalence, persistence and relation to hypertension. *Int J Pediatr Endocrinol*. 2014;2014(1):3

109. Rademacher ER, Jacobs DR Jr, Moran A, Steinberger J, Prineas RJ, Sinaiko A. Relation of blood pressure and body mass index during childhood to cardiovascular risk factor levels in young adults. *J Hypertens*. 2009;27(9):1766–1774

110. Maahs DM, Daniels SR, de Ferranti SD, et al; American Heart Association Atherosclerosis, Hypertension and Obesity in Youth Committee of the Council on Cardiovascular Disease in the Young; Council on Clinical Cardiology; Council on Cardiovascular and Stroke Nursing; Council for High Blood Pressure Research; Council on Lifestyle and Cardiometabolic Health. Cardiovascular disease risk factors in youth with diabetes mellitus: a scientific statement from the American Heart Association. *Circulation*. 2014;130(17):1532–1558

111. Levitt Katz L, Gidding SS, Bacha F, et al; TODAY Study Group. Alterations in left ventricular, left atrial, and right ventricular structure and function to cardiovascular risk factors in adolescents with type 2 diabetes participating in the TODAY clinical trial. *Pediatr Diabetes*. 2015;16(1):39–47

112. Hager A, Kanz S, Kaemmerer H, Schreiber C, Hess J. Coarctation Long-term Assessment (COALA): significance of arterial hypertension in a cohort of 404 patients up to 27 years after surgical repair of isolated coarctation of the aorta, even in the absence of restenosis and prosthetic material. *J Thorac Cardiovasc Surg*. 2007;134(3):738–745

113. O'Sullivan JJ, Derrick G, Darnell R. Prevalence of hypertension in children after early repair of coarctation of the aorta: a cohort study using casual and 24 hour blood pressure measurement. *Heart*. 2002;88(2):163–166

114. Becker AM, Goldberg JH, Henson M, et al. Blood pressure abnormalities in children with sickle cell anemia. *Pediatr Blood Cancer*. 2014;61(3):518–522

115. Brady TM, Solomon BS, Neu AM, Siberry GK, Parekh RS. Patient-, provider-, and clinic-level predictors of unrecognized elevated blood pressure in children. *Pediatrics*. 2010;125(6). Available at: www.pediatrics.org/cgi/content/full/125/6/e1286

116. Stabouli S, Sideras L, Vareta G, et al. Hypertension screening during healthcare pediatric visits. *J Hypertens*. 2015;33(5):1064–1068

117. Shapiro DJ, Hersh AL, Cabana MD, Sutherland SM, Patel AI. Hypertension screening during ambulatory pediatric visits in the United States, 2000-2009. *Pediatrics*. 2012;130(4):604–610

118. Bijlsma MW, Blufpand HN, Key Action Statementpers GJ, Bökenkamp A. Why pediatricians fail to diagnose hypertension: a multicenter survey. *J Pediatr*. 2014;164(1):173–177.e7

119. Chaudhry B, Wang J, Wu S, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. *Ann Intern Med*. 2006;144(10):742–752

120. Shojania KG, Jennings A, Mayhew A, Ramsay CR, Eccles MP, Grimshaw J. The effects of on-screen, point of care computer reminders on processes and outcomes of care. *Cochrane Database Syst Rev*. 2009;(3):CD001096

121. Garg AX, Adhikari NKJ, McDonald H, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *JAMA*. 2005;293(10):1223–1238

122. Hicks LS, Sequist TD, Ayanian JZ, et al. Impact of computerized decision support on blood pressure management and control: a randomized controlled trial. *J Gen Intern Med*. 2008;23(4):429–441

123. Samal L, Linder JA, Lipsitz SR, Hicks LS. Electronic health records, clinical decision support, and blood pressure control. *Am J Manag Care*. 2011;17(9):626–632

124. Heymann AD, Hoch I, Valinsky L, Shalev V, Silber H, Kokia E. Mandatory computer field for blood pressure measurement improves screening. *Fam Pract*. 2005;22(2):168–169

125. Brady TM, Neu AM, Miller ER III, Appel LJ, Siberry GK, Solomon BS. Real-time electronic medical record alerts increase high blood pressure recognition in children. *Clin Pediatr (Phila)*. 2015;54(7):667–675

126. Romano MJ, Stafford RS. Electronic health records and clinical decision support systems: impact on national ambulatory care quality. *Arch Intern Med*. 2011;171(10):897–903

127. Alpert BS, Quinn D, Gallick D. Oscillometric blood pressure: a review for clinicians. *J Am Soc Hypertens*. 2014;8(12):930–938

128. Alpert BS. Oscillometric blood pressure values are algorithm-specific. *Am J Cardiol*. 2010;106(10):1524–1525, author reply 1524–1525

129. Flynn JT, Pierce CB, Miller ER III, et al; Chronic Kidney Disease in Children Study Group. Reliability of resting blood pressure measurement and classification using an oscillometric device in children with chronic kidney disease. *J Pediatr*. 2012;160(3):434–440.e1

130. Kamath N, Goud BR, Phadke KD, Iyengar A. Use of oscillometric devices for the measurement of blood pressure-comparison with the gold standard. *Indian J Pediatr*. 2012;79(9):1230–1232

131. Chiolero A, Bovet P, Stergiou GS. Automated oscillometric blood pressure measurement in children. *J Clin Hypertens (Greenwich)*. 2014;16(6):468

132. Chiolero A, Paradis G, Lambert M. Accuracy of oscillometric devices in children and adults. *Blood Press*. 2010;19(4):254–259

133. Chio SS, Urbina EM, Lapointe J, Tsai J, Berenson GS. Korotkoff sound versus oscillometric cuff sphygmomanometers: comparison between auscultatory and DynaPulse blood pressure measurements. *J Am Soc Hypertens*. 2011;5(1):12–20

134. Eliasdottir SB, Steinthorsdottir SD, Indridason OS, Palsson R, Edvardsson VO. Comparison of aneroid and oscillometric blood pressure measurements in children. *J Clin Hypertens (Greenwich)*. 2013;15(11):776–783

135. Urbina EM, Khoury PR, McCoy CE, Daniels SR, Dolan LM, Kimball TR. Comparison of mercury sphygmomanometry blood pressure readings with oscillometric and central blood pressure in predicting target organ damage in youth. *Blood Press Monit*. 2015;20(3):150–156

136. Negroni-Balasquide X, Bell CS, Samuel J, Samuels JA. Is one measurement enough to evaluate blood pressure among adolescents? A blood pressure screening experience in more than 9000 children with a subset comparison of auscultatory to mercury measurements. *J Am Soc Hypertens*. 2016;10(2):95–100

137. Leblanc M-É, Croteau S, Ferland A, et al. Blood pressure assessment in severe obesity: validation of a forearm approach. *Obesity (Silver Spring)*. 2013;21(12):E533–E541

138. Altunkan S, Genç Y, Altunkan E. A comparative study of an ambulatory blood pressure measuring device and a wrist blood pressure monitor with a position sensor versus a mercury sphygmomanometer. *Eur J Intern Med*. 2007;18(2):118–123

139. Uen S, Fimmers R, Brieger M, Nickenig G, Mengden T. Reproducibility of wrist home blood pressure measurement with position sensor and automatic data storage. *BMC Cardiovasc Disord*. 2009;9:20

140. Fania C, Benetti E, Palatini P. Validation of the A&D BP UB-543 wrist device for home blood pressure measurement according to the European Society of Hypertension International Protocol revision 2010. *Blood Press Monit*. 2015;20(4):237–240

141. Kang Y-Y, Chen Q, Li Y, Wang JG. Validation of the SCIAN LD-735 wrist blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol revision 2010. *Blood Press Monit*. 2016;21(4):255–258

142. Xie P, Wang Y, Xu X, Huang F, Pan J. Validation of the Pangao PG-800A11 wrist device assessed according to the European Society of Hypertension and the British Hypertension Society protocols. *Blood Press Monit*. 2015;20(2):108–111

143. Zweiker R, Schumacher M, Fruhwald FM, Watzinger N, Klein W. Comparison of wrist blood pressure measurement with conventional sphygmomanometry at a cardiology outpatient clinic. *J Hypertens*. 2000;18(8):1013–1018

144. Altunkan S, Yildiz S, Azer S. Wrist blood pressure-measuring devices: a comparative study of accuracy with a standard auscultatory method using a mercury manometer. *Blood Press Monit*. 2002;7(5):281–284

145. Palatini P, Longo D, Toffanin G, Bertolo O, Zaetta V, Pessina AC. Wrist blood pressure overestimates blood pressure measured at the upper arm. *Blood Press Monit*. 2004;9(2):77–81

146. Stergiou GS, Christodoulakis GR, Nasothimiou EG, Giovas PP, Kalogeropoulos PG. Can validated wrist devices with position sensors replace arm devices for self-home blood pressure monitoring? A randomized crossover trial using ambulatory monitoring as reference. *Am J Hypertens*. 2008;21(7):753–758

147. Khoshdel AR, Carney S, Gillies A. The impact of arm position and pulse pressure on the validation of a wrist-cuff blood pressure measurement device in a high risk population. *Int J Gen Med*. 2010;3:119–125

148. Kikuya M, Chonan K, Imai Y, Goto E, Ishii M; Research Group to Assess the Validity of Automated Blood Pressure Measurement Devices in Japan. Accuracy and reliability of wrist-cuff devices for self-measurement of blood pressure. *J Hypertens*. 2002;20(4):629–638

149. Westhoff TH, Schmidt S, Meissner R, Zidek W, van der Giet M. The impact of pulse pressure on the accuracy of wrist blood pressure measurement. *J Hum Hypertens*. 2009;23(6):391–395

150. Deutsch C, Krüger R, Saito K, et al. Comparison of the Omron RS6 wrist blood pressure monitor with the positioning sensor on or off with a standard mercury sphygmomanometer. *Blood Press Monit*. 2014;19(5):306–313

151. Yarows SA. Comparison of the Omron HEM-637 wrist monitor to the auscultation method with the wrist position sensor on or disabled. *Am J Hypertens*. 2004;17(1):54–58

152. Menezes AMB, Dumith SC, Noal RB, et al. Validity of a wrist digital monitor for blood pressure measurement in comparison to a mercury sphygmomanometer. *Arq Bras Cardiol*. 2010;94(3):345–349, 365–370

153. Wankum PC, Thurman TL, Holt SJ, Hall RA, Simpson PM, Heulitt MJ. Validation of a noninvasive blood pressure

monitoring device in normotensive and hypertensive pediatric intensive care patients. *J Clin Monit Comput*. 2004;18(4):253–263

154. Cua CL, Thomas K, Zurakowski D, Laussen PC. A comparison of the Vasotrac with invasive arterial blood pressure monitoring in children after pediatric cardiac surgery. *Anesth Analg*. 2005;100(5): 1289–1294

155. Flynn JT, Daniels SR, Hayman LL, et al; American Heart Association Atherosclerosis, Hypertension and Obesity in Youth Committee of the Council on Cardiovascular Disease in the Young. Update: ambulatory blood pressure monitoring in children and adolescents: a scientific statement from the American Heart Association. *Hypertension*. 2014;63(5): 1116–1135

156. Siu AL; U.S. Preventive Services Task Force. Screening for high blood pressure in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2015;163(10):778–786

157. Díaz LN, Garin EH. Comparison of ambulatory blood pressure and Task Force criteria to identify pediatric hypertension. *Pediatr Nephrol*. 2007;22(4):554–558

158. Salice P, Ardissino G, Zanchetti A, et al. Age-dependent differences in office (OBP) vs ambulatory blood pressure monitoring (ABPM) in hypertensive children and adolescents: 8C.03. *J Hypertens*. 2010;28:e423–e424

159. Stergiou GS, Alamara CV, Salgami EV, Vaindirlis IN, Dacou-Voutetakis C, Mountokalakis TD. Reproducibility of home and ambulatory blood pressure in children and adolescents. *Blood Press Monit*. 2005;10(3):143–147

160. Li Z, Snieder H, Harshfield GA, Treiber FA, Wang X. A 15-year longitudinal study on ambulatory blood pressure tracking from childhood to early adulthood. *Hypertens Res*. 2009;32(5):404–410

161. Seeman T, Palyzová D, Dusek J, Janda J. Reduced nocturnal blood pressure dip and sustained nighttime hypertension are specific markers of secondary hypertension. *J Pediatr*. 2005;147(3):366–371

162. Bjelakovic B, Jaddoe VW, Vukomanovic V, et al. The relationship between currently recommended ambulatory systolic blood pressure measures and left ventricular mass index in pediatric hypertension. *Curr Hypertens Rep*. 2015;17(4):534

163. Brady TM, Fivush B, Flynn JT, Parekh R. Ability of blood pressure to predict left ventricular hypertrophy in children with primary hypertension. *J Pediatr*. 2008;152(1):73–78, 78.e1

164. McNiece KL, Gupta-Malhotra M, Samuels J, et al; National High Blood Pressure Education Program Working Group. Left ventricular hypertrophy in hypertensive adolescents: analysis of risk by 2004 National High Blood Pressure Education Program Working Group staging criteria. *Hypertension*. 2007;50(2):392–395

165. Richey PA, Disessa TG, Hastings MC, Somes GW, Alpert BS, Jones DP. Ambulatory blood pressure and increased left ventricular mass in children at risk for hypertension. *J Pediatr*. 2008;152(3):343–348

166. Conkar S, Yılmaz E, Hacıkara Ş, Bozabalı S, Mir S. Is daytime systolic load an important risk factor for target organ damage in pediatric hypertension? *J Clin Hypertens (Greenwich)*. 2015;17(10):760–766

167. Flynn JT. Differentiation between primary and secondary hypertension in children using ambulatory blood pressure monitoring. *Pediatrics*. 2002;110(1, pt 1):89–93

168. Dursun H, Bayazit AK, Cengiz N, et al. Ambulatory blood pressure monitoring and renal functions in children with a solitary kidney. *Pediatr Nephrol*. 2007;22(4):559–564

169. Patzer L, Seeman T, Luck C, Wühl E, Janda J, Misselwitz J. Day- and night-time blood pressure elevation in children with higher grades of renal scarring. *J Pediatr*. 2003;142(2):117–122

170. Fidan K, Kandur Y, Buyukkaragoz B, Akdemir UO, Soylemezoglu O. Hypertension in pediatric patients with renal scarring in association with vesicoureteral reflux. *Urology*. 2013;81(1):173–177

171. Basiratnia M, Esteghamati M, Ajami GH, et al. Blood pressure profile in renal transplant recipients and its relation to diastolic function: tissue Doppler echocardiographic study. *Pediatr Nephrol*. 2011;26(3):449–457

172. Chaudhuri A, Sutherland SM, Begin B, et al. Role of twenty-four-hour ambulatory blood pressure monitoring in children on dialysis. *Clin J Am Soc Nephrol*. 2011;6(4):870–876

173. Wühl E, Trivelli A, Picca S, et al; ESCAPE Trial Group. Strict blood-pressure control and progression of renal failure in children. *N Engl J Med*. 2009;361(17):1639–1650

174. Chatterjee M, Speiser PW, Pellizzarri M, et al. Poor glycemic control is associated with abnormal changes in 24-hour ambulatory blood pressure in children and adolescents with type 1 diabetes mellitus. *J Pediatr Endocrinol Metab*. 2009;22(11):1061–1067

175. Darcan S, Goksen D, Mir S, et al. Alterations of blood pressure in type 1 diabetic children and adolescents. *Pediatr Nephrol*. 2006;21(5):672–676

176. Dost A, Klinkert C, Kapellen T, et al; DPV Science Initiative. Arterial hypertension determined by ambulatory blood pressure profiles: contribution to microalbuminuria risk in a multicenter investigation in 2,105 children and adolescents with type 1 diabetes. *Diabetes Care*. 2008;31(4):720–725

177. Ettinger LM, Freeman K, DiMartino-Nardi JR, Flynn JT. Microalbuminuria and abnormal ambulatory blood pressure in adolescents with type 2 diabetes mellitus. *J Pediatr*. 2005;147(1):67–73

178. Lurbe E, Redon J, Kesani A, et al. Increase in nocturnal blood pressure and progression to microalbuminuria in type 1 diabetes. *N Engl J Med*. 2002;347(11):797–805

179. Nagasako SS, Nogueira PC, Machado PG, Pestana JO. Risk factors for hypertension 3 years after renal transplantation in children. *Pediatr Nephrol*. 2007;22(9):1363–1368

180. Roche SL, Kaufmann J, Dipchand AI, Kantor PF. Hypertension after pediatric heart transplantation is primarily associated with immunosuppressive

regimen. *J Heart Lung Transplant*. 2008;27(5):501–507

181. Paripovic D, Kostic M, Spasojevic B, Kruscic D, Peco-Antic A. Masked hypertension and hidden uncontrolled hypertension after renal transplantation. *Pediatr Nephrol*. 2010;25(9):1719–1724
182. Ferraris JR, Ghezzi L, Waisman G, Krmar RT. ABPM vs office blood pressure to define blood pressure control in treated hypertensive paediatric renal transplant recipients. *Pediatr Transplant*. 2007;11(1):24–30
183. McGlothan KR, Wyatt RJ, Ault BH, et al. Predominance of nocturnal hypertension in pediatric renal allograft recipients. *Pediatr Transplant*. 2006;10(5):558–564
184. Balzano R, Lindblad YT, Vavilis G, Jogestrand T, Berg UB, Krmar RT. Use of annual ABPM, and repeated carotid scan and echocardiography to monitor cardiovascular health over nine yr in pediatric and young adult renal transplant recipients. *Pediatr Transplant*. 2011;15(6):635–641
185. Krmar RT, Berg UB. Blood pressure control in hypertensive pediatric renal transplants: role of repeated ABPM following transplantation. *Am J Hypertens*. 2008;21(10):1093–1099
186. Ambrosi P, Kreitmann B, Habib G. Home blood pressure monitoring in heart transplant recipients: comparison with ambulatory blood pressure monitoring. *Transplantation*. 2014;97(3):363–367
187. Seeman T, Simková E, Kreisinger J, et al. Reduction of proteinuria during intensified antihypertensive therapy in children after renal transplantation. *Transplant Proc*. 2007;39(10):3150–3152
188. Seeman T, Simková E, Kreisinger J, et al. Improved control of hypertension in children after renal transplantation: results of a two-yr interventional trial. *Pediatr Transplant*. 2007;11(5):491–497
189. Lurbe E, Alvarez V, Liao Y, et al. The impact of obesity and body fat distribution on ambulatory blood pressure in children and adolescents. *Am J Hypertens*. 1998;11(4, pt 1):418–424
190. Lurbe E, Alvarez V, Redon J. Obesity, body fat distribution, and ambulatory blood pressure in children and adolescents. *J Clin Hypertens (Greenwich)*. 2001;3(6):362–367
191. Marcovecchio ML, Patricelli L, Zito M, et al. Ambulatory blood pressure monitoring in obese children: role of insulin resistance. *J Hypertens*. 2006;24(12):2431–2436
192. Shatat IF, Freeman KD, Vuguin PM, Dimartino-Nardi JR, Flynn JT. Relationship between adiponectin and ambulatory blood pressure in obese adolescents. *Pediatr Res*. 2009;65(6):691–695
193. Amin RS, Carroll JL, Jeffries JL, et al. Twenty-four-hour ambulatory blood pressure in children with sleep-disordered breathing. *Am J Respir Crit Care Med*. 2004;169(8):950–956
194. Leung LC, Ng DK, Lau MW, et al. Twenty-four-hour ambulatory BP in snoring children with obstructive sleep apnea syndrome. *Chest*. 2006;130(4):1009–1017
195. Akyürek N, Atabek ME, Eklioglu BS, Alp H. Ambulatory blood pressure and subclinical cardiovascular disease in children with turner syndrome. *Pediatr Cardiol*. 2014;35(1):57–62
196. Salgado CM, Jardim PC, Teles FB, Nunes MC. Low birth weight as a marker of changes in ambulatory blood pressure monitoring. *Arq Bras Cardiol*. 2009;92(2):107–121
197. Gimpel C, Wühl E, Arbeiter K, et al; ESCAPE Trial Group. Superior consistency of ambulatory blood pressure monitoring in children: implications for clinical trials. *J Hypertens*. 2009;27(8):1568–1574
198. Suláková T, Feber J. Should mean arterial pressure be included in the definition of ambulatory hypertension in children? *Pediatr Nephrol*. 2013;28(7):1105–1112
199. Lurbe E, Torro I, Alvarez V, et al. Prevalence, persistence, and clinical significance of masked hypertension in youth. *Hypertension*. 2005;45(4):493–498
200. Stabouli S, Kotsis V, Toumanidis S, Papamichael C, Constantopoulos A, Zakopoulos N. White-coat and masked hypertension in children: association with target-organ damage. *Pediatr Nephrol*. 2005;20(8):1151–1155
201. Furusawa ÉA, Filho UD, Junior DM, Koch VH. Home and ambulatory blood pressure to identify white coat and masked hypertension in the pediatric patient. *Am J Hypertens*. 2011;24(8):893–897
202. Wells TG, Portman R, Norman P, Haertter S, Davidai G, Fei Wang. Safety, efficacy, and pharmacokinetics of telmisartan in pediatric patients with hypertension. *Clin Pediatr (Phila)*. 2010;49(10):938–946
203. Mitsnefes M, Flynn J, Cohn S, et al; CKiD Study Group. Masked hypertension associates with left ventricular hypertrophy in children with CKD. *J Am Soc Nephrol*. 2010;21(1):137–144
204. Lurbe E, Redon J. Discrepancies in office and ambulatory blood pressure in adolescents: help or hindrance? *Pediatr Nephrol*. 2008;23(3):341–345
205. Pogue V, Rahman M, Lipkowitz M, et al; African American Study of Kidney Disease and Hypertension Collaborative Research Group. Disparate estimates of hypertension control from ambulatory and clinic blood pressure measurements in hypertensive kidney disease. *Hypertension*. 2009;53(1):20–27
206. Urbina EM, Williams RV, Alpert BS, et al; American Heart Association Atherosclerosis, Hypertension, and Obesity in Youth Committee of the Council on Cardiovascular Disease in the Young. Noninvasive assessment of subclinical atherosclerosis in children and adolescents: recommendations for standard assessment for clinical research: a scientific statement from the American Heart Association. *Hypertension*. 2009;54(5):919–950
207. Kavey RE, Kveselis DA, Atallah N, Smith FC. White coat hypertension in childhood: evidence for end-organ effect. *J Pediatr*. 2007;150(5):491–497
208. Swartz SJ, Srivaths PR, Croix B, Feig DI. Cost-effectiveness of ambulatory blood pressure monitoring in the initial evaluation of hypertension in children. *Pediatrics*. 2008;122(6):1177–1181

209. Briasoulis A, Androulakis E, Palla M, Papageorgiou N, Tousoulis D. White-coat hypertension and cardiovascular events: a meta-analysis. *J Hypertens*. 2016;34(4):593–599

210. Valent-Morić B, Zigman T, Zaja-Franulović O, Malenica M, Cuk M. The importance of ambulatory blood pressure monitoring in children and adolescents. *Acta Clin Croat*. 2012;51(1):59–64

211. Palatini P, Parati G. Blood pressure measurement in very obese patients: a challenging problem. *J Hypertens*. 2011;29(3):425–429

212. Halm MA. Arm circumference, shape, and length: how interplaying variables affect blood pressure measurement in obese persons. *Am J Crit Care*. 2014;23(2):166–170

213. Ostchega Y, Hughes JP, Prineas RJ, Zhang G, Nwankwo T, Chiappa MM. Mid-arm circumference and recommended blood pressure cuffs for children and adolescents aged between 3 and 19 years: data from the National Health and Nutrition Examination Survey, 1999-2010. *Blood Press Monit*. 2014;19(1):26–31

214. Bonso E, Saladini F, Zanier A, Benetti E, Dorigatti F, Palatini P. Accuracy of a single rigid conical cuff with standard-size bladder coupled to an automatic oscillometric device over a wide range of arm circumferences. *Hypertens Res*. 2010;33(11):1186–1191

215. Palatini P, Benetti E, Fania C, Malipiero G, Saladini F. Rectangular cuffs may overestimate blood pressure in individuals with large conical arms. *J Hypertens*. 2012;30(3):530–536

216. Aguilar A, Ostrow V, De Luca F, Suarez E. Elevated ambulatory blood pressure in a multi-ethnic population of obese children and adolescents. *J Pediatr*. 2010;156(6):930–935

217. Ostrow V, Wu S, Aguilar A, Bonner R Jr, Suarez E, De Luca F. Association between oxidative stress and masked hypertension in a multi-ethnic population of obese children and adolescents. *J Pediatr*. 2011;158(4):628–633.e1

218. Woroniecki RP, Flynn JT. How are hypertensive children evaluated and managed? A survey of North American pediatric nephrologists. *Pediatr Nephrol*. 2005;20(6):791–797

219. Mengden T, Hernandez Medina RM, Beltran B, Alvarez E, Kraft K, Vetter H. Reliability of reporting self-measured blood pressure values by hypertensive patients. *Am J Hypertens*. 1998;11(12):1413–1417

220. Palatini P, Frick GN. Techniques for self-measurement of blood pressure: limitations and needs for future research. *J Clin Hypertens (Greenwich)*. 2012;14(3):139–143

221. Stergiou GS, Karpettas N, Kapoyiannis A, Stefanidis CJ, Vazeou A. Home blood pressure monitoring in children and adolescents: a systematic review. *J Hypertens*. 2009;27(10):1941–1947

222. Stergiou GS, Nasothimiou E, Giovas P, Kapoyiannis A, Vazeou A. Diagnosis of hypertension in children and adolescents based on home versus ambulatory blood pressure monitoring. *J Hypertens*. 2008;26(8):1556–1562

223. Furusawa EA, Filho UD, Koch VH. Home blood pressure monitoring in paediatric chronic hypertension. *J Hum Hypertens*. 2009;23(7):464–469

224. Stergiou GS, Nasothimiou EG, Giovas PP, Rarra VC. Long-term reproducibility of home vs. office blood pressure in children and adolescents: the Arsakeion school study. *Hypertens Res*. 2009;32(4):311–315

225. Wühl E, Hadtstein C, Mehls O, Schaefer F; Escape Trial Group. Home, clinic, and ambulatory blood pressure monitoring in children with chronic renal failure. *Pediatr Res*. 2004;55(3):492–497

226. Stergiou GS, Karpettas N, Panagiotakos DB, Vazeou A. Comparison of office, ambulatory and home blood pressure in children and adolescents on the basis of normalcy tables. *J Hum Hypertens*. 2011;25(4):218–223

227. Stergiou GS, Alamara CV, Kalkana CB, et al. Out-of-office blood pressure in children and adolescents: disparate findings by using home or ambulatory monitoring. *Am J Hypertens*. 2004;17(10):869–875

228. Stergiou GS, Rarra VC, Yiannes NG. Changing relationship between home and office blood pressure with increasing age in children: the Arsakeion School study. *Am J Hypertens*. 2008;21(1):41–46

229. Salgado CM, Jardim PC, Viana JK, Jardim TS, Velasquez PP. Home blood pressure in children and adolescents: a comparison with office and ambulatory blood pressure measurements. *Acta Paediatr*. 2011;100(10):e163–e168

230. Stergiou GS, Ntineri A, Kollias A, Destounis A, Nasothimiou E, Roussias L. Changing relationship among clinic, home, and ambulatory blood pressure with increasing age. *J Am Soc Hypertens*. 2015;9(7):544–552

231. Stergiou GS, Yiannes NG, Rarra VC, Panagiotakos DB. Home blood pressure normalcy in children and adolescents: the Arsakeion School study. *J Hypertens*. 2007;25(7):1375–1379

232. Sorof JM, Turner J, Franco K, Portman RJ. Characteristics of hypertensive children identified by primary care referral compared with school-based screening. *J Pediatr*. 2004;144(4):485–489

233. King CA, Meadows BB, Engelke MK, Swanson M. Prevalence of elevated body mass index and blood pressure in a rural school-aged population: implications for school nurses. *J Sch Health*. 2006;76(4):145–149

234. Underwood SM, Averhart L, Dean A, et al. Clinical evaluation and follow-up of body mass and blood pressure in pre-elementary school children: program review. *J Natl Black Nurses Assoc*. 2012;23(1):8–15

235. Kapur G, Ahmed M, Pan C, Mitsnefes M, Chiang M, Mattoo TK. Secondary hypertension in overweight and stage 1 hypertensive children: a Midwest Pediatric Nephrology Consortium report. *J Clin Hypertens (Greenwich)*. 2010;12(1):34–39

236. Flynn JT, Alderman MH. Characteristics of children with primary hypertension seen at a referral center. *Pediatr Nephrol*. 2005;20(7):961–966

237. Gomes RS, Quirino IG, Pereira RM, et al. Primary versus secondary

hypertension in children followed up at an outpatient tertiary unit. *Pediatr Nephrol*. 2011;26(3):441–447

238. Welch WP, Yang W, Taylor-Zapata P, Flynn JT. Antihypertensive drug use by children: are the drugs labeled and indicated? *J Clin Hypertens (Greenwich)*. 2012;14(6):388–395

239. Flynn J, Zhang Y, Solar-Yohay S, Shi V. Clinical and demographic characteristics of children with hypertension. *Hypertension*. 2012;60(4):1047–1054

240. Baracco R, Kapur G, Mattoo T, et al. Prediction of primary vs secondary hypertension in children. *J Clin Hypertens (Greenwich)*. 2012;14(5):316–321

241. Silverstein DM, Champoux E, Aviles DH, Vehaskari VM. Treatment of primary and secondary hypertension in children. *Pediatr Nephrol*. 2006;21(6):820–827

242. Flynn JT, Meyers KEC, Neto JP, et al; Pediatric Valsartan Study Group. Efficacy and safety of the angiotensin receptor blocker valsartan in children with hypertension aged 1 to 5 years. *Hypertension*. 2008;52(2):222–228

243. Schaefer F, van de Walle J, Zurowska A, et al; Candesartan in Children with Hypertension Investigators. Efficacy, safety and pharmacokinetics of candesartan cilexetil in hypertensive children from 1 to less than 6 years of age. *J Hypertens*. 2010;28(5):1083–1090

244. Webb NJ, Wells TG, Shahinfar S, et al. A randomized, open-label, dose-response study of losartan in hypertensive children. *Clin J Am Soc Nephrol*. 2014;9(8):1441–1448

245. Coleman DM, Eliason JL, Ohye RG, Stanley JC. Long-segment thoracoabdominal aortic occlusions in childhood. *J Vasc Surg*. 2012;56(2):482–485

246. Lee MG, Kowalski R, Galati JC, et al. Twenty-four-hour ambulatory blood pressure monitoring detects a high prevalence of hypertension late after coarctation repair in patients with hypoplastic arches. *J Thorac Cardiovasc Surg*. 2012;144(5):1110–1116

247. Agnoletti G, Bonnet C, Bonnet D, Sidi D, Aggoun Y. Mid-term effects of implanting stents for relief of aortic recoarctation on systemic hypertension, carotid mechanical properties, intimal medial thickness and reflection of the pulse wave. *Cardiol Young*. 2005;15(3):245–250

248. Young WF. Endocrine hypertension. In: Melmed S, Polonsky KS, Larsen R, Kronenberg HM, eds. *Williams Textbook of Endocrinology*. 13th ed. Philadelphia, PA: Elsevier Inc; 2016:556–588

249. Bausch B, Wellner U, Bausch D, et al. Long-term prognosis of patients with pediatric pheochromocytoma. *Endocr Relat Cancer*. 2013;21(1):17–25

250. Waguespack SG, Rich T, Grubbs E, et al. A current review of the etiology, diagnosis, and treatment of pediatric pheochromocytoma and paraganglioma. *J Clin Endocrinol Metab*. 2010;95(5):2023–2037

251. Fishbein L, Merrill S, Fraker DL, Cohen DL, Nathanson KL. Inherited mutations in pheochromocytoma and paraganglioma: why all patients should be offered genetic testing. *Ann Surg Oncol*. 2013;20(5):1444–1450

252. Barontini M, Levin G, Sanso G. Characteristics of pheochromocytoma in a 4- to 20-year-old population. *Ann N Y Acad Sci*. 2006;1073:30–37

253. Welander J, Söderkvist P, Gimm O. Genetics and clinical characteristics of hereditary pheochromocytomas and paragangliomas. *Endocr Relat Cancer*. 2011;18(6):R253–R276

254. Eisenhofer G, Peitzsch M. Laboratory evaluation of pheochromocytoma and paraganglioma. *Clin Chem*. 2014;60(12):1486–1499

255. Funder JW, Carey RM, Mantero F, et al. The management of primary aldosteronism: case detection, diagnosis, and treatment: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2016;101(5):1889–1916

256. Stowasser M, Gordon RD. Monogenic mineralocorticoid hypertension. *Best Pract Res Clin Endocrinol Metab*. 2006;20(3):401–420

257. White PC, Dupont J, New MI, Leiberman E, Hochberg Z, Rösler A. A mutation in CYP11B1 (Arg-448---His) associated with steroid 11 beta-hydroxylase deficiency in Jews of Moroccan origin. *J Clin Invest*. 1991;87(5):1664–1667

258. Parsa AA, New MI. Low-renin hypertension of childhood. *Endocrinol Metab Clin North Am*. 2011;40(2):369–377, viii

259. Parajes S, Loidi L, Reisch N, et al. Functional consequences of seven novel mutations in the CYP11B1 gene: four mutations associated with nonclassic and three mutations causing classic 11beta-hydroxylase deficiency. *J Clin Endocrinol Metab*. 2010;95(2):779–788

260. New MI, Geller DS, Fallo F, Wilson RC. Monogenic low renin hypertension. *Trends Endocrinol Metab*. 2005;16(3):92–97

261. Imai T, Yanase T, Waterman MR, Simpson ER, Pratt JJ. Canadian Mennonites and individuals residing in the Friesland region of The Netherlands share the same molecular basis of 17 alpha-hydroxylase deficiency. *Hum Genet*. 1992;89(1):95–96

262. Dhir V, Reisch N, Bleicken CM, et al. Steroid 17alpha-hydroxylase deficiency: functional characterization of four mutations (A174E, V178D, R440C, L465P) in the CYP17A1 gene. *J Clin Endocrinol Metab*. 2009;94(8):3058–3064

263. Aglony M, Martínez-Aguayo A, Carvajal CA, et al. Frequency of familial hyperaldosteronism type 1 in a hypertensive pediatric population: clinical and biochemical presentation. *Hypertension*. 2011;57(6):1117–1121

264. Speiser PW, White PC. Congenital adrenal hyperplasia. *N Engl J Med*. 2003;349(8):776–788

265. Funder JW. Genetic disorders in primary aldosteronism — familial and somatic. *J Steroid Biochem Mol Biol*. 2017;165(pt A):154–157

266. Carss KJ, Stowasser M, Gordon RD, O'Shaughnessy KM. Further study of chromosome 7p22 to identify the molecular basis of familial hyperaldosteronism type II. *J Hum Hypertens*. 2011;25(9):560–564

267. So A, Duffy DL, Gordon RD, et al. Familial hyperaldosteronism type II is linked to the chromosome 7p22 region but also shows predicted heterogeneity. *J Hypertens*. 2005;23(8):1477–1484

268. Geller DS, Zhang J, Wisgerhof MV, Shackleton C, Key Action Statementhgarian M, Lifton RP. A novel form of human mendelian hypertension featuring nonglucocorticoid-remediable aldosteronism. *J Clin Endocrinol Metab*. 2008;93(8):3117–3123

269. Boulkroun S, Beuschlein F, Rossi GP, et al. Prevalence, clinical, and molecular correlates of KCNJ5 mutations in primary aldosteronism. *Hypertension*. 2012;59(3):592–598

270. Scholl UI, Nelson-Williams C, Yue P, et al. Hypertension with or without adrenal hyperplasia due to different inherited mutations in the potassium channel KCNJ5. *Proc Natl Acad Sci USA*. 2012;109(7):2533–2538

271. Scholl UI, Goh G, Stölting G, et al. Somatic and germline CACNA1D calcium channel mutations in aldosterone-producing adenomas and primary aldosteronism. *Nat Genet*. 2013;45(9):1050–1054

272. Scholl UI, Stölting G, Nelson-Williams C, et al. Recurrent gain of function mutation in calcium channel CACNA1H causes early-onset hypertension with primary aldosteronism. *Elife*. 2015;4:e06315

273. Rothenbuhler A, Stratakis CA. Clinical and molecular genetics of Carney complex. *Best Pract Res Clin Endocrinol Metab*. 2010;24(3):389–399

274. Stratakis CA, Salpea P, Raygada M. *Carney Complex*. Seattle, WA: University of Washington; 2015

275. Lietman SA, Schwindinger WF, Levine MA. Genetic and molecular aspects of McCune-Albright syndrome. *Pediatr Endocrinol Rev*. 2007;4(suppl 4):380–385

276. Lumbroso S, Paris F, Sultan C. McCune-Albright syndrome: molecular genetics. *J Pediatr Endocrinol Metab*. 2002;15(suppl 3):875–882

277. Malchoff CD, Javier EC, Malchoff DM, et al. Primary cortisol resistance presenting as isosexual precocity. *J Clin Endocrinol Metab*. 1990;70(2):503–507

278. Nicolaides NC, Charmandari E. Chrousos syndrome: from molecular pathogenesis to therapeutic management. *Eur J Clin Invest*. 2015;45(5):504–514

279. Malchoff DM, Brufsky A, Reardon G, et al. A mutation of the glucocorticoid receptor in primary cortisol resistance. *J Clin Invest*. 1993;91(5):1918–1925

280. Ferrari P. The role of 11β-hydroxysteroid dehydrogenase type 2 in human hypertension. *Biochim Biophys Acta*. 2010;1802(12):1178–1187

281. Morineau G, Sulmont V, Salomon R, et al. Apparent mineralocorticoid excess: report of six new cases and extensive personal experience. *J Am Soc Nephrol*. 2006;17(11):3176–3184

282. Nesterov V, Krueger B, Bertog M, Dahlmann A, Palmisano R, Korbmacher C. In Liddle syndrome, epithelial sodium channel is hyperactive mainly in the early part of the aldosterone-sensitive distal nephron. *Hypertension*. 2016;67(6):1256–1262

283. Hanukoglu I, Hanukoglu A. Epithelial sodium channel (ENaC) family: Phylogeny, structure-function, tissue distribution, and associated inherited diseases. *Gene*. 2016;579(2):95–132

284. Geller DS, Farhi A, Pinkerton N, et al. Activating mineralocorticoid receptor mutation in hypertension exacerbated by pregnancy. *Science*. 2000;289(5476):119–123

285. Wilson FH, Disse-Nicodème S, Choate KA, et al. Human hypertension caused by mutations in WNK kinases. *Science*. 2001;293(5532):1107–1112

286. Boyden LM, Choi M, Choate KA, et al. Mutations in kelch-like 3 and cullin 3 cause hypertension and electrolyte abnormalities. *Nature*. 2012;482(7383):98–102

287. Stowasser M, Pimenta E, Gordon RD. Familial or genetic primary aldosteronism and Gordon syndrome. *Endocrinol Metab Clin North Am*. 2011;40(2):343–368, viii

288. Sacerdote A, Weiss K, Tran T, Rokeya Noor B, McFarlane SI. Hypertension in patients with Cushing's disease: pathophysiology, diagnosis, and management. *Curr Hypertens Rep*. 2005;7(3):212–218

289. Baid S, Nieman LK. Glucocorticoid excess and hypertension. *Curr Hypertens Rep*. 2004;6(6):493–499

290. Michalkiewicz E, Sandrini R, Figueiredo B, et al. Clinical and outcome characteristics of children with adrenocortical tumors: a report from the International Pediatric Adrenocortical Tumor Registry. *J Clin Oncol*. 2004;22(5):838–845

291. Danzi S, Klein I. Thyroid hormone and blood pressure regulation. *Curr Hypertens Rep*. 2003;5(6):513–520

292. Bahn RS, Burch HB, Cooper DS, et al; American Thyroid Association; American Association of Clinical Endocrinologists. Hyperthyroidism and other causes of thyrotoxicosis: management guidelines of the American Thyroid Association and American Association of Clinical Endocrinologists. *Endocr Pract*. 2011;17(3):456–520

293. Heyliger A, Tangpricha V, Weber C, Sharma J. Parathyroidectomy decreases systolic and diastolic blood pressure in hypertensive patients with primary hyperparathyroidism. *Surgery*. 2009;146(6):1042–1047

294. Rydberg E, Birgander M, Bondeson AG, Bondeson L, Willenheimer R. Effect of successful parathyroidectomy on 24-hour ambulatory blood pressure in patients with primary hyperparathyroidism. *Int J Cardiol*. 2010;142(1):15–21

295. Gambelunghe A, Sallsten G, Borné Y, et al. Low-level exposure to lead, blood pressure, and hypertension in a population-based cohort. *Environ Res*. 2016;149:157–163

296. Lee BK, Ahn J, Kim NS, Lee CB, Park J, Kim Y. Association of blood pressure with exposure to lead and cadmium: analysis of data from the 2008-2013 Korean National Health and Nutrition Examination Survey. *Biol Trace Elem Res*. 2016;174(1):40–51

297. Rapisarda V, Ledda C, Ferrante M, et al. Blood pressure and occupational

exposure to noise and lead (Pb): a cross-sectional study. *Toxicol Ind Health*. 2016;32(10):1729–1736

298. Hara A, Thijs L, Asayama K, et al. Blood pressure in relation to environmental lead exposure in the national health and nutrition examination survey 2003 to 2010. *Hypertension*. 2015;65(1):62–69

299. Gump BB, Reihman J, Stewart P, Lonky E, Darvill T, Matthews KA. Blood lead (Pb) levels: a potential environmental mechanism explaining the relation between socioeconomic status and cardiovascular reactivity in children. *Health Psychol*. 2007;26(3):296–304

300. Chen A, Rhoads GG, Cai B, Salganik M, Rogan WJ. The effect of chelation on blood pressure in lead-exposed children: a randomized study. *Environ Health Perspect*. 2006;114(4):579–583

301. Chen X, Zhu G, Lei L, Jin T. The association between blood pressure and blood cadmium in a Chinese population living in cadmium polluted area. *Environ Toxicol Pharmacol*. 2013;36(2):595–599

302. Tellez-Plaza M, Navas-Acien A, Crainiceanu CM, Guallar E. Cadmium exposure and hypertension in the 1999-2004 National Health and Nutrition Examination Survey (NHANES). *Environ Health Perspect*. 2008;116(1):51–56

303. Gallagher CM, Meliker JR. Blood and urine cadmium, blood pressure, and hypertension: a systematic review and meta-analysis. *Environ Health Perspect*. 2010;118(12):1676–1684

304. Swaddiwudhipong W, Mahasakpan P, Jeekeeree W, et al. Renal and blood pressure effects from environmental cadmium exposure in Thai children. *Environ Res*. 2015;136:82–87

305. Cao Y, Chen A, Radcliffe J, et al. Postnatal cadmium exposure, neurodevelopment, and blood pressure in children at 2, 5, and 7 years of age. *Environ Health Perspect*. 2009;117(10):1580–1586

306. Park JD, Zheng W. Human exposure and health effects of inorganic and elemental mercury. *J Prev Med Public Health*. 2012;45(6):344–352

307. Weidemann DK, Weaver VM, Fadrowski JJ. Toxic environmental exposures and kidney health in children. *Pediatr Nephrol*. 2016;31(11):2043–2054

308. Torres AD, Rai AN, Hardiek ML. Mercury intoxication and arterial hypertension: report of two patients and review of the literature. *Pediatrics*. 2000;105(3). Available at: www.pediatrics.org/cgi/content/full/105/3/e34

309. Brannan EH, Su S, Alverson BK. Elemental mercury poisoning presenting as hypertension in a young child. *Pediatr Emerg Care*. 2012;28(8):812–814

310. Mercer JJ, Bercovitch L, Muglia JJ. Acrodynia and hypertension in a young girl secondary to elemental mercury toxicity acquired in the home. *Pediatr Dermatol*. 2012;29(2):199–201

311. Valvi D, Casas M, Romaguera D, et al. Prenatal phthalate exposure and childhood growth and blood pressure: evidence from the Spanish INMA-Sabadell Birth Cohort Study. *Environ Health Perspect*. 2015;123(10):1022–1029

312. Trasande L, Sathyanarayana S, Spanier AJ, Trachtman H, Attina TM, Urbina EM. Urinary phthalates are associated with higher blood pressure in childhood. *J Pediatr*. 2013;163(3):747–753.e1

313. Trasande L, Attina TM. Association of exposure to di-2-ethylhexylphthalate replacements with increased blood pressure in children and adolescents. *Hypertension*. 2015;66(2):301–308

314. Saif I, Seriki D, Moore R, Woywodt A. Midaortic syndrome in neurofibromatosis type 1 resulting in bilateral renal artery stenosis. *Am J Kidney Dis*. 2010;56(6):1197–1201

315. Kimura M, Kakizaki S, Kawano K, Sato S, Kure S. Neurofibromatosis type 1 complicated by atypical coarctation of the thoracic aorta. *Case Rep Pediatr*. 2013;2013:458543

316. Malav IC, Kothari SS. Renal artery stenosis due to neurofibromatosis. *Ann Pediatr Cardiol*. 2009;2(2):167–169

317. Mavani G, Kesar V, Devita MV, Rosenstock JL, Michelis MF, Schwimmer JA. Neurofibromatosis type 1-associated hypertension secondary to coarctation of the thoracic aorta. *Clin Kidney J*. 2014;7(4):394–395

318. Duan L, Feng K, Tong A, Liang Z. Renal artery stenosis due to neurofibromatosis type 1: case report and literature review. *Eur J Med Res*. 2014;19:17

319. Srinivasan A, Krishnamurthy G, Fontalvo-Herazo L, et al. Spectrum of renal findings in pediatric fibromuscular dysplasia and neurofibromatosis type 1. *Pediatr Radiol*. 2011;41(3):308–316

320. Dubov T, Toledano-Alhadef H, Chernin G, Constantini S, Cleper R, Ben-Shachar S. High prevalence of elevated blood pressure among children with neurofibromatosis type 1. *Pediatr Nephrol*. 2016;31(1):131–136

321. Erem C, Onder Ersöz H, Ukinç K, et al. Neurofibromatosis type 1 associated with pheochromocytoma: a case report and a review of the literature. *J Endocrinol Invest*. 2007;30(1):59–64

322. Zinnamosca L, Petramala L, Cotesta D, et al. Neurofibromatosis type 1 (NF1) and pheochromocytoma: prevalence, clinical and cardiovascular aspects. *Arch Dermatol Res*. 2011;303(5):317–325

323. Nawrot TS, Den Hond E, Fagard RH, Hoppenbrouwers K, Staessen JA. Blood pressure, serum total cholesterol and contraceptive pill use in 17-year-old girls. *Eur J Cardiovasc Prev Rehabil*. 2003;10(6):438–442

324. Le-Ha C, Beilin LJ, Burrows S, et al. Oral contraceptive use in girls and alcohol consumption in boys are associated with increased blood pressure in late adolescence. *Eur J Prev Cardiol*. 2013;20(6):947–955

325. Du Y, Rosner BM, Knopf H, Schwarz S, Dören M, Scheidt-Nave C. Hormonal contraceptive use among adolescent girls in Germany in relation to health behavior and biological cardiovascular risk factors. *J Adolesc Health*. 2011;48(4):331–337

326. Samuels JA, Franco K, Wan F, Sorof JM. Effect of stimulants on 24-h ambulatory blood pressure in children with ADHD: a double-blind, randomized, cross-over trial. *Pediatr Nephrol*. 2006;21(1):92–95

327. Covar RA, Leung DY, McCormick D, Steelman J, Zeitler P, Spahn JD. Risk

factors associated with glucocorticoid-induced adverse effects in children with severe asthma. *J Allergy Clin Immunol*. 2000;106(4):651–659

328. Vehaskari VM. Heritable forms of hypertension. *Pediatr Nephrol*. 2009;24(10):1929–1937

329. Halperin F, Dluhy RG. Glucocorticoid-remediable aldosteronism. *Endocrinol Metab Clin North Am*. 2011;40(2):333–341, viii

330. Staley JR, Bradley J, Silverwood RJ, et al. Associations of blood pressure in pregnancy with offspring blood pressure trajectories during childhood and adolescence: findings from a prospective study. *J Am Heart Assoc*. 2015;4(5):e001422

331. Daniels SD, Meyer RA, Loggie JM. Determinants of cardiac involvement in children and adolescents with essential hypertension. *Circulation*. 1990;82(4):1243–1248

332. Yang Q, Zhang Z, Kuklina EV, et al. Sodium intake and blood pressure among US children and adolescents. *Pediatrics*. 2012;130(4):611–619

333. He FJ, MacGregor GA. Importance of salt in determining blood pressure in children: meta-analysis of controlled trials. *Hypertension*. 2006;48(5):861–869

334. Aeberli I, Spinas GA, Lehmann R, l'Allemand D, Molinari L, Zimmermann MB. Diet determines features of the metabolic syndrome in 6- to 14-year-old children. *Int J Vitam Nutr Res*. 2009;79(1):14–23

335. Colín-Ramírez E, Castillo-Martínez L, Orea-Tejeda A, Villa Romero AR, Vergara Castañeda A, Asensio Lafuente E. Waist circumference and fat intake are associated with high blood pressure in Mexican children aged 8 to 10 years. *J Am Diet Assoc*. 2009;109(6):996–1003

336. Niinikoski H, Jula A, Viikari J, et al. Blood pressure is lower in children and adolescents with a low-saturated-fat diet since infancy: the special turku coronary risk factor intervention project. *Hypertension*. 2009;53(6):918–924

337. Institute of Medicine. *Strategies to Reduce Sodium Intake in the United States*. Washington, DC: National Academies Press; 2010

338. Adler AJ, Taylor F, Martin N, Gottlieb S, Taylor RS, Ebrahim S. Reduced dietary salt for the prevention of cardiovascular disease. *Cochrane Database Syst Rev*. 2014;(12):CD009217

339. Rebholz CM, Gu D, Chen J, et al; GenSalt Collaborative Research Group. Physical activity reduces salt sensitivity of blood pressure: the Genetic Epidemiology Network of Salt Sensitivity study. *Am J Epidemiol*. 2012;176(suppl 7):S106–S113

340. Torrance B, McGuire KA, Lewanczuk R, McGavock J. Overweight, physical activity and high blood pressure in children: a review of the literature. *Vasc Health Risk Manag*. 2007;3(1):139–149

341. Chen HH, Chen YL, Huang CY, Lee SD, Chen SC, Kuo CH. Effects of one-year swimming training on blood pressure and insulin sensitivity in mild hypertensive young patients. *Chin J Physiol*. 2010;53(3):185–189

342. Farpour-Lambert NJ, Aggoun Y, Marchand LM, Martin XE, Herrmann FR, Beghetti M. Physical activity reduces systemic blood pressure and improves early markers of atherosclerosis in pre-pubertal obese children. *J Am Coll Cardiol*. 2009;54(25):2396–2406

343. Cai L, Wu Y, Cheskin LJ, Wilson RF, Wang Y. Effect of childhood obesity prevention programmes on blood lipids: a systematic review and meta-analysis. *Obes Rev*. 2014;15(12):933–944

344. Kelley GA, Kelley KS, Tran ZV. The effects of exercise on resting blood pressure in children and adolescents: a meta-analysis of randomized controlled trials. *Prev Cardiol*. 2003;6(1):8–16

345. van Dijk AE, van Eijsden M, Stronks K, Gemke RJ, Vrijkotte TG. The association between prenatal psychosocial stress and blood pressure in the child at age 5-7 years. *PLoS One*. 2012;7(8):e43548

346. Stein DJ, Scott K, Haro Abad JM, et al. Early childhood adversity and later hypertension: data from the World Mental Health Survey. *Ann Clin Psychiatry*. 2010;22(1):19–28

347. Halonen JI, Stenholm S, Pentti J, et al. Childhood psychosocial adversity and adult neighborhood disadvantage as predictors of cardiovascular disease: a cohort study. *Circulation*. 2015;132(5):371–379

348. Maggio AB, Martin XE, Saunders Gasser C, et al. Medical and non-medical complications among children and adolescents with excessive body weight. *BMC Pediatr*. 2014;14:232

349. Yun M, Li S, Sun D, et al. Tobacco smoking strengthens the association of elevated blood pressure with arterial stiffness: the Bogalusa Heart Study. *J Hypertens*. 2015;33(2):266–274

350. Priest JR, Nead KT, Wehner MR, Cooke JP, Leeper NJ. Self-reported history of childhood smoking is associated with an increased risk for peripheral arterial disease independent of lifetime smoking burden. *PLoS One*. 2014;9(2):e88972

351. Hagan JFSJ, Duncan PM. *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*. 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2008

352. Benson L, Baer HJ, Greco PJ, Kaelber DC. When is family history obtained? - Lack of timely documentation of family history among overweight and hypertensive paediatric patients. *J Paediatr Child Health*. 2010;46(10):600–605

353. Flynn JT. Evaluation and management of hypertension in childhood. *Prog Pediatr Cardiol*. 2001;12(2):177–188

354. Wiesen J, Adkins M, Fortune S, et al. Evaluation of pediatric patients with mild-to-moderate hypertension: yield of diagnostic testing. *Pediatrics*. 2008;122(5). Available at: www.pediatrics.org/cgi/content/full/122/5/e988

355. Yoon EY, Cohn L, Rocchini A, et al. Use of diagnostic tests in adolescents with essential hypertension. *Arch Pediatr Adolesc Med*. 2012;166(9):857–862

356. Killian L, Simpson JM, Savis A, Rawlins D, Sinha MD. Electrocardiography is a poor screening test to detect left ventricular hypertrophy in children. *Arch Dis Child*. 2010;95(10):832–836

357. Ramaswamy P, Patel E, Fahey M, Mahgerefteh J, Lytrivi ID, Kupferman JC. Electrocardiographic predictors of left ventricular hypertrophy in pediatric hypertension. *J Pediatr*. 2009;154(1):106–110

358. Rijnbeek PR, van Herpen G, Kapusta L, Ten Harkel AD, Witsenburg M, Kors JA. Electrocardiographic criteria for left ventricular hypertrophy in children. *Pediatr Cardiol*. 2008;29(5):923–928

359. Grossman A, Prokupetz A, Koren-Morag N, Grossman E, Shamiss A. Comparison of usefulness of Sokolow and Cornell criteria for left ventricular hypertrophy in subjects aged <20 years versus >30 years. *Am J Cardiol*. 2012;110(3):440–444

360. Caselli S, Maron MS, Urbano-Moral JA, Pandian NG, Maron BJ, Pelliccia A. Differentiating left ventricular hypertrophy in athletes from that in patients with hypertrophic cardiomyopathy. *Am J Cardiol*. 2014;114(9):1383–1389

361. Urbina EM, Gidding SS, Bao W, Pickoff AS, Berdusis K, Berenson GS. Effect of body size, ponderosity, and blood pressure on left ventricular growth in children and young adults in the Bogalusa Heart Study. *Circulation*. 1995;91(9):2400–2406

362. Kuznetsova T, Haddad F, Tikhonoff V, et al; European Project On Genes in Hypertension (EPOGH) Investigators. Impact and pitfalls of scaling of left ventricular and atrial structure in population-based studies. *J Hypertens*. 2016;34(6):1186–1194

363. Armstrong AC, Gidding S, Gjesdal O, Wu C, Bluemke DA, Lima JA. LV mass assessed by echocardiography and CMR, cardiovascular outcomes, and medical practice. *JACC Cardiovasc Imaging*. 2012;5(8):837–848

364. Armstrong AC, Jacobs DR Jr, Gidding SS, et al. Framingham score and LV mass predict events in young adults: CARDIA study. *Int J Cardiol*. 2014;172(2):350–355

365. Gidding SS, Palermo RA, DeLoach SS, Keith SW, Falkner B. Associations of cardiac structure with obesity, blood pressure, inflammation, and insulin resistance in African-American adolescents. *Pediatr Cardiol*. 2014;35(2):307–314

366. Hanevold C, Waller J, Daniels S, Portman R, Sorof J; International Pediatric Hypertension Association. The effects of obesity, gender, and ethnic group on left ventricular hypertrophy and geometry in hypertensive children: a collaborative study of the International Pediatric Hypertension Association. *Pediatrics*. 2004;113(2):328–333

367. Daniels SR, Loggie JM, Khoury P, Kimball TR. Left ventricular geometry and severe left ventricular hypertrophy in children and adolescents with essential hypertension. *Circulation*. 1998;97(19):1907–1911

368. Devereux RB, Wachtell K, Gerdts E, et al. Prognostic significance of left ventricular mass change during treatment of hypertension. *JAMA*. 2004;292(19):2350–2356

369. Lang RM, Badano LP, Mor-Avi V, et al. Recommendations for cardiac chamber quantification by echocardiography in adults: an update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging.*J Am Soc Echocardiogr*. 2015;28(1):1–39.e14

370. Daniels SR, Kimball TR, Morrison JA, Khoury P, Witt S, Meyer RA. Effect of lean body mass, fat mass, blood pressure, and sexual maturation on left ventricular mass in children and adolescents. Statistical, biological, and clinical significance. *Circulation*. 1995;92(11):3249–3254

371. Lopez L, Colan SD, Frommelt PC, et al. Recommendations for quantification methods during the performance of a pediatric echocardiogram: a report from the Pediatric Measurements Writing Group of the American Society of Echocardiography Pediatric and Congenital Heart Disease Council. *J Am Soc Echocardiogr*. 2010;23(5):465–495, quiz 576–577

372. Foster BJ, Khoury PR, Kimball TR, Mackie AS, Mitsnefes M. New reference centiles for left ventricular mass relative to lean body mass in children. *J Am Soc Echocardiogr*. 2016;29(5):441–447.e2

373. Khoury PR, Mitsnefes M, Daniels SR, Kimball TR. Age-specific reference intervals for indexed left ventricular mass in children. *J Am Soc Echocardiogr*. 2009;22(6):709–714

374. Lipshultz SE, Easley KA, Orav EJ, et al. Reliability of multicenter pediatric echocardiographic measurements of left ventricular structure and function: the prospective P(2)C(2) HIV study. *Circulation*. 2001;104(3):310–316

375. Urbina EM. Abnormalities of vascular structure and function in pediatric hypertension. *Pediatr Nephrol*. 2016;31(7):1061–1070

376. Elmenhorst J, Hulpke-Wette M, Barta C, Dalla Pozza R, Springer S, Oberhoffer R. Percentiles for central blood pressure and pulse wave velocity in children and adolescents recorded with an oscillometric device. *Atherosclerosis*. 2015;238(1):9–16

377. Hidvégi EV, Illyés M, Benczúr B, et al. Reference values of aortic pulse wave velocity in a large healthy population aged between 3 and 18 years. *J Hypertens*. 2012;30(12):2314–2321

378. Miyai N, Utsumi M, Gowa Y, et al. Age-specific nomogram of brachial-ankle pulse wave velocity in Japanese adolescents. *Clin Exp Hypertens*. 2013;35(2):95–101

379. Urbina EM, Khoury PR, McCoy CE, Dolan LM, Daniels SR, Kimball TR. Triglyceride to HDL-C ratio and increased arterial stiffness in children, adolescents, and young adults [published correction appears in *Pediatrics*. 2013;132(4):780]. *Pediatrics*. 2013;131(4). Available at: www.pediatrics.org/cgi/content/full/131/4/e1082

380. Lurbe E, Torro I, Garcia-Vicent C, Alvarez J, Fernández-Fornoso JA, Redon J. Blood pressure and obesity exert independent influences on pulse wave velocity in youth. *Hypertension*. 2012;60(2):550–555

381. Zhu H, Yan W, Ge D, et al. Relationships of cardiovascular phenotypes with healthy weight, at risk of overweight, and overweight in US youths. *Pediatrics*. 2008;121(1):115–122

382. Charakida M, Jones A, Falaschetti E, et al. Childhood obesity and vascular

phenotypes: a population study. *J Am Coll Cardiol*. 2012;60(25):2643–2650

383. Doyon A, Kracht D, Bayazit AK, et al; 4C Study Consortium. Carotid artery intima-media thickness and distensibility in children and adolescents: reference values and role of body dimensions. *Hypertension*. 2013;62(3):550–556

384. Urbina EM, Kimball TR, McCoy CE, Khoury PR, Daniels SR, Dolan LM. Youth with obesity and obesity-related type 2 diabetes mellitus demonstrate abnormalities in carotid structure and function. *Circulation*. 2009;119(22):2913–2919

385. Keehn L, Milne L, McNeill K, Chowienczyk P, Sinha MD. Measurement of pulse wave velocity in children: comparison of volumetric and tonometric sensors, brachial-femoral and carotid-femoral pathways. *J Hypertens*. 2014;32(7):1464–1469, discussion 1469

386. Kis E, Cseprekál O, Kerti A, et al. Measurement of pulse wave velocity in children and young adults: a comparative study using three different devices. *Hypertens Res*. 2011;34(11):1197–1202

387. Chhadia S, Cohn RA, Vural G, Donaldson JS. Renal Doppler evaluation in the child with hypertension: a reasonable screening discriminator? *Pediatr Radiol*. 2013;43(12):1549–1556

388. Castelli PK, Dillman JR, Kershaw DB, Khalatbari S, Stanley JC, Smith EA. Renal sonography with Doppler for detecting suspected pediatric renin-mediated hypertension - is it adequate? *Pediatr Radiol*. 2014;44(1):42–49

389. Rountas C, Vlychou M, Vassiou K, et al. Imaging modalities for renal artery stenosis in suspected renovascular hypertension: prospective intraindividual comparison of color Doppler US, CT angiography, GD-enhanced MR angiography, and digital substraction angiography. *Ren Fail*. 2007;29(3):295–302

390. Marks SD, Tullus K. Update on imaging for suspected renovascular hypertension in children and adolescents. *Curr Hypertens Rep*. 2012;14(6):591–595

391. Lagomarsino E, Orellana P, Muñoz J, Velásquez C, Cavagnaro F, Valdés F. Captopril scintigraphy in the study of arterial hypertension in pediatrics. *Pediatr Nephrol*. 2004;19(1):66–70

392. Abdulsamea S, Anderson P, Biassoni L, et al. Pre- and postcaptopril renal scintigraphy as a screening test for renovascular hypertension in children. *Pediatr Nephrol*. 2010;25(2):317–322

393. Günay EC, Oztürk MH, Ergün EL, et al. Losartan renography for the detection of renal artery stenosis: comparison with captopril renography and evaluation of dose and timing. *Eur J Nucl Med Mol Imaging*. 2005;32(9):1064–1074

394. Reusz GS, Kis E, Cseprekál O, Szabó AJ, Kis E. Captopril-enhanced renal scintigraphy in the diagnosis of pediatric hypertension. *Pediatr Nephrol*. 2010;25(2):185–189

395. Loeffler LF, Navas-Acien A, Brady TM, Miller ER III, Fadrowski JJ. Uric acid level and elevated blood pressure in US adolescents: National Health and Nutrition Examination Survey, 1999-2006. *Hypertension*. 2012;59(4):811–817

396. Shatat IF, Abdallah RT, Sas DJ, Hailpern SM. Serum uric acid in U.S. adolescents: distribution and relationship to demographic characteristics and cardiovascular risk factors. *Pediatr Res*. 2012;72(1):95–100

397. Viazzi F, Antolini L, Giussani M, et al. Serum uric acid and blood pressure in children at cardiovascular risk. *Pediatrics*. 2013;132(1). Available at: www.pediatrics.org/cgi/content/full/132/1/e93

398. Reschke LD, Miller ER III, Fadrowski JJ, et al. Elevated uric acid and obesity-related cardiovascular disease risk factors among hypertensive youth. *Pediatr Nephrol*. 2015;30(12):2169–2176

399. Alper AB Jr, Chen W, Yau L, Srinivasan SR, Berenson GS, Hamm LL. Childhood uric acid predicts adult blood pressure: the Bogalusa Heart Study. *Hypertension*. 2005;45(1):34–38

400. Soletsky B, Feig DI. Uric acid reduction rectifies prehypertension in obese adolescents. *Hypertension*. 2012;60(5):1148–1156

401. Feig DI, Soletsky B, Johnson RJ. Effect of allopurinol on blood pressure of adolescents with newly diagnosed essential hypertension: a randomized trial. *JAMA*. 2008;300(8):924–932

402. Assadi F. Allopurinol enhances the blood pressure lowering effect of enalapril in children with hyperuricemic essential hypertension. *J Nephrol*. 2014;27(1):51–56

403. Feig DI, Nakagawa T, Karumanchi SA, et al. Hypothesis: uric acid, nephron number, and the pathogenesis of essential hypertension. *Kidney Int*. 2004;66(1):281–287

404. Viazzi F, Rebora P, Giussani M, et al. Increased serum uric acid levels blunt the antihypertensive efficacy of lifestyle modifications in children at cardiovascular risk. *Hypertension*. 2016;67(5):934–940

405. Klausen K, Borch-Johnsen K, Feldt-Rasmussen B, et al. Very low levels of microalbuminuria are associated with increased risk of coronary heart disease and death independently of renal function, hypertension, and diabetes. *Circulation*. 2004;110(1):32–35

406. Bigazzi R, Bianchi S, Baldari D, Campese VM. Microalbuminuria predicts cardiovascular events and renal insufficiency in patients with essential hypertension. *J Hypertens*. 1998;16(9):1325–1333

407. Chugh A, Bakris GL. Microalbuminuria: what is it? Why is it important? What should be done about it? An update. *J Clin Hypertens (Greenwich)*. 2007;9(3):196–200

408. Flynn JT. Microalbuminuria in children with primary hypertension. *J Clin Hypertens (Greenwich)*. 2016;18(10):962–965

409. Radhakishun NN, van Vliet M, von Rosenstiel IA, Beijnen JH, Diamant M. Limited value of routine microalbuminuria assessment in multi-ethnic obese children. *Pediatr Nephrol*. 2013;28(7):1145–1149

410. Tsioufis C, Mazaraki A, Dimitriadis K, Stefanidis CJ, Stefanadis C. Microalbuminuria in the paediatric age: current knowledge and

emerging questions. *Acta Paediatr*. 2011;100(9):1180–1184

411. Seeman T, Pohl M, Palyzova D, John U. Microalbuminuria in children with primary and white-coat hypertension. *Pediatr Nephrol*. 2012;27(3):461–467

412. Sanad M, Gharib A. Evaluation of microalbuminuria in obese children and its relation to metabolic syndrome. *Pediatr Nephrol*. 2011;26(12):2193–2199

413. Assadi F. Effect of microalbuminuria lowering on regression of left ventricular hypertrophy in children and adolescents with essential hypertension. *Pediatr Cardiol*. 2007;28(1):27–33

414. Niemirska A, Litwin M, Feber J, Jurkiewicz E. Blood pressure rhythmicity and visceral fat in children with hypertension. *Hypertension*. 2013;62(4):782–788

415. Kupferman JC, Paterno K, Mahgerefteh J, et al. Improvement of left ventricular mass with antihypertensive therapy in children with hypertension. *Pediatr Nephrol*. 2010;25(8):1513–1518

416. Falkner B, DeLoach S, Keith SW, Gidding SS. High risk blood pressure and obesity increase the risk for left ventricular hypertrophy in African-American adolescents. *J Pediatr*. 2013;162(1):94–100

417. Stabouli S, Kotsis V, Rizos Z, et al. Left ventricular mass in normotensive, prehypertensive and hypertensive children and adolescents. *Pediatr Nephrol*. 2009;24(8):1545–1551

418. Tirosh A, Afek A, Rudich A, et al. Progression of normotensive adolescents to hypertensive adults: a study of 26,980 teenagers. *Hypertension*. 2010;56(2):203–209

419. Chobanian AV, Bakris GL, Black HR; National Heart, Lung, and Blood Institute Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; National High Blood Pressure Education Program Coordinating Committee. The seventh report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure: the JNC 7 report [published correction appears in *JAMA*. 2003;290(2):197]. *JAMA*. 2003;289(19):2560–2571

420. Moreno-Luna R, Muñoz-Hernandez R, Miranda ML, et al. Olive oil polyphenols decrease blood pressure and improve endothelial function in young women with mild hypertension. *Am J Hypertens*. 2012;25(12):1299–1304

421. Damasceno MM, de Araújo MF, de Freitas RW, de Almeida PC, Zanetti ML. The association between blood pressure in adolescents and the consumption of fruits, vegetables and fruit juice--an exploratory study. *J Clin Nurs*. 2011;20(11–12):1553–1560

422. Juonala M, Viikari JS, Kähönen M, et al. Life-time risk factors and progression of carotid atherosclerosis in young adults: the Cardiovascular Risk in Young Finns study. *Eur Heart J*. 2010;31(14):1745–1751

423. Yuan WL, Kakinami L, Gray-Donald K, Czernichow S, Lambert M, Paradis G. Influence of dairy product consumption on children's blood pressure: results from the QUALITY cohort. *J Acad Nutr Diet*. 2013;113(7):936–941

424. Moore LL, Bradlee ML, Singer MR, Qureshi MM, Buendia JR, Daniels SR. Dietary approaches to stop hypertension (DASH) eating pattern and risk of elevated blood pressure in adolescent girls. *Br J Nutr*. 2012;108(9):1678–1685

425. Günther AL, Liese AD, Bell RA, et al. Association between the dietary approaches to hypertension diet and hypertension in youth with diabetes mellitus. *Hypertension*. 2009;53(1):6–12

426. Couch SC, Saelens BE, Levin L, Dart K, Falciglia G, Daniels SR. The efficacy of a clinic-based behavioral nutrition intervention emphasizing a DASH-type diet for adolescents with elevated blood pressure. *J Pediatr*. 2008;152(4):494–501

427. Davis JN, Ventura EE, Cook LT, Gyllenhammer LE, Gatto NMLA. LA Sprouts: a gardening, nutrition, and cooking intervention for Latino youth improves diet and reduces obesity. *J Am Diet Assoc*. 2011;111(8):1224–1230

428. Saneei P, Hashemipour M, Kelishadi R, Rajaei S, Esmaillzadeh A. Effects of recommendations to follow the dietary approaches to stop hypertension (DASH) diet v. usual dietary advice on childhood metabolic syndrome: a randomised cross-over clinical trial. *Br J Nutr*. 2013;110(12):2250–2259

429. Barnes TL, Crandell JL, Bell RA, Mayer-Davis EJ, Dabelea D, Liese AD. Change in DASH diet score and cardiovascular risk factors in youth with type 1 and type 2 diabetes mellitus: the SEARCH for Diabetes in Youth study. *Nutr Diabetes*. 2013;3:e91

430. Rao M, Afshin A, Singh G, Mozaffarian D. Do healthier foods and diet patterns cost more than less healthy options? A systematic review and meta-analysis. *BMJ Open*. 2013;3(12):e004277

431. Monzavi R, Dreimane D, Geffner ME, et al. Improvement in risk factors for metabolic syndrome and insulin resistance in overweight youth who are treated with lifestyle intervention. *Pediatrics*. 2006;117(6). Available at: www.pediatrics.org/cgi/content/full/117/6/e1111

432. Asghari G, Yuzbashian E, Mirmiran P, Hooshmand F, Najafi R, Azizi F. Dietary approaches to stop hypertension (DASH) dietary pattern is associated with reduced incidence of metabolic syndrome in children and adolescents. *J Pediatr*. 2016;174:178–184.e1

433. Pacifico L, Anania C, Martino F, et al. Management of metabolic syndrome in children and adolescents. *Nutr Metab Cardiovasc Dis*. 2011;21(6):455–466

434. Puri M, Flynn JT. Management of hypertension in children and adolescents with the metabolic syndrome. *J Cardiometab Syndr*. 2006;1(4):259–268

435. Davis MM, Gance-Cleveland B, Hassink S, Johnson R, Paradis G, Resnicow K. Recommendations for prevention of childhood obesity. *Pediatrics*. 2007;120(suppl 4):S229–S253

436. Ogedegbe G, Chaplin W, Schoenthaler A, et al. A practice-based trial of motivational interviewing and adherence in hypertensive African Americans. *Am J Hypertens*. 2008;21(10):1137–1143

437. Bosworth HB, Olsen MK, Neary A, et al. Take Control of Your Blood Pressure (TCYB) study: a multifactorial tailored behavioral and educational intervention for achieving blood pressure control. *Patient Educ Couns*. 2008;70(3):338–347

438. Resnicow K, McMaster F, Bocian A, et al. Motivational interviewing and dietary counseling for obesity in primary care: an RCT. *Pediatrics*. 2015;135(4):649–657

439. Davoli AM, Broccoli S, Bonvicini L, et al. Pediatrician-led motivational interviewing to treat overweight children: an RCT. *Pediatrics*. 2013;132(5). Available at: www.pediatrics.org/cgi/content/full/132/5/e1236

440. Broccoli S, Davoli AM, Bonvicini L, et al. Motivational interviewing to treat overweight children: 24-month follow-up of a randomized controlled trial. *Pediatrics*. 2016;137(1):e20151979

441. Flattum C, Friend S, Neumark-Sztainer D, Story M. Motivational interviewing as a component of a school-based obesity prevention program for adolescent girls. *J Am Diet Assoc*. 2009;109(1):91–94

442. Schwartz RP, Hamre R, Dietz WH, et al. Office-based motivational interviewing to prevent childhood obesity: a feasibility study. *Arch Pediatr Adolesc Med*. 2007;161(5):495–501

443. Döring N, Ghaderi A, Bohman B, et al. Motivational interviewing to prevent childhood obesity: a cluster RCT. *Pediatrics*. 2016;137(5):1–10

444. Spear BA, Barlow SE, Ervin C, et al. Recommendations for treatment of child and adolescent overweight and obesity. *Pediatrics*. 2007;120(4, suppl 4):S254–S288

445. Kabat-Zinn J, Hanh TN. *Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness*. New York, NY: Delta; 1990

446. Gregoski MJ, Barnes VA, Tingen MS, Harshfield GA, Treiber FA. Breathing awareness meditation and LifeSkills Training programs influence upon ambulatory blood pressure and sodium excretion among African American adolescents. *J Adolesc Health*. 2011;48(1):59–64

447. Barnes VA, Kapuku GK, Treiber FA. Impact of transcendental meditation on left ventricular mass in African American adolescents.*Evid Based Complement Alternat Med*. 2012;2012:923153

448. Sieverdes JC, Mueller M, Gregoski MJ, et al. Effects of Hatha yoga on blood pressure, salivary α-amylase, and cortisol function among normotensive and prehypertensive youth. *J Altern Complement Med*. 2014;20(4):241–250

449. Sorof JM, Cargo P, Graepel J, et al. β-blocker/thiazide combination for treatment of hypertensive children: a randomized double-blind, placebo-controlled trial. *Pediatr Nephrol*. 2002;17(5):345–350

450. Trachtman H, Hainer JW, Sugg J, Teng R, Sorof JM, Radcliffe J; Candesartan in Children with Hypertension (CINCH) Investigators. Efficacy, safety, and pharmacokinetics of candesartan cilexetil in hypertensive children aged 6 to 17 years. *J Clin Hypertens (Greenwich)*. 2008;10(10):743–750

451. Herder SD, Weber E, Winkemann A, Herder C, Morck H. Efficacy and safety of angiotensin II receptor type 1 antagonists in children and adolescents. *Pediatr Nephrol*. 2010;25(5):801–811

452. Schaefer F, Litwin M, Zachwieja J, et al. Efficacy and safety of valsartan compared to enalapril in hypertensive children: a 12-week, randomized, double-blind, parallel-group study. *J Hypertens*. 2011;29(12):2484–2490

453. Gartenmann AC, Fossali E, von Vigier RO, et al. Better renoprotective effect of angiotensin II antagonist compared to dihydropyridine calcium channel blocker in childhood. *Kidney Int*. 2003;64(4):1450–1454

454. Chaturvedi S, Lipszyc DH, Licht C, Craig JC, Parekh R. Pharmacological interventions for hypertension in children. *Evid Based Child Health*. 2014;9(3):498–580

455. Flynn JT. Efficacy and safety of prolonged amlodipine treatment in hypertensive children. *Pediatr Nephrol*. 2005;20(5):631–635

456. Schaefer F, Coppo R, Bagga A, et al. Efficacy and safety of valsartan in hypertensive children 6 months to 5 years of age. *J Hypertens*. 2013;31(5):993–1000

457. Batisky DL, Sorof JM, Sugg J, et al; Toprol-XL Pediatric Hypertension Investigators. Efficacy and safety of extended release metoprolol succinate in hypertensive children 6 to 16 years of age: a clinical trial experience. *J Pediatr*. 2007;150(2):134–139, 139.e1

458. Wells T, Blumer J, Meyers KE, et al; Valsartan Pediatric Hypertension Study Group. Effectiveness and safety of valsartan in children aged 6 to 16 years with hypertension. *J Clin Hypertens (Greenwich)*. 2011;13(5):357–365

459. Trachtman H, Frank R, Mahan JD, et al. Clinical trial of extended-release felodipine in pediatric essential hypertension. *Pediatr Nephrol*. 2003;18(6):548–553

460. Shahinfar S, Cano F, Soffer BA, et al. A double-blind, dose-response study of losartan in hypertensive children. *Am J Hypertens*. 2005;18(2, pt 1):183–190

461. Hazan L, Hernández Rodriguez OA, Bhorat AE, Miyazaki K, Tao B, Heyrman R; Assessment of Efficacy and Safety of Olmesartan in Pediatric Hypertension Study Group. A double-blind, dose-response study of the efficacy and safety of olmesartan medoxomil in children and adolescents with hypertension. *Hypertension*. 2010;55(6):1323–1330

462. Flynn JT, Newburger JW, Daniels SR, et al; PATH-1 Investigators. A randomized, placebo-controlled trial of amlodipine in children with hypertension. *J Pediatr*. 2004;145(3):353–359

463. Simonetti GD, Rizzi M, Donadini R, Bianchetti MG. Effects of antihypertensive drugs on blood pressure and proteinuria in childhood. *J Hypertens*. 2007;25(12):2370–2376

464. Seeman T, Dusek J, Vondrák K, Flögelová H, Geier P, Janda J. Ramipril in the treatment of hypertension and proteinuria in children with chronic kidney diseases. *Am J Hypertens*. 2004;17(5, pt 1):415–420

465. Hammer GB, Verghese ST, Drover DR, Yaster M, Tobin JR. Pharmacokinetics and pharmacodynamics of fenoldopam mesylate for blood pressure control

in pediatric patients. *BMC Anesthesiol*. 2008;8:6

466. Blowey DL. Update on the pharmacologic treatment of hypertension in pediatrics. *J Clin Hypertens (Greenwich)*. 2012;14(6):383–387

467. Li JS, Flynn JT, Portman R, et al. The efficacy and safety of the novel aldosterone antagonist eplerenone in children with hypertension: a randomized, double-blind, dose-response study. *J Pediatr*. 2010;157(2):282–287

468. U.S. Food and Drug Administration. Pediatric product development. Available at: www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm049867.htm. Accessed February 6, 2017

469. Croxtall JD. Valsartan: in children and adolescents with hypertension. *Paediatr Drugs*. 2012;14(3):201–207

470. Menon S, Berezny KY, Kilaru R, et al. Racial differences are seen in blood pressure response to fosinopril in hypertensive children. *Am Heart J*. 2006;152(2):394–399

471. Li JS, Baker-Smith CM, Smith PB, et al. Racial differences in blood pressure response to angiotensin-converting enzyme inhibitors in children: a meta-analysis. *Clin Pharmacol Ther*. 2008;84(3):315–319

472. Seeman T, Dostálek L, Gilík J. Control of hypertension in treated children and its association with target organ damage. *Am J Hypertens*. 2012;25(3):389–395

473. Redwine K, Howard L, Simpson P, et al; Network of Pediatric Pharmacology Research Units. Effect of placebo on ambulatory blood pressure monitoring in children. *Pediatr Nephrol*. 2012;27(10):1937–1942

474. Halbach SM, Hamman R, Yonekawa K, Hanevold C. Utility of ambulatory blood pressure monitoring in the evaluation of elevated clinic blood pressures in children. *J Am Soc Hypertens*. 2016;10(5):406–412

475. White WB, Turner JR, Sica DA, et al. Detection, evaluation, and treatment of severe and resistant hypertension: proceedings from an American Society of Hypertension Interactive forum held in Bethesda, MD, U.S.A., October 10th, 2013. *J Am Soc Hypertens*. 2014;8(10):743–757

476. Narayan H, Webb DJ. New evidence supporting the use of mineralocorticoid receptor blockers in drug-resistant hypertension. *Curr Hypertens Rep*. 2016;18(5):34

477. Williams B, MacDonald TM, Morant S, et al; British Hypertension Society's PATHWAY Studies Group. Spironolactone versus placebo, bisoprolol, and doxazosin to determine the optimal treatment for drug-resistant hypertension (PATHWAY-2): a randomised, double-blind, crossover trial. *Lancet*. 2015;386(10008):2059–2068

478. Mitsnefes M, Ho PL, McEnery PT. Hypertension and progression of chronic renal insufficiency in children: a report of the North American Pediatric Renal Transplant Cooperative Study (NAPRTCS). *J Am Soc Nephrol*. 2003;14(10):2618–2622

479. Dionne JM. Evidence-based guidelines for the management of hypertension in children with chronic kidney disease. *Pediatr Nephrol*. 2015;30(11):1919–1927

480. VanDeVoorde RG, Mitsnefes MM. Hypertension and CKD. *Adv Chronic Kidney Dis*. 2011;18(5):355–361

481. Mitsnefes MM, Kimball TR, Kartal J, et al. Progression of left ventricular hypertrophy in children with early chronic kidney disease: 2-year follow-up study. *J Pediatr*. 2006;149(5):671–675

482. Wright JT Jr, Williamson JD, Whelton PK, et al; SPRINT Research Group. A randomized trial of intensive versus standard blood-pressure control. *N Engl J Med*. 2015;373(22):2103–2116

483. Wong H, Mylrea K, Feber J, Drukker A, Filler G. Prevalence of complications in children with chronic kidney disease according to KDOQI. *Kidney Int*. 2006;70(3):585–590

484. Simonetti GD, von Vigier RO, Konrad M, Rizzi M, Fossali E, Bianchetti MG. Candesartan cilexetil in children with hypertension or proteinuria: preliminary data. *Pediatr Nephrol*. 2006;21(10):1480–1482

485. White CT, Macpherson CF, Hurley RM, Matsell DG. Antiproteinuric effects of enalapril and losartan: a pilot study. *Pediatr Nephrol*. 2003;18(10):1038–1043

486. Webb NJ, Lam C, Loeys T, et al. Randomized, double-blind, controlled study of losartan in children with proteinuria. *Clin J Am Soc Nephrol*. 2010;5(3):417–424

487. Webb NJ, Shahinfar S, Wells TG, et al. Losartan and enalapril are comparable in reducing proteinuria in children. *Kidney Int*. 2012;82(7):819–826

488. Wühl E, Mehls O, Schaefer F; ESCAPE Trial Group. Antihypertensive and antiproteinuric efficacy of ramipril in children with chronic renal failure. *Kidney Int*. 2004;66(2):768–776

489. Eppens MC, Craig ME, Cusumano J, et al. Prevalence of diabetes complications in adolescents with type 2 compared with type 1 diabetes. *Diabetes Care*. 2006;29(6):1300–1306

490. Mayer-Davis EJ, Ma B, Lawson A, et al; SEARCH for Diabetes in Youth Study Group. Cardiovascular disease risk factors in youth with type 1 and type 2 diabetes: implications of a factor analysis of clustering. *Metab Syndr Relat Disord*. 2009;7(2):89–95

491. Margeirsdottir HD, Larsen JR, Brunborg C, Overby NC, Dahl-Jørgensen K; Norwegian Study Group for Childhood Diabetes. High prevalence of cardiovascular risk factors in children and adolescents with type 1 diabetes: a population-based study. *Diabetologia*. 2008;51(4):554–561

492. Orchard TJ, Forrest KY, Kuller LH, Becker DJ; Pittsburgh Epidemiology of Diabetes Complications Study. Lipid and blood pressure treatment goals for type 1 diabetes: 10-year incidence data from the Pittsburgh Epidemiology of Diabetes Complications Study. *Diabetes Care*. 2001;24(6):1053–1059

493. Copeland KC, Zeitler P, Geffner M, et al; TODAY Study Group. Characteristics of adolescents and youth with recent-onset type 2 diabetes: the TODAY cohort at baseline. *J Clin Endocrinol Metab*. 2011;96(1):159–167

494. Klingensmith GJ, Connor CG, Ruedy KJ, et al; Pediatric Diabetes Consortium. Presentation of youth with type 2

diabetes in the Pediatric Diabetes Consortium. *Pediatr Diabetes*. 2016;17(4):266–273

495. Shah AS, Dolan LM, Gao Z, Kimball TR, Urbina EM. Racial differences in arterial stiffness among adolescents and young adults with type 2 diabetes. *Pediatr Diabetes*. 2012;13(2):170–175

496. TODAY Study Group. Rapid rise in hypertension and nephropathy in youth with type 2 diabetes: the TODAY clinical trial. *Diabetes Care*. 2013;36(6):1735–1741

497. Shah AS, Khoury PR, Dolan LM, et al. The effects of obesity and type 2 diabetes mellitus on cardiac structure and function in adolescents and young adults. *Diabetologia*. 2011;54(4):722–730

498. Nambam B, DuBose SN, Nathan BM, et al; T1D Exchange Clinic Network. Therapeutic inertia: underdiagnosed and undertreated hypertension in children participating in the T1D Exchange Clinic Registry. *Pediatr Diabetes*. 2016;17(1):15–20

499. American Diabetes Association. Supplemental issue: standards of medical care in diabetes - 2016. *Diabetes Care*. 2016;39(suppl 1):S1–S2

500. Donaghue KC, Chiarelli F, Trotta D, Allgrove J, Dahl-Jorgensen K. Microvascular and macrovascular complications associated with diabetes in children and adolescents. *Pediatr Diabetes*. 2009;10(suppl 12): 195–203

501. Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents; National Heart, Lung, and Blood Institute. Expert panel on integrated guidelines for cardiovascular health and risk reduction in children and adolescents: summary report. *Pediatrics*. 2011;128(suppl 5):S213–S256

502. Stern MP. Diabetes and cardiovascular disease. The "common soil" hypothesis. *Diabetes*. 1995;44(4):369–374

503. Martino F, Puddu PE, Pannarale G, et al. Hypertension in children and adolescents attending a lipid clinic. *Eur J Pediatr*. 2013;172(12):1573–1579

504. Rodríguez-Morán M, Guerrero-Romero F, Aradillas-García C, et al. Atherogenic indices and prehypertension in obese and non-obese children. *Diab Vasc Dis Res*. 2013;10(1):17–24

505. Li J, Motsko SP, Goehring EL Jr, Vendiola R, Maneno M, Jones JK. Longitudinal study on pediatric dyslipidemia in population-based claims database. *Pharmacoepidemiol Drug Saf*. 2010;19(1):90–98

506. Liao CC, Su TC, Chien KL, et al. Elevated blood pressure, obesity, and hyperlipidemia.*J Pediatr*. 2009;155(1):79–83, 83.e1

507. Marcus CL, Brooks LJ, Draper KA, et al; American Academy of Pediatrics. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. 2012;130(3). Available at: www.pediatrics.org/cgi/content/full/130/3/e714

508. Kuo YL, Kang KT, Chiu SN, Weng WC, Lee PL, Hsu WC. Blood pressure after surgery among obese and nonobese children with obstructive sleep apnea. *Otolaryngol Head Neck Surg*. 2015;152(5):931–940

509. Lande MB, Adams HR, Kupferman JC, Hooper SR, Szilagyi PG, Batisky DL. A multicenter study of neurocognition in children with hypertension: methods, challenges, and solutions. *J Am Soc Hypertens*. 2013;7(5):353–362

510. Lande MB, Adams H, Falkner B, et al. Parental assessments of internalizing and externalizing behavior and executive function in children with primary hypertension. *J Pediatr*. 2009;154(2):207–212

511. Adams HR, Szilagyi PG, Gebhardt L, Lande MB. Learning and attention problems among children with pediatric primary hypertension. *Pediatrics*. 2010;126(6). Available at: www.pediatrics.org/cgi/content/full/126/6/e1425

512. Settakis G, Páll D, Molnár C, Katona E, Bereczki D, Fülesdi B. Hyperventilation-induced cerebrovascular reactivity among hypertensive and healthy adolescents. *Kidney Blood Press Res*. 2006;29(5):306–311

513. Wong LJ, Kupferman JC, Prohovnik I, et al. Hypertension impairs vascular reactivity in the pediatric brain. *Stroke*. 2011;42(7):1834–1838

514. Lande MB, Kupferman JC, Adams HR. Neurocognitive alterations in hypertensive children and adolescents. *J Clin Hypertens (Greenwich)*. 2012;14(6):353–359

515. Ostrovskaya MA, Rojas M, Kupferman JC, et al. Executive function and cerebrovascular reactivity in pediatric hypertension. *J Child Neurol*. 2015;30(5):543–546

516. Ong KL, Cheung BM, Man YB, Lau CP, Lam KS. Prevalence, awareness, treatment, and control of hypertension among United States adults 1999-2004. *Hypertension*. 2007;49(1):69–75

517. Guo F, He D, Zhang W, Walton RG. Trends in prevalence, awareness, management, and control of hypertension among United States adults, 1999 to 2010. *J Am Coll Cardiol*. 2012;60(7):599–606

518. Hajjar I, Kotchen TA. Trends in prevalence, awareness, treatment, and control of hypertension in the United States, 1988-2000. *JAMA*. 2003;290(2):199–206

519. Daniels SR, McMahon RP, Obarzanek E, et al. Longitudinal correlates of change in blood pressure in adolescent girls. *Hypertension*. 1998;31(1):97–103

520. Wang X, Poole JC, Treiber FA, Harshfield GA, Hanevold CD, Snieder H. Ethnic and gender differences in ambulatory blood pressure trajectories: results from a 15-year longitudinal study in youth and young adults. *Circulation*. 2006;114(25):2780–2787

521. Rosner B, Cook N, Portman R, Daniels S, Falkner B. Blood pressure differences by ethnic group among United States children and adolescents. *Hypertension*. 2009;54(3):502–508

522. Peacock WF IV, Hilleman DE, Levy PD, Rhoney DH, Varon J. A systematic review of nicardipine vs labetalol for the management of hypertensive crises. *Am J Emerg Med*. 2012;30(6):981–993

523. Wiest DB, Garner SS, Uber WE, Sade RM. Esmolol for the management of pediatric hypertension after cardiac operations. *J Thorac Cardiovasc Surg*. 1998;115(4):890–897

524. Flynn JT, Mottes TA, Brophy PD, Kershaw DB, Smoyer WE, Bunchman TE. Intravenous nicardipine for treatment of severe hypertension in children. *J Pediatr*. 2001;139(1):38–43

525. Tabbutt S, Nicolson SC, Adamson PC, et al. The safety, efficacy, and pharmacokinetics of esmolol for blood pressure control immediately after repair of coarctation of the aorta in infants and children: a multicenter, double-blind, randomized trial. *J Thorac Cardiovasc Surg*. 2008;136(2):321–328

526. Miyashita Y, Peterson D, Rees JM, Flynn JT. Isradipine for treatment of acute hypertension in hospitalized children and adolescents. *J Clin Hypertens (Greenwich)*. 2010;12(11):850–855

527. Thomas CA, Moffett BS, Wagner JL, Mott AR, Feig DI. Safety and efficacy of intravenous labetalol for hypertensive crisis in infants and small children. *Pediatr Crit Care Med*. 2011;12(1):28–32

528. Kako H, Gable A, Martin D, et al. A prospective, open-label trial of clevidipine for controlled hypotension during posterior spinal fusion. *J Pediatr Pharmacol Ther*. 2015;20(1):54–60

529. Hammer GB, Lewandowski A, Drover DR, et al. Safety and efficacy of sodium nitroprusside during prolonged infusion in pediatric patients. *Pediatr Crit Care Med*. 2015;16(5):397–403

530. Flynn JT, Bradford MC, Harvey EM. Intravenous hydralazine in hospitalized children and adolescents with hypertension. *J Pediatr*. 2016;168:88–92

531. Yang WC, Zhao LL, Chen CY, Wu YK, Chang YJ, Wu HP. First-attack pediatric hypertensive crisis presenting to the pediatric emergency department. *BMC Pediatr*. 2012;12:200

532. Baracco R, Mattoo TK. Pediatric hypertensive emergencies. *Curr Hypertens Rep*. 2014;16(8):456

533. Flynn JT, Tullus K. Severe hypertension in children and adolescents: pathophysiology and treatment [published correction appears in *Pediatr Nephrol*. 2012;27(3):503–504]. *Pediatr Nephrol*. 2009;24(6):1101–1112

534. Patel NH, Romero SK, Kaelber DC. Evaluation and management of pediatric hypertensive crises: hypertensive urgency and hypertensive emergencies. *Open Access Emerg Med*. 2012;4:85–92

535. Chen YL, Liu YF, Huang CY, et al. Normalization effect of sports training on blood pressure in hypertensives. *J Sports Sci*. 2010;28(4):361–367

536. Hupin D, Roche F, Gremeaux V, et al. Even a low-dose of moderate-to-vigorous physical activity reduces mortality by 22% in adults aged ≥60 years: a systematic review and meta-analysis. *Br J Sports Med*. 2015;49(19):1262–1267

537. Di Paolo FM, Schmied C, Zerguini YA, et al. The athlete's heart in adolescent Africans: an electrocardiographic and echocardiographic study. *J Am Coll Cardiol*. 2012;59(11):1029–1036

538. McCambridge TM, Benjamin HJ, Brenner JS, et al; Council on Sports Medicine and Fitness. Athletic participation by children and adolescents who have systemic hypertension. *Pediatrics*. 2010;125(6):1287–1294

539. Black HR, Sica D, Ferdinand K, White WB. Eligibility and disqualification recommendations for competitive athletes with cardiovascular abnormalities: Task Force 6: hypertension: a scientific statement from the American Heart Association and the American College of Cardiology. *J Am Coll Cardiol*. 2015;66(21):2393–2397

540. Tainio J, Qvist E, Miettinen J, et al. Blood pressure profiles 5 to 10 years after transplant in pediatric solid organ recipients. *J Clin Hypertens (Greenwich)*. 2015;17(2):154–161

541. Seeman T, Simková E, Kreisinger J, et al. Control of hypertension in children after renal transplantation. *Pediatr Transplant*. 2006;10(3):316–322

542. Gülhan B, Topaloğlu R, Karabulut E, et al. Post-transplant hypertension in pediatric kidney transplant recipients. *Pediatr Nephrol*. 2014;29(6):1075–1080

543. Arbeiter K, Pichler A, Stemberger R, et al. ACE inhibition in the treatment of children after renal transplantation. *Pediatr Nephrol*. 2004;19(2):222–226

544. Suszynski TM, Rizzari MD, Gillingham KJ, et al. Antihypertensive pharmacotherapy and long-term outcomes in pediatric kidney transplantation. *Clin Transplant*. 2013;27(3):472–480

545. Sakallı H, Baskın E, Bayrakcı US, Moray G, Haberal M. Acidosis and hyperkalemia caused by losartan and enalapril in pediatric kidney transplant recipients. *Exp Clin Transplant*. 2014;12(4):310–313

546. Cooley WC, Sagerman PJ; American Academy of Pediatrics; American Academy of Family Physicians; American College of Physicians; Transitions Clinical Report Authoring Group. Supporting the health care transition from adolescence to adulthood in the medical home. *Pediatrics*. 2011;128(1):182–200

547. Julius S, Nesbitt SD, Egan BM, et al; Trial of Preventing Hypertension (TROPHY) Study Investigators. Feasibility of treating prehypertension with an angiotensin-receptor blocker. *N Engl J Med*. 2006;354(16):1685–1697

548. Kurioka S, Horie S, Inoue A, Mafune K, Tsuda Y, Otsuji Y. Risk of progression to hypertension in nonhypertensive Japanese workers aged 20-64 years. *J Hypertens*. 2014;32(2):236–244

549. Stabouli S, Papakatsika S, Kotsis V. The role of obesity, salt and exercise on blood pressure in children and adolescents. *Expert Rev Cardiovasc Ther*. 2011;9(6):753–761

550. Holm JC, Gamborg M, Neland M, et al. Longitudinal changes in blood pressure during weight loss and regain of weight in obese boys and girls. *J Hypertens*. 2012;30(2):368–374

551. Gillman MW, Ellison RC. Childhood prevention of essential hypertension. *Pediatr Clin North Am*. 1993;40(1):179–194

552. Krousel-Wood MA, Muntner P, He J, Whelton PK. Primary prevention of essential hypertension. *Med Clin North Am*. 2004;88(1):223–238

553. Whelton PK, He J, Appel LJ, et al; National High Blood Pressure Education Program Coordinating Committee. Primary prevention of

hypertension: clinical and public health advisory from the National High Blood Pressure Education Program. *JAMA*. 2002;288(15):1882–1888

554. Kim N, Seo DC, King MH, Lederer AM, Sovinski D. Long-term predictors of blood pressure among adolescents during an 18-month school-based obesity prevention intervention. *J Adolesc Health*. 2014;55(4):521–527

555. Aburto NJ, Ziolkovska A, Hooper L, Elliott P, Cappuccio FP, Meerpohl JJ. Effect of lower sodium intake on health: systematic review and meta-analyses. *BMJ*. 2013;346:f1326

556. American Academy of Pediatrics. EQIPP: hypertension recognition and management. Available at: http://shop.aap.org/eqipp-hypertension-identification-and-management. Accessed February 6, 2017

557. American Academy of Pediatrics, Council on Quality Improvement and Patient Safety. Implementation guide. Available at: https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/coqips/Pages/Implementation-Guide.aspx. Accessed July 28, 2017

558. Wang YC, Cheung AM, Bibbins-Domingo K, et al. Effectiveness and cost-effectiveness of blood pressure screening in adolescents in the United States. *J Pediatr*. 2011;158(2):257–264. e1–e7

559. Davis ML, Ferguson MA, Zachariah JP. Clinical predictors and impact of ambulatory blood pressure monitoring in pediatric hypertension referrals. *J Am Soc Hypertens*. 2014;8(9):660–667

560. Leu MG, Austin E, Foti JL, et al. A framework for evaluating value of new clinical recommendations. *Hosp Pediatr*. 2016;6(10):578–586

561. Bradshaw B. The role of the family in managing therapy in minority children with type 2 diabetes mellitus. *J Pediatr Endocrinol Metab*. 2002;15(suppl 1):547–551

562. Pinhas-Hamiel O, Standiford D, Hamiel D, Dolan LM, Cohen R, Zeitler PS. The type 2 family: a setting for development and treatment of adolescent type 2 diabetes mellitus. *Arch Pediatr Adolesc Med*. 1999;153(10):1063–1067

563. Mulvaney SA, Schlundt DG, Mudasiru E, et al. Parent perceptions of caring for adolescents with type 2 diabetes. *Diabetes Care*. 2006;29(5):993–997

564. Summerbell CD, Ashton V, Campbell KJ, Edmunds L, Kelly S, Waters E. Interventions for treating obesity in children. *Cochrane Database Syst Rev*. 2003;(3):CD001872

565. Skinner AC, Weinberger M, Mulvaney S, Schlundt D, Rothman RL. Accuracy of perceptions of overweight and relation to self-care behaviors among adolescents with type 2 diabetes and their parents. *Diabetes Care*. 2008;31(2):227–229

566. Thompson M, Dana T, Bougatsos C, Blazina I, Norris SL. Screening for hypertension in children and adolescents to prevent cardiovascular disease. *Pediatrics*. 2013;131(3):490–525

567. Urbina EM, de Ferranti S, Steinberger J. Observational studies may be more important than randomized clinical trials: weaknesses in US Preventive Services Task Force recommendation on blood pressure screening in youth. *Hypertension*. 2014;63(4):638–640

568. Flynn JT. Ambulatory blood pressure monitoring in children: imperfect yet essential. *Pediatr Nephrol*. 2011;26(12):2089–2094

569. Juonala M, Magnussen CG, Venn A, et al. Influence of age on associations between childhood risk factors and carotid intima-media thickness in adulthood: the Cardiovascular Risk in Young Finns Study, the Childhood Determinants of Adult Health Study, the Bogalusa Heart Study, and the Muscatine Study for the International Childhood Cardiovascular Cohort (i3C) Consortium. *Circulation*. 2010;122(24):2514–2520

570. Muntner P, Becker RC, Calhoun D, et al. Introduction to the American Heart Association's hypertension strategically focused research network. *Hypertension*. 2016;67(4):674–680

High Blood Pressure Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents
- *ICD-10-CM* Coding Quick Reference for High Blood Pressure

Action Statement Summary

Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents

Key Action Statement 1

BP should be measured annually in children and adolescents ≥3 years of age (grade C, moderate recommendation).

Key Action Statement 2

BP should be checked in all children and adolescents ≥3 years of age at every health care encounter if they have obesity, are taking medications known to increase BP, have renal disease, a history of aortic arch obstruction or coarctation, or diabetes (grade C, moderate recommendation).

Key Action Statement 3

Trained health care professionals in the office setting should make a diagnosis of HTN if a child or adolescent has auscultatory-confirmed BP readings ≥95th percentile on 3 different visits (grade C, moderate recommendation).

Key Action Statement 4

Organizations with EHRs used in an office setting should consider including flags for abnormal BP values both when the values are being entered and when they are being viewed (grade C, weak recommendation).

Key Action Statement 5

Oscillometric devices may be used for BP screening in children and adolescents. When doing so, providers should use a device that has been validated in the pediatric age group. If elevated BP is suspected on the basis of oscillometric readings, confirmatory measurements should be obtained by auscultation (grade B, strong recommendation).

Key Action Statement 6

ABPM should be performed for the confirmation of HTN in children and adolescents with office BP measurements in the elevated BP category for 1 year or more or with stage 1 HTN over 3 clinic visits (grade C, moderate recommendation).

Key Action Statement 7

The routine performance of ABPM should be strongly considered in children and adolescents with high-risk conditions to assess HTN severity and determine if abnormal circadian BP patterns are present, which may indicate increased risk for target organ damage (grade B, moderate recommendation).

Key Action Statement 8

ABPM should be performed by using a standardized approach with monitors that have been validated in a pediatric population, and studies should be interpreted by using pediatric normative data (grade C, moderate recommendation).

Key Action Statement 9

Children and adolescents with suspected WCH should undergo ABPM. Diagnosis is based on the presence of mean SBP and DBP <95th percentile and SBP and DBP load <25% (grade B, strong recommendation).

Key Action Statement 10

Home BP monitoring should not be used to diagnose HTN, MH, or WCH but may be a useful adjunct to office and ambulatory BP measurement after HTN has been diagnosed (grade C, moderate recommendation).

Key Action Statement 11

Children and adolescents ≥6 years of age do not require an extensive evaluation for secondary causes of HTN if they have a positive family history of HTN, are overweight or obese, and/or do not have history or physical examination findings suggestive of a secondary cause of HTN (grade C, moderate recommendation).

Key Action Statement 12

Children and adolescents who have undergone coarctation repair should undergo ABPM for the detection of HTN (including MH) (grade B, strong recommendation).

Key Action Statement 13

In children and adolescents being evaluated for high BP, the provider should obtain a perinatal history, appropriate nutritional history, physical activity history, psychosocial history, and family history and perform a physical examination to identify findings suggestive of secondary causes of HTN (grade B, strong recommendation).

Key Action Statement 14

Clinicians should not perform electrocardiography in hypertensive children and adolescents being evaluated for LVH (grade B, strong recommendation).

Key Action Statement 15

1. It is recommended that echocardiography be performed to assess for cardiac target organ damage (LV mass, geometry, and function) at the time of consideration of pharmacologic treatment of HTN;
2. LVH should be defined as LV mass >51 g/m$^{2.7}$ (boys and girls) for children and adolescents older than 8 years and defined by LV mass >115 g/BSA for boys and LV mass >95 g/BSA for girls;
3. Repeat echocardiography may be performed to monitor improvement or progression of target organ damage at 6- to 12-month intervals. Indications to repeat echocardiography include persistent HTN despite treatment, concentric LV hypertrophy, or reduced LV ejection fraction; and
4. In patients without LV target organ injury at initial echocardiographic assessment, repeat echocardiography at yearly intervals may be considered in those with stage 2 HTN, secondary HTN, or chronic stage 1 HTN incompletely treated (noncompliance or drug resistance) to assess for the development of worsening LV target organ injury (grade C, moderate recommendation).

Key Action Statement 16

Doppler renal ultrasonography may be used as a noninvasive screening study for the evaluation of possible RAS in normal-weight children and adolescents ≥8 years of age who are suspected of having renovascular HTN and who will cooperate with the procedure (grade C, moderate recommendation).

Key Action Statement 17

In children and adolescents suspected of having RAS, either CTA or MRA may be performed as a noninvasive imaging study. Nuclear renography is less useful in pediatrics and should generally be avoided (grade D, weak recommendation).

Key Action Statement 18

Routine testing for MA is not recommended for children and adolescents with primary HTN (grade C, moderate recommendation).

Key Action Statement 19

In children and adolescents diagnosed with HTN, the treatment goal with nonpharmacologic and pharmacologic therapy should be a reduction in SBP and DBP to <90th percentile and <130/80 mm Hg in adolescents ≥13 years of age (grade C, moderate recommendation).

Key Action Statement 20

At the time of diagnosis of elevated BP or HTN in a child or adolescent, clinicians should provide advice on the DASH diet and recommend moderate to vigorous physical activity at least 3 to 5 days per week (30–60 minutes per session) to help reduce BP (grade C, weak recommendation).

Key Action Statement 21

In hypertensive children and adolescents who have failed lifestyle modifications (particularly those who have LV hypertrophy on echocardiography, symptomatic HTN, or stage 2 HTN without a clearly modifiable factor [eg, obesity]), clinicians should initiate pharmacologic treatment with an ACE inhibitor, ARB, long-acting calcium channel blocker, or thiazide diuretic (grade B, moderate recommendation).

Key Action Statement 22

ABPM may be used to assess treatment effectiveness in children and adolescents with HTN, especially when clinic and/or home BP measurements indicate insufficient BP response to treatment (grade B, moderate recommendation).

Key Action Statement 23

1. Children and adolescents with CKD should be evaluated for HTN at each medical encounter;
2. Children or adolescents with both CKD and HTN should be treated to lower 24-hour MAP to <50th percentile by ABPM; and
3. Regardless of apparent control of BP with office measures, children and adolescents with CKD and a history of HTN should have BP assessed by ABPM at least yearly to screen for MH (grade B, strong recommendation).

Key Action Statement 24

Children and adolescents with CKD and HTN should be evaluated for proteinuria (grade B, strong recommendation).

Key Action Statement 25

Children and adolescents with CKD, HTN, and proteinuria should be treated with an ACE inhibitor or ARB (grade B, strong recommendation).

Key Action Statement 26

Children and adolescents with T1DM or T2DM should be evaluated for HTN at each medical encounter and treated if BP is ≥95th percentile or >130/80 mm Hg in adolescents ≥13 years of age (grade C, moderate recommendation).

Key Action Statement 27

In children and adolescents with acute severe HTN and life-threatening symptoms, immediate treatment with short-acting antihypertensive medication should be initiated, and BP should be reduced by no more than 25% of the planned reduction over the first 8 hours (grade expert opinion D, weak recommendation).

Key Action Statement 28

Children and adolescents with HTN may participate in competitive sports once hypertensive target organ effects and risk have been assessed (grade C, moderate recommendation).

Key Action Statement 29

Children and adolescents with HTN should receive treatment to lower BP below stage 2 thresholds before participating in competitive sports (grade C, weak recommendation).

Key Action Statement 30

Adolescents with elevated BP or HTN (whether they are receiving antihypertensive treatment) should typically have their care transitioned to an appropriate adult care provider by 22 years of age (recognizing that there may be individual cases in which this upper age limit is exceeded, particularly in the case of youth with special health care needs). There should be a transfer of information regarding HTN etiology and past manifestations and complications of the patient's HTN (grade X, strong recommendation).

Coding Quick Reference for High Blood Pressure

ICD-10-CM		
I10	**Essential (primary) hypertension**	
I11.9	Hypertensive heart disease without heart failure	
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease*	
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease*	
I15.0 **I15.1** **I15.2** **I15.8** **I15.9**	Renovascular hypertension [secondary] Hypertension secondary to other renal disorders Hypertension secondary to endocrine disorders Other secondary hypertension Secondary hypertension, unspecified	Underlying cause coded in addition*
R03.0	Elevated blood-pressure reading, without diagnosis of hypertension	
P29.2	Neonatal hypertension	
***Underlying Causes**		
E25.0	Congenital adrenogenital disorders associated with enzyme deficiency	
E26.02	Glucocorticoid-remediable aldosteronism	
N18.1	Chronic kidney disease, stage 1	
N18.2	Chronic kidney disease, stage 2 (mild)	
N18.3	Chronic kidney disease, stage 3 (moderate)	
N18.4	Chronic kidney disease, stage 4 (severe)	
N18.5	Chronic kidney disease, stage 5	
N18.9	Chronic kidney disease, unspecified	
Q25.1	Coarctation of aorta	
Q25.71	Coarctation of pulmonary artery	
Q27.1	Congenital renal artery stenosis	
Q85.00	Neurofibromatosis, unspecified	
Q85.01	Neurofibromatosis, type 1	
Z83.49	Family history of other endocrine, nutritional and metabolic diseases [hyperaldosteronism]	
Z87.74	Personal history of (corrected) congenital malformations of heart and circulatory system [coarctation repair]	

Coding Quick Reference for High Blood Pressure, continued	
Z77.011	Contact with and (suspected) exposure to lead
Z77.018	Contact with and (suspected) exposure to other hazardous metals
Z79.3	Long term (current) use of hormonal contraceptives
Z79.51	Long term (current) use of inhaled steroids
Z79.52	Long term (current) use of systemic steroids
Z79.899	Other long term (current) drug therapy [CNS stimulant]

Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation

- *Clinical Practice Guideline*

AMERICAN ACADEMY OF PEDIATRICS

CLINICAL PRACTICE GUIDELINE

Subcommittee on Hyperbilirubinemia

Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation

ABSTRACT. Jaundice occurs in most newborn infants. Most jaundice is benign, but because of the potential toxicity of bilirubin, newborn infants must be monitored to identify those who might develop severe hyperbilirubinemia and, in rare cases, acute bilirubin encephalopathy or kernicterus. The focus of this guideline is to reduce the incidence of severe hyperbilirubinemia and bilirubin encephalopathy while minimizing the risks of unintended harm such as maternal anxiety, decreased breastfeeding, and unnecessary costs or treatment. Although kernicterus should almost always be preventable, cases continue to occur. These guidelines provide a framework for the prevention and management of hyperbilirubinemia in newborn infants of 35 or more weeks of gestation. In every infant, we recommend that clinicians 1) promote and support successful breastfeeding; 2) perform a systematic assessment before discharge for the risk of severe hyperbilirubinemia; 3) provide early and focused follow-up based on the risk assessment; and 4) when indicated, treat newborns with phototherapy or exchange transfusion to prevent the development of severe hyperbilirubinemia and, possibly, bilirubin encephalopathy (kernicterus). *Pediatrics* 2004; 114:297–316; *hyperbilirubinemia, newborn, kernicterus, bilirubin encephalopathy, phototherapy.*

ABBREVIATIONS. AAP, American Academy of Pediatrics; TSB, total serum bilirubin; TcB, transcutaneous bilirubin; G6PD, glucose-6-phosphate dehydrogenase; $ETCO_c$, end-tidal carbon monoxide corrected for ambient carbon monoxide; B/A, bilirubin/albumin; UB, unbound bilirubin.

BACKGROUND

In October 1994, the Provisional Committee for Quality Improvement and Subcommittee on Hyperbilirubinemia of the American Academy of Pediatrics (AAP) produced a practice parameter dealing with the management of hyperbilirubinemia in the healthy term newborn.[1] The current guideline represents a consensus of the committee charged by the AAP with reviewing and updating the existing guideline and is based on a careful review of the evidence, including a comprehensive literature review by the New England Medical Center Evidence-Based Practice Center.[2] (See "An Evidence-Based Review of Important Issues Concerning Neonatal Hyperbilirubinemia"[3] for a description of the methodology, questions addressed, and conclusions of this report.) This guideline is intended for use by hospitals and pediatricians, neonatologists, family physicians, physician assistants, and advanced practice nurses who treat newborn infants in the hospital and as outpatients. A list of frequently asked questions and answers for parents is available in English and Spanish at www.aap.org/family/jaundicefaq.htm.

The recommendations in this guideline do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

DEFINITION OF RECOMMENDATIONS

The evidence-based approach to guideline development requires that the evidence in support of a policy be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations are based on the quality of evidence and the balance of benefits and harms that is anticipated when the recommendation is followed. This guideline uses the definitions for quality of evidence and balance of benefits and harms established by the AAP Steering Committee on Quality Improvement Management.[4] See Appendix 1 for these definitions.

The draft practice guideline underwent extensive peer review by committees and sections within the AAP, outside organizations, and other individuals identified by the subcommittee as experts in the field. Liaison representatives to the subcommittee were invited to distribute the draft to other representatives and committees within their specialty organizations. The resulting comments were reviewed by the subcommittee and, when appropriate, incorporated into the guideline.

BILIRUBIN ENCEPHALOPATHY AND KERNICTERUS

Although originally a pathologic diagnosis characterized by bilirubin staining of the brainstem nuclei and cerebellum, the term "kernicterus" has come to be used interchangeably with both the acute and chronic findings of bilirubin encephalopathy. Bilirubin encephalopathy describes the clinical central nervous system findings caused by bilirubin toxicity to the basal ganglia and various brainstem nuclei. To avoid confusion and encourage greater consistency in the literature, the committee recommends that in infants the term "acute bilirubin encephalopathy" be used to describe the acute manifestations of bilirubin

toxicity seen in the first weeks after birth and that the term "kernicterus" be reserved for the chronic and permanent clinical sequelae of bilirubin toxicity.

See Appendix 1 for the clinical manifestations of acute bilirubin encephalopathy and kernicterus.

FOCUS OF GUIDELINE

The overall aim of this guideline is to promote an approach that will reduce the frequency of severe neonatal hyperbilirubinemia and bilirubin encephalopathy and minimize the risk of unintended harm such as increased anxiety, decreased breastfeeding, or unnecessary treatment for the general population and excessive cost and waste. Recent reports of kernicterus indicate that this condition, although rare, is still occurring.[2,5–10]

Analysis of these reported cases of kernicterus suggests that if health care personnel follow the recommendations listed in this guideline, kernicterus would be largely preventable.

These guidelines emphasize the importance of universal systematic assessment for the risk of severe hyperbilirubinemia, close follow-up, and prompt intervention when indicated. The recommendations apply to the care of infants at 35 or more weeks of gestation. These recommendations seek to further the aims defined by the Institute of Medicine as appropriate for health care:[11] safety, effectiveness, efficiency, timeliness, patient-centeredness, and equity. They specifically emphasize the principles of patient safety and the key role of timeliness of interventions to prevent adverse outcomes resulting from neonatal hyperbilirubinemia.

The following are the key elements of the recommendations provided by this guideline. Clinicians should:

1. Promote and support successful breastfeeding.
2. Establish nursery protocols for the identification and evaluation of hyperbilirubinemia.
3. Measure the total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) level on infants jaundiced in the first 24 hours.
4. Recognize that visual estimation of the degree of jaundice can lead to errors, particularly in darkly pigmented infants.
5. Interpret all bilirubin levels according to the infant's age in hours.
6. Recognize that infants at less than 38 weeks' gestation, particularly those who are breastfed, are at higher risk of developing hyperbilirubinemia and require closer surveillance and monitoring.
7. Perform a systematic assessment on all infants before discharge for the risk of severe hyperbilirubinemia.
8. Provide parents with written and verbal information about newborn jaundice.
9. Provide appropriate follow-up based on the time of discharge and the risk assessment.
10. Treat newborns, when indicated, with phototherapy or exchange transfusion.

PRIMARY PREVENTION

In numerous policy statements, the AAP recommends breastfeeding for all healthy term and near-term newborns. This guideline strongly supports this general recommendation.

RECOMMENDATION 1.0: Clinicians should advise mothers to nurse their infants at least 8 to 12 times per day for the first several days[12] *(evidence quality C: benefits exceed harms).*

Poor caloric intake and/or dehydration associated with inadequate breastfeeding may contribute to the development of hyperbilirubinemia.[6,13,14] Increasing the frequency of nursing decreases the likelihood of subsequent significant hyperbilirubinemia in breastfed infants.[15–17] Providing appropriate support and advice to breastfeeding mothers increases the likelihood that breastfeeding will be successful.

Additional information on how to assess the adequacy of intake in a breastfed newborn is provided in Appendix 1.

RECOMMENDATION 1.1: The AAP recommends against routine supplementation of nondehydrated breastfed infants with water or dextrose water (evidence quality B and C: harms exceed benefits).

Supplementation with water or dextrose water will not prevent hyperbilirubinemia or decrease TSB levels.[18,19]

SECONDARY PREVENTION

RECOMMENDATION 2.0: Clinicians should perform ongoing systematic assessments during the neonatal period for the risk of an infant developing severe hyperbilirubinemia.

Blood Typing

RECOMMENDATION 2.1: All pregnant women should be tested for ABO and Rh (D) blood types and have a serum screen for unusual isoimmune antibodies (evidence quality B: benefits exceed harms).

RECOMMENDATION 2.1.1: If a mother has not had prenatal blood grouping or is Rh-negative, a direct antibody test (or Coombs' test), blood type, and an Rh (D) type on the infant's (cord) blood are strongly recommended (evidence quality B: benefits exceed harms).

RECOMMENDATION 2.1.2: If the maternal blood is group O, Rh-positive, it is an option to test the cord blood for the infant's blood type and direct antibody test, but it is not required provided that there is appropriate surveillance, risk assessment before discharge, and follow-up[20] *(evidence quality C: benefits exceed harms).*

Clinical Assessment

RECOMMENDATION 2.2: Clinicians should ensure that all infants are routinely monitored for the development of jaundice, and nurseries should have established protocols for the assessment of jaundice. Jaundice should be assessed whenever the infant's vital signs are measured but no less than every 8 to 12 hours (evidence quality D: benefits versus harms exceptional).

In newborn infants, jaundice can be detected by blanching the skin with digital pressure, revealing the underlying color of the skin and subcutaneous tissue. The assessment of jaundice must be per-

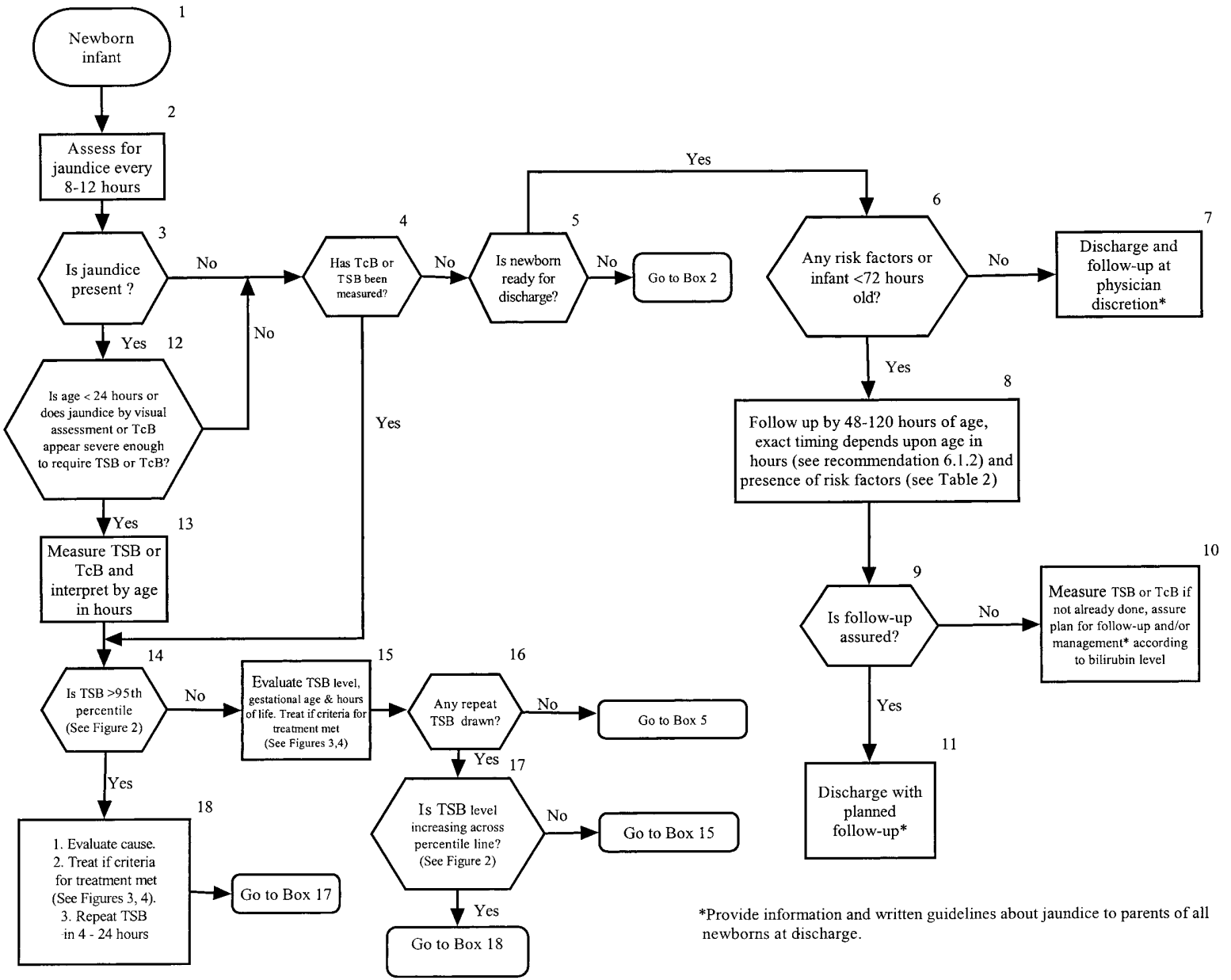


Fig 1. Algorithm for the management of jaundice in the newborn nursery.

formed in a well-lit room or, preferably, in daylight at a window. Jaundice is usually seen first in the face and progresses caudally to the trunk and extremities,[21] but visual estimation of bilirubin levels from the degree of jaundice can lead to errors.[22–24] In most infants with TSB levels of less than 15 mg/dL (257 μmol/L), noninvasive TcB-measurement devices can provide a valid estimate of the TSB level.[2,25–29] See Appendix 1 for additional information on the clinical evaluation of jaundice and the use of TcB measurements.

RECOMMENDATION 2.2.1: Protocols for the assessment of jaundice should include the circumstances in which nursing staff can obtain a TcB level or order a TSB measurement (evidence quality D: benefits versus harms exceptional).

Laboratory Evaluation

RECOMMENDATION 3.0: A TcB and/or TSB measurement should be performed on every infant who is jaundiced in the first 24 hours after birth (Fig 1 and Table 1)[30] (evidence quality C: benefits exceed harms). The need for and timing of a repeat TcB or TSB measurement will depend on the zone in which the TSB falls (Fig 2),[25,31] the age of the infant, and the evolution of the hyperbilirubinemia. Recommendations for TSB measurements after the age of 24 hours are provided in Fig 1 and Table 1.

See Appendix 1 for capillary versus venous bilirubin levels.

RECOMMENDATION 3.1: A TcB and/or TSB measurement should be performed if the jaundice appears excessive for the infant's age (evidence quality D: benefits versus harms exceptional). If there is any doubt about the degree of jaundice, the TSB or TcB should be measured. Visual estimation of bilirubin levels from the degree of jaundice can lead to errors, particularly in darkly pigmented infants (evidence quality C: benefits exceed harms).

RECOMMENDATION 3.2: All bilirubin levels should be interpreted according to the infant's age in hours (Fig 2) (evidence quality C: benefits exceed harms).

Cause of Jaundice

RECOMMENDATION 4.1: The possible cause of jaundice should be sought in an infant receiving phototherapy or whose TSB level is rising rapidly (ie, crossing percentiles [Fig 2]) and is not explained by the history and physical examination (evidence quality D: benefits versus harms exceptional).

RECOMMENDATION 4.1.1: Infants who have an elevation of direct-reacting or conjugated bilirubin should have a urinalysis and urine culture.[32] Additional laboratory evaluation for sepsis should be performed if indicated by history and physical examination (evidence quality C: benefits exceed harms).

See Appendix 1 for definitions of abnormal levels of direct-reacting and conjugated bilirubin.

RECOMMENDATION 4.1.2: Sick infants and those who are jaundiced at or beyond 3 weeks should have a measurement of total and direct or conjugated bilirubin to identify cholestasis (Table 1) (evidence quality D: benefit versus harms exceptional). The results of the newborn thyroid and galactosemia screen should also be checked in these infants (evidence quality D: benefits versus harms exceptional).

RECOMMENDATION 4.1.3: If the direct-reacting or conjugated bilirubin level is elevated, additional evaluation for the causes of cholestasis is recommended (evidence quality C: benefits exceed harms).

RECOMMENDATION 4.1.4: Measurement of the glucose-6-phosphate dehydrogenase (G6PD) level is recommended for a jaundiced infant who is receiving phototherapy and whose family history or ethnic or geographic origin suggest the likelihood of G6PD deficiency or for an infant in whom the response to phototherapy is poor (Fig 3) (evidence quality C: benefits exceed harms).

G6PD deficiency is widespread and frequently unrecognized, and although it is more common in the populations around the Mediterranean and in the Middle East, Arabian peninsula, Southeast Asia, and Africa, immigration and intermarriage have transformed G6PD deficiency into a global problem.[33,34]

TABLE 1. Laboratory Evaluation of the Jaundiced Infant of 35 or More Weeks' Gestation

Indications	Assessments
Jaundice in first 24 h	Measure TcB and/or TSB
Jaundice appears excessive for infant's age	Measure TcB and/or TSB
Infant receiving phototherapy or TSB rising rapidly (ie, crossing percentiles [Fig 2]) and unexplained by history and physical examination	Blood type and Coombs' test, if not obtained with cord blood Complete blood count and smear Measure direct or conjugated bilirubin It is an option to perform reticulocyte count, G6PD, and $ETCO_c$, if available Repeat TSB in 4–24 h depending on infant's age and TSB level
TSB concentration approaching exchange levels or not responding to phototherapy	Perform reticulocyte count, G6PD, albumin, $ETCO_c$, if available
Elevated direct (or conjugated) bilirubin level	Do urinalysis and urine culture. Evaluate for sepsis if indicated by history and physical examination
Jaundice present at or beyond age 3 wk, or sick infant	Total and direct (or conjugated) bilirubin level If direct bilirubin elevated, evaluate for causes of cholestasis Check results of newborn thyroid and galactosemia screen, and evaluate infant for signs or symptoms of hypothyroidism

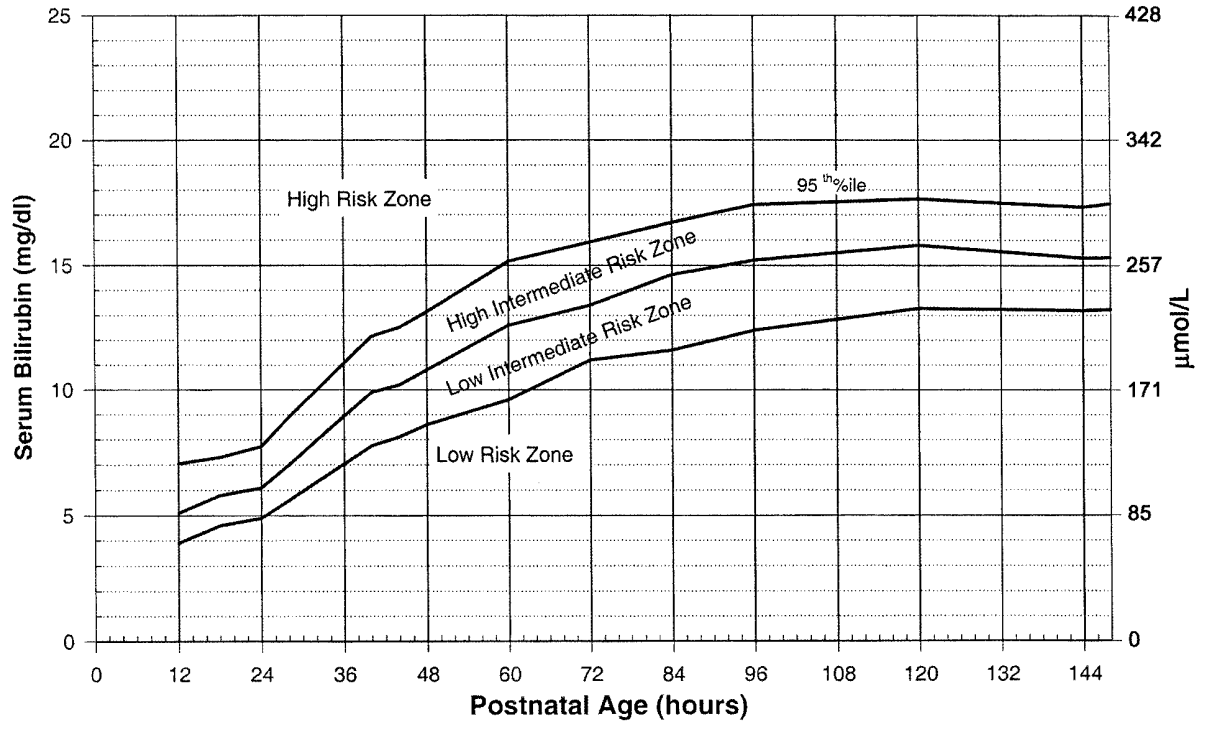


Fig 2. Nomogram for designation of risk in 2840 well newborns at 36 or more weeks' gestational age with birth weight of 2000 g or more or 35 or more weeks' gestational age and birth weight of 2500 g or more based on the hour-specific serum bilirubin values. The serum bilirubin level was obtained before discharge, and the zone in which the value fell predicted the likelihood of a subsequent bilirubin level exceeding the 95th percentile (high-risk zone) as shown in Appendix 1, Table 4. Used with permission from Bhutani et al.[31] See Appendix 1 for additional information about this nomogram, which should not be used to represent the natural history of neonatal hyperbilirubinemia.

Furthermore, G6PD deficiency occurs in 11% to 13% of African Americans, and kernicterus has occurred in some of these infants.[5,33] In a recent report, G6PD deficiency was considered to be the cause of hyperbilirubinemia in 19 of 61 (31.5%) infants who developed kernicterus.[5] (See Appendix 1 for additional information on G6PD deficiency.)

Risk Assessment Before Discharge

RECOMMENDATION 5.1: Before discharge, every newborn should be assessed for the risk of developing severe hyperbilirubinemia, and all nurseries should establish protocols for assessing this risk. Such assessment is particularly important in infants who are discharged before the age of 72 hours (evidence quality C: benefits exceed harms).

RECOMMENDATION 5.1.1: The AAP recommends 2 clinical options used individually or in combination for the systematic assessment of risk: predischarge measurement of the bilirubin level using TSB or TcB and/or assessment of clinical risk factors. Whether either or both options are used, appropriate follow-up after discharge is essential (evidence quality C: benefits exceed harms).

The best documented method for assessing the risk of subsequent hyperbilirubinemia is to measure the TSB or TcB level[25,31,35–38] and plot the results on a nomogram (Fig 2). A TSB level can be obtained at the time of the routine metabolic screen, thus obviating the need for an additional blood sample. Some authors have suggested that a TSB measurement should be part of the routine screening of all newborns.[5,31] An infant whose predischarge TSB is in the low-risk zone (Fig 2) is at very low risk of developing severe hyperbilirubinemia.[5,38]

Table 2 lists those factors that are clinically signif-

TABLE 2. Risk Factors for Development of Severe Hyperbilirubinemia in Infants of 35 or More Weeks' Gestation (in Approximate Order of Importance)

Major risk factors
Predischarge TSB or TcB level in the high-risk zone (Fig 2)[25,31]
Jaundice observed in the first 24 h[30]
Blood group incompatibility with positive direct antiglobulin test, other known hemolytic disease (eg, G6PD deficiency), elevated $ETCO_c$
Gestational age 35–36 wk[39,40]
Previous sibling received phototherapy[40,41]
Cephalohematoma or significant bruising[39]
Exclusive breastfeeding, particularly if nursing is not going well and weight loss is excessive[39,40]
East Asian race[39]*
Minor risk factors
Predischarge TSB or TcB level in the high intermediate-risk zone[25,31]
Gestational age 37–38 wk[39,40]
Jaundice observed before discharge[40]
Previous sibling with jaundice[40,41]
Macrosomic infant of a diabetic mother[42,43]
Maternal age ≥25 y[39]
Male gender[39,40]
Decreased risk (these factors are associated with decreased risk of significant jaundice, listed in order of decreasing importance)
TSB or TcB level in the low-risk zone (Fig 2)[25,31]
Gestational age ≥41 wk[39]
Exclusive bottle feeding[39,40]
Black race[38]*
Discharge from hospital after 72 h[40,44]

* Race as defined by mother's description.

icant and most frequently associated with an increase in the risk of severe hyperbilirubinemia. But, because these risk factors are common and the risk of hyperbilirubinemia is small, individually the factors are of limited use as predictors of significant hyperbilirubinemia.[39] Nevertheless, if no risk factors are present, the risk of severe hyperbilirubinemia is extremely low, and the more risk factors present, the greater the risk of severe hyperbilirubinemia.[39] The important risk factors most frequently associated with severe hyperbilirubinemia are breastfeeding, gestation below 38 weeks, significant jaundice in a previous sibling, and jaundice noted before discharge.[39,40] A formula-fed infant of 40 or more weeks' gestation is at very low risk of developing severe hyperbilirubinemia.[39]

Hospital Policies and Procedures

RECOMMENDATION 6.1: All hospitals should provide written and verbal information for parents at the time of discharge, which should include an explanation of jaundice, the need to monitor infants for jaundice, and advice on how monitoring should be done (evidence quality D: benefits versus harms exceptional).

An example of a parent-information handout is available in English and Spanish at www.aap.org/family/jaundicefaq.htm.

Follow-up

RECOMMENDATION 6.1.1: All infants should be examined by a qualified health care professional in the first few days after discharge to assess infant well-being and the presence or absence of jaundice. The timing and location of this assessment will be determined by the length of stay in the nursery, presence or absence of risk factors for hyperbilirubinemia (Table 2 and Fig 2), and risk of other neonatal problems (evidence quality C: benefits exceed harms).

Timing of Follow-up

RECOMMENDATION 6.1.2: Follow-up should be provided as follows:

Infant Discharged	Should Be Seen by Age
Before age 24 h	72 h
Between 24 and 47.9 h	96 h
Between 48 and 72 h	120 h

For some newborns discharged before 48 hours, 2 follow-up visits may be required, the first visit between 24 and 72 hours and the second between 72 and 120 hours. Clinical judgment should be used in determining follow-up. Earlier or more frequent follow-up should be provided for those who have risk factors for hyperbilirubinemia (Table 2), whereas those discharged with few or no risk factors can be seen after longer intervals (evidence quality C: benefits exceed harms).

RECOMMENDATION 6.1.3: If appropriate follow-up cannot be ensured in the presence of elevated risk for developing severe hyperbilirubinemia, it may be necessary to delay discharge either until appropriate follow-up can be ensured or the period of greatest risk has passed (72-96 hours) (evidence quality D: benefits versus harms exceptional).

Follow-up Assessment

RECOMMENDATION 6.1.4: The follow-up assessment should include the infant's weight and percent change from birth weight, adequacy of intake, the pattern of voiding and stooling, and the presence or absence of jaundice (evidence quality C: benefits exceed harms). Clinical judgment should be used to determine the need for a bilirubin measurement. If there is any doubt about the degree of jaundice, the TSB or TcB level should be measured. Visual estimation of bilirubin levels can lead to errors, particularly in darkly pigmented infants (evidence quality C: benefits exceed harms).

See Appendix 1 for assessment of the adequacy of intake in breastfeeding infants.

TREATMENT

Phototherapy and Exchange Transfusion

RECOMMENDATION 7.1: Recommendations for treatment are given in Table 3 and Figs 3 and 4 (evidence quality C: benefits exceed harms). If the TSB does not fall or continues to rise despite intensive phototherapy, it is very likely that hemolysis is occurring. The committee's recommendations for discontinuing phototherapy can be found in Appendix 2.

RECOMMENDATION 7.1.1: In using the guidelines for phototherapy and exchange transfusion (Figs 3 and 4), the direct-reacting (or conjugated) bilirubin level should not be subtracted from the total (evidence quality D: benefits versus harms exceptional).

In unusual situations in which the direct bilirubin level is 50% or more of the total bilirubin, there are no good data to provide guidance for therapy, and consultation with an expert in the field is recommended.

RECOMMENDATION 7.1.2: If the TSB is at a level at which exchange transfusion is recommended (Fig 4) or if the TSB level is 25 mg/dL (428 μmol/L) or higher at any time, it is a medical emergency and the infant should be admitted immediately and directly to a hospital pediatric service for intensive phototherapy. These infants should not be referred to the emergency department, because it delays the initiation of treatment[54] (evidence quality C: benefits exceed harms).

RECOMMENDATION 7.1.3: Exchange transfusions should be performed only by trained personnel in a neonatal intensive care unit with full monitoring and resuscitation capabilities (evidence quality D: benefits versus harms exceptional).

RECOMMENDATION 7.1.4: In isoimmune hemolytic disease, administration of intravenous γ-globulin (0.5-1 g/kg over 2 hours) is recommended if the TSB is rising despite intensive phototherapy or the TSB level is within 2 to 3 mg/dL (34-51 μmol/L) of the exchange level (Fig 4).[55] If necessary, this dose can be repeated in 12 hours (evidence quality B: benefits exceed harms).

Intravenous γ-globulin has been shown to reduce the need for exchange transfusions in Rh and ABO hemolytic disease.[55–58] Although data are limited, it is reasonable to assume that intravenous γ-globulin will also be helpful in the other types of Rh hemolytic disease such as anti-C and anti-E.

TABLE 3. Example of a Clinical Pathway for Management of the Newborn Infant Readmitted for Phototherapy or Exchange Transfusion

Treatment
Use intensive phototherapy and/or exchange transfusion as indicated in Figs 3 and 4 (see Appendix 2 for details of phototherapy use)
Laboratory tests
TSB and direct bilirubin levels
Blood type (ABO, Rh)
Direct antibody test (Coombs')
Serum albumin
Complete blood cell count with differential and smear for red cell morphology
Reticulocyte count
$ETCO_c$ (if available)
G6PD if suggested by ethnic or geographic origin or if poor response to phototherapy
Urine for reducing substances
If history and/or presentation suggest sepsis, perform blood culture, urine culture, and cerebrospinal fluid for protein, glucose, cell count, and culture
Interventions
If TSB ≥25 mg/dL (428 μmol/L) or ≥20 mg/dL (342 μmol/L) in a sick infant or infant <38 wk gestation, obtain a type and crossmatch, and request blood in case an exchange transfusion is necessary
In infants with isoimmune hemolytic disease and TSB level rising in spite of intensive phototherapy or within 2–3 mg/dL (34–51 μmol/L) of exchange level (Fig 4), administer intravenous immunoglobulin 0.5–1 g/kg over 2 h and repeat in 12 h if necessary
If infant's weight loss from birth is >12% or there is clinical or biochemical evidence of dehydration, recommend formula or expressed breast milk. If oral intake is in question, give intravenous fluids.
For infants receiving intensive phototherapy
Breastfeed or bottle-feed (formula or expressed breast milk) every 2–3 h
If TSB ≥25 mg/dL (428 μmol/L), repeat TSB within 2–3 h
If TSB 20–25 mg/dL (342–428 μmol/L), repeat within 3–4 h. If TSB <20 mg/dL (342 μmol/L), repeat in 4–6 h. If TSB continues to fall, repeat in 8–12 h
If TSB is not decreasing or is moving closer to level for exchange transfusion or the TSB/albumin ratio exceeds levels shown in Fig 4, consider exchange transfusion (see Fig 4 for exchange transfusion recommendations)
When TSB is <13–14 mg/dL (239 μmol/L), discontinue phototherapy
Depending on the cause of the hyperbilirubinemia, it is an option to measure TSB 24 h after discharge to check for rebound

Serum Albumin Levels and the Bilirubin/Albumin Ratio

RECOMMENDATION 7.1.5: It is an option to measure the serum albumin level and consider an albumin level of less than 3.0 g/dL as one risk factor for lowering the threshold for phototherapy use (see Fig 3) (evidence quality D: benefits versus risks exceptional.).

RECOMMENDATION 7.1.6: If an exchange transfusion is being considered, the serum albumin level should be measured and the bilirubin/albumin (B/A) ratio used in conjunction with the TSB level and other factors in determining the need for exchange transfusion (see Fig 4) (evidence quality D: benefits versus harms exceptional).

The recommendations shown above for treating hyperbilirubinemia are based primarily on TSB levels and other factors that affect the risk of bilirubin encephalopathy. This risk might be increased by a prolonged (rather than a brief) exposure to a certain TSB level.[59,60] Because the published data that address this issue are limited, however, it is not possible to provide specific recommendations for intervention based on the duration of hyperbilirubinemia.

See Appendix 1 for the basis for recommendations 7.1 through 7.1.6 and for the recommendations provided in Figs 3 and 4. Appendix 1 also contains a discussion of the risks of exchange transfusion and the use of B/A binding.

Acute Bilirubin Encephalopathy

RECOMMENDATION 7.1.7: Immediate exchange transfusion is recommended in any infant who is jaundiced and manifests the signs of the intermediate to advanced stages of acute bilirubin encephalopathy[61,62] (hypertonia, arching, retrocollis, opisthotonos, fever, high-pitched cry) even if the TSB is falling (evidence quality D: benefits versus risks exceptional).

Phototherapy

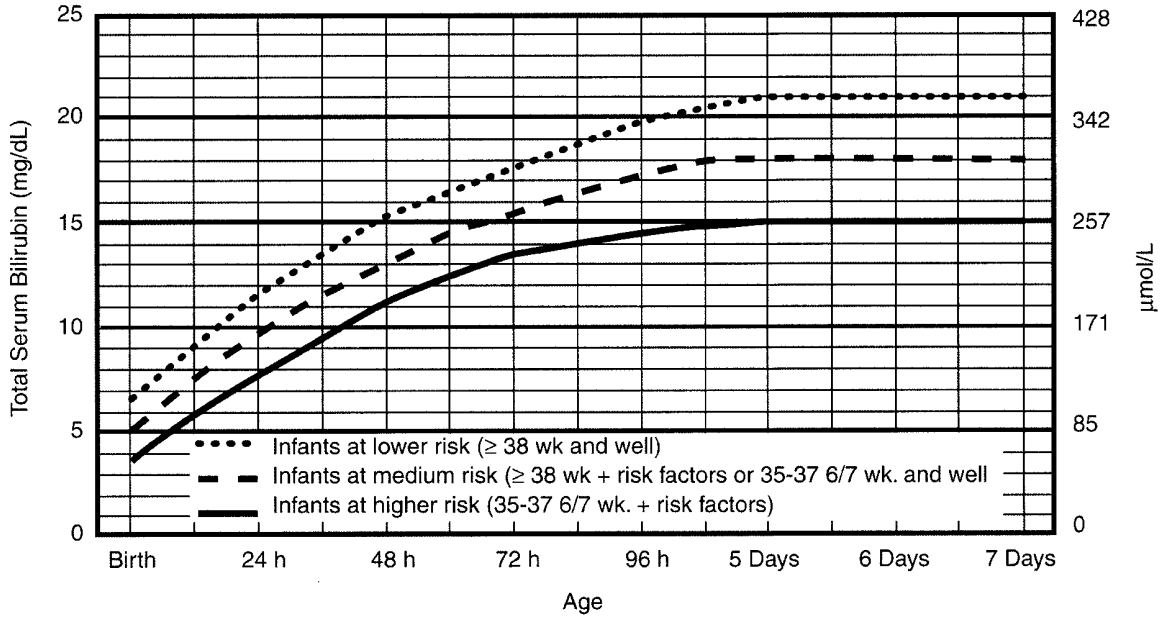
RECOMMENDATION 7.2: All nurseries and services treating infants should have the necessary equipment to provide intensive phototherapy (see Appendix 2) (evidence quality D: benefits exceed risks).

Outpatient Management of the Jaundiced Breastfed Infant

RECOMMENDATION 7.3: In breastfed infants who require phototherapy (Fig 3), the AAP recommends that, if possible, breastfeeding should be continued (evidence quality C: benefits exceed harms). It is also an option to interrupt temporarily breastfeeding and substitute formula. This can reduce bilirubin levels and/or enhance the efficacy of phototherapy[63–65] (evidence quality B: benefits exceed harms). In breastfed infants receiving phototherapy, supplementation with expressed breast milk or formula is appropriate if the infant's intake seems inadequate, weight loss is excessive, or the infant seems dehydrated.

IMPLEMENTATION STRATEGIES

The Institute of Medicine[11] recommends a dramatic change in the way the US health care system



- Use total bilirubin. Do not subtract direct reacting or conjugated bilirubin.
- Risk factors = isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis, or albumin < 3.0g/dL (if measured)
- For well infants 35-37 6/7 wk can adjust TSB levels for intervention around the medium risk line. It is an option to intervene at lower TSB levels for infants closer to 35 wks and at higher TSB levels for those closer to 37 6/7 wk.
- It is an option to provide conventional phototherapy in hospital or at home at TSB levels 2-3 mg/dL (35-50mmol/L) below those shown but home phototherapy should not be used in any infant with risk factors.

Fig 3. Guidelines for phototherapy in hospitalized infants of 35 or more weeks' gestation.

Note: These guidelines are based on limited evidence and the levels shown are approximations. The guidelines refer to the use of intensive phototherapy which should be used when the TSB exceeds the line indicated for each category. Infants are designated as "higher risk" because of the potential negative effects of the conditions listed on albumin binding of bilirubin,[45–47] the blood-brain barrier,[48] and the susceptibility of the brain cells to damage by bilirubin.[48]

"Intensive phototherapy" implies irradiance in the blue-green spectrum (wavelengths of approximately 430–490 nm) of at least 30 $\mu W/cm^2$ per nm (measured at the infant's skin directly below the center of the phototherapy unit) and delivered to as much of the infant's surface area as possible. Note that irradiance measured below the center of the light source is much greater than that measured at the periphery. Measurements should be made with a radiometer specified by the manufacturer of the phototherapy system.

See Appendix 2 for additional information on measuring the dose of phototherapy, a description of intensive phototherapy, and of light sources used. If total serum bilirubin levels approach or exceed the exchange transfusion line (Fig 4), the sides of the bassinet, incubator, or warmer should be lined with aluminum foil or white material.[50] This will increase the surface area of the infant exposed and increase the efficacy of phototherapy.[51]

If the total serum bilirubin does not decrease or continues to rise in an infant who is receiving intensive phototherapy, this strongly suggests the presence of hemolysis.

Infants who receive phototherapy and have an elevated direct-reacting or conjugated bilirubin level (cholestatic jaundice) may develop the bronze-baby syndrome. See Appendix 2 for the use of phototherapy in these infants.

ensures the safety of patients. The perspective of safety as a purely individual responsibility must be replaced by the concept of safety as a property of systems. Safe systems are characterized by a shared knowledge of the goal, a culture emphasizing safety, the ability of each person within the system to act in a manner that promotes safety, minimizing the use of memory, and emphasizing the use of standard procedures (such as checklists), and the involvement of patients/families as partners in the process of care.

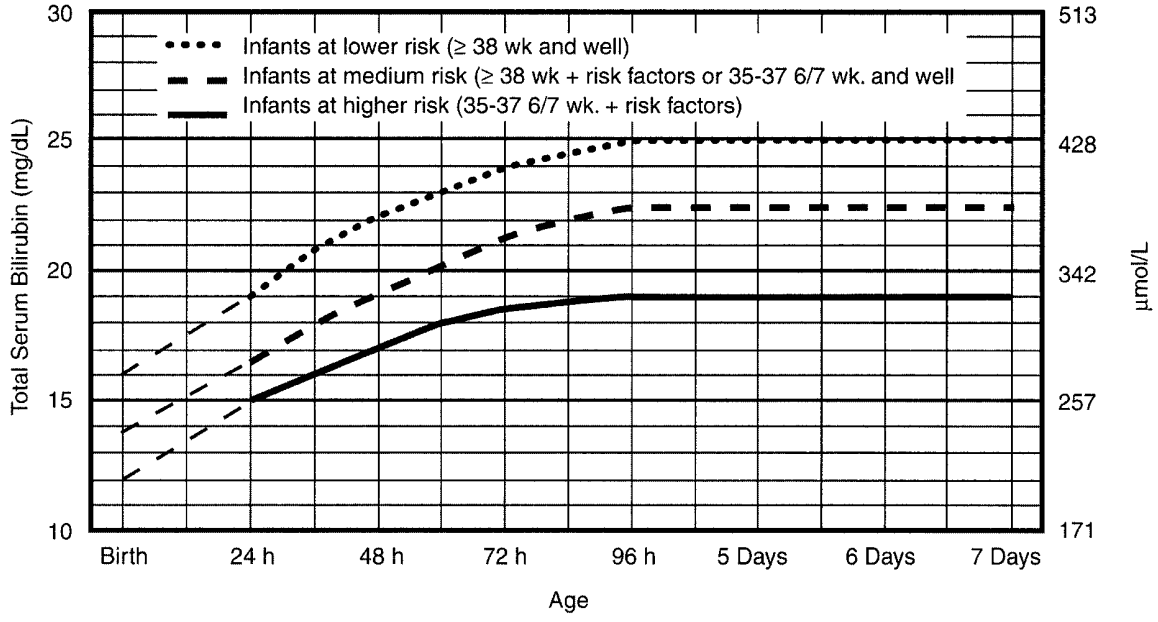
These principles can be applied to the challenge of preventing severe hyperbilirubinemia and kernicterus. A systematic approach to the implementation of these guidelines should result in greater safety. Such approaches might include

- The establishment of standing protocols for nursing assessment of jaundice, including testing TcB and TSB levels, without requiring physician orders.
- Checklists or reminders associated with risk factors, age at discharge, and laboratory test results that provide guidance for appropriate follow-up.
- Explicit educational materials for parents (a key component of all AAP guidelines) concerning the identification of newborns with jaundice.

FUTURE RESEARCH

Epidemiology of Bilirubin-Induced Central Nervous System Damage

There is a need for appropriate epidemiologic data to document the incidence of kernicterus in the newborn population, the incidence of other adverse effects attributable to hyperbilirubinemia and its management, and the number of infants whose TSB levels exceed 25 or 30 mg/dL (428-513 μmol/L). Organizations such as the Centers for Disease Control and Prevention should implement strategies for appropriate data gathering to identify the number of



- The dashed lines for the first 24 hours indicate uncertainty due to a wide range of clinical circumstances and a range of responses to phototherapy.
- Immediate exchange transfusion is recommended if infant shows signs of acute bilirubin encephalopathy (hypertonia, arching, retrocollis, opisthotonos, fever, high pitched cry) or if TSB is ≥5 mg/dL (85 µmol/L) above these lines.
- Risk factors - isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy, temperature instability, sepsis, acidosis.
- Measure serum albumin and calculate B/A ratio (See legend)
- Use total bilirubin. Do not subtract direct reacting or conjugated bilirubin
- If infant is well and 35-37 6/7 wk (median risk) can individualize TSB levels for exchange based on actual gestational age.

Fig 4. Guidelines for exchange transfusion in infants 35 or more weeks' gestation.

Note that these suggested levels represent a consensus of most of the committee but are based on limited evidence, and the levels shown are approximations. See ref. 3 for risks and complications of exchange transfusion. During birth hospitalization, exchange transfusion is recommended if the TSB rises to these levels despite intensive phototherapy. For readmitted infants, if the TSB level is above the exchange level, repeat TSB measurement every 2 to 3 hours and consider exchange if the TSB remains above the levels indicated after intensive phototherapy for 6 hours.

The following B/A ratios can be used together with but in not in lieu of the TSB level as an additional factor in determining the need for exchange transfusion[52]:

Risk Category	B/A Ratio at Which Exchange Transfusion Should be Considered	
	TSB mg/dL/Alb, g/dL	TSB µmol/L/Alb, µmol/L
Infants ≥38 0/7 wk	8.0	0.94
Infants 35 0/7–36 6/7 wk and well or ≥38 0/7 wk if higher risk or isoimmune hemolytic disease or G6PD deficiency	7.2	0.84
Infants 35 0/7–37 6/7 wk if higher risk or isoimmune hemolytic disease or G6PD deficiency	6.8	0.80

If the TSB is at or approaching the exchange level, send blood for immediate type and crossmatch. Blood for exchange transfusion is modified whole blood (red cells and plasma) crossmatched against the mother and compatible with the infant.[53]

infants who develop serum bilirubin levels above 25 or 30 mg/dL (428-513 µmol/L) and those who develop acute and chronic bilirubin encephalopathy. This information will help to identify the magnitude of the problem; the number of infants who need to be screened and treated to prevent 1 case of kernicterus; and the risks, costs, and benefits of different strategies for prevention and treatment of hyperbilirubinemia. In the absence of these data, recommendations for intervention cannot be considered definitive.

Effect of Bilirubin on the Central Nervous System

The serum bilirubin level by itself, except when it is extremely high and associated with bilirubin encephalopathy, is an imprecise indicator of long-term neurodevelopmental outcome.[2] Additional studies are needed on the relationship between central nervous system damage and the duration of hyperbilirubinemia, the binding of bilirubin to albumin, and changes seen in the brainstem auditory evoked response. These studies could help to better identify

risk, clarify the effect of bilirubin on the central nervous system, and guide intervention.

Identification of Hemolysis

Because of their poor specificity and sensitivity, the standard laboratory tests for hemolysis (Table 1) are frequently unhelpful.[66,67] However, end-tidal carbon monoxide, corrected for ambient carbon monoxide ($ETCO_c$), levels can confirm the presence or absence of hemolysis, and measurement of $ETCO_c$ is the only clinical test that provides a direct measurement of the rate of heme catabolism and the rate of bilirubin production.[68,69] Thus, $ETCO_c$ may be helpful in determining the degree of surveillance needed and the timing of intervention. It is not yet known, however, how $ETCO_c$ measurements will affect management.

Nomograms and the Measurement of Serum and TcB

It would be useful to develop an age-specific (by hour) nomogram for TSB in populations of newborns that differ with regard to risk factors for hyperbilirubinemia. There is also an urgent need to improve the precision and accuracy of the measurement of TSB in the clinical laboratory.[70,71] Additional studies are also needed to develop and validate noninvasive (transcutaneous) measurements of serum bilirubin and to understand the factors that affect these measurements. These studies should also assess the cost-effectiveness and reproducibility of TcB measurements in clinical practice.[2]

Pharmacologic Therapy

There is now evidence that hyperbilirubinemia can be effectively prevented or treated with tin-mesoporphyrin,[72–75] a drug that inhibits the production of heme oxygenase. Tin-mesoporphyrin is not approved by the US Food and Drug Administration. If approved, tin-mesoporphyrin could find immediate application in preventing the need for exchange transfusion in infants who are not responding to phototherapy.[75]

Dissemination and Monitoring

Research should be directed toward methods for disseminating the information contained in this guideline to increase awareness on the part of physicians, residents, nurses, and parents concerning the issues of neonatal hyperbilirubinemia and strategies for its management. In addition, monitoring systems should be established to identify the impact of these guidelines on the incidence of acute bilirubin encephalopathy and kernicterus and the use of phototherapy and exchange transfusions.

CONCLUSIONS

Kernicterus is still occurring but should be largely preventable if health care personnel follow the recommendations listed in this guideline. These recommendations emphasize the importance of universal, systematic assessment for the risk of severe hyperbilirubinemia, close follow-up, and prompt intervention, when necessary.

Subcommittee on Hyperbilirubinemia
M. Jeffrey Maisels, MB, BCh, Chairperson
Richard D. Baltz, MD
Vinod K. Bhutani, MD
Thomas B. Newman, MD, MPH
Heather Palmer, MB, BCh
Warren Rosenfeld, MD
David K. Stevenson, MD
Howard B. Weinblatt, MD

Consultant
Charles J. Homer, MD, MPH, Chairperson
American Academy of Pediatrics Steering Committee on Quality Improvement and Management

Staff
Carla T. Herrerias, MPH

ACKNOWLEDGMENTS

M.J.M. received grant support from Natus Medical, Inc, for multinational study of ambient carbon monoxide; WellSpring Pharmaceutical Corporation for study of Stannsoporfin (tin-mesoporphyrin); and Minolta, Inc, for study of the Minolta/Hill-Rom Air-Shields transcutaneous jaundice meter model JM-103. V.K.B. received grant support from WellSpring Pharmaceutical Corporation for study of Stannsoporfin (tin-mesoporphyrin) and Natus Medical, Inc, for multinational study of ambient carbon monoxide and is a consultant (volunteer) to SpectrX (BiliChek transcutaneous bilirubinometer). D.K.S. is a consultant to and holds stock options through Natus Medical, Inc.

The American Academy of Pediatrics Subcommittee on Hyperbilirubinemia gratefully acknowledges the help of the following organizations, committees, and individuals who reviewed drafts of this guideline and provided valuable criticisms and commentary: American Academy of Pediatrics Committee on Nutrition; American Academy of Pediatrics Committee on Practice and Ambulatory Medicine; American Academy of Pediatrics Committee on Child Health Financing; American Academy of Pediatrics Committee on Medical Liability; American Academy of Pediatrics Committee on Fetus and Newborn; American Academy of Pediatrics Section on Perinatal Pediatrics; Centers for Disease Control and Prevention; Parents of Infants and Children With Kernicterus (PICK); Charles Ahlfors, MD; Daniel Batton, MD; Thomas Bojko, MD; Sarah Clune, MD; Sudhakar Ezhuthachan, MD; Lawrence Gartner, MD; Cathy Hammerman, MD; Thor Hansen, MD; Lois Johnson, MD; Michael Kaplan, MB, ChB; Tony McDonagh, PhD; Gerald Merenstein, MD; Mary O'Shea, MD; Max Perlman, MD; Ronald Poland, MD; Alex Robertson, MD; Firmino Rubaltelli, MD; Steven Shapiro, MD; Stanford Singer, MD; Ann Stark, MD; Gautham Suresh, MD; Margot VandeBor, MD; Hank Vreman, PhD; Philip Walson, MD; Jon Watchko, MD; Richard Wennberg, MD; and Chap-Yung Yeung, MD.

REFERENCES

1. American Academy of Pediatrics, Provisional Committee for Quality Improvement and Subcommittee on Hyperbilirubinemia. Practice parameter: management of hyperbilirubinemia in the healthy term newborn. *Pediatrics.* 1994;94:558–562
2. Ip S, Glicken S, Kulig J, Obrien R, Sege R, Lau J. *Management of Neonatal Hyperbilirubinemia.* Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2003. AHRQ Publication 03-E011
3. Ip S, Chung M, Kulig J. et al. An evidence-based review of important issues concerning neonatal hyperbilirubinemia. *Pediatrics.* 2004;113(6). Available at: www.pediatrics.org/cgi/content/full/113/6/e644
4. American Academy of Pediatrics, Steering Committee on Quality Improvement and Management. A taxonomy of recommendations. *Pediatrics.* 2004; In press
5. Johnson LH, Bhutani VK, Brown AK. System-based approach to management of neonatal jaundice and prevention of kernicterus. *J Pediatr.* 2002;140:396–403

6. Maisels MJ, Newman TB. Kernicterus in otherwise healthy, breast-fed term newborns. *Pediatrics.* 1995;96:730–733
7. MacDonald M. Hidden risks: early discharge and bilirubin toxicity due to glucose-6-phosphate dehydrogenase deficiency. *Pediatrics.* 1995;96: 734–738
8. Penn AA, Enzman DR, Hahn JS, Stevenson DK. Kernicterus in a full term infant. *Pediatrics.* 1994;93:1003–1006
9. Washington EC, Ector W, Abboud M, Ohning B, Holden K. Hemolytic jaundice due to G6PD deficiency causing kernicterus in a female newborn. *South Med J.* 1995;88:776–779
10. Ebbesen F. Recurrence of kernicterus in term and near-term infants in Denmark. *Acta Paediatr.* 2000;89:1213–1217
11. Institue of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001
12. American Academy of Pediatrics, American College of Obstetricians and Gynecologists. *Guidelines for Perinatal Care*. 5th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2002:220–224
13. Bertini G, Dani C, Trochin M, Rubaltelli F. Is breastfeeding really favoring early neonatal jaundice? *Pediatrics.* 2001;107(3). Available at: www.pediatrics.org/cgi/content/full/107/3/e41
14. Maisels MJ, Gifford K. Normal serum bilirubin levels in the newborn and the effect of breast-feeding. *Pediatrics.* 1986;78:837–843
15. Yamauchi Y, Yamanouchi I. Breast-feeding frequency during the first 24 hours after birth in full-term neonates. *Pediatrics.* 1990;86:171–175
16. De Carvalho M, Klaus MH, Merkatz RB. Frequency of breastfeeding and serum bilirubin concentration. *Am J Dis Child.* 1982;136:737–738
17. Varimo P, Similä S, Wendt L, Kolvisto M. Frequency of breast feeding and hyperbilirubinemia [letter]. *Clin Pediatr (Phila).* 1986;25:112
18. De Carvalho M, Holl M, Harvey D. Effects of water supplementation on physiological jaundice in breast-fed babies. *Arch Dis Child.* 1981;56: 568–569
19. Nicoll A, Ginsburg R, Tripp JH. Supplementary feeding and jaundice in newborns. *Acta Paediatr Scand.* 1982;71:759–761
20. Madlon-Kay DJ. Identifying ABO incompatibility in newborns: selective vs automatic testing. *J Fam Pract.* 1992;35:278–280
21. Kramer LI. Advancement of dermal icterus in the jaundiced newborn. *Am J Dis Child.* 1969;118:454–458
22. Moyer VA, Ahn C, Sneed S. Accuracy of clinical judgment in neonatal jaundice. *Arch Pediatr Adolesc Med.* 2000;154:391–394
23. Davidson LT, Merritt KK, Weech AA. Hyperbilirubinemia in the newborn. *Am J Dis Child.* 1941;61:958–980
24. Tayaba R, Gribetz D, Gribetz I, Holzman IR. Noninvasive estimation of serum bilirubin. *Pediatrics.* 1998;102(3). Available at: www.pediatrics.org/cgi/content/full/102/3/e28
25. Bhutani V, Gourley GR, Adler S, Kreamer B, Dalman C, Johnson LH. Noninvasive measurement of total serum bilirubin in a multiracial predischarge newborn population to assess the risk of severe hyperbilirubinemia. *Pediatrics.* 2000;106(2). Available at: www.pediatrics.org/cgi/content/full/106/2/e17
26. Yasuda S, Itoh S, Isobe K, et al. New transcutaneous jaundice device with two optical paths. *J Perinat Med.* 2003;31:81–88
27. Maisels MJ, Ostrea EJ Jr, Touch S, et al. Evaluation of a new transcutaneous bilirubinometer. *Pediatrics.* 2004;113:1638–1645
28. Ebbesen F, Rasmussen LM, Wimberley PD. A new transcutaneous bilirubinometer, bilicheck, used in the neonatal intensive care unit and the maternity ward. *Acta Paediatr.* 2002;91:203–211
29. Rubaltelli FF, Gourley GR, Loskamp N, et al. Transcutaneous bilirubin measurement: a multicenter evaluation of a new device. *Pediatrics.* 2001;107:1264–1271
30. Newman TB, Liljestrand P, Escobar GJ. Jaundice noted in the first 24 hours after birth in a managed care organization. *Arch Pediatr Adolesc Med.* 2002;156:1244–1250
31. Bhutani VK, Johnson L, Sivieri EM. Predictive ability of a predischarge hour-specific serum bilirubin for subsequent significant hyperbilirubinemia in healthy term and near-term newborns. *Pediatrics.* 1999;103: 6–14
32. Garcia FJ, Nager AL. Jaundice as an early diagnostic sign of urinary tract infection in infancy. *Pediatrics.* 2002;109:846–851
33. Kaplan M, Hammerman C. Severe neonatal hyperbilirubinemia: a potential complication of glucose-6-phosphate dehydrogenase deficiency. *Clin Perinatol.* 1998;25:575–590
34. Valaes T. Severe neonatal jaundice associated with glucose-6-phosphate dehydrogenase deficiency: pathogenesis and global epidemiology. *Acta Paediatr Suppl.* 1994;394:58–76
35. Alpay F, Sarici S, Tosuncuk HD, Serdar MA, Inanç N, Gökçay E. The value of first-day bilirubin measurement in predicting the development of significant hyperbilirubinemia in healthy term newborns. *Pediatrics.* 2000;106(2). Available at: www.pediatrics.org/cgi/content/full/106/2/e16
36. Carbonell X, Botet F, Figueras J, Riu-Godo A. Prediction of hyperbilirubinaemia in the healthy term newborn. *Acta Paediatr.* 2001;90:166–170
37. Kaplan M, Hammerman C, Feldman R, Brisk R. Predischarge bilirubin screening in glucose-6-phosphate dehydrogenase-deficient neonates. *Pediatrics.* 2000;105:533–537
38. Stevenson DK, Fanaroff AA, Maisels MJ, et al. Prediction of hyperbilirubinemia in near-term and term infants. *Pediatrics.* 2001;108:31–39
39. Newman TB, Xiong B, Gonzales VM, Escobar GJ. Prediction and prevention of extreme neonatal hyperbilirubinemia in a mature health maintenance organization. *Arch Pediatr Adolesc Med.* 2000;154:1140–1147
40. Maisels MJ, Kring EA. Length of stay, jaundice, and hospital readmission. *Pediatrics.* 1998;101:995–998
41. Gale R, Seidman DS, Dollberg S, Stevenson DK. Epidemiology of neonatal jaundice in the Jerusalem population. *J Pediatr Gastroenterol Nutr.* 1990;10:82–86
42. Berk MA, Mimouni F, Miodovnik M, Hertzberg V, Valuck J. Macrosomia in infants of insulin-dependent diabetic mothers. *Pediatrics.* 1989; 83:1029–1034
43. Peevy KJ, Landaw SA, Gross SJ. Hyperbilirubinemia in infants of diabetic mothers. *Pediatrics.* 1980;66:417–419
44. Soskolne El, Schumacher R, Fyock C, Young ML, Schork A. The effect of early discharge and other factors on readmission rates of newborns. *Arch Pediatr Adolesc Med.* 1996;150:373–379
45. Ebbesen F, Brodersen R. Risk of bilirubin acid precipitation in preterm infants with respiratory distress syndrome: considerations of blood/brain bilirubin transfer equilibrium. *Early Hum Dev.* 1982;6:341–355
46. Cashore WJ, Oh W, Brodersen R. Reserve albumin and bilirubin toxicity index in infant serum. *Acta Paediatr Scand.* 1983;72:415–419
47. Cashore WJ. Free bilirubin concentrations and bilirubin-binding affinity in term and preterm infants. *J Pediatr.* 1980;96:521–527
48. Bratlid D. How bilirubin gets into the brain. *Clin Perinatol.* 1990;17: 449–465
49. Wennberg RP. Cellular basis of bilirubin toxicity. *N Y State J Med.* 1991;91:493–496
50. Eggert P, Stick C, Schroder H. On the distribution of irradiation intensity in phototherapy. Measurements of effective irradiance in an incubator. *Eur J Pediatr.* 1984;142:58–61
51. Maisels MJ. Why use homeopathic doses of phototherapy? *Pediatrics.* 1996;98:283–287
52. Ahlfors CE. Criteria for exchange transfusion in jaundiced newborns. *Pediatrics.* 1994;93:488–494
53. American Association of Blood Banks Technical Manual Committee. Perinatal issues in transfusion practice. In: Brecher M, ed. *Technical Manual*. Bethesda, MD: American Association of Blood Banks; 2002: 497–515
54. Garland JS, Alex C, Deacon JS, Raab K. Treatment of infants with indirect hyperbilirubinemia. Readmission to birth hospital vs nonbirth hospital. *Arch Pediatr Adolesc Med.* 1994;148:1317–1321
55. Gottstein R, Cooke R. Systematic review of intravenous immunoglobulin in haemolytic disease of the newborn. *Arch Dis Child Fetal Neonatal Ed.* 2003;88:F6–F10
56. Sato K, Hara T, Kondo T, Iwao H, Honda S, Ueda K. High-dose intravenous gammaglobulin therapy for neonatal immune haemolytic jaundice due to blood group incompatibility. *Acta Paediatr Scand.* 1991; 80:163–166
57. Rubo J, Albrecht K, Lasch P, et al. High-dose intravenous immune globulin therapy for hyperbilirubinemia caused by Rh hemolytic disease. *J Pediatr.* 1992;121:93–97
58. Hammerman C, Kaplan M, Vreman HJ, Stevenson DK. Intravenous immune globulin in neonatal ABO isoimmunization: factors associated with clinical efficacy. *Biol Neonate.* 1996;70:69–74
59. Johnson L, Boggs TR. Bilirubin-dependent brain damage: incidence and indications for treatment. In: Odell GB, Schaffer R, Simopoulos AP, eds. *Phototherapy in the Newborn: An Overview*. Washington, DC: National Academy of Sciences; 1974:122–149
60. Ozmert E, Erdem G, Topcu M. Long-term follow-up of indirect hyperbilirubinemia in full-term Turkish infants. *Acta Paediatr.* 1996;85: 1440–1444
61. Volpe JJ. *Neurology of the Newborn*. 4th ed. Philadelphia, PA: W. B. Saunders; 2001
62. Harris M, Bernbaum J, Polin J, Zimmerman R, Polin RA. Developmental follow-up of breastfed term and near-term infants with marked hyperbilirubinemia. *Pediatrics.* 2001;107:1075–1080
63. Osborn LM, Bolus R. Breast feeding and jaundice in the first week of life. *J Fam Pract.* 1985;20:475–480

64. Martinez JC, Maisels MJ, Otheguy L, et al. Hyperbilirubinemia in the breast-fed newborn: a controlled trial of four interventions. *Pediatrics.* 1993;91:470–473
65. Amato M, Howald H, von Muralt G. Interruption of breast-feeding versus phototherapy as treatment of hyperbilirubinemia in full-term infants. *Helv Paediatr Acta.* 1985;40:127–131
66. Maisels MJ, Gifford K, Antle CE, Leib GR. Jaundice in the healthy newborn infant: a new approach to an old problem. *Pediatrics.* 1988;81: 505–511
67. Newman TB, Easterling MJ. Yield of reticulocyte counts and blood smears in term infants. *Clin Pediatr (Phila).* 1994;33:71–76
68. Herschel M, Karrison T, Wen M, Caldarelli L, Baron B. Evaluation of the direct antiglobulin (Coombs') test for identifying newborns at risk for hemolysis as determined by end-tidal carbon monoxide concentration (ETCOc); and comparison of the Coombs' test with ETCOc for detecting significant jaundice. *J Perinatol.* 2002;22:341–347
69. Stevenson DK, Vreman HJ. Carbon monoxide and bilirubin production in neonates. *Pediatrics.* 1997;100:252–254
70. Vreman HJ, Verter J, Oh W, et al. Interlaboratory variability of bilirubin measurements. *Clin Chem.* 1996;42:869–873
71. Lo S, Doumas BT, Ashwood E. Performance of bilirubin determinations in US laboratories—revisited. *Clin Chem.* 2004;50:190–194
72. Kappas A, Drummond GS, Henschke C, Valaes T. Direct comparison of Sn-mesoporphyrin, an inhibitor of bilirubin production, and phototherapy in controlling hyperbilirubinemia in term and near-term newborns. *Pediatrics.* 1995;95:468–474
73. Martinez JC, Garcia HO, Otheguy L, Drummond GS, Kappas A. Control of severe hyperbilirubinemia in full-term newborns with the inhibitor of bilirubin production Sn-mesoporphyrin. *Pediatrics.* 1999;103:1–5
74. Suresh G, Martin CL, Soll R. Metalloporphyrins for treatment of unconjugated hyperbilirubinemia in neonates. *Cochrane Database Syst Rev.* 2003;2:CD004207
75. Kappas A, Drummond GS, Munson DP, Marshall JR. Sn-mesoporphyrin interdiction of severe hyperbilirubinemia in Jehovah's Witness newborns as an alternative to exchange transfusion. *Pediatrics.* 2001;108: 1374–1377

APPENDIX 1: Additional Notes

Definitions of Quality of Evidence and Balance of Benefits and Harms

The Steering Committee on Quality Improvement and Management categorizes evidence quality in 4 levels:

1. Well-designed, randomized, controlled trials or diagnostic studies on relevant populations
2. Randomized, controlled trials or diagnostic studies with minor limitations; overwhelming, consistent evidence from observational studies
3. Observational studies (case-control and cohort design)
4. Expert opinion, case reports, reasoning from first principles

The AAP defines evidence-based recommendations as follows:[1]

- Strong recommendation: the committee believes that the benefits of the recommended approach clearly exceed the harms of that approach and that the quality of the supporting evidence is either excellent or impossible to obtain. Clinicians should follow these recommendations unless a clear and compelling rationale for an alternative approach is present.
- Recommendation: the committee believes that the benefits exceed the harms, but the quality of evidence on which this recommendation is based is not as strong. Clinicians should also generally follow these recommendations but should be alert to new information and sensitive to patient preferences. In this guideline, the term "should" implies a recommendation by the committee.
- Option: either the quality of the evidence that exists is suspect or well-performed studies have shown little clear advantage to one approach over another. Patient preference should have a substantial role in influencing clinical decision-making when a policy is described as an option.
- No recommendation: there is a lack of pertinent evidence and the anticipated balance of benefits and harms is unclear.

Anticipated Balance Between Benefits and Harms

The presence of clear benefits or harms supports stronger statements for or against a course of action. In some cases, however, recommendations are made when analysis of the balance of benefits and harms provides an exceptional dysequilibrium and it would be unethical or impossible to perform clinical trials to "prove" the point. In these cases the balance of benefit and harm is termed "exceptional."

Clinical Manifestations of Acute Bilirubin Encephalopathy and Kernicterus

Acute Bilirubin Encephalopathy

In the early phase of acute bilirubin encephalopathy, severely jaundiced infants become lethargic and hypotonic and suck poorly.[2,3] The intermediate phase is characterized by moderate stupor, irritability, and hypertonia. The infant may develop a fever and high-pitched cry, which may alternate with drowsiness and hypotonia. The hypertonia is manifested by backward arching of the neck (retrocollis) and trunk (opisthotonos). There is anecdotal evidence that an emergent exchange transfusion at this stage, in some cases, might reverse the central nervous system changes.[4] The advanced phase, in which central nervous system damage is probably irreversible, is characterized by pronounced retrocollis-opisthotonos, shrill cry, no feeding, apnea, fever, deep stupor to coma, sometimes seizures, and death.[2,3,5]

Kernicterus

In the chronic form of bilirubin encephalopathy, surviving infants may develop a severe form of athetoid cerebral palsy, auditory dysfunction, dental-enamel dysplasia, paralysis of upward gaze, and, less often, intellectual and other handicaps. Most infants who develop kernicterus have manifested some or all of the signs listed above in the acute phase of bilirubin encephalopathy. However, occasionally there are infants who have developed very high bilirubin levels and, subsequently, the signs of kernicterus but have exhibited few, if any, antecedent clinical signs of acute bilirubin encephalopathy.[3,5,6]

Clinical Evaluation of Jaundice and TcB Measurements

Jaundice is usually seen in the face first and progresses caudally to the trunk and extremities,[7] but because visual estimation of bilirubin levels from the degree of jaundice can lead to errors,[8–10] a low threshold should be used for measuring the TSB.

Devices that provide a noninvasive TcB measurement have proven very useful as screening tools,[11] and newer instruments give measurements that provide a valid estimate of the TSB level.[12–17] Studies using the new TcB-measurement instruments are limited, but the data published thus far suggest that in most newborn populations, these instruments generally provide measurements within 2 to 3 mg/dL (34–51 μmol/L) of the TSB and can replace a measurement of serum bilirubin in many circumstances, particularly for TSB levels less than 15 mg/dL (257 μmol/L).[12–17] Because phototherapy "bleaches" the skin, both visual assessment of jaundice and TcB measurements in infants undergoing phototherapy are not reliable. In addition, the ability of transcutaneous instruments to provide accurate measurements in different racial groups requires additional study.[18,19] The limitations of the accuracy and reproducibility of TSB measurements in the clinical laboratory[20–22] must also be recognized and are discussed in the technical report.[23]

Capillary Versus Venous Serum Bilirubin Measurement

Almost all published data regarding the relationship of TSB levels to kernicterus or developmental outcome are based on capillary blood TSB levels. Data regarding the differences between capillary and venous TSB levels are conflicting.[24,25] In 1 study the capillary TSB levels were higher, but in another they were lower than venous TSB levels.[24,25] Thus, obtaining a venous sample to "confirm" an elevated capillary TSB level is not recommended, because it will delay the initiation of treatment.

Direct-Reacting and Conjugated Bilirubin

Although commonly used interchangeably, direct-reacting bilirubin is not the same as conjugated bilirubin. Direct-reacting bilirubin is the bilirubin that reacts directly (without the addition of an accelerating agent) with diazotized sulfanilic acid. Conjugated bilirubin is bilirubin made water soluble by binding with glucuronic acid in the liver. Depending on the technique used, the clinical laboratory will report total and direct-reacting or unconjugated and conjugated bilirubin levels. In this guideline and for clinical purposes, the terms may be used interchangeably.

Abnormal Direct and Conjugated Bilirubin Levels

Laboratory measurement of direct bilirubin is not precise,[26] and values between laboratories can vary widely. If the TSB is at or below 5 mg/dL (85 μmol/L), a direct or conjugated bilirubin of more than 1.0 mg/dL (17.1 μmol/L) is generally considered abnormal. For TSB values higher than 5 mg/dL (85 μmol/L), a direct bilirubin of more than 20% of the TSB is considered abnormal. If the hospital laboratory measures conjugated bilirubin using the Vitros (formerly Ektachem) system (Ortho-Clinical Diagnostics, Raritan, NJ), any value higher than 1 mg/dL is considered abnormal.

Assessment of Adequacy of Intake in Breastfeeding Infants

The data from a number of studies[27–34] indicate that unsupplemented, breastfed infants experience their maximum weight loss by day 3 and, on average, lose 6.1% ± 2.5% (SD) of their birth weight. Thus, ~5% to 10% of fully breastfed infants lose 10% or more of their birth weight by day 3, suggesting that adequacy of intake should be evaluated and the infant monitored if weight loss is more than 10%.[35] Evidence of adequate intake in breastfed infants also includes 4 to 6 thoroughly wet diapers in 24 hours and the passage of 3 to 4 stools per day by the fourth day. By the third to fourth day, the stools in adequately breastfed infants should have changed from meconium to a mustard yellow, mushy stool.[36] The above assessment will also help to identify breastfed infants who are at risk for dehydration because of inadequate intake.

Nomogram for Designation of Risk

Note that this nomogram (Fig 2) does not describe the natural history of neonatal hyperbilirubinemia, particularly after 48 to 72 hours, for which, because of sampling bias, the lower zones are spuriously elevated.[37] This bias, however, will have much less effect on the high-risk zone (95th percentile in the study).[38]

G6PD Dehydrogenase Deficiency

It is important to look for G6PD deficiency in infants with significant hyperbilirubinemia, because some may develop a sudden increase in the TSB. In addition, G6PD-deficient infants require intervention at lower TSB levels (Figs 3 and 4). It should be noted also that in the presence of hemolysis, G6PD levels can be elevated, which may obscure the diagnosis in the newborn period so that a normal level in a hemolyzing neonate does not rule out G6PD deficiency.[39] If G6PD deficiency is strongly suspected, a repeat level should be measured when the infant is 3 months old. It is also recognized that immediate laboratory determination of G6PD is generally not available in most US hospitals, and thus translating the above information into clinical practice is cur-

TABLE 4. Risk Zone as a Predictor of Hyperbilirubinemia[39]

TSB Before Discharge	Newborns (Total = 2840), *n* (%)	Newborns Who Subsequently Developed a TSB Level >95th Percentile, *n* (%)
High-risk zone (>95th percentile)	172 (6.0)	68 (39.5)
High intermediate-risk zone	356 (12.5)	46 (12.9)
Low intermediate-risk zone	556 (19.6)	12 (2.26)
Low-risk zone	1756 (61.8)	0

rently difficult. Nevertheless, practitioners are reminded to consider the diagnosis of G6PD deficiency in infants with severe hyperbilirubinemia, particularly if they belong to the population groups in which this condition is prevalent. This is important in the African American population, because these infants, as a group, have much lower TSB levels than white or Asian infants.[40,41] Thus, severe hyperbilirubinemia in an African American infant should always raise the possibility of G6PD deficiency.

Basis for the Recommendations 7.1.1 Through 7.1.6 and Provided in Figs 3 and 4

Ideally, recommendations for when to implement phototherapy and exchange transfusions should be based on estimates of when the benefits of these interventions exceed their risks and cost. The evidence for these estimates should come from randomized trials or systematic observational studies. Unfortunately, there is little such evidence on which to base these recommendations. As a result, treatment guidelines must necessarily rely on more uncertain estimates and extrapolations. For a detailed discussion of this question, please see "An Evidence-Based Review of Important Issues Concerning Neonatal Hyperbilirubinemia."[23]

The recommendations for phototherapy and exchange transfusion are based on the following principles:

- The main demonstrated value of phototherapy is that it reduces the risk that TSB levels will reach a level at which exchange transfusion is recommended.[42–44] Approximately 5 to 10 infants with TSB levels between 15 and 20 mg/dL (257–342 μmol/L) will receive phototherapy to prevent the TSB in 1 infant from reaching 20 mg/dL (the number needed to treat).[12] Thus, 8 to 9 of every 10 infants with these TSB levels will not reach 20 mg/dL (342 μmol/L) even if they are not treated. Phototherapy has proven to be a generally safe procedure, although rare complications can occur (see Appendix 2).
- Recommended TSB levels for exchange transfusion (Fig 4) are based largely on the goal of keeping TSB levels below those at which kernicterus has been reported.[12,45–48] In almost all cases, exchange transfusion is recommended only after phototherapy has failed to keep the TSB level below the exchange transfusion level (Fig 4).
- The recommendations to use phototherapy and exchange transfusion at lower TSB levels for infants of lower gestation and those who are sick are based on limited observations suggesting that sick infants (particularly those with the risk factors listed in Figs 3 and 4)[49–51] and those of lower gestation[51–54] are at greater risk for developing kernicterus at lower bilirubin levels than are well infants of more than 38 6/7 weeks' gestation. Nevertheless, other studies have not confirmed all of these associations.[52,55,56] There is no doubt, however, that infants at 35 to 37 6/7 weeks' gestation are at a much greater risk of developing very high TSB levels.[57,58] Intervention for these infants is based on this risk as well as extrapolations from more premature, lower birth-weight infants who do have a higher risk of bilirubin toxicity.[52,53]
- For all newborns, treatment is recommended at lower TSB levels at younger ages because one of the primary goals of treatment is to prevent additional increases in the TSB level.

Subtle Neurologic Abnormalities Associated With Hyperbilirubinemia

There are several studies demonstrating measurable transient changes in brainstem-evoked potentials, behavioral patterns, and the infant's cry[59–63] associated with TSB levels of 15 to 25 mg/dL (257–428 μmol/L). In these studies, the abnormalities identified were transient and disappeared when the serum bilirubin levels returned to normal with or without treatment.[59,60,62,63]

A few cohort studies have found an association between hyperbilirubinemia and long-term adverse neurodevelopmental effects that are more subtle than kernicterus.[64–67] Current studies, however, suggest that although phototherapy lowers the TSB levels, it has no effect on these long-term neurodevelopmental outcomes.[68–70]

Risks of Exchange Transfusion

Because exchange transfusions are now rarely performed, the risks of morbidity and mortality associated with the procedure are difficult to quantify. In addition, the complication rates listed below may not be generalizable to the current era if, like most procedures, frequency of performance is an important determinant of risk. Death associated with exchange transfusion has been reported in approximately 3 in 1000 procedures,[71,72] although in otherwise well infants of 35 or more weeks' gestation, the risk is probably much lower.[71–73] Significant morbidity (apnea, bradycardia, cyanosis, vasospasm, thrombosis, necrotizing enterocolitis) occurs in as many as 5% of exchange transfusions,[71] and the risks associated with the use of blood products must always be considered.[74] Hypoxic-ischemic encephalopathy and acquired immunodeficiency syndrome have occurred in otherwise healthy infants receiving exchange transfusions.[73,75]

Serum Albumin Levels and the B/A Ratio

The legends to Figs 3 and 4 and recommendations 7.1.5 and 7.1.6 contain references to the serum albumin level and the B/A ratio as factors that can be considered in the decision to initiate phototherapy (Fig 3) or perform an exchange transfusion (Fig 4). Bilirubin is transported in the plasma tightly bound to albumin, and the portion that is unbound or loosely bound can more readily leave the intravascular space and cross the intact blood-brain barrier.[76] Elevations of unbound bilirubin (UB) have been associated with kernicterus in sick preterm newborns.[77,78] In addition, elevated UB concentrations are more closely associated than TSB levels with transient abnormalities in the audiometric brainstem response in term[79] and preterm[80] infants. Long-term

studies relating B/A binding in infants to developmental outcome are limited and conflicting.[69,81,82] In addition, clinical laboratory measurement of UB is not currently available in the United States.

The ratio of bilirubin (mg/dL) to albumin (g/dL) does correlate with measured UB in newborns[83] and can be used as an approximate surrogate for the measurement of UB. It must be recognized, however, that both albumin levels and the ability of albumin to bind bilirubin vary significantly between newborns.[83,84] Albumin binding of bilirubin is impaired in sick infants,[84–86] and some studies show an increase in binding with increasing gestational[86,87] and postnatal[87,88] age, but others have not found a significant effect of gestational age on binding.[89] Furthermore, the risk of bilirubin encephalopathy is unlikely to be a simple function of the TSB level or the concentration of UB but is more likely a combination of both (ie, the total amount of bilirubin available [the miscible pool of bilirubin] as well as the tendency of bilirubin to enter the tissues [the UB concentration]).[83] An additional factor is the possible susceptibility of the cells of the central nervous system to damage by bilirubin.[90] It is therefore a clinical option to use the B/A ratio together with, but not in lieu of, the TSB level as an additional factor in determining the need for exchange transfusion[83] (Fig 4).

REFERENCES

1. American Academy of Pediatrics, Steering Committee on Quality Improvement and Management. Classification of recommendations for clinical practice guidelines. *Pediatrics*. 2004; In press
2. Johnson LH, Bhutani VK, Brown AK. System-based approach to management of neonatal jaundice and prevention of kernicterus. *J Pediatr*. 2002;140:396–403
3. Volpe JJ. *Neurology of the Newborn*. 4th ed. Philadelphia, PA: W. B. Saunders; 2001
4. Harris M, Bernbaum J, Polin J, Zimmerman R, Polin RA. Developmental follow-up of breastfed term and near-term infants with marked hyperbilirubinemia. *Pediatrics*. 2001;107:1075–1080
5. Van Praagh R. Diagnosis of kernicterus in the neonatal period. *Pediatrics*. 1961;28:870–876
6. Jones MH, Sands R, Hyman CB, Sturgeon P, Koch FP. Longitudinal study of incidence of central nervous system damage following erythroblastosis fetalis. *Pediatrics*. 1954;14:346–350
7. Kramer LI. Advancement of dermal icterus in the jaundiced newborn. *Am J Dis Child*. 1969;118:454–458
8. Moyer VA, Ahn C, Sneed S. Accuracy of clinical judgment in neonatal jaundice. *Arch Pediatr Adolesc Med*. 2000;154:391–394
9. Davidson LT, Merritt KK, Weech AA. Hyperbilirubinemia in the newborn. *Am J Dis Child*. 1941;61:958–980
10. Tayaba R, Gribetz D, Gribetz I, Holzman IR. Noninvasive estimation of serum bilirubin. *Pediatrics*. 1998;102(3). Available at: www.pediatrics.org/cgi/content/full/102/3/e28
11. Maisels MJ, Kring E. Transcutaneous bilirubinometry decreases the need for serum bilirubin measurements and saves money. *Pediatrics*. 1997;99:599–601
12. Ip S, Glicken S, Kulig J, Obrien R, Sege R, Lau J. *Management of Neonatal Hyperbilirubinemia*. Rockville, MD: US Department of Health and Human Services, Agency for Healthcare Research and Quality; 2003. AHRQ Publication 03-E011
13. Bhutani V, Gourley GR, Adler S, Kreamer B, Dalman C, Johnson LH. Noninvasive measurement of total serum bilirubin in a multiracial predischarge newborn population to assess the risk of severe hyperbilirubinemia. *Pediatrics*. 2000;106(2). Available at: www.pediatrics.org/cgi/content/full/106/2/e17
14. Yasuda S, Itoh S, Isobe K, et al. New transcutaneous jaundice device with two optical paths. *J Perinat Med*. 2003;31:81–88
15. Maisels MJ, Ostrea EJ Jr, Touch S, et al. Evaluation of a new transcutaneous bilirubinometer. *Pediatrics*. 2004;113:1638–1645
16. Ebbesen F, Rasmussen LM, Wimberley PD. A new transcutaneous bilirubinometer, bilicheck, used in the neonatal intensive care unit and the maternity ward. *Acta Paediatr*. 2002;91:203–211
17. Rubaltelli FF, Gourley GR, Loskamp N, et al. Transcutaneous bilirubin measurement: a multicenter evaluation of a new device. *Pediatrics*. 2001;107:1264–1271
18. Engle WD, Jackson GL, Sendelbach D, Manning D, Frawley W. Assessment of a transcutaneous device in the evaluation of neonatal hyperbilirubinemia in a primarily Hispanic population. *Pediatrics*. 2002;110:61–67
19. Schumacher R. Transcutaneous bilirubinometry and diagnostic tests: "the right job for the tool." *Pediatrics*. 2002;110:407–408
20. Vreman HJ, Verter J, Oh W, et al. Interlaboratory variability of bilirubin measurements. *Clin Chem*. 1996;42:869–873
21. Doumas BT, Eckfeldt JH. Errors in measurement of total bilirubin: a perennial problem. *Clin Chem*. 1996;42:845–848
22. Lo S, Doumas BT, Ashwood E. Performance of bilirubin determinations in US laboratories—revisited. *Clin Chem*. 2004;50:190–194
23. Ip S, Chung M, Kulig J. et al. An evidence-based review of important issues concerning neonatal hyperbilirubinemia. *Pediatrics*. 2004;113(6). Available at: www.pediatrics.org/cgi/content/full/113/6/e644
24. Leslie GI, Philips JB, Cassady G. Capillary and venous bilirubin values: are they really different? *Am J Dis Child*. 1987;141:1199–1200
25. Eidelman AI, Schimmel MS, Algur N, Eylath U. Capillary and venous bilirubin values: they are different—and how [letter]! *Am J Dis Child*. 1989;143:642
26. Watkinson LR, St John A, Penberthy LA. Investigation into paediatric bilirubin analyses in Australia and New Zealand. *J Clin Pathol*. 1982;35:52–58
27. Bertini G, Dani C, Trochin M, Rubaltelli F. Is breastfeeding really favoring early neonatal jaundice? *Pediatrics*. 2001;107(3). Available at: www.pediatrics.org/cgi/content/full/107/3/e41
28. De Carvalho M, Klaus MH, Merkatz RB. Frequency of breastfeeding and serum bilirubin concentration. *Am J Dis Child*. 1982;136:737–738
29. De Carvalho M, Holl M, Harvey D. Effects of water supplementation on physiological jaundice in breast-fed babies. *Arch Dis Child*. 1981;56:568–569
30. Nicoll A, Ginsburg R, Tripp JH. Supplementary feeding and jaundice in newborns. *Acta Paediatr Scand*. 1982;71:759–761
31. Butler DA, MacMillan JP. Relationship of breast feeding and weight loss to jaundice in the newborn period: review of the literature and results of a study. *Cleve Clin Q*. 1983;50:263–268
32. De Carvalho M, Robertson S, Klaus M. Fecal bilirubin excretion and serum bilirubin concentration in breast-fed and bottle-fed infants. *J Pediatr*. 1985;107:786–790
33. Gourley GR, Kreamer B, Arend R. The effect of diet on feces and jaundice during the first three weeks of life. *Gastroenterology*. 1992;103:660–667
34. Maisels MJ, Gifford K. Breast-feeding, weight loss, and jaundice. *J Pediatr*. 1983;102:117–118
35. Laing IA, Wong CM. Hypernatraemia in the first few days: is the incidence rising? *Arch Dis Child Fetal Neonatal Ed*. 2002;87:F158–F162
36. Lawrence RA. Management of the mother-infant nursing couple. In: *A Breastfeeding Guide for the Medical Profession*. 4th ed. St Louis, MO: Mosby-Year Book, Inc; 1994:215-277
37. Maisels MJ, Newman TB. Predicting hyperbilirubinemia in newborns: the importance of timing. *Pediatrics*. 1999;103:493–495
38. Bhutani VK, Johnson L, Sivieri EM. Predictive ability of a predischarge hour-specific serum bilirubin for subsequent significant hyperbilirubinemia in healthy term and near-term newborns. *Pediatrics*. 1999;103:6–14
39. Beutler E. Glucose-6-phosphate dehydrogenase deficiency. *Blood*. 1994;84:3613–3636
40. Linn S, Schoenbaum SC, Monson RR, Rosner B, Stubblefield PG, Ryan KJ. Epidemiology of neonatal hyperbilirubinemia. *Pediatrics*. 1985;75:770–774
41. Newman TB, Easterling MJ, Goldman ES, Stevenson DK. Laboratory evaluation of jaundiced newborns: frequency, cost and yield. *Am J Dis Child*. 1990;144:364–368
42. Martinez JC, Maisels MJ, Otheguy L, et al. Hyperbilirubinemia in the breast-fed newborn: a controlled trial of four interventions. *Pediatrics*. 1993;91:470–473
43. Maisels MJ. Phototherapy—traditional and nontraditional. *J Perinatol*. 2001;21(suppl 1):S93–S97
44. Brown AK, Kim MH, Wu PY, Bryla DA. Efficacy of phototherapy in prevention and management of neonatal hyperbilirubinemia. *Pediatrics*. 1985;75:393–400

45. Armitage P, Mollison PL. Further analysis of controlled trials of treatment of hemolytic disease of the newborn. *J Obstet Gynaecol Br Emp*. 1953;60:602–605
46. Mollison PL, Walker W. Controlled trials of the treatment of haemolytic disease of the newborn. *Lancet*. 1952;1:429–433
47. Hsia DYY, Allen FH, Gellis SS, Diamond LK. Erythroblastosis fetalis. VIII. Studies of serum bilirubin in relation to kernicterus. *N Engl J Med*. 1952;247:668–671
48. Newman TB, Maisels MJ. Does hyperbilirubinemia damage the brain of healthy full-term infants? *Clin Perinatol*. 1990;17:331–358
49. Ozmert E, Erdem G, Topcu M. Long-term follow-up of indirect hyperbilirubinemia in full-term Turkish infants. *Acta Paediatr*. 1996;85: 1440–1444
50. Perlman JM, Rogers B, Burns D. Kernicterus findings at autopsy in 2 sick near-term infants. *Pediatrics*. 1997;99:612–615
51. Gartner LM, Snyder RN, Chabon RS, Bernstein J. Kernicterus: high incidence in premature infants with low serum bilirubin concentration. *Pediatrics*. 1970;45:906–917
52. Watchko JF, Oski FA. Kernicterus in preterm newborns: past, present, and future. *Pediatrics*. 1992;90:707–715
53. Watchko J, Claassen D. Kernicterus in premature infants: current prevalence and relationship to NICHD Phototherapy Study exchange criteria. *Pediatrics*. 1994;93(6 Pt 1):996–999
54. Stern L, Denton RL. Kernicterus in small, premature infants. *Pediatrics*. 1965;35:486–485
55. Turkel SB, Guttenberg ME, Moynes DR, Hodgman JE. Lack of identifiable risk factors for kernicterus. *Pediatrics*. 1980;66:502–506
56. Kim MH, Yoon JJ, Sher J, Brown AK. Lack of predictive indices in kernicterus. A comparison of clinical and pathologic factors in infants with or without kernicterus. *Pediatrics*. 1980;66:852–858
57. Newman TB, Xiong B, Gonzales VM, Escobar GJ. Prediction and prevention of extreme neonatal hyperbilirubinemia in a mature health maintenance organization. *Arch Pediatr Adolesc Med*. 2000;154:1140–1147
58. Newman TB, Escobar GJ, Gonzales VM, Armstrong MA, Gardner MN, Folck BF. Frequency of neonatal bilirubin testing and hyperbilirubinemia in a large health maintenance organization. *Pediatrics*. 1999;104: 1198–1203
59. Vohr BR. New approaches to assessing the risks of hyperbilirubinemia. *Clin Perinatol*. 1990;17:293–306
60. Perlman M, Fainmesser P, Sohmer H, Tamari H, Wax Y, Pevsmer B. Auditory nerve-brainstem evoked responses in hyperbilirubinemic neonates. *Pediatrics*. 1983;72:658–664
61. Nakamura H, Takada S, Shimabuku R, Matsuo M, Matsuo T, Negishi H. Auditory and brainstem responses in newborn infants with hyperbilirubinemia. *Pediatrics*. 1985;75:703–708
62. Nwaesei CG, Van Aerde J, Boyden M, Perlman M. Changes in auditory brainstem responses in hyperbilirubinemic infants before and after exchange transfusion. *Pediatrics*. 1984;74:800–803
63. Wennberg RP, Ahlfors CE, Bickers R, McMurtry CA, Shetter JL. Abnormal auditory brainstem response in a newborn infant with hyperbilirubinemia: improvement with exchange transfusion. *J Pediatr*. 1982;100:624–626
64. Soorani-Lunsing I, Woltil H, Hadders-Algra M. Are moderate degrees of hyperbilirubinemia in healthy term neonates really safe for the brain? *Pediatr Res*. 2001;50:701–705
65. Grimmer I, Berger-Jones K, Buhrer C, Brandl U, Obladen M. Late neurological sequelae of non-hemolytic hyperbilirubinemia of healthy term neonates. *Acta Paediatr*. 1999;88:661–663
66. Seidman DS, Paz I, Stevenson DK, Laor A, Danon YL, Gale R. Neonatal hyperbilirubinemia and physical and cognitive performance at 17 years of age. *Pediatrics*. 1991;88:828–833
67. Newman TB, Klebanoff MA. Neonatal hyperbilirubinemia and long-term outcome: another look at the collaborative perinatal project. *Pediatrics*. 1993;92:651–657
68. Scheidt PC, Bryla DA, Nelson KB, Hirtz DG, Hoffman HJ. Phototherapy for neonatal hyperbilirubinemia: six-year follow-up of the National Institute of Child Health and Human Development clinical trial. *Pediatrics*. 1990;85:455–463
69. Scheidt PC, Graubard BI, Nelson KB, et al. Intelligence at six years in relation to neonatal bilirubin levels: follow-up of the National Institute of Child Health and Human Development Clinical Trial of Phototherapy. *Pediatrics*. 1991;87:797–805
70. Seidman DS, Paz I, Stevenson DK, Laor A, Danon YL, Gale R. Effect of phototherapy for neonatal jaundice on cognitive performance. *J Perinatol*. 1994;14:23–28
71. Keenan WJ, Novak KK, Sutherland JM, Bryla DA, Fetterly KL. Morbidity and mortality associated with exchange transfusion. *Pediatrics*. 1985; 75:417–421
72. Hovi L, Siimes MA. Exchange transfusion with fresh heparinized blood is a safe procedure: Experiences from 1069 newborns. *Acta Paediatr Scand*. 1985;74:360–365
73. Jackson JC. Adverse events associated with exchange transfusion in healthy and ill newborns. *Pediatrics*. 1997;99(5):e7. Available at: www.pediatrics.org/cgi/content/full/99/5/e7
74. Schreiber GB, Busch MP, Kleinman SH, Korelitz JJ. The risk of transfusion-transmitted viral infections. *N Engl J Med*. 1996;334:1685–1690
75. Maisels MJ, Newman TB. Kernicterus in otherwise healthy, breast-fed term newborns. *Pediatrics*. 1995;96:730–733
76. Bratlid D. How bilirubin gets into the brain. *Clin Perinatol*. 1990;17: 449–465
77. Cashore WJ, Oh W. Unbound bilirubin and kernicterus in low-birthweight infants. *Pediatrics*. 1982;69:481–485
78. Nakamura H, Yonetani M, Uetani Y, Funato M, Lee Y. Determination of serum unbound bilirubin for prediction of kernicterus in low birthweight infants. *Acta Paediatr Jpn*. 1992;34:642–647
79. Funato M, Tamai H, Shimada S, Nakamura H. Vigintiphobia, unbound bilirubin, and auditory brainstem responses. *Pediatrics*. 1994;93:50–53
80. Amin SB, Ahlfors CE, Orlando MS, Dalzell LE, Merle KS, Guillet R. Bilirubin and serial auditory brainstem responses in premature infants. *Pediatrics*. 2001;107:664–670
81. Johnson L, Boggs TR. Bilirubin-dependent brain damage: incidence and indications for treatment. In: Odell GB, Schaffer R, Simopoulos AP, eds. *Phototherapy in the Newborn: An Overview*. Washington, DC: National Academy of Sciences; 1974:122–149
82. Odell GB, Storey GNB, Rosenberg LA. Studies in kernicterus. 3. The saturation of serum proteins with bilirubin during neonatal life and its relationship to brain damage at five years. *J Pediatr*. 1970;76:12–21
83. Ahlfors CE. Criteria for exchange transfusion in jaundiced newborns. *Pediatrics*. 1994;93:488–494
84. Cashore WJ. Free bilirubin concentrations and bilirubin-binding affinity in term and preterm infants. *J Pediatr*. 1980;96:521–527
85. Ebbesen F, Brodersen R. Risk of bilirubin acid precipitation in preterm infants with respiratory distress syndrome: considerations of blood/brain bilirubin transfer equilibrium. *Early Hum Dev*. 1982;6:341–355
86. Cashore WJ, Oh W, Brodersen R. Reserve albumin and bilirubin toxicity index in infant serum. *Acta Paediatr Scand*. 1983;72:415–419
87. Ebbesen F, Nyboe J. Postnatal changes in the ability of plasma albumin to bind bilirubin. *Acta Paediatr Scand*. 1983;72:665–670
88. Esbjorner E. Albumin binding properties in relation to bilirubin and albumin concentrations during the first week of life. *Acta Paediatr Scand*. 1991;80:400–405
89. Robertson A, Sharp C, Karp W. The relationship of gestational age to reserve albumin concentration for binding of bilirubin. *J Perinatol*. 1988; 8:17–18
90. Wennberg RP. Cellular basis of bilirubin toxicity. *N Y State J Med*. 1991;91:493–496

APPENDIX 2: Phototherapy

There is no standardized method for delivering phototherapy. Phototherapy units vary widely, as do the types of lamps used in the units. The efficacy of phototherapy depends on the dose of phototherapy administered as well as a number of clinical factors (Table 5).[1]

Measuring the Dose of Phototherapy

Table 5 shows the radiometric quantities used in measuring the phototherapy dose. The quantity most commonly reported in the literature is the spectral irradiance. In the nursery, spectral irradiance can be measured by using commercially available radiometers. These instruments take a single measurement across a band of wavelengths, typically 425 to 475 or 400 to 480 nm. Unfortunately, there is no standardized method for reporting phototherapy dosages in the clinical literature, so it is difficult to compare published studies on the efficacy of phototherapy and manufacturers' data for the irradiance produced by different systems.[2] Measurements of irradiance from the same system, using different radiometers,

TABLE 5. Factors That Affect the Dose and Efficacy of Phototherapy

Factor	Mechanism/Clinical Relevance	Implementation and Rationale	Clinical Application
Spectrum of light emitted	Blue-green spectrum is most effective. At these wavelengths, light penetrates skin well and is absorbed maximally by bilirubin.	Special blue fluorescent tubes or other light sources that have most output in the blue-green spectrum and are most effective in lowering TSB.	Use special blue tubes or LED light source with output in blue-green spectrum for intensive PT.
Spectral irradiance (irradiance in certain wavelength band) delivered to surface of infant	↑ irradiance → ↑ rate of decline in TSB	Irradiance is measured with a radiometer as $\mu W/cm^2$ per nm. Standard PT units deliver 8–10 $\mu W/cm^2$ per nm (Fig 6). Intensive PT requires >30 $\mu W/cm^2$ per nm.	If special blue fluorescent tubes are used, bring tubes as close to infant as possible to increase irradiance (Fig 6). Note: This cannot be done with halogen lamps because of the danger of burn. Special blue tubes 10–15 cm above the infant will produce an irradiance of at least 35 $\mu W/cm^2$ per nm.
Spectral power (average spectral irradiance across surface area)	↑ surface area exposed → ↑ rate of decline in TSB	For intensive PT, expose maximum surface area of infant to PT.	Place lights above and fiber-optic pad or special blue fluorescent tubes* below the infant. For maximum exposure, line sides of bassinet, warmer bed, or incubator with aluminum foil.
Cause of jaundice	PT is likely to be less effective if jaundice is due to hemolysis or if cholestasis is present. (↑ direct bilirubin)		When hemolysis is present, start PT at lower TSB levels. Use intensive PT. Failure of PT suggests that hemolysis is the cause of jaundice. If ↑ direct bilirubin, watch for bronze baby syndrome or blistering.
TSB level at start of PT	The higher the TSB, the more rapid the decline in TSB with PT.		Use intensive PT for higher TSB levels. Anticipate a more rapid decrease in TSB when TSB >20 mg/dL (342 μmol/L).

PT indicates phototherapy; LED, light-emitting diode.
* Available in the Olympic BiliBassinet (Olympic Medical, Seattle, WA).

can also produce significantly different results. The width of the phototherapy lamp's emissions spectrum (narrow versus broad) will affect the measured irradiance. Measurements under lights with a very focused emission spectrum (eg, blue light-emitting diode) will vary significantly from one radiometer to another, because the response spectra of the radiometers vary from manufacturer to manufacturer. Broader-spectrum lights (fluorescent and halogen) have fewer variations among radiometers. Manufacturers of phototherapy systems generally recommend the specific radiometer to be used in measuring the dose of phototherapy when their system is used.

It is important also to recognize that the measured irradiance will vary widely depending on where the measurement is taken. Irradiance measured below the center of the light source can be more than double that measured at the periphery, and this dropoff at the periphery will vary with different phototherapy units. Ideally, irradiance should be measured at multiple sites under the area illuminated by the unit and the measurements averaged. The International Electrotechnical Commission[3] defines the "effective surface area" as the intended treatment surface that is illuminated by the phototherapy light. The commission uses 60 × 30 cm as the standard-sized surface.

Is It Necessary to Measure Phototherapy Doses Routinely?

Although it is not necessary to measure spectral irradiance before each use of phototherapy, it is important to perform periodic checks of phototherapy units to make sure that an adequate irradiance is being delivered.

The Dose-Response Relationship of Phototherapy

Figure 5 shows that there is a direct relationship between the irradiance used and the rate at which the serum bilirubin declines under phototherapy.[4] The data in Fig 5 suggest that there is a saturation point beyond which an increase in the irradiance produces no added efficacy. We do not know, however, that a saturation point exists. Because the conversion of bilirubin to excretable photoproducts is partly irreversible and follows first-order kinetics, there may not be a saturation point, so we do not know the maximum effective dose of phototherapy.

Effect on Irradiance of the Light Spectrum and the Distance Between the Infant and the Light Source

Figure 6 shows that as the distance between the light source and the infant decreases, there is a corresponding increase in the spectral irradiance.[5] Fig 6 also demonstrates the dramatic difference in irradi-

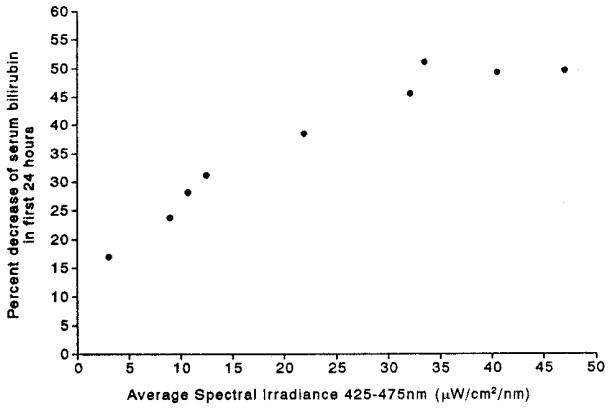


Fig 5. Relationship between average spectral irradiance and decrease in serum bilirubin concentration. Term infants with nonhemolytic hyperbilirubinemia were exposed to special blue lights (Phillips TL 52/20W) of different intensities. Spectral irradiance was measured as the average of readings at the head, trunk, and knees. Drawn from the data of Tan.[4] Source: *Pediatrics*. 1996;98: 283-287.

ance produced within the important 425- to 475-nm band by different types of fluorescent tubes.

What is Intensive Phototherapy?

Intensive phototherapy implies the use of high levels of irradiance in the 430- to 490-nm band (usually 30 $\mu W/cm^2$ per nm or higher) delivered to as much of the infant's surface area as possible. How this can be achieved is described below.

Using Phototherapy Effectively

Light Source

The spectrum of light delivered by a phototherapy unit is determined by the type of light source and any filters used. Commonly used phototherapy units contain daylight, cool white, blue, or "special blue" fluorescent tubes. Other units use tungsten-halogen lamps in different configurations, either free-standing or as part of a radiant warming device. Recently, a system using high-intensity gallium nitride light-emitting diodes has been introduced.[6] Fiber-optic systems deliver light from a high-intensity lamp to a fiber-optic blanket. Most of these devices deliver enough output in the blue-green region of the visible spectrum to be effective for standard phototherapy use. However, when bilirubin levels approach the range at which intensive phototherapy is recommended, maximal efficiency must be sought. The most effective light sources currently commercially available for phototherapy are those that use special blue fluorescent tubes[7] or a specially designed light-emitting diode light (Natus Inc, San Carlos, CA).[6] The special blue fluorescent tubes are labeled F20T12/BB (General Electric, Westinghouse, Sylvania) or TL52/20W (Phillips, Eindhoven, The Netherlands). It is important to note that special blue tubes provide much greater irradiance than regular blue tubes (labeled F20T12/B) (Fig 6). Special blue tubes are most effective because they provide light predominantly in the blue-green spectrum. At these wavelengths, light penetrates skin well and is absorbed maximally by bilirubin.[7]

There is a common misconception that ultraviolet light is used for phototherapy. The light systems used do not emit significant ultraviolet radiation, and the small amount of ultraviolet light that is emitted by fluorescent tubes and halogen bulbs is in longer wavelengths than those that cause erythema. In addition, almost all ultraviolet light is absorbed by the glass wall of the fluorescent tube and the Plexiglas cover of the phototherapy unit.

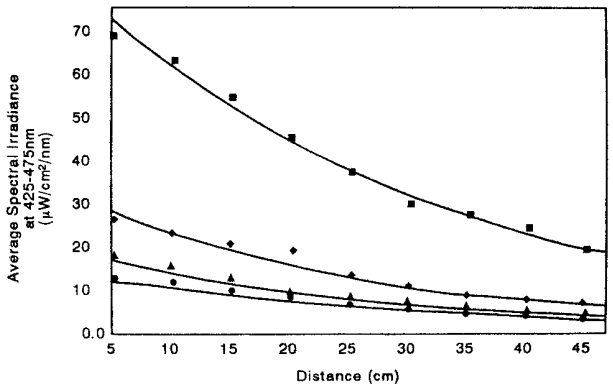


Fig 6. Effect of light source and distance from the light source to the infant on average spectral irradiance. Measurements were made across the 425- to 475-nm band by using a commercial radiometer (Olympic Bilimeter Mark II) and are the average of measurements taken at different locations at each distance (irradiance at the center of the light is much higher than at the periphery). The phototherapy unit was fitted with eight 24-in fluorescent tubes. ■ indicates special blue, General Electric 20-W F20T12/BB tube; ◆, blue, General Electric 20-W F20T12/B tube; ▲, daylight blue, 4 General Electric 20-W F20T12/B blue tubes and 4 Sylvania 20-W F20T12/D daylight tubes; •, daylight, Sylvania 20-W F20T12/D daylight tube. Curves were plotted by using linear curve fitting (True Epistat, Epistat Services, Richardson, TX). The best fit is described by the equation $y = Ae^{Bx}$. Source: *Pediatrics*. 1996;98:283-287.

Distance From the Light

As can be seen in Fig 6, the distance of the light source from the infant has a dramatic effect on the spectral irradiance, and this effect is most significant when special blue tubes are used. To take advantage of this effect, the fluorescent tubes should be placed as close to the infant as possible. To do this, the infant should be in a bassinet, not an incubator, because the top of the incubator prevents the light from being brought sufficiently close to the infant. In a bassinet, it is possible to bring the fluorescent tubes within approximately 10 cm of the infant. Naked term infants do not become overheated under these lights. It is important to note, however, that the halogen spot phototherapy lamps cannot be positioned closer to the infant than recommended by the manufacturers without incurring the risk of a burn. When halogen lamps are used, manufacturers recommendations should be followed. The reflectors, light source, and transparent light filters (if any) should be kept clean.

Surface Area

A number of systems have been developed to provide phototherapy above and below the infant.[8,9] One commercially available system that does this is the BiliBassinet (Olympic Medical, Seattle, WA). This

unit provides special blue fluorescent tubes above and below the infant. An alternative is to place fiber-optic pads below an infant with phototherapy lamps above. One disadvantage of fiber-optic pads is that they cover a relatively small surface area so that 2 or 3 pads may be needed.[5] When bilirubin levels are extremely high and must be lowered as rapidly as possible, it is essential to expose as much of the infant's surface area to phototherapy as possible. In these situations, additional surface-area exposure can be achieved by lining the sides of the bassinet with aluminum foil or a white cloth.[10]

In most circumstances, it is not necessary to remove the infant's diaper, but when bilirubin levels approach the exchange transfusion range, the diaper should be removed until there is clear evidence of a significant decline in the bilirubin level.

What Decline in the Serum Bilirubin Can You Expect?

The rate at which the bilirubin declines depends on the factors listed in Table 5, and different responses can be expected depending on the clinical circumstances. When bilirubin levels are extremely high (more than 30 mg/dL [513 μmol/L]), and intensive phototherapy is used, a decline of as much as 10 mg/dL (171 μmol/L) can occur within a few hours,[11] and a decrease of at least 0.5 to 1 mg/dL per hour can be expected in the first 4 to 8 hours.[12] On average, for infants of more than 35 weeks' gestation readmitted for phototherapy, intensive phototherapy can produce a decrement of 30% to 40% in the initial bilirubin level by 24 hours after initiation of phototherapy.[13] The most significant decline will occur in the first 4 to 6 hours. With standard phototherapy systems, a decrease of 6% to 20% of the initial bilirubin level can be expected in the first 24 hours.[8,14]

Intermittent Versus Continuous Phototherapy

Clinical studies comparing intermittent with continuous phototherapy have produced conflicting results.[15–17] Because all light exposure increases bilirubin excretion (compared with darkness), no plausible scientific rationale exists for using intermittent phototherapy. In most circumstances, however, phototherapy does not need to be continuous. Phototherapy may be interrupted during feeding or brief parental visits. Individual judgment should be exercised. If the infant's bilirubin level is approaching the exchange transfusion zone (Fig 4), phototherapy should be administered continuously until a satisfactory decline in the serum bilirubin level occurs or exchange transfusion is initiated.

Hydration

There is no evidence that excessive fluid administration affects the serum bilirubin concentration. Some infants who are admitted with high bilirubin levels are also mildly dehydrated and may need supplemental fluid intake to correct their dehydration. Because these infants are almost always breastfed, the best fluid to use in these circumstances is a milk-based formula, because it inhibits the enterohepatic circulation of bilirubin and should help to lower the serum bilirubin level. Because the photoproducts responsible for the decline in serum bilirubin are excreted in urine and bile,[18] maintaining adequate hydration and good urine output should help to improve the efficacy of phototherapy. Unless there is evidence of dehydration, however, routine intravenous fluid or other supplementation (eg, with dextrose water) of term and near-term infants receiving phototherapy is not necessary.

When Should Phototherapy Be Stopped?

There is no standard for discontinuing phototherapy. The TSB level for discontinuing phototherapy depends on the age at which phototherapy is initiated and the cause of the hyperbilirubinemia.[13] For infants who are readmitted after their birth hospitalization (usually for TSB levels of 18 mg/dL [308 μmol/L] or higher), phototherapy may be discontinued when the serum bilirubin level falls below 13 to 14 mg/dL (239-239 μmol/L). Discharge from the hospital need not be delayed to observe the infant for rebound.[13,19,20] If phototherapy is used for infants with hemolytic diseases or is initiated early and discontinued before the infant is 3 to 4 days old, a follow-up bilirubin measurement within 24 hours after discharge is recommended.[13] For infants who are readmitted with hyperbilirubinemia and then discharged, significant rebound is rare, but a repeat TSB measurement or clinical follow-up 24 hours after discharge is a clinical option.[13]

Home Phototherapy

Because the devices available for home phototherapy may not provide the same degree of irradiance or surface-area exposure as those available in the hospital, home phototherapy should be used only in infants whose bilirubin levels are in the "optional phototherapy" range (Fig 3); it is not appropriate for infants with higher bilirubin concentrations. As with hospitalized infants, it is essential that serum bilirubin levels be monitored regularly.

Sunlight Exposure

In their original description of phototherapy, Cremer et al[21] demonstrated that exposure of newborns to sunlight would lower the serum bilirubin level. Although sunlight provides sufficient irradiance in the 425- to 475-nm band to provide phototherapy, the practical difficulties involved in safely exposing a naked newborn to the sun either inside or outside (and avoiding sunburn) preclude the use of sunlight as a reliable therapeutic tool, and it therefore is not recommended.

Complications

Phototherapy has been used in millions of infants for more than 30 years, and reports of significant toxicity are exceptionally rare. Nevertheless, phototherapy in hospital separates mother and infant, and eye patching is disturbing to parents. The most important, but uncommon, clinical complication occurs in infants with cholestatic jaundice. When these infants are exposed to phototherapy, they may develop a dark, grayish-brown discoloration of the skin, serum, and urine (the bronze infant syndrome).[22] The

pathogenesis of this syndrome is unknown, but it may be related to an accumulation of porphyrins and other metabolites in the plasma of infants who develop cholestasis.[22,23] Although it occurs exclusively in infants with cholestasis, not all infants with cholestatic jaundice develop the syndrome.

This syndrome generally has had few deleterious consequences, and if there is a need for phototherapy, the presence of direct hyperbilirubinemia should not be considered a contraindication to its use. This is particularly important in sick neonates. Because the products of phototherapy are excreted in the bile, the presence of cholestasis will decrease the efficacy of phototherapy. Nevertheless, infants with direct hyperbilirubinemia often show some response to phototherapy. In infants receiving phototherapy who develop the bronze infant syndrome, exchange transfusion should be considered if the TSB is in the intensive phototherapy range and phototherapy does not promptly lower the TSB. Because of the paucity of data, firm recommendations cannot be made. Note, however, that the direct serum bilirubin should not be subtracted from the TSB concentration in making decisions about exchange transfusions (see Fig 4).

Rarely, purpura and bullous eruptions have been described in infants with severe cholestatic jaundice receiving phototherapy,[24,25] and severe blistering and photosensitivity during phototherapy have occurred in infants with congenital erythropoietic porphyria.[26,27] Congenital porphyria or a family history of porphyria is an absolute contraindication to the use of phototherapy, as is the concomitant use of drugs or agents that are photosensitizers.[28]

REFERENCES

1. Maisels MJ. Phototherapy—traditional and nontraditional. *J Perinatol*. 2001;21(suppl 1):S93–S97
2. Fiberoptic phototherapy systems. *Health Devices*. 1995;24:132–153
3. International Electrotechnical Commission. Medical electrical equipment—part 2-50: particular requirements for the safety of infant phototherapy equipment. 2000. IEC 60601-2-50. Available at www.iec.ch. Accessed June 7, 2004
4. Tan KL. The pattern of bilirubin response to phototherapy for neonatal hyperbilirubinemia. *Pediatr Res*. 1982;16:670–674
5. Maisels MJ. Why use homeopathic doses of phototherapy? *Pediatrics*. 1996;98:283–287
6. Seidman DS, Moise J, Ergaz Z, et al. A new blue light-emitting phototherapy device: a prospective randomized controlled study. *J Pediatr*. 2000;136:771–774
7. Ennever JF. Blue light, green light, white light, more light: treatment of neonatal jaundice. *Clin Perinatol*. 1990;17:467–481
8. Garg AK, Prasad RS, Hifzi IA. A controlled trial of high-intensity double-surface phototherapy on a fluid bed versus conventional phototherapy in neonatal jaundice. *Pediatrics*. 1995;95:914–916
9. Tan KL. Phototherapy for neonatal jaundice. *Clin Perinatol*. 1991;18: 423–439
10. Eggert P, Stick C, Schroder H. On the distribution of irradiation intensity in phototherapy. Measurements of effective irradiance in an incubator. *Eur J Pediatr*. 1984;142:58–61
11. Hansen TW. Acute management of extreme neonatal jaundice—the potential benefits of intensified phototherapy and interruption of enterohepatic bilirubin circulation. *Acta Paediatr*. 1997;86:843–846
12. Newman TB, Liljestrand P, Escobar GJ. Infants with bilirubin levels of 30 mg/dL or more in a large managed care organization. *Pediatrics*. 2003;111(6 Pt 1):1303–1311
13. Maisels MJ, Kring E. Bilirubin rebound following intensive phototherapy. *Arch Pediatr Adolesc Med*. 2002;156:669–672
14. Tan KL. Comparison of the efficacy of fiberoptic and conventional phototherapy for neonatal hyperbilirubinemia. *J Pediatr*. 1994;125: 607–612
15. Rubaltelli FF, Zanardo V, Granati B. Effect of various phototherapy regimens on bilirubin decrement. *Pediatrics*. 1978;61:838–841
16. Maurer HM, Shumway CN, Draper DA, Hossaini AA. Controlled trial comparing agar, intermittent phototherapy, and continuous phototherapy for reducing neonatal hyperbilirubinemia. *J Pediatr*. 1973;82:73–76
17. Lau SP, Fung KP. Serum bilirubin kinetics in intermittent phototherapy of physiological jaundice. *Arch Dis Child*. 1984;59:892–894
18. McDonagh AF, Lightner DA. 'Like a shrivelled blood orange'—bilirubin, jaundice, and phototherapy. *Pediatrics*. 1985;75:443–455
19. Yetman RJ, Parks DK, Huseby V, Mistry K, Garcia J. Rebound bilirubin levels in infants receiving phototherapy. *J Pediatr*. 1998;133:705–707
20. Lazar L, Litwin A, Merlob P. Phototherapy for neonatal nonhemolytic hyperbilirubinemia. Analysis of rebound and indications for discontinuing therapy. *Clin Pediatr (Phila)*. 1993;32:264–267
21. Cremer RJ, Perryman PW, Richards DH. Influence of light on the hyperbilirubinemia of infants. *Lancet*. 1958;1(7030):1094–1097
22. Rubaltelli FF, Jori G, Reddi E. Bronze baby syndrome: a new porphyrin-related disorder. *Pediatr Res*. 1983;17:327–330
23. Meisel P, Jahrig D, Theel L, Ordt A, Jahrig K. The bronze baby syndrome: consequence of impaired excretion of photobilirubin? *Photobiochem Photobiophys*. 1982;3:345–352
24. Mallon E, Wojnarowska F, Hope P, Elder G. Neonatal bullous eruption as a result of transient porphyrinemia in a premature infant with hemolytic disease of the newborn. *J Am Acad Dermatol*. 1995;33:333–336
25. Paller AS, Eramo LR, Farrell EE, Millard DD, Honig PJ, Cunningham BB. Purpuric phototherapy-induced eruption in transfused neonates: relation to transient porphyrinemia. *Pediatrics*. 1997;100:360–364
26. Tonz O, Vogt J, Filippini L, Simmler F, Wachsmuth ED, Winterhalter KH. Severe light dermatosis following phototherapy in a newborn infant with congenital erythropoietic urophyria [in German]. *Helv Paediatr Acta*. 1975;30:47–56
27. Soylu A, Kavukcu S, Turkmen M. Phototherapy sequela in a child with congenital erythropoietic porphyria. *Eur J Pediatr*. 1999;158:526–527
28. Kearns GL, Williams BJ, Timmons OD. Fluorescein phototoxicity in a premature infant. *J Pediatr*. 1985;107:796–798

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

ERRATUM

Two errors appeared in the American Academy of Pediatrics clinical practice guideline, titled "Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation," that was published in the July 2004 issue of *Pediatrics* (2004;114:297–316). On page 107, Background section, first paragraph, the second sentence should read: "The current guideline represents a consensus of the committee charged by the AAP with reviewing and updating the existing guideline and is based on a careful review of the evidence, including a comprehensive literature review by the Agency for Healthcare Research and Quality and the New England Medical Center Evidence-Based Practice Center.[2″] On page 118, Appendix 1, first paragraph, the 4 levels of evidence quality should have been labeled A, B, C, and D rather than 1, 2, 3, and 4, respectively. The American Academy of Pediatrics regrets these errors.

Hyperbilirubinemia Clinical Practice Guideline Quick Reference Tools

- Recommendation Summary
  — Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation
- *ICD-10-CM* Coding Quick Reference for Hyperbilirubinemia
- AAP Patient Education Handout
  — *Jaundice and Your Newborn*

Recommendation Summary

Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation

The following are the key elements of the recommendations provided by this guideline. Clinicians should:

1. Promote and support successful breastfeeding.
2. Establish nursery protocols for the identification and evaluation of hyperbilirubinemia.
3. Measure the total serum bilirubin (TSB) or transcutaneous bilirubin (TcB) level on infants jaundiced in the first 24 hours.
4. Recognize that visual estimation of the degree of jaundice can lead to errors, particularly in darkly pigmented infants.
5. Interpret all bilirubin levels according to the infant's age in hours.
6. Recognize that infants at less than 38 weeks' gestation, particularly those who are breastfed, are at higher risk of developing hyperbilirubinemia and require closer surveillance and monitoring.
7. Perform a systematic assessment on all infants before discharge for the risk of severe hyperbilirubinemia.
8. Provide parents with written and verbal information about newborn jaundice.
9. Provide appropriate follow-up based on the time of discharge and the risk assessment.
10. Treat newborns, when indicated, with phototherapy or exchange transfusion.

Coding Quick Reference for Hyperbilirubinemia	
ICD-10-CM	
P59.0	Neonatal jaundice associated with preterm delivery
P59.3	Neonatal jaundice from breast milk inhibitor
P59.9	Neonatal jaundice, unspecified
R17	Unspecified jaundice

Jaundice and Your Newborn

Congratulations on the birth of your new baby!

To make sure your baby's first week is safe and healthy, it is important that

1. **You find a primary care provider, such as a pediatrician you are comfortable with, for your baby's ongoing care.**
2. **Your baby is checked for jaundice in the hospital.**
3. **If you are breastfeeding, you get the help you need to make sure it is going well.**
4. **You make sure your baby is seen by a doctor or nurse at 3 to 5 days of age.**
5. **If your baby is discharged before age 72 hours, your baby should be seen by a doctor or nurse within 2 days of discharge from the hospital.**

Q: What is jaundice?

A: Jaundice is the yellow color seen in the skin of many newborns. It happens when a chemical called *bilirubin* builds up in the baby's blood. Jaundice can occur in babies of any race or color.

Q: Why is jaundice common in newborns?

A: Everyone's blood contains bilirubin, which comes from red blood cells and is removed by the liver. Before birth, the mother's liver does this for the baby. Most babies develop jaundice in the first few days after birth because it takes a few days for the baby's liver to get better at removing bilirubin.

Q: How can I tell if my baby is jaundiced?

A: The skin of a baby with jaundice usually appears yellow. The best way to see jaundice is in good light, such as daylight or under fluorescent lights. Jaundice usually appears first in the face and then moves to the chest, abdomen, arms, and legs as the bilirubin level increases. The whites of the eyes may also be yellow. Jaundice may be harder to see in babies with darker skin color.

Q: Can jaundice hurt my baby?

A: Most babies have mild jaundice that is harmless, but in unusual situations the bilirubin level can get very high and might cause brain damage. This is why newborns should be checked carefully for jaundice and treated to prevent a high bilirubin level.

Q: How should my baby be checked for jaundice?

A: If your baby looks jaundiced in the first few days after birth, your baby's doctor or nurse may use a skin or blood test to check your baby's bilirubin level. However, because estimating the bilirubin level based on the baby's appearance can be difficult, most experts recommend that a skin or blood test be done in the first 2 days even if your baby does not appear jaundiced. A bilirubin level is always needed if jaundice develops before the baby is 24 hours old. Whether a test is needed after that depends on the baby's age, the amount of jaundice, and whether the baby has other factors that make jaundice more likely or harder to see.

Q: Does breastfeeding affect jaundice?

A: Breast milk (human milk) is the ideal food for your baby. Jaundice is more common in babies who are breastfed than babies who are formula-fed. However, this occurs more often in newborns who are not getting enough breast milk because their mothers are not producing enough milk (especially if the milk comes in late) or if breastfeeding is not going well, such as babies not latching on properly.

For the first 24 hours after birth, normal breastfed newborns receive only about 1 teaspoon of milk with each feeding. The amount of breast milk provided increases with each day. If you are breastfeeding, you should breastfeed your baby at least 8 to 12 times a day for the first few days. This will help you produce enough milk and will help keep the baby's bilirubin level down. If you are having trouble breastfeeding, ask your baby's doctor or nurse or a lactation specialist for help.

Q: When should my baby get checked after leaving the hospital?

A: It is important for your baby to be seen by a nurse or doctor when the baby is between 3 and 5 days old, because this is usually when a baby's bilirubin level is highest. This is why, if your baby is discharged before age 72 hours, your baby should be seen within 2 days of discharge. The timing of this visit may vary depending on your baby's age when released from the hospital and other factors.

Q: Why do some babies need an earlier follow-up visit after leaving the hospital?

A: Some babies have a greater risk for high levels of bilirubin and may need to be seen sooner after discharge from the hospital. Ask your doctor about an early follow-up visit if your baby has any of the following symptoms:

- A high bilirubin level before leaving the hospital
- Early birth (more than 2 weeks before the due date)
- Jaundice in the first 24 hours after birth
- Breastfeeding that is not going well
- A lot of bruising or bleeding under the scalp related to labor and delivery
- A parent, brother, or sister who had a high bilirubin level and received light therapy

Q: When should I call my baby's doctor?

A: Call your baby's doctor if

- Your baby's skin turns more yellow.
- Your baby's abdomen, arms, or legs are yellow.
- The whites of your baby's eyes are yellow.
- Your baby is jaundiced and is hard to wake, fussy, or not nursing or taking formula well.

Q: How is harmful jaundice prevented?

A: Most jaundice requires no treatment. When treatment is necessary, placing your baby under special lights while he or she is undressed will lower the bilirubin level. Depending on your baby's bilirubin level, this can be done in the hospital or at home. Jaundice is treated at levels that are much lower than those at which brain damage is a concern. In some babies, supplementing breast milk with formula

can also help to lower the bilirubin level and prevent the need for phototherapy. Treatment can prevent the harmful effects of jaundice.

> **Note:** Exposing your baby to sunlight through a window might help lower the bilirubin level, but this will only work if the baby is undressed. Make sure the temperature in your home is comfortable and not too cold for your baby. Newborns should never be put in direct sunlight outside because they might get sunburned.

Q: When does jaundice go away?

A: In breastfed babies, it is common for jaundice to last 1 month or occasionally longer. In formula-fed babies, most jaundice goes away by 2 weeks. However, if your baby is jaundiced for more than 3 weeks, see your baby's doctor.

From Your Doctor

The American Academy of Pediatrics (AAP) is an organization of 66,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

Clinical Practice Guideline for the Management of Infantile Hemangiomas

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Clinical Practice Guideline for the Management of Infantile Hemangiomas

Daniel P. Krowchuk, MD, FAAP,[a] Ilona J. Frieden, MD, FAAP,[b] Anthony J. Mancini, MD, FAAP,[c] David H. Darrow, MD, DDS, FAAP,[d] Francine Blei, MD, MBA, FAAP,[e] Arin K. Greene, MD, FAAP,[f] Aparna Annam, DO, FAAP,[g] Cynthia N. Baker, MD, FAAP,[h] Peter C. Frommelt, MD, FAAP,[i] Amy Hodak, CPMSM,[j] Brian M. Pate, MD, FHM, FAAP,[k] Janice L. Pelletier, MD, FAAP,[l] Deborah Sandrock, MD, FAAP,[m] Stuart T. Weinberg, MD, FAAP,[n] Mary Anne Whelan, MD, PhD, FAAP,[o] SUBCOMMITTEE ON THE MANAGEMENT OF INFANTILE HEMANGIOMAS

abstract

Infantile hemangiomas (IHs) occur in as many as 5% of infants, making them the most common benign tumor of infancy. Most IHs are small, innocuous, self-resolving, and require no treatment. However, because of their size or location, a significant minority of IHs are potentially problematic. These include IHs that may cause permanent scarring and disfigurement (eg, facial IHs), hepatic or airway IHs, and IHs with the potential for functional impairment (eg, periorbital IHs), ulceration (that may cause pain or scarring), and associated underlying abnormalities (eg, intracranial and aortic arch vascular abnormalities accompanying a large facial IH). This clinical practice guideline for the management of IHs emphasizes several key concepts. It defines those IHs that are potentially higher risk and should prompt concern, and emphasizes increased vigilance, consideration of active treatment and, when appropriate, specialty consultation. It discusses the specific growth characteristics of IHs, that is, that the most rapid and significant growth occurs between 1 and 3 months of age and that growth is completed by 5 months of age in most cases. Because many IHs leave behind permanent skin changes, there is a window of opportunity to treat higher-risk IHs and optimize outcomes. Early intervention and/or referral (ideally by 1 month of age) is recommended for infants who have potentially problematic IHs. When systemic treatment is indicated, propranolol is the drug of choice at a dose of 2 to 3 mg/kg per day. Treatment typically is continued for at least 6 months and often is maintained until 12 months of age (occasionally longer). Topical timolol may be used to treat select small, thin, superficial IHs. Surgery and/or laser treatment are most useful for the treatment of residual skin changes after involution and, less commonly, may be considered earlier to treat some IHs.

Departments of [a]Pediatrics and Dermatology, Wake Forest School of Medicine, Winston-Salem, North Carolina; Departments of [b]Dermatology and Pediatrics, School of Medicine, University of California, San Francisco, San Francisco, California; Departments of [c]Pediatrics and Dermatology, Feinberg School of Medicine, Northwestern University and Ann and Robert H. Lurie Children's Hospital of Chicago, Chicago, Illinois; Departments of [d]Otolaryngology and Pediatrics, Eastern Virginia Medical School and Children's Hospital of the King's Daughters, Norfolk, Virginia; [e]Donald and Barbara Zucker School of Medicine, Northwell Health, New York City, New York; [f]Department of Plastic and Oral Surgery, Boston Children's Hospital and Harvard Medical School, Harvard University, Boston, Massachusetts; [g]Department of Radiology, University of Colorado School of Medicine, Children's Hospital Colorado, Aurora, Colorado; [h]Department of Pediatrics, Kaiser Permanente Medical Center, Los Angeles, California; [i]Department of Pediatrics, Cardiology, Medical College of Wisconsin and Children's Hospital of Wisconsin, Milwaukee, Wisconsin; [j]American Board of Pediatrics, Chapel Hill, North Carolina; [k]Department of Pediatrics, University of Kansas School of Medicine-Wichita, Wichita, Kansas; [l]Department of Pediatrics, Northern Light Health, Bangor, Maine; [m]St Christopher's Hospital for Children and College of Medicine, Drexel University, Philadelphia, Pennsylvania; Departments of [n]Biomedical Informatics and Pediatrics, School of Medicine, Vanderbilt University, Nashville, Tennessee; and [o]College of Physicians and Surgeons, Columbia University, New York City, New York

To cite: Krowchuk DP, Frieden IJ, Mancini AJ, et al. Clinical Practice Guideline for the Management of Infantile Hemangiomas. *Pediatrics*. 2019;143(1):e20183475

INTRODUCTION

This is the first clinical practice guideline (CPG) from the American Academy of Pediatrics (AAP) regarding the management of infantile hemangiomas (IHs). Similar consensus statements have been published by European[1] and Australasian expert groups.[2] In addition, a recent AAP clinical report provided a comprehensive review of the pathogenesis, clinical features, and treatment of IH; it is available at http://pediatrics.aappublications.org/content/136/4/e1060.[3]

IHs occur in approximately 4% to 5% of infants, making them the most common benign tumor of childhood. They are more common in girls, twins, infants born preterm or with low birth weight (up to 30% of infants born weighing <1 kg are affected), and white neonates. The pathogenesis of IHs has yet to be fully defined. A leading hypothesis is that circulating endothelial progenitor cells migrate to locations in which conditions (eg, hypoxia and developmental field disturbances) are favorable for growth.[3]

Knowledge about IHs has advanced dramatically in the past decade, particularly regarding the unique timing and nature of proliferation and involution, risks of sequelae, and newer treatment options. As a result, pediatric providers have an opportunity to improve care and reduce morbidity in infants with IHs by promptly recognizing which IHs are potentially high risk and when intervention is needed.

In the broadest sense, the goal of this CPG from the AAP is to enhance primary care providers' ability to confidently evaluate, triage, and manage IHs, employing an evidence-based approach. Specifically, the CPG will:

- provide an approach to risk stratification and recognition of potentially problematic IHs;
- emphasize that early and frequent monitoring in the first few weeks and months of life is crucial in identifying those IHs that require intervention because IHs may change rapidly during this time period;
- review the role of imaging in patients who have IHs; and
- offer evidence-based guidance for the management of IHs, including indications for consultation, referral and possible intervention, pharmacologic options for therapy, the role of surgical modalities, and ongoing management and monitoring (including parent education).

This CPG is intended for pediatricians and other primary care providers who (1) manage IHs collaboratively with a hemangioma specialist (defined below), (2) care for children with IHs being managed primarily by a hemangioma specialist, or (3) manage IHs independently on the basis of their knowledge and expertise. It does not address the management of vascular malformations, congenital hemangiomas, or other vascular tumors. The CPG encourages enhanced communication between primary care clinicians and hemangioma specialists to ensure early assessment and treatment of infants in whom active intervention is indicated, to improve patient outcomes, and to enhance anticipatory guidance. It is not intended to be a sole source of guidance in the management of children with IHs, to replace clinical judgment, or to establish a protocol for all infants with IHs. Rather, it provides a framework for clinical decision-making.

METHODS

The methods of this CPG are discussed in detail in the Methods section of the Supplemental Information. Briefly, a comparative effectiveness review of potential benefits and harms of diagnostic modalities and pharmacologic and surgical treatments was conducted on behalf of the Agency for Healthcare Research and Quality (AHRQ). The literature search strategy employed Medline via the PubMed interface, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Excerpta Medica Database (Embase). Searches were limited to the English language and to studies published from 1982 to June

TABLE 1 Highlights of This CPG

- IH growth characteristics are different than once taught.
  - Most rapid IH growth occurs between 1 and 3 months of age.
  - Although IHs involute, this process may be incomplete, leaving permanent skin changes that may be life altering. This is especially true for IHs that are thick.
  - There is a window of opportunity to treat problematic IHs. Consult early (by 1 month of age) for lesions that are potentially high risk because of the following associations (Table 3):
    - potential for disfigurement (the most common reason treatment is needed);
    - life-threatening complications;
    - functional impairment;
    - ulceration; and
    - underlying abnormalities.
- Oral propranolol is the treatment of choice for problematic IHs that require systemic therapy.
- Topical timolol may be used to treat some thin and/or superficial IHs.
- Surgery and/or laser treatment are most useful for the treatment of residual skin changes after involution. They may be used earlier to treat selected IHs.

TABLE 2 Definitions

Hemangioma specialist:	Unlike many diseases, management of IHs is not limited to 1 medical or surgical specialty. A hemangioma specialist may have expertise in dermatology, hematologyoncology, pediatrics, facial plastic and reconstructive surgery, ophthalmology, otolaryngology, pediatric surgery, and/or plastic surgery, and his or her practice is often focused primarily or exclusively on the pediatric age group.
Hemangioma specialists should:	• understand the time-sensitive nature of IHs during the growth phase and be able to accommodate requests for urgent evaluation; • have experience with accurate risk stratification and potential complications associated with IHs; • be able to provide recommendations for various management options, including observation, medical therapies, and surgical or laser procedures, and provide counseling regarding the potential risks and benefits of these interventions for specific patients; and • have a thorough knowledge of past and emerging medical literature regarding IHs. • Such specialists often have 1 or more of the following characteristics: o participated in a vascular anomalies program during previous medical training; o devotes a significant part of his or her clinical practice to IHs; o is a member of or collaborates with a multidisciplinary vascular anomalies center; o maintains membership in professional organizations or groups with a special interest in IHs; o participates in research studies in the field of IHs; or o publishes medical literature in the field of IHs.
IHs: infantile hemangiomas	Benign vascular tumors of infancy and childhood with unique clinical and histopathologic characteristics that distinguish them from other vascular tumors (eg, congenital hemangiomas) or malformations. These characteristics include development during the first weeks or months of life, a typical natural history of rapid growth followed by gradual involution, and immunohistochemical staining of biopsy specimens with erythrocyte-type glucose transporter protein and other unique markers not present on other benign vascular tumors. Many other entities are also called hemangiomas. Some are true vascular tumors, and others are vascular malformations. Therefore, it is important to use the adjective "infantile" when referring to true IHs. IHs are classified on the basis of soft-tissue depth and the pattern of anatomic involvement (see Supplemental Figs 5–10 for photographic examples).
Soft-tissue depth:	• Superficial: red with little or no evidence of a subcutaneous component (formerly called strawberry" hemangiomas); • Deep: blue and located below the skin surface (formerly called "cavernous" hemangiomas); and • Combined (mixed): both superficial and deep components are present.
Anatomic appearance:	• Localized: well-defined focal lesions (appearing to arise from a central point); • Segmental: IH involving an anatomic region that is often plaque-like and often measuring at >5 cm in diameter; • Indeterminate (undetermined): neither clearly localized or segmental (often called partial segmental); and • Multifocal: multiple discrete IHs at disparate sites.

2015. Because the therapy of IHs has been evolving rapidly, the CPG subcommittee performed an updated literature review for the period of July 2015 to January 2017 to augment the original search. This most recent search employed only Medline because previously, virtually all relevant articles had been accessed via this database. The search was concentrated on pharmacologic interventions, including topical timolol (an emerging therapeutic alternative for which limited data were available at the time of the original search). The original methodology and report, including the evidence search and review, are available in their entirety and as an executive summary at www.effectivehealthcare.ahrq.gov/reports/final.cfm.[4]

DEVELOPMENT OF THE CLINICAL PRACTICE GUIDELINE

In December 2016, the AAP convened a multidisciplinary subcommittee composed of IH experts in the fields of dermatology, cardiology, hematology-oncology, otolaryngology(head and neck surgery), plastic surgery, and radiology. The subcommittee also included general pediatricians, a parent representative, an implementation scientist, a representative from the Partnership for Policy Implementation (https://www.aap.org/en-us/professional-resources/quality-improvement/Pages/Partnership-for-Policy-Implementation.aspx), and an epidemiologist and methodologist. All panel members declared potential conflicts on the basis of the AAP policy on Conflict of Interest and Voluntary Disclosure. Subcommittee members repeated this process at the time of the publication of the guideline. All potential conflicts of interest are listed at the end of this document. The project was funded by the AAP.

The final recommendations were based on articles identified in the AHRQ and updated systematic reviews. Decisions and the strength of recommendations were based on a systematic grading of the quality of evidence by independent reviewers. Expert consensus was used when definitive data were not available. Key action statements (KASs), summarized in Table 4, were generated by subcommittee members authoring individual components of the CPG using

TABLE 3 High-Risk IHs

IH Clinical Findings	IH Risk
Life-threatening	
"Beard-area" IH	Obstructive airway hemangiomas
≥5 cutaneous IHs	Liver hemangiomas, cardiac failure, hypothyroidism
Functional impairment	
Periocular IH (>1 cm)	Astigmatism, anisometropia, proptosis, amblyopia
IH involving lip or oral cavity	Feeding impairment
Ulceration	
Segmental IH: IH of any size involving any of the following sites: lips, columella, superior helix of ear, gluteal cleft and/or perineum, perianal skin, and other intertriginous areas (eg, neck, axillae, inguinal region)	Increased risk of ulceration
Associated structural anomalies	
Segmental IH of face or scalp	PHACE syndrome
Segmental IH of lumbosacral and/or perineal area	LUMBAR syndrome
Disfigurement	
Segmental IH, especially of face and scalp	High risk of scarring and/or permanent disfigurement
Facial IH (measurements refer to size during infancy): nasal tip or lip (any size) or any facial location ≥2 cm (>1 cm if ≤3 mo of age)	Risk of disfigurement via distortion of anatomic landmarks and/or scarring and/or permanent skin changes
Scalp IH >2 cm	Permanent alopecia (especially if the hemangioma becomes thick or bulky); profuse bleeding if ulceration develops (typically more bleeding than at other anatomic sites)
Neck, trunk, or extremity IH >2 cm, especially in growth phase or if abrupt transition from normal to affected skin (ie, ledge effect); thick superficial IH (eg, ≥2 mm thickness)	Greater risk of leaving permanent scarring and/or permanent skin changes depending on anatomic location
Breast IH (female infants)	Permanent changes in breast development (eg, breast asymmetry) or nipple contour

Categorization of IH as high risk is based on published literature (including the AHRQ review and hemangioma severity scores) and consensus of CPG subcommittee members. Given the wide variation in IH location, size, and age at presentation, the subcommittee acknowledges that there may be situations in which an IH meets high-risk criteria and, therefore, merits consultation or referral, but the practitioner and parents do not believe this is necessary or practical. Clinical judgment is always involved in such decisions, and any plan of action needs to be individualized on the basis of a number of factors, including location of the lesion, age of child, family preferences, and geographic access to care.

the results of the literature review. These sections were reviewed and refined by the subcommittee chairperson and co-chairperson and ultimately by all subcommittee members.

Evidence-based guideline recommendations from the AAP may be graded as strong, moderate, weak on the basis of low-quality evidence, or weak on the basis of balance between benefits and harms. Strong and moderate recommendations usually are associated with "should" and "should not" recommendation statements, whereas some moderate and all weak recommendations may be recognized by use of "may" or "need not," signifying that moderate recommendations are based on a range of evidence strengths within the boundaries of the definition (Table 5, Fig 1).

The CPG underwent a comprehensive review by stakeholders (including AAP councils, committees, and sections), selected outside organizations, and individuals identified by the subcommittee as experts in the field before formal approval by the AAP. All comments were reviewed by the subcommittee and incorporated into the final guideline when appropriate.

RISK STRATIFICATION, TRIAGE, AND REFERRAL

Key Action Statement 1A (Table 6)

Clinicians should classify an IH as high risk if there is evidence of or potential for the following: (1) life-threatening complications, (2) functional impairment or ulceration, (3) structural anomalies (eg, in PHACE syndrome or LUMBAR syndrome), or (4) permanent disfigurement (grade X, strong recommendation).

The purpose of this statement is to ensure timely identification of IHs that may require early intervention. Clinicians in the primary care setting caring for infants with IH face 2 major challenges: disease heterogeneity and the unique growth characteristics of IHs.[24] For example, because IHs involute spontaneously, many that are small, are superficial, occur in areas covered by clothing, and/or are unlikely to cause disfigurement do not require hemangioma specialist evaluation or treatment. However, some IHs may be considered high risk, and depending on the clinician's comfort level and local access to specialty care, require a higher level of experience and expertise to determine if additional intervention is indicated. These high-risk IHs and their associated clinical findings are summarized in Table 3 and illustrated in Figs 2–4, Supplemental Table 22, and Supplemental Fig 11. Of particular note and as discussed later, segmental hemangiomas, those that cover an anatomic territory arising from 1 or more developmental units, confer a higher risk of morbidity and life-threatening complications than those that are localized, that is, seeming to arise from a central focal point.[5] At the same time, smaller IHs in particular anatomic locations, such as the cheek, tip of the

TABLE 4 Summary of Key Action Statements (KASs) for the Management of IHs

In Managing IH, Recommendations for Clinicians	Evidence Quality; Strength of Recommendation
1. Risk stratification	
1A. Classify an IH as high risk if there is evidence of or potential for the following: (1) life-threatening complications, (2) functional impairment or ulceration, (3) structural anomalies (eg, in PHACE syndrome or LUMBAR syndrome), or (4) permanent disfigurement	X; strong
1B. After identifying an IH as high risk, facilitate evaluation by a hemangioma specialist as soon possible	X; strong
2. Imaging	
2A. Do not perform imaging unless the diagnosis of IH is uncertain, there are ≥5 cutaneous IHs, or associated anatomic abnormalities are suspected	B; moderate
2B. Perform ultrasonography as the initial imaging modality when the diagnosis of IH is uncertain	C; weak
2C. Perform MRI when concerned about associated structural abnormalities (eg, PHACE syndrome or LUMBAR syndrome)	B; moderate
3. Pharmacotherapy	
3A. Use oral propranolol as the first-line agent for IHs requiring systemic treatment	A; strong
3B. Dose propranolol between 2 and 3 mg/kg per d unless there are comorbidities (eg, PHACE syndrome) or adverse effects (eg, sleep disturbance) that necessitate a lower dose	A; moderate
3C. Counsel that propranolol be administered with or after feeding and that doses be held at times of diminished oral intake or vomiting to reduce the risk of hypoglycemia	X; strong
3D. Evaluate patients for and educate caregivers about potential adverse effects of propranolol, including sleep disturbances, bronchial irritation, and clinically symptomatic bradycardia and hypotension	X; strong
3E. May prescribe oral prednisolone or prednisone to treat IHs if there are contraindications or an inadequate response to oral propranolol	B; moderate
3F. May recommend intralesional injection of triamcinolone and/or betamethasone to treat focal, bulky IHs during proliferation or in certain critical anatomic locations (eg, the lip)	B; moderate
3G. May prescribe topical timolol maleate as a therapy for thin and/or superficial IHs	B; moderate
4. Surgical management	
4. May recommend surgery and laser therapy as treatment options in managing selected IHs	C; moderate
5. Parent education	
5. Educate caregivers of infants with an IH about the condition, including the expected natural history and its potential for causing complications or disfigurement	X; strong

TABLE 5 Guideline Definitions for Key Action Statements

Statement	Definition	Implication
Strong recommendation	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), and quality of evidence is excellent or unobtainable.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Moderate recommendation	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), and the quality of evidence is good but not excellent (or is unobtainable).	Clinicians would be prudent to follow a moderate recommendation but should remain alert to new information and sensitive to patient preferences.
Weak recommendation (based on low-quality evidence)	A particular action is favored because anticipated benefits clearly exceed harms (or vice versa), but the quality of evidence is weak.	Clinicians would be prudent to follow a weak recommendation but should remain alert to new information and sensitive to patient preferences.
Weak recommendation (based on balance of benefits and harms)	A weak recommendation is provided when the aggregate database shows evidence of both benefit and harm that appears to be similar in magnitude for any available courses of action.	Clinicians should consider the options in their decision-making, but patient preference may have a substantial role.

PHACE indicates posterior fossa defects, hemangiomas, cerebrovascular arterial anomalies, cardiovascular anomalies including coarctation of the aorta, and eye anomalies; LUMBAR, lower body IH and other cutaneous defects, urogenital anomalies and ulceration, myelopathy, bony deformities, anorectal malformations, and arterial anomalies and renal anomalies.

nose, and perioral and periocular skin, can confer a high risk of complications as well (see discussion below).

There are 5 major indications for consideration of early treatment or need for further evaluation of IHs:

1. life-threatening complications;
2. functional impairment or risk thereof;
3. ulceration or risk thereof;
4. evaluation to identify important associated structural anomalies; and
5. risk of leaving permanent scarring or distortion of anatomic landmarks

Life-threatening Complications

Life-threatening lesions include obstructing IHs of the airway, liver IHs associated with high-output congestive heart failure and severe hypothyroidism, and, rarely, profuse bleeding from an ulcerated IH. Obstructing IHs of the airway typically involve the subglottis,

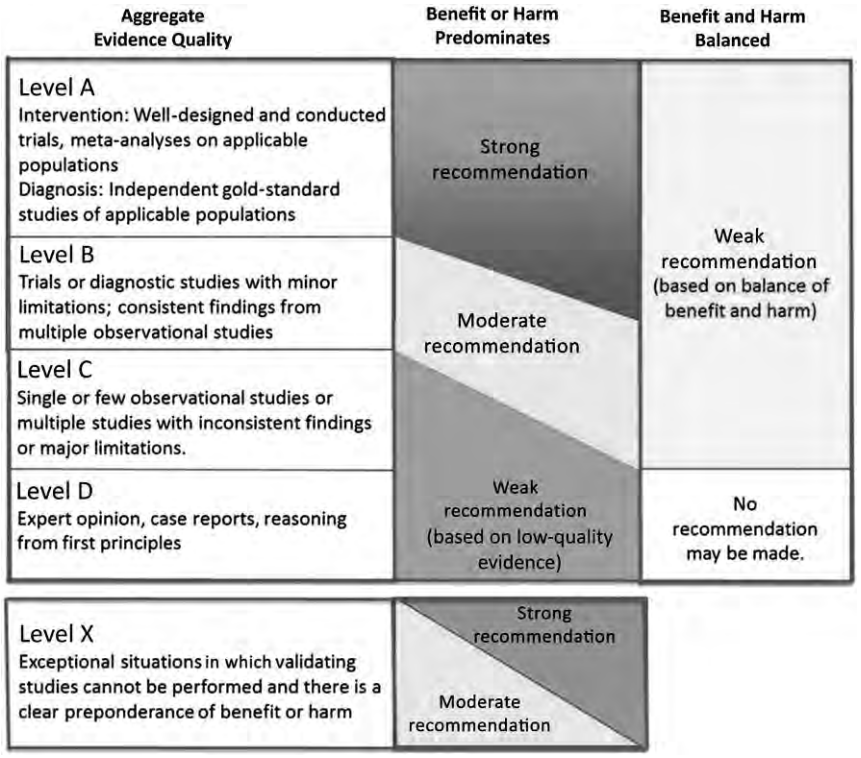


FIGURE 1
AAP rating of evidence and recommendations.

TABLE 6 Key Action Statement 1A: Clinicians should classify an IH as high risk if there is evidence of or potential for the following: (1) life-threatening complications, (2) functional impairment or ulceration, (3) structural anomalies (eg, in PHACE syndrome or LUMBAR syndrome), or (4) permanent disfigurement (grade X, strong recommendation).

Aggregate Evidence Quality	Grade X
Benefits	Early recognition of high-risk, potentially problematic IHs facilitates early specialist evaluation and management and potential avoidance of complications
Risks, harm, cost	Unnecessary parental concern regarding lesions inappropriately characterized as high-risk IHs
Benefit-harm assessment	The benefits of identifying high-risk IHs outweigh the harm
Intentional vagueness	None
Role of patient preference	None
Exclusions	Vascular lesions that are not true IHs
Strength	Strong recommendation
Key references	5–23

further compromising the narrowest portion of the pediatric airway. Although the mean age at the time of diagnosis is about 4 months, symptoms usually present much earlier but are often mistaken as infectious or inflammatory croup or reactive airway disease.[25–27] Most children who are affected develop biphasic stridor and barky cough as the IH enlarges. Approximately half of infants in whom an airway IH is diagnosed also will have a cutaneous IH. Segmental IH of the lower face (“beard distribution”) or anterior neck and oral and/or pharyngeal mucosal IHs are the greatest risk factors for an airway IH.[6,27–29]

Hepatic hemangiomas have been characterized as occurring in 3 patterns: focal, multifocal, and diffuse; the latter 2 are attributable to IHs, whereas focal lesions more often represent congenital hemangiomas.[7,8] Most multifocal hepatic IHs are asymptomatic and do not require treatment. However, a minority of these lesions are associated with macrovascular shunting, causing high flow that can, in rare cases, result in high-output cardiac failure. So-called “diffuse” hepatic IHs are another rare subset that confers an even greater risk for morbidity and mortality. Infants who are affected typically present before 4 months of age with severe hepatomegaly, which can lead to potentially lethal abdominal compartment syndrome attributable to compromised ventilation, renal failure attributable to renal vein compression, or compromised inferior vena cava blood flow to the heart.[7,8] A consumptive form of hypothyroidism caused by the inactivation of thyroid hormones by type 3 iodothyronine deiodinase present in IH tissue can also be a complication of multifocal or diffuse hepatic IHs.[9] Although liver IHs can occasionally be seen in infants with 1 or no IH of the skin, the greatest risk for liver IHs is in infants who have 5 or more cutaneous IHs,[10] for whom screening ultrasonography is recommended (see KAS 2A).[11,30] Other sites of extracutaneous hemangiomas can occur, including the gastrointestinal tract, brain, and other organs. However, such involvement is rare and occurs mostly in association with large segmental IHs, and screening for these extracutaneous hemangiomas is not recommended unless signs or symptoms are present.[31,32] Severe bleeding, although often feared by parents, is an extremely rare complication of ulcerated IHs (see discussion of ulceration). Another potentially life-threatening complication is severe coarctation of the aorta not attributable to IHs but rather to structural anomalies seen in association with IHs in PHACE syndrome.

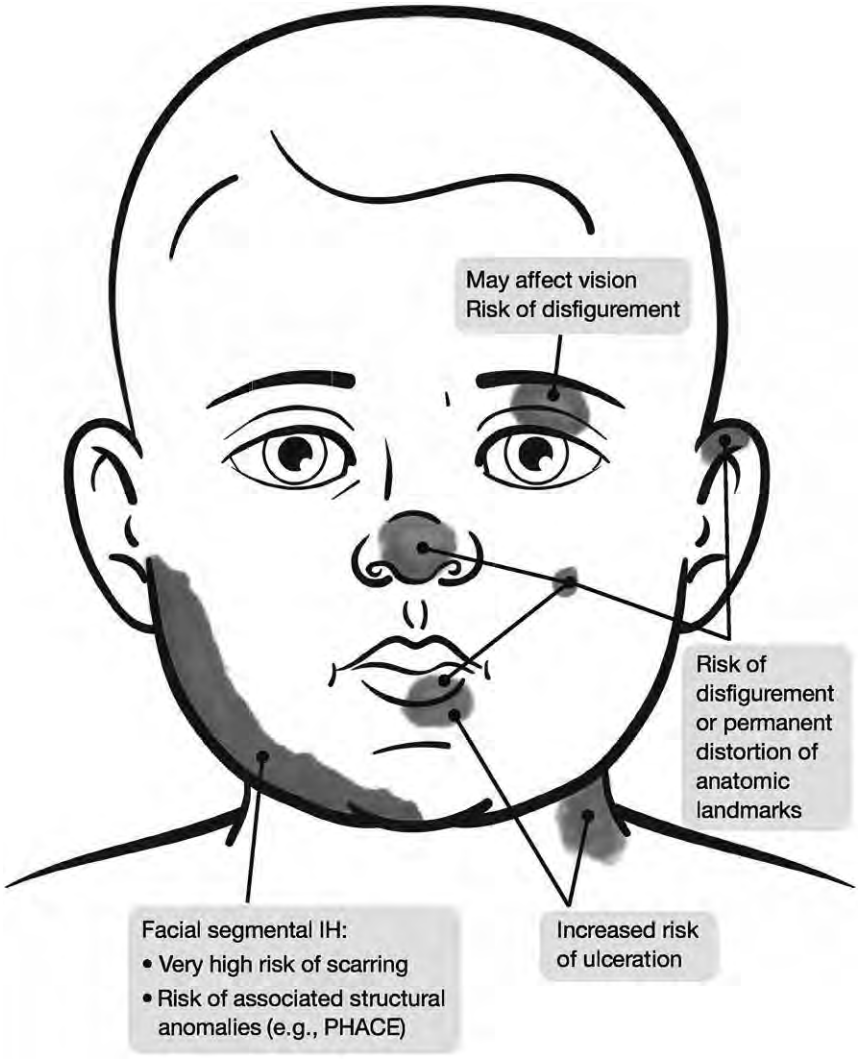


FIGURE 2
High-risk IHs involving the face and neck.

Functional Impairment

Examples of functional impairment include visual disturbance and interference with feeding because of IH involvement of the lips or mouth. IHs occurring in the periocular region have the potential to cause mechanical ptosis, strabismus, anisometropia, or astigmatism, which can quickly lead to the development of amblyopia.[12,13,33] Specific characteristics that place an infant at a higher risk for amblyopia include an IH size of >1 cm, upper eyelid involvement, associated ptosis, eyelid margin changes, medial location, and segmental morphology or displacement of the globe.[13,34,35] Feeding impairment can occur in infants with IHs involving either the perioral region or the airway. Infants with ulcerated lip IHs may have feeding difficulties secondary to severe pain.[36] Airway IHs may complicate breathing and swallowing, leading also to impaired feeding.[37]

Ulceration

Skin or mucosal ulceration of the IH surface occurs with an estimated incidence of 5% to 21% in referral populations.[14,38] Ulceration can lead to significant pain, bleeding, and secondary infection and virtually always results in scarring. Depending on the anatomic site of involvement, it can result in disfigurement. Ulceration occurs most frequently in infants younger than 4 months, during the period of active IH proliferation. Certain types of IHs are at higher risk, including superficial and mixed types, segmental IHs, and those involving the scalp, neck, and perioral, perineal, perianal, and intertriginous sites, the latter likely caused by maceration and friction. In addition, protuberant IHs can ulcerate as a result of trauma. Although concern for potential bleeding in IHs is common among caregivers and providers, most IH bleeding is minor and easily controllable with pressure. In rare cases, particularly IHs involving the scalp or with deep ulceration, bleeding can be more profuse, even life-threatening.[14,15]

Associated Structural Anomalies

A small subset of children with IHs have associated congenital anomalies. The best known phenomenon is PHACE syndrome (OMIM 606519).[39] The acronym "PHACES" is sometimes used instead to include potential ventral midline defects, specifically sternal cleft and/or supraumbilical raphe. Cerebrovascular anomalies, present in more than 90% of patients with PHACE syndrome, are the most common extracutaneous feature of the syndrome, followed by cardiac anomalies (67%) and structural brain anomalies (52%). The hallmark of PHACE syndrome is a large (often >5 cm in diameter) segmental IH that typically involves the face, scalp, and/or neck, although in rare cases, the face or scalp are spared, with a segmental IH located on the torso and upper extremity instead.[5,16] The risk of PHACE syndrome in an infant presenting with a large segmental IH of the head or neck is approximately 30%.[5] Revised consensus criteria for the diagnosis of PHACE syndrome and the care of infants who are affected have recently been published.[16]

LUMBAR syndrome may best be viewed as the "lower half of the body" equivalent of PHACE syndrome.[17] IHs in LUMBAR syndrome are almost invariably segmental, involving the

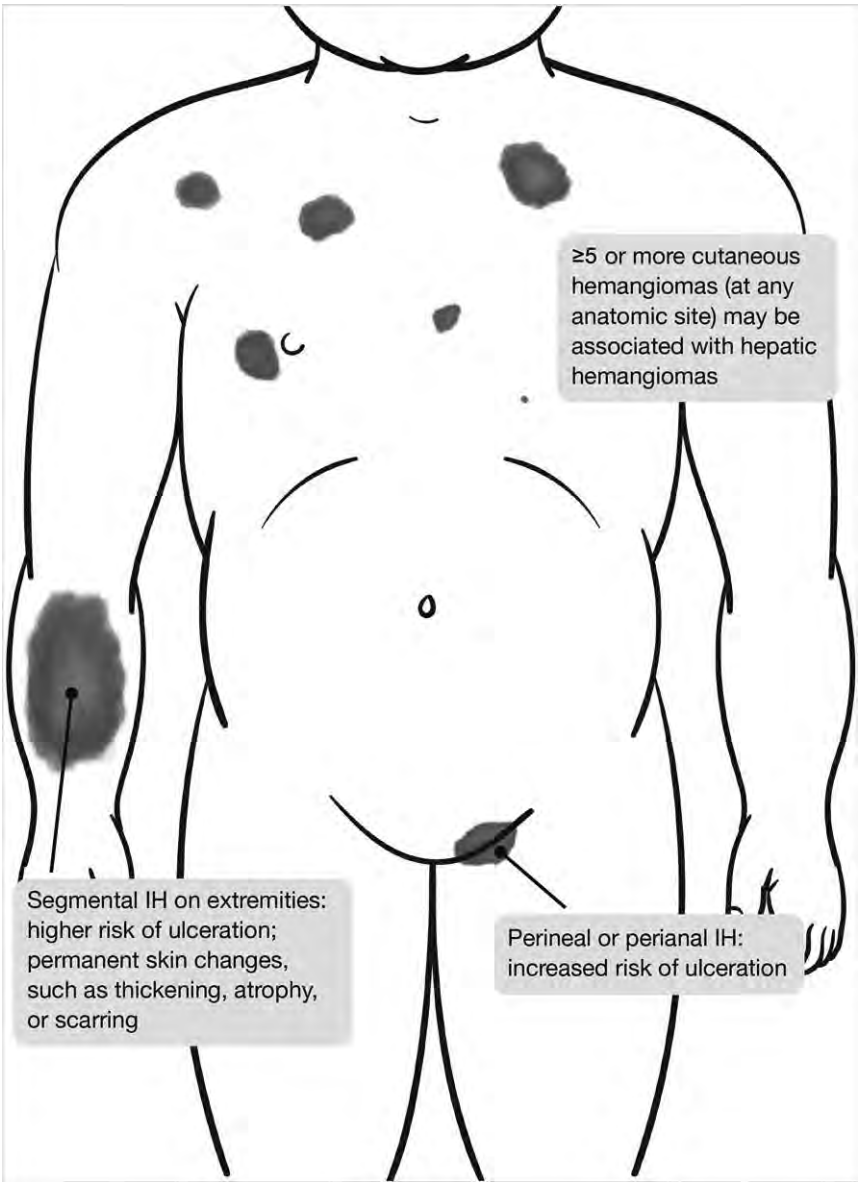


FIGURE 3
High-risk IHs involving the trunk, extremities, and perineum.

lumbosacral or perineal skin and often extending onto 1 leg. Many IHs in LUMBAR syndrome are minimally proliferative morphologically, with telangiectatic vascular stains predominating over bulkier superficial hemangiomas. In such cases, ulceration can be an early clue to the diagnosis.[17] Rarely, undergrowth or overgrowth of an affected limb may be present. Like PHACE syndrome, the cutaneous IH and underlying anomalies in LUMBAR syndrome reveal regional correlation. Myelopathy, particularly spinal dysraphism, is the most common extracutaneous anomaly.[17]

Disfigurement

IHs can lead to permanent disfigurement either via scarring of the skin or distortion of anatomic landmarks (see Table 3 for specific information). The risk of disfigurement is much higher than the risk of functional or life-threatening consequences. The majority of infants who receive treatment of IHs do so to prevent uncontrolled growth leading to permanent disfigurement.[1,18,40]

This indication for treatment represents a paradigm shift from the hands-off approach of the late 1950s through 1980s, when many experts recommended treatment only for those IHs causing functional impairment.[41] One reason for this change is an increased recognition that although IHs involute, they often leave behind permanent skin changes that, although not life or function threatening, are potentially life altering.[19,20] Moreover, with the advent of β-blocker therapies for IHs, there are now better treatment options with greater efficacy and lower potential toxicity than oral corticosteroids, the previous gold standard. There is also increased recognition that parental and patient quality of life can be adversely affected by visible birthmarks and resultant scarring, particularly in areas that cannot be easily covered with clothing, such as the face, neck, arms, and hands, as well as other emotionally sensitive areas, such as the breasts and genitalia.[42–44]

The precise risk of a patient in a primary care setting having permanent skin changes from an IH is not known, but in a referral setting, such changes are seen in 55% to 69% of those with untreated IHs.[19,20] This risk is greatest in IHs with a prominent and thick superficial (strawberry) component, especially when there is a steep step-off (ie, ledge effect) from affected to surrounding normal skin. However, the degree of superficial thickening may be difficult to predict in early infancy. Thus, even in IHs that do not initially appear to be high risk, it is prudent to serially follow lesion growth and establish a means for prompt evaluation if ongoing or rapid growth is observed because this could alter management.

Key Action Statement 1B (Table 7)

After identifying an IH as high risk, clinicians should facilitate an evaluation by a hemangioma specialist as soon as possible (grade X, strong recommendation).

The purpose of this statement is to ensure timely evaluation by a

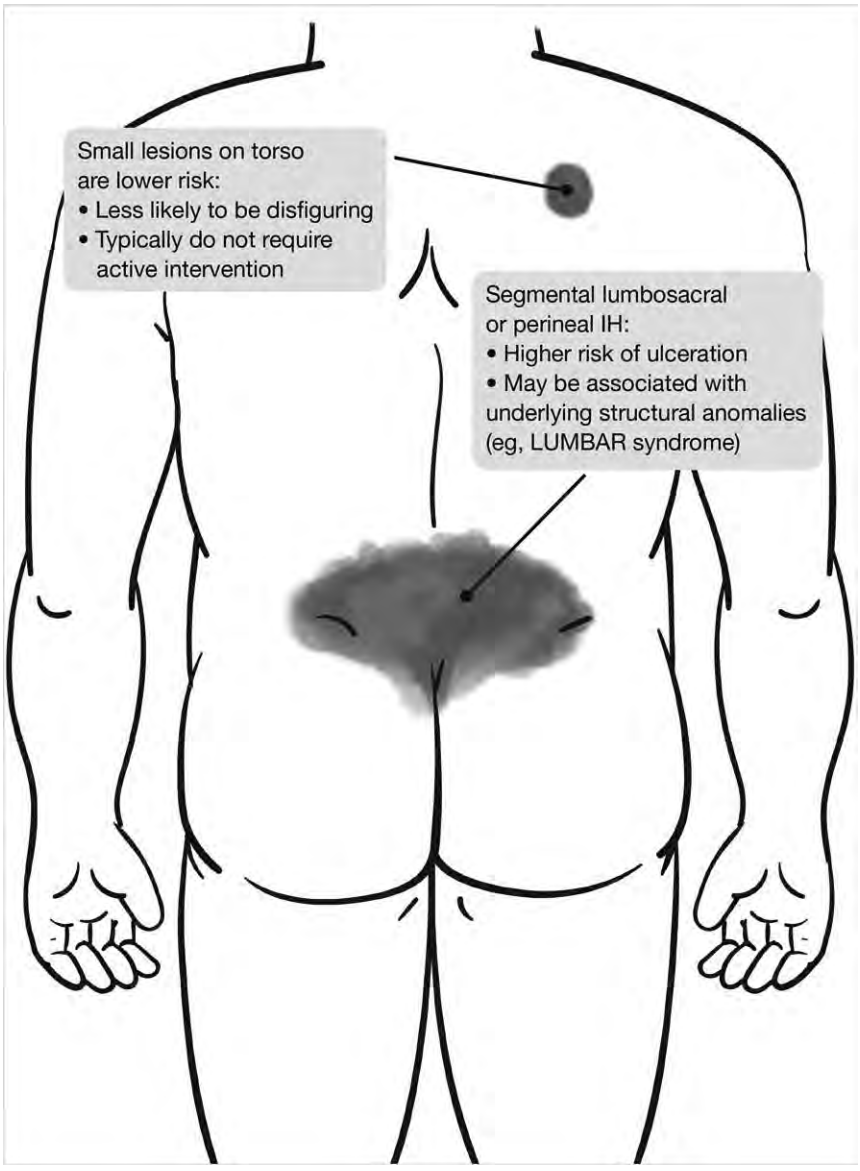


FIGURE 4
IHs involving the posterior trunk.

hemangioma specialist of an IH identified as high risk. IH is a disease with a window of opportunity in which to intervene and prevent poorer outcomes, and this critical time frame for optimizing outcomes can be missed if there are delays in referral or treatment. Recent literature suggests that the presence and growth of IHs is apparent much earlier than originally thought.[21,22] Premonitory findings appear in the skin during early infancy, including localized blanching or macular telangiectatic erythema.[21] As endothelial cell proliferation continues, the IH enlarges, becomes more elevated, and develops a rubbery consistency. IHs typically have their clinical onset before 4 weeks of age.[21,22]

Several studies have helped to better characterize the proliferative phase of IHs. Although IHs proliferate for variable periods of time and to varying degrees, the most rapid growth of superficial IHs typically occurs between 1 and 3 months' chronological age.[21] IHs reach 80% of their ultimate size by 3 months of age, and the large majority of IHs have completed growth by 5 months of age.[22] In a study in which parents' photographs were used, early IH growth was found to be nonlinear, with an accelerated period of rapid growth between 5 and 7 weeks of age, and the optimal time for referral or initiation of treatment was 1 month of age, a time far earlier than the time most infants with IHs are typically referred to (or seen by) hemangioma specialists.[21,22]

These observations regarding growth are helpful, but their impact in individual case management is limited by the tremendous degree of disease heterogeneity of IHs. Even for the most experienced clinicians, it can be difficult to predict the degree of IH growth until several weeks to months after the lesion is first noticed. By that time, damage to the dermis and subcutaneous tissues as well as permanent distortion of important anatomic landmarks, such as the nose or lips, may already have occurred.[19,20,44] Hence, decisions regarding intervention must be based on risk stratification, including the age of the child (in anticipation of possible IH growth), health considerations (like prematurity), anatomic site, the size of the IH, any actual or potential complications, and parental preferences. In high-risk IHs, a wait-and-see approach can result in a missed window of opportunity to prevent adverse outcomes.

The rate of growth and ultimate size of an IH can vary dramatically from patient to patient. Predicting the growth of a particular IH is, therefore, difficult and made even more challenging by the minority of lesions that do not exhibit the typical pattern of proliferation followed by slow involution.[23,45] Differences in growth can even be evident when comparing 1 IH to another on the same patient. For example, in patients who have 2 or more IHs, 1 lesion may become large and problematic, and others may barely grow. A subset of IHs known as infantile hemangiomas with minimal or arrested growth (IH-MAGs) typically present as a patch of fine or coarsely reticulated

TABLE 7 Key Action Statement 1B: After identifying an IH as high risk, clinicians should facilitate an evaluation by a hemangioma specialist as soon as possible (grade X, strong recommendation).

Aggregate Evidence Quality	Grade X
Benefits	Potential for early intervention for IH at a high risk of causing complications
Risks, harm, cost	Potential for delay in intervention if specialist evaluation cannot be arranged promptly or is unavailable in the geographic region; costs associated with specialist evaluation for IH incorrectly identified as high risk
Benefit-harm assessment	The benefits of specialist evaluation outweigh harms and costs
Intentional vagueness	The subcommittee recognizes the multidisciplinary nature of IH management and the diverse level of expertise among individuals in this field. As a result, the definition of a specialist with expertise in vascular birthmarks is vague. The subcommittee also recognizes that the time frame "as soon as possible" is vague.
Role of patient preference	Parental preference should be considered in the decision to see a specialist and in the choice of specialist
Exclusions	IHs not considered high risk
Strength	Strong recommendation
Key references	19–23

telangiectasias, often within a zone of vasoconstriction.[23] They may be mistaken for a port-wine stain or other vascular birthmark. Although they lack the robust proliferative phase characteristic of many IHs, IH-MAGs may be associated with complications, such as ulceration or, if segmental, structural anomalies. The growth trajectory of deeper IHs or those with deeper soft-tissue components also differs from that of localized superficial IHs, often presenting at a later age (eg, 1–2 months and, occasionally, even later).[22]

On the basis of this information, the consensus recommendation of the subcommittee is that patients with IHs identified as high risk have expedited consultation and/or referral to a hemangioma specialist (Supplemental Table 22, Supplemental Fig 11). The type of hemangioma specialist may depend on the specific concern (eg, a hemangioma specialist experienced in airway management will be needed if concern exists for a subglottic hemangioma). Because the time to appointment with a hemangioma specialist may exceed the window of opportunity during which evaluation and possible treatment would be of maximum benefit, those who care for infants with IHs should have mechanisms in place to expedite such appointments, including the education of office staff to give young infants with high-risk IHs priority appointments. In-person consultation may not always be possible or mandatory. Clinicians may also use telemedicine (either live interactive or store and forward of photographs taken in the office) to assist with triage, evaluation, and management.

Key Action Statement 2A (Table 8)

Clinicians should not perform imaging unless the diagnosis of IH is uncertain, there are 5 or more cutaneous IHs, or associated anatomic abnormalities are suspected (grade B, moderate recommendation).

The purpose of this statement is to provide guidance to clinicians regarding the indications for imaging of IHs. Most IHs can be diagnosed clinically. Therefore, imaging of IHs is not indicated for diagnostic purposes unless the lesion has an atypical appearance (ie, the diagnosis is uncertain) or it behaves in a manner that is inconsistent with the expected proliferative growth and involution phases within the expected time frame.[46,47] Noninvasive imaging may be used to monitor response to treatment but typically is not required.[47] Occasionally, differentiating an IH from a highly vascularized malignant tumor may be difficult. Clinical history, response to therapy, and imaging characteristics considered together are extremely important in this differentiation. In rare cases, a tissue biopsy may be needed to confirm the diagnosis.

Clinicians should use imaging, specifically abdominal ultrasonography, if 5 or more cutaneous IHs are present to screen for hepatic IH.[30] Ultrasonography has a sensitivity of 95% for detection of hepatic hemangiomas and avoids the need for sedation and exposure to ionizing radiation.[46] Early detection of these lesions may lead to improved monitoring and initiation of appropriate treatment, resulting in decreased morbidity and mortality.[8,46,49]

Imaging also is indicated if concern exists for structural anomalies, as would be the case in infants at risk for PHACE syndrome or LUMBAR syndrome. These infants would typically have large (eg, >5 cm in diameter) segmental facial or scalp IHs or segmental IHs of the perineum, gluteal cleft, or lumbosacral area, with or without lower extremity IHs (see KAS 2C for further discussion).[16,17,47,48]

Key Action Statement 2B (Table 9)

Clinicians should perform ultrasonography as the initial imaging modality when the diagnosis of IH is uncertain (grade C, weak recommendation).

Ultrasonography (with Doppler imaging) is the initial imaging modality of choice when the diagnosis of IH is uncertain. The study can be performed without sedation and does not necessitate exposure to ionizing radiation, which can be risky, particularly in young infants. On ultrasonography, most IHs appear as a well-defined mass with high-flow vascular characteristics and no arteriovenous shunting (an exception to the latter is that hepatic IHs may exhibit arteriovenous shunting). This may change as the IH involutes and has a more fatty appearance with decreased vascularity.[47,50] Doppler ultrasonography is also the modality of choice when screening for hepatic IHs and can be used to monitor

TABLE 8 Key Action Statement 2A: Clinicians should not perform imaging unless the diagnosis of IH is uncertain, there are 5 or more cutaneous IHs, or associated anatomic abnormalities are suspected (grade B, moderate recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Avoid the cost, risk of sedation, and radiation associated with unnecessary imaging
Risks, harm, cost	Potential misdiagnosis if imaging is not performed
Benefit-harm assessment	Benefits outweigh harm
Intentional vagueness	None
Role of patient preference	Minimal; when parental anxiety is significant, ultrasonography is a low-cost and low-risk means of confirming the diagnosis
Exclusions	None
Strength	Moderate recommendation
Key references	8,46–48

TABLE 9 Key Action Statement 2B: Clinicians should perform ultrasonography as the initial imaging modality when the diagnosis of IH is uncertain (grade C, weak recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Select the appropriate imaging study to aid in diagnosis and identify associated abnormalities; avoid ionizing radiation and sedation
Risks, harm, cost	Risk that ultrasonography may not be sufficiently diagnostic or may result in the misdiagnosis of a lesion believed to represent an IH
Benefit-harm assessment	Benefits outweigh harms
Intentional vagueness	None
Role of patient preference	Minimal
Exclusions	None
Strength	Weak recommendation
Key references	47,50

progression of disease and response to treatment.[47]

Key Action Statement 2C (Table 10)

Clinicians should perform MRI when concerned about associated structural abnormalities (eg, PHACE syndrome or LUMBAR syndrome) (grade B, moderate recommendation).

Imaging for associated structural anomalies is indicated in infants at risk for PHACE syndrome or LUMBAR syndrome. For example, an infant with a large (eg, >5 cm in diameter) segmental facial or scalp IH is at risk for PHACE syndrome, and further evaluation with MRI and/or magnetic resonance angiography (MRA) of the head and neck (including the aortic arch and brachiocephalic origins) and echocardiography is advisable.[16,47]

For patients with segmental IHs of the perineum, gluteal cleft, or lumbosacral area (with or without lower extremity IHs), imaging for LUMBAR syndrome should be considered.[17,48] If there is uncertainty about whether there is a risk of associated structural anomalies, consultation with a hemangioma specialist or other appropriate expert (eg, pediatric neurologist, neurosurgeon, or radiologist) can be helpful to determine if imaging is required and which studies should be performed.

MRI is the optimal imaging modality to define underlying structural abnormalities, and contrast is needed to assess vascular components.[46] MRA can illustrate the vascular anatomy. Thus, MRI and MRA, with and without contrast of the head and neck, are the best studies to detect PHACE syndrome. MRI does not use ionizing radiation but may require sedation given the duration of the examination.[51,52] The duration of imaging is important because it has been theorized that prolonged (>3 hours) or repeated exposures to general anesthetic and sedative drugs in children younger than 3 years may negatively affect brain development.[53,54] Single, brief exposures are unlikely to have similar effects. As more rapid MRI scanning protocols are developed, the need for sedation may diminish. As an alternative to sedation, young infants fed immediately before an MRI and swaddled may sleep through the procedure. Discussion between the radiologist, ordering clinician, and sedation team is critical to determine the optimal imaging and sedation protocols.[55]

In patients in whom there is a risk of LUMBAR syndrome, spinal ultrasonography (for those with a corrected age of less than 6 months) and Doppler ultrasonography of the abdomen and pelvis can be used as an initial screen for abnormalities.[56–58] Ultimately, however, MRI likely will be required to provide greater definition. For example, if a high suspicion for spinal abnormalities remains despite normal ultrasonography (ie, there are associated markers of dysraphism [eg, sacral dimple, skin appendage, tuft of hair, and lipoma]), MRI is a more sensitive diagnostic modality.[47]

Computed tomography is not the modality of choice for imaging IHs because it involves ionizing radiation, which should be avoided in children, particularly young infants, unless absolutely necessary. Advantages of computed tomography are that it can be rapidly performed and may not require sedation.

MANAGEMENT: PHARMACOTHERAPY

Key Action Statement 3A (Table 11)

Clinicians should use oral propranolol as the first-line agent for IHs requiring

TABLE 10 Key Action Statement 2C: Clinicians should perform MRI when concerned about associated structural abnormalities (eg, PHACE syndrome or LUMBAR syndrome) (grade B, moderate recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Select the appropriate imaging study to aid in diagnosis and identify associated abnormalities; avoid ionizing radiation and sedation
Risks, harm, cost	Risk of sedation or general anesthesia Cost of MRI (but offers greater diagnostic sensitivity)
Benefit-harm assessment	Benefits outweigh harms
Intentional vagueness	None
Role of patient preference	Minimal
Exclusions	None
Strength	Moderate recommendation
Key references	46,51–55

TABLE 11 Key Action Statement 3A: Clinicians should use oral propranolol as the first-line agent for IHs requiring systemic treatment (grade A, strong recommendation).

Aggregate Evidence Quality	Grade A
Benefits	Improve IH treatment; avoid adverse effects associated with oral steroid therapy
Risks, harm, cost	Occurrence of adverse effects associated with propranolol use (see KAS 3D); medication cost and cost of hospitalization if drug is initiated while infant is an inpatient
Benefit-harm assessment	Benefits outweigh harms
Intentional vagueness	None
Role of patient preference	Parents should be involved in shared decision-making regarding treatment.
Exclusions	Caution (but not exclusion) in infants <5 wk of age, postconceptional age of <48 wk; potential exclusions that require appropriate subspecialty evaluation and/or clearance; evidence of cardiogenic shock or heart failure; sinus bradycardia; heart block greater than first degree; known or suspected PHACE syndrome, including presence or risk of coarctation of the aorta and cerebrovascular anomalies; known asthma and/or reactive airway disease; known hypersensitivity to propranolol
Strength	Strong recommendation
Key references	3,46,59–61

systemic treatment (grade A, strong recommendation).

The purpose of this statement is to advise clinicians that oral propranolol is the current treatment of choice for IHs requiring systemic therapy. After the serendipitous observation of its utility in treating IHs,[59] propranolol, a nonselective antagonist of both β-1 and β-2 adrenergic receptors, has evolved to become the treatment of choice for IHs.[1,3,60] The precise mechanisms of action of propranolol on IHs are unclear but have been hypothesized to be attributable to vasoconstriction, angiogenesis inhibition, induction of apoptosis, inhibition of nitric oxide production, and regulation of the renin-angiotensin system.[61–69] Oral propranolol hydrochloride (Hemangeol) was approved by the US Food and Drug Administration (FDA) in March 2014 for use in proliferating IHs requiring systemic therapy. This therapy has now replaced the previous gold standard therapy for threatening IHs, systemic or intralesional corticosteroids.[70]

In the AHRQ review, 18 studies were included in a network meta-analysis of the effectiveness and harms of corticosteroids and β-blockers. The mean estimate of expected clearance for oral propranolol was 95%, which was superior to other interventions.[46] Ten studies compared propranolol versus another modality, including steroids, pulsed-dye laser (PDL), bleomycin, or other treatments (Table 12). Propranolol was more effective in 3 studies, effectiveness did not differ significantly in 2 other studies, and studies comparing propranolol versus steroids to reduce IH size had conflicting results. Harms are discussed in subsequent KASs, but in the AHRQ analysis, propranolol's superior safety profile is confirmed.

The subcommittee's additional review yielded another 19 studies, 4 of which met inclusion criteria for benefits of interventions (and 9 of which met inclusion criteria for harms of interventions). These 4 studies evaluated propranolol versus placebo or observation. Propranolol was associated with significantly greater clearance of IH compared with the control group in all studies. The strength of evidence (SOE) was considered high for greater effectiveness of propranolol versus placebo or observation. The review also confirmed the superiority of oral propranolol over a variety of comparators. Propranolol was superior to ibuprofen and paracetamol in treating ulcerated hemangiomas[71] and to oral captopril in patients with problematic IHs.[72] In a randomized controlled trial (RCT) of oral propranolol compared with observation for IHs, the overall efficacy of propranolol (defined as excellent, good, or medium response) was 98.97%, compared with 31.25% in the observation group ($P < .05$).[73] Last, Aly et al[74] compared oral propranolol alone versus oral propranolol combined with 2 weeks of "priming" with oral prednisolone. Those in the prednisolone-primed propranolol group showed a statistically superior reduction in IH size at weeks 2, 4, and 8 compared with the propranolol group, but the 6-month response was equivocal for both groups regarding all assessed variables.[74]

TABLE 12 AHRQ Summary of Comparative Efficacy of Various Treatments for IHs

Drug	Mean Estimate of Expected Clearance, %	95% Bayesian Credible Interval, %
Propranolol	95	88–99
Topical timolol	62	39–83
Intralesional triamcinolone	58	21–93
Oral steroid	43	21–66
Control	6	1–11

Limited data exist on the utility of β-blockers other than propranolol or different delivery mechanisms for propranolol. The AHRQ review included 3 small studies comparing propranolol versus nadolol or atenolol and 1 study comparing oral, intralesional, and topical propranolol. Atenolol and nadolol each demonstrated effectiveness on lesion size, with little difference in efficacy between propranolol and atenolol and greater efficacy of nadolol in 1 small study. The review did not find differences in response with propranolol, nadolol, or atenolol, but the SOE in comparing these was low.[46] The subcommittee's additional review yielded 1 article on oral atenolol for IH, which did not meet the AHRQ inclusion criteria for comparative effectiveness but revealed an excellent treatment response in 56.5% of patients.[75]

Key Action Statement 3B (Table 13)

Clinicians should dose propranolol between 2 and 3 mg/kg per day unless there are comorbidities (eg, PHACE syndrome) or adverse effects (eg, sleep disturbance) that necessitate a lower dose (grade A, moderate recommendation).

The purpose of this statement is to provide clinicians guidance in dosing oral propranolol for IHs. To date, authors of most studies favor dosing at 2 to 3 mg/kg per day. An RCT of 456 infants compared a placebo versus 1 of 4 propranolol regimens (1 mg/kg per day or 3 mg/kg per day for 3 or 6 months duration). The regimen of 3 mg/kg per day for 6 months was superior, with complete or nearly complete resolution in 60% of patients, compared with 4% of patients in the placebo arm ($P < .0001$).[76] The FDA approval of propranolol hydrochloride oral solution (4.28 mg/mL) recommends a starting dose of 0.6 mg/kg twice daily, with a gradual increase over 2 weeks to a maintenance dose of 1.7 mg/kg twice daily (3.4 mg/kg per day based on expression as the hydrochloride salt of propranolol). As noted in the AHRQ review, other studies typically reported dosing of 2 to 2.5 mg/kg per day,[46] and a multidisciplinary, multiinstitutional expert panel and a European expert consensus group[1,61] support a starting dose of 1 mg/kg per day and a target dose of 2 to 3 mg/kg per day. Data comparing 2 and 3 mg/kg per day are lacking.

Similarly, available data do not permit evidence-based recommendations on dosing frequency (twice daily versus 3 times daily), but both the FDA and the European Medicine Evaluation Agency labeling is for twice-daily dosing. The site for initiation of propranolol (outpatient versus inpatient) is evolving as more evidence accumulates that cardiovascular and other acute toxicities occur rarely. Although in both the aforementioned consensus articles, initiation in an inpatient setting is favored for infants younger than 8 weeks, those with cardiovascular or respiratory comorbidities, and those with poor social support, FDA labeling sanctions initiation in an outpatient setting for infants >5 weeks' corrected gestational age.

A duration of 6 months of therapy was shown to be superior to 3 months in the large RCT conducted by Léauté-Labrèze et al.[76] In the AHRQ review, the duration of propranolol treatment ranged from 3 to 13 months.[46] Rebound growth during tapering or after stopping the medication may occur in 10% to 25% of patients and can occur even after 6 months of therapy.[18,76] A large multicenter retrospective cohort study found the greatest risk of rebound occurred in those in whom therapy was discontinued at <12 months of age (and especially before 9 months), and the lowest risk was in those in whom treatment was discontinued between 12 and 15 months of age.[18] Risk factors for rebound growth noted in this study were the presence of mixed or deep morphology and female sex. These observations have led many experts to recommend continuing therapy until at least 1 year of age.

Dosing may need to be modified in certain situations. Patients with PHACE syndrome may have an increased risk of stroke, and this risk may be greater if certain neurovascular anomalies are present.[16] In patients who merit systemic IH therapy, the benefits and risks must be carefully weighed. Evaluation with MRI and/or MRA of the head and neck and echocardiography should be performed before or shortly after the initiation of therapy.[61] If patients who are at high risk require treatment with propranolol, it is advisable to use the lowest effective dose, slowly titrate the dose, and administer the drug 3 times daily (to minimize abrupt changes in blood pressure); comanagement with a pediatric neurologist is recommended.[1,16,61,77] Other patients who may require lower propranolol doses include those with progressive IH ulceration while receiving therapy and those who experience adverse effects (such as sleep disturbances).

Key Action Statement 3C (Table 14)

Clinicians should counsel that propranolol be administered with or after feeding and that doses be held at times of diminished oral intake or vomiting to reduce the risk of hypoglycemia (grade X, strong recommendation).

TABLE 13 Key Action Statement 3B: Clinicians should dose propranolol between 2 and 3 mg/kg per day unless there are comorbidities (eg, PHACE syndrome) or adverse effects (eg, sleep disturbance) that necessitate a lower dose (grade A, moderate recommendation).

Aggregate Evidence Quality	Grade A
Benefits	The recommended doses have been associated with high clearance rates of IH
Risks, harm, cost	Response rates for higher or lower doses have not been well studied
Benefit-harm assessment	Benefits outweigh harms
Intentional vagueness	None
Role of patient preference	Parents will be involved in the decision about dosing in the setting of PHACE syndrome or the occurrence of adverse effects
Exclusions	See KAS 3A; dosing may be modified if comorbidities exist
Strength	Moderate recommendation
Key references	1,46,61,76

TABLE 14 Key Action Statement 3C: Clinicians should counsel that propranolol be administered with or after feeding and that doses be held at times of diminished oral intake or vomiting to reduce the risk of hypoglycemia (grade X, strong recommendation).

Aggregate Evidence Quality	Grade X
Benefits	Reduce the likelihood of adverse reactions
Risks, harm, cost	Risk that parents will decline therapy because of concerns about potential medication adverse effects
Benefit-harm assessment	Benefits outweigh harms
Intentional vagueness	None
Role of patient preference	None
Exclusions	None
Strength	Strong recommendation
Key references	46,60,61,76,78–80

The purpose of this statement is to reinforce the importance of administering oral propranolol with feeds and of holding therapy at times of restricted oral intake to prevent hypoglycemia and hypoglycemia-induced seizures. The association between hypoglycemia and propranolol in infants and children is well established and is related to effects on glycogenolysis and gluconeogenesis.[78] β-blockade by propranolol can affect these processes, and infants and children may be particularly susceptible to this effect.[78,79] Early clinical features of hypoglycemia in infants, which may be masqueraded by β-adrenergic blockade, include sweating, tachycardia, shakiness, and anxious appearance, whereas later manifestations (signs of neuroglycopenia) may include lethargy, poor feeding, apnea, seizures, stupor, and loss of consciousness.[79]

The AHRQ review identified 24 comparative studies (4 good quality) and 56 case series (4 good quality) that reported harms data of β-blockers for IHs. Rates of clinically important harms (hypoglycemia, hypotension, bradycardia, and bronchospasm) varied widely, and the authors assigned a moderate SOE for the association of propranolol with both clinically important and minor harms (with high study limitations).[46] Harms overall did not cause treatment discontinuation.

The subcommittee's additional review yielded 8 reports that met inclusion criteria for harms regarding oral propranolol for treatment of IHs. These reports provided more detailed information about the occurrence of hypoglycemia. Three of the 8 articles reported hypoglycemia; these articles included 1021 patients, 10 of whom experienced hypoglycemia (3 of these suffered hypoglycemic seizures in the setting of viral gastroenteritis and poor oral intake).[80–82]

In a large meta-analysis of oral propranolol for IHs not included in the AHRQ review, adverse events were reported for 1945 of 5862 patients who were treated.[60] The investigators identified 24 cases of hypoglycemia and 2 cases of hypoglycemic seizures among 3766 patients who were treated with propranolol from their literature review (some of whom are included in aforementioned studies). Of the 14 events with resolution details, 9 led to dose adjustment or temporary discontinuation of propranolol, and 1 led to permanent discontinuation of treatment. The authors mention that 1 case of hypoglycemic seizure was related to overdose, and the other was associated with diminished oral intake because of infection.[60]

Although the risk of hypoglycemia must be considered when prescribing oral propranolol for IHs, routine glucose screening is not indicated.[1,61] Hypoglycemia occurs infrequently and can be minimized with appropriate education of caregivers on the importance of administering propranolol during or immediately after a feeding and of temporarily withdrawing therapy during periods of fasting (including poor oral intake because of illness or before general anesthesia) or vomiting.[60] Prolonged fasting should be avoided, and parents should be advised that hypoglycemia becomes more likely after ≥8 hours of fasting in infants and young children.[83,84]

Key Action Statement 3D (Table 15)

Clinicians should evaluate patients for and educate caregivers about potential adverse effects of propranolol, including sleep disturbances, bronchial irritation, and clinically symptomatic bradycardia and hypotension (grade X, strong recommendation).

The purpose of this statement is to increase awareness of potential propranolol-associated adverse effects other than hypoglycemia for clinicians

and caregivers of patients receiving this medical therapy for IHs. Propranolol has been used in pediatric patients for decades, primarily in an off-label fashion. In young infants, is has been used primarily for cardiac disorders and for the treatment of thyrotoxicosis at doses up to 6 to 8 mg/kg per day. Despite this use, many pediatricians will be unfamiliar with the drug, and reviewing its possible adverse effects is warranted.

As noted in the discussion of KAS 3C, the AHRQ review identified a number of adverse effects during propranolol treatment. Adverse effects most frequently reported included sleep disturbances, cold extremities, gastrointestinal symptoms, bronchial irritation (classified as hyperreactivity, bronchospasm, bronchiolitis, and cold-induced wheezing), and a decrease in heart rate or blood pressure. Rates of clinically important harms (hypoglycemia, hypotension, bradycardia, and bronchospasm) varied widely across the studies, and the authors assigned a moderate SOE for the association of propranolol with both clinically important and minor harms (with high study limitations).[46] Overall, harms did not cause treatment discontinuation.

Our additional review yielded 8 reports that met inclusion criteria for harms of interventions. Sleep disturbance, sleeping disorders, agitation during the night, and nightmares or night terrors were mentioned in 6 of 8 reports and occurred in 2% to 18.5% of patients who were treated.[80,82,85,86,89,90] In 3 of these 6 reports, propranolol treatment was modified (reduction in dosage, earlier-evening dosing, and early discontinuation of therapy) in response to these effects.[80,82,85]

In 4 reports, possible respiratory adverse effects were mentioned, including labored breathing in 0.9%,[86] breathing-related problems in 11.5%,[89] respiratory disorders in 3.4%,[80] and wheezing or bronchiolitis in 12.9%.[82] In 3 of these series treatment modifications in response to the respiratory events were mentioned, including temporary discontinuation of therapy[80,82] and decreased dosage of propranolol.[89]

TABLE 15 Key Action Statement 3D: Clinicians should evaluate patients for and educate caregivers about potential adverse effects of propranolol, including sleep disturbances, bronchial irritation, and clinically symptomatic bradycardia and hypotension (grade X, strong recommendation).

Aggregate Evidence Quality	Grade X
Benefits	Recognition of adverse effects of propranolol treatment
Risks, harm, cost	Risk of caregivers declining medical therapy because of concern about potential adverse effects
Benefit-harm assessment	Benefits outweigh harms
Intentional vagueness	None
Role of patient preference	None
Exclusions	None
Strength	Strong recommendation
Key references	3,46,61,76,80,85–88

Although bradycardia and hypotension are known to accompany propranolol-associated β-receptor blockade, both tend to be mild and asymptomatic in children treated for IHs who have no preexisting cardiac comorbidities.[3,84,87,88,91–93] In the subcommittee's review, only 1 of the 8 reports mentioned hypotension or bradycardia as an adverse event, with 1 of 906 patients (0.1%) exhibiting bradycardia and 2 of 906 exhibiting asymptomatic hypotension.[80] The use of pretreatment electrocardiography (ECG) is controversial. Although this initially was advocated by some, several studies have revealed no actionable findings with continuous ECG monitoring, and researchers have questioned its value.[61,91] FDA guidelines for patient monitoring do not include routine ECG.[61] In their consensus recommendations, Drolet et al[61] suggest ECG screening only (1) in infants with a baseline heart rate below normal for age, (2) in infants with a family history of congenital heart conditions or arrhythmias or with a maternal history of connective tissue disease, or (3) when there is a history of arrhythmia or one is auscultated during examination. Currently, the FDA-approved administration guidelines mirror those used in the pivotal clinical trial, with a recommendation for in-office intermittent heart rate and blood pressure monitoring for 2 hours after the first dose of propranolol or for increasing the dose for infants 5 weeks' adjusted gestational age or older.[76] Monitoring for those who are younger or for those with other comorbidities should be individualized and may require brief hospitalization for medication initiation. These recommendations may change over time as more information becomes available now that the medication is in widespread use.

Theoretical concerns about adverse effects of propranolol on brain development have been raised. As a highly lipophilic β-blocker, propranolol has the ability to cross the blood brain barrier.[94] Adult studies have revealed impairments in short- and long-term memory, psychomotor function, and mood, and prenatal β-blockade has been associated with long-term cognitive impairment,[95,96] leading some to question the potential central nervous system effects of this agent when used to treat young children with IHs.[97,98] In the large prospective randomized propranolol trial conducted by Léauté-Labrèze et al,[76] no appreciable neurodevelopmental differences were noted between the propranolol-treated groups and the placebo group at week 96. Four other studies addressing development in infants treated with propranolol for

IHs have yielded conflicting results. In 2 case series (with a total of 272 patients), gross motor delay was reported in 4.8% to 6.9%.[99,100] In contrast, a case series of 141 patients found psychomotor delay in only 1 child, and a controlled trial of 82 children found no increase in the rate of developmental concerns as assessed by the Ages and Stages Questionnaire.[101,102] Although these latter studies are reassuring, further prospective psychometric studies of children treated with oral propranolol for IHs may be warranted.

Key Action Statement 3E (Table 16)

Clinicians may prescribe oral prednisolone or prednisone to treat IHs if there are contraindications or an inadequate response to oral propranolol (grade B, moderate recommendation).

The purpose of this statement is to highlight the utility of systemic corticosteroid therapy for IHs in certain settings, such as for patients in whom β-blocker therapy is contraindicated, poorly tolerated, or ineffective. Systemic therapy with corticosteroids was considered the standard of care for several decades before being supplanted by oral propranolol.

In the AHRQ review, oral steroids had a mean estimate of expected clearance of 43% (Table 12).[46,103] The AHRQ report identified 24 studies (3 RCTs, 1 cohort study, and 20 case series) reporting outcomes and/or harms after corticosteroid use in children with IHs. One RCT was judged as good, 1 as fair, and 1 as poor quality, and the cohort study was judged as fair quality (all case series were judged as poor quality for harms reporting). The steroids studied varied in terms of dose, type, route of administration, and patient ages. Children in steroid treatment arms typically had modest improvement in lesion size, but outcomes were difficult to compare given differences in scales. The optimal dosing of systemic corticosteroids for IHs remains unclear. Dose ranges of prednisone or prednisolone reported most frequently in the literature are between 2 and 5 mg/kg per day,[3,70,104–106] and most consider optimal dosing to be 2 to 3 mg/kg per day. Typical protocols include treating at full dose for 4 to 12 weeks followed by a gradual taper and completion of therapy by 9 to 12 months of age.[3,70,105,106] Some have advocated for shorter treatment durations (1–6 weeks), with multiple intermittent courses as needed.[107]

In the AHRQ review, steroids were consistently associated with clinically important harms, including Cushingoid appearance, infection, growth retardation, hypertension, and mood changes. The authors considered the SOE to be moderate for the association of steroids with clinically important harms.[46]

Key Action Statement 3F (Table 17)

Clinicians may recommend intralesional injection of triamcinolone and/or betamethasone to treat focal, bulky IHs during proliferation or in certain critical anatomic locations (eg, the lip) (grade B, moderate recommendation).

The purpose of this statement is to highlight the utility of intralesional corticosteroid injection for certain IH subsets. Numerous studies have reported success in the use of steroid injections for IHs, demonstrating it to be safe and effective.[108–114] This modality is most often reserved for IHs that are relatively small and well localized where proliferation is resulting in increased bulk and threatening anatomic landmarks (eg, the lip or nose). Larger or more extensive lesions are poorer candidates for this treatment modality given the larger volume of steroids necessary (and the inherent systemic risks), the difficulty of obtaining even distribution throughout the tumor, and the potential for local complications in lesions that are mostly flat or superficial.[3] Most studies have used triamcinolone either alone or in conjunction with betamethasone, with injections given on average every 4 to 6 weeks (but with wide variability). Repeat injections are often administered, with the number used ranging in most reports from 1 to 7.[109–112]

The AHRQ review found that intralesional triamcinolone had a mean estimate of expected clearance of 58% (Table 12).[46,103] Overall, the SOE was low for intralesional steroids having a modest effect relative to control, with wide confidence bounds.[46] The subcommittee's additional search yielded 1 report that met inclusion criteria for benefits of interventions as a comparative study. This was a retrospective review of patients with periocular IHs treated with oral propranolol, who were compared with a cohort treated with intralesional corticosteroid injection. Both groups showed a reduction in astigmatism over 12 months, and neither experienced significant adverse effects necessitating dose reduction or treatment cessation.[115] The authors concluded that oral propranolol (given its efficacy and safety profiles) has emerged as the treatment of choice for periocular IHs requiring therapy.[115]

Steroids (oral and intralesional forms were grouped together in the AHRQ harms analysis) were consistently associated with clinically important harms, including Cushingoid appearance, infection, growth retardation, hypertension, and mood changes. The authors considered the SOE to be moderate for the association of steroids with clinically important harms. The most commonly reported complications associated with intralesional steroid injection for IHs are transient Cushingoid features, failure to thrive, and local skin complications.[109–112] Local complications may include fat and/or dermal atrophy and pigmentary changes.[108–110] Adrenal suppression is infrequently reported in association with intralesional steroid injections but has been observed when large doses (eg, >4 mg/kg) have been administered.[116,117] There have been rare reports of central retinal artery embolization, usually after injection into IHs of the upper eyelid, likely related to high injection pressures and/or volumes.[118–121]

TABLE 16 Key Action Statement 3E: Clinicians may prescribe oral prednisolone or prednisone to treat IHs if there are contraindications or an inadequate response to oral propranolol (grade B, moderate recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Modest benefit in IH clearance; medication cost is low
Risks, harm, cost	Clinically important harms; cost associated with the evaluation and treatment of adverse effects
Intentional vagueness	None
Benefit-harm assessment	Benefits outweigh harms
Role of patient preference	Shared decision-making regarding treatment
Exclusions	None
Strength	Moderate recommendation
Key references	46,70,103

TABLE 17 Key Action Statement 3F: Clinicians may recommend intralesional injection of triamcinolone and/or betamethasone to treat focal, bulky IHs during proliferation or in certain critical anatomic locations (eg, the lip) (grade B, moderate recommendation).

Aggregate Evidence Quality	Grade B
Benefits	Modest benefit in IH clearance
Risks, harm, cost	Clinically important harms; cost of medication, visits for injection; risk of anesthesia if used
Benefit-harm assessment	Benefits outweigh harms in selected clinical situations
Intentional vagueness	None
Role of patient preference	Shared decision-making regarding route of drug delivery
Exclusions	None
Strength	Moderate recommendation
Key references	3,46,103,108–112

Key Action Statement 3G (Table 18)

Clinicians may prescribe topical timolol maleate as a therapy for thin and/or superficial IHs (grade B, moderate recommendation).

The purpose of this statement is to highlight the potential utility of topical timolol in treating thin and/or superficial IHs. Topical timolol maleate, a nonselective β-adrenergic receptor inhibitor, has been used in the treatment of pediatric glaucoma as a first-line agent for several decades.[122,127,128] Treatment of IHs with ophthalmic timolol maleate was initially reported in 2010, and since that time, there have been many reports (including some with hundreds of patients), as well as an RCT, with positive findings.[40,122–125,129–134] On the basis of these reports showing efficacy with minimal adverse effects, timolol is increasingly being used for thin and superficial IHs, and many centers report that their use of timolol exceeds that of oral β-blockers.[135]

In the AHRQ review, 2 RCTs and 4 cohort studies were included. Topical timolol had a mean estimate of expected clearance of 62% (Table 12).[46,103] Timolol was significantly more effective than observation or a placebo in 3 studies; 1 study comparing topical imiquimod with timolol did not demonstrate superiority of either agent but was found to have insufficient SOE.[46] Our subsequent review found 3 further reports meeting criteria for efficacy, including 1study comparing timolol to an ultrapotent corticosteroid and 2 other studies of timolol alone.[40,133,134] In the largest of these, a multicenter retrospective cohort study of 731 patients, most infants were treated with the 0.5% gel-forming solution. The study reveal improvement in nearly 70% of patients treated for 1 to 3 months and in 92.3% of patients who received 6 to 9 months of therapy. The greatest improvement was in color; however, with a longer duration of treatment, improvement in size, extent, and volume were also observed. Best responses were observed in thinner superficial IHs (ie, <1 mm thick) versus mixed or deep IHs. The large majority of infants studied were 6 months or younger at time of initiation of treatment, and 41% were ≤3 months of age. This suggests that early topical timolol treatment may also inhibit IH growth. Only 7% of infants required subsequent treatment with a systemic β-blocker.[40]

Although pharmacokinetic data are limited, evidence suggests that timolol maleate can be detected in the blood or urine of at least some infants treated topically.[126,136] Additional pharmacokinetic studies are needed given occasional reports of systemic toxicity.[137–139] It should be noted that timolol is significantly more potent than propranolol, and topical application avoids first-pass liver metabolism, as would occur with an oral β-blocker.[127] Pending the results of ongoing studies, these factors should lead to caution when using timolol, especially if prescribing more than 1 drop twice daily or when treating preterm or young infants.

The AHRQ report emphasized that there were far more reports of harms with oral β-blockers than with timolol but did note 1 report of shortness of breath and insomnia.[46] Subsequent to that report, tolerability data have been reassuring overall, but some adverse events have been reported.[40,122,124,125,131–134,140] In the large cohort study of 731 patients conducted by Püttgen et al,[40] adverse events were noted in 3.4% of patients and included local irritation (nearly half of the adverse events) and bronchospasm (in 3 patients); no cardiovascular events were reported. No adverse events were significant enough to necessitate drug discontinuation.[40] In a retrospective case series of 30 children with ulcerated IHs treated with topical timolol maleate 0.5% gel-forming solution and evaluating for

TABLE 18 Key Action Statement 3G: Clinicians may prescribe topical timolol maleate as a therapy for thin and/or superficial IHs (grade B, moderate recommendation).

Aggregate Evidence Quality	Grade B
Benefit	Modest benefit in IH clearance
Harm	Low but possible risk of local irritation, sleep disturbance, cold extremities, bronchospasm, and bradycardia, with more caution needed in preterm infants and those without intact skin (ie, ulceration)
Cost	Cost of medication
Benefits-harm assessment	Benefits outweigh harms
Value judgments	None
Role of patient preference	Parents have a significant role in decision-making regarding the desire to treat small superficial lesions for which timolol may be effective
Intentional vagueness	None
Exclusions	Lesions that are large size, significantly elevated, or life-threatening
Strength	Moderate recommendation
Key references	40,46,85,122–126

adverse events, sleep disturbance was observed in 1 infant (who was treated simultaneously with oral propranolol and topical timolol) and a single episode of cold extremities was reported in another. The remainder had no reported adverse events.[141] Bradycardia, both symptomatic and asymptomatic, was reported in 4 of 22 young and preterm infants given timolol for IHs. Two infants had bradycardia that was mild and asymptomatic, but in 2 (both of whom were born preterm and weighed less than 2500 g at initiation of therapy) there were associated symptoms.[126] To address concerns regarding potential percutaneous absorption and toxicity, many authors have advocated using limited amounts of medication (eg, 1 drop 2–3 times per day),[40] and some have cautioned against application to ulcerated lesions.[127]

SURGICAL MANAGEMENT

Key Action Statement 4 (Table 19)

Clinicians may recommend surgery and laser therapy as treatment options in managing selected IHs (grade C, moderate recommendation).

The purpose of this statement is to support surgery and laser therapy as treatment options for selected IHs, although it is recommended that decisions regarding their use should be made in consultation with a hemangioma specialist, especially in young infants. With the advent of β-blocker therapy, surgical and laser approaches are used less frequently.

In general, surgical interventions are not performed in infancy. During this time, anesthetic risks are of greater concern, and the tumor is highly vascular, posing a higher risk of blood loss, iatrogenic injury, and an inferior outcome.[142,143,145]

In certain locations, such as the lip and nasal tip, the final cosmetic result is superior when growth of the lesion has ceased and the number of surgical interventions can be kept to a minimum. Furthermore, there is no psychosocial urgency to improve a deformity caused by IHs in this age group because long-term memory and self-esteem are not established until later in childhood.[143,146–148] There are certain clinical situations, however, in which early surgery can be an important treatment option. These include IHs that ulcerate, obstruct or deform vital structures (such as the airway or orbit), or involve aesthetically sensitive areas. In these circumstances, surgery may be indicated when (1) the lesion has failed to improve with local wound care and/or pharmacotherapy; (2) the lesion is well localized, and early surgery will simplify later reconstruction (eg, a prominent IH involving the ear or eyelid [causing ptosis]); (3) the lesion is well localized in an anatomically favorable area; or (4) resection is likely to be necessary in the future, and the resultant scar would be the same.[142,143,145] The decision to undertake surgery during infancy should take into consideration current knowledge of the risks of general anesthesia in this age group.[53–55]

Surgery also is an important treatment option for IHs that, despite involution, have left residual skin changes (eg, thinned skin, scar, fibrofatty tissue, telangiectasias, and/or anatomic deformities in areas such as the nose, ear, or lip).[19,20,143] In most cases, deferring surgery until the child is 3 to 5 years of age is reasonable because: (1) the lesion may resolve significantly without leaving a deformity that necessitates intervention; (2) the tumor is smaller than it was during infancy, and thus, the operation is often easier, and the resultant scar may be smaller; and (3) the IH primarily is adipose tissue instead of blood vessels, and thus, the operation is safer.[142,143,145] However, it is usually unnecessary to wait longer than 3 to 5 years of age because the previously accepted adage that 50% of IHs complete involution by 5 years of age, 70% by 7 years of age, and 90% by 9 years of age has proven to be incorrect.[19,143,149] In fact, most IHs do not improve significantly after 3 to 4 years of age.[20,143] Moreover, performing surgery at this earlier age can be beneficial in minimizing stigma and impact on a child's self-esteem.[143] There is less urgency to correct a residual deformity in an area that is concealed by clothing (eg, a lesion on the trunk). Some parents may elect to wait until the child is older and able to help in decision-making, especially if the reason for surgery is the management of less disfiguring skin changes.[143]

Laser Management

PDL has been used for several decades to treat IHs. The AHRQ review noted that most studies that were reviewed

TABLE 19 Key Action Statement 4: Clinicians may recommend surgery and laser therapy as treatment options in managing selected IHs (grade C, moderate recommendation).

Aggregate Evidence Quality	Grade C
Benefits	Early surgical intervention after infancy corrects residual deformities before the child's self-esteem develops
Risks, harm, cost	Risk of surgical complications and general anesthesia; costs associated with operative intervention, anesthesia, and postoperative care
Benefits-harm assessment	Preponderance of benefit
Intentional vagueness	None
Role of patient preference	Significant
Exclusions	Children with a nonproblematic IH
Strength	Moderate recommendation
Key references	20,142–144

evaluated PDL (as opposed to other lasers) and examined heterogeneous end points (the latter factor limiting the ability to draw conclusions). However, there is low SOE that PDL is more effective in reducing IH size when compared with observation.[46] There is evidence that PDL is superior to other lasers. In contrast, there is wide recognition that PDL is effective and safe in removing residual macular erythema and superficial telangiectasias in involuting or involuted IHs, but it often requires several treatments to achieve optimal results.[1,142] Other lasers, such as erbium-yttrium-aluminum-garnet, have been reportedly effective in ameliorating textural changes in small case series.[150] Harms associated with laser therapy that were identified in the AHRQ review included skin atrophy, bleeding, scarring, ulceration, purpura, and pigmentation changes.[46] The AHRQ review also noted that most studies of lasers reviewed evaluated lasers as a first-line treatment, a practice that is less common since the advent of β-blocker treatment.

There is controversy regarding whether PDL should be used to treat IHs early in infancy (ie, during the proliferative phase). Several case reports and case series have revealed an increased risk of ulceration, scarring, and hypopigmentation when PDL is used during this period.[1,144,151] Moreover, PDL penetrates only into the superficial dermis, and thus, although redness may be diminished, deeper elements of the IH (that increase the risk of residual skin changes) are not affected.[144,152,153]

Some authors advocate for using PDL as a treatment of ulceration. However, evidence supporting the use of PDL for this indication comes from case reports and small case series. Propranolol has been associated with faster healing of ulceration when compared with laser therapy and antibiotics.[46]

PARENT EDUCATION

Key Action Statement 5 (Table 20)

Clinicians should educate parents of infants with an IH about the condition, including the expected natural history, and its potential for causing complications or disfigurement (grade X, strong recommendation).

The purpose of this statement is to ensure that parents are knowledgeable about their child's IH and to provide clinicians with a framework for educating those parents about IHs. The information provided by clinicians should be as specific to the patient's IH as possible (eg, indicating whether and why an IH is low risk and, thus, likely to cause no problems or sequelae or is potentially high risk and requires urgent evaluation or treatment; Table 3, illustrated in Figs 2–4, Supplemental Table 22, and Supplemental Fig 11).

IHs That Do Not Raise Concern

In a primary care setting, the majority of IHs are not problematic and require no active intervention (ie, are low risk; Supplemental Table 22, Supplemental Fig 11). However, given their appearance, even nonproblematic (that is, low-risk) IHs may cause significant parental anxiety and concern. These emotions may be amplified by information gleaned from Internet searches that show photographs emphasizing the more severe end of the disease spectrum as well as public reactions to the child's IH if the lesion is located at a site not easily covered by clothing.[42,155,156] Formal educational efforts can reduce parental anxiety and enhance comfort with a plan to observe the IH for any unexpected or worrisome changes.[154]

Parents should be educated about the natural history of IHs. Specifically, they may be advised that, although growth characteristics vary from case to case, most superficial IHs have a maximum growth potential between 1 and 3 months of age[3,21,157] and that the majority of growth is complete by 5 months of age.[22] Deeper IHs may have a slightly later onset and a more prolonged duration of growth. During the period of growth, clinicians should encourage parents to call, schedule an office visit, or share photographs of the IH with them to reassess if concerns exist about the lesion's appearance, unexpectedly rapid growth, ulceration, bleeding, or pain, all findings that indicate that a lesion is no longer low risk.

Parents should be advised that by age 5 to 12 months, most IHs have stopped growing and are beginning to involute. For IHs with a superficial component, this appears as a gradual change in color from red to milky-white or gray. Lesions gradually flatten and shrink from the center outward. Involution proceeds more slowly than growth. Newer studies have demonstrated that 90% of IH involution is complete by 4 years of age.[20,143] This

is in contrast to traditional teaching that involution proceeds at 10% per year (ie, 50% of IHs resolve by 5 years of age and 90% by 9 years of age). Parents should be advised that even after involution, residual changes, such as telangiectasias, redundant skin, or a scar,[3,19] may be left. It is usually possible to tell whether such changes are going to persist by 4 years of age, and if concerning, consultation for management of these skin changes, particularly laser or surgical treatment, may be pursued.

A collection of serial photographs can be useful to demonstrate to parents the natural history of IHs and the process of spontaneous involution.[154] Such photos are available on the Hemangioma Investigator Group (https://hemangiomaeducation.org/) and Yale Dermatology (http://medicine.yale.edu/dermatology/patient/conditions/hemangioma.aspx) Web sites. Information sheets (ie, handouts) are available from the Society for Pediatric Dermatology Web site (http://pedsderm.net/) under the "For Patients and Families" tab, and adapted versions of their hemangioma patient information and propranolol sheets are included in the What Are Hemangiomas? Propranolol for Hemangiomas, and Medication Information sections of the Supplemental Information. A video for parents is also available on the Society for Pediatric Dermatology Web site (https://pedsderm.net/for-patients-families/patient-education-videos/#InfantileHemangiomas). Information also is available from the AHRQ (https://effectivehealthcare.ahrq.gov/topics/infantile-hemangioma/consumer/),[158] and answers to frequently asked questions are available on the Hemangioma Investigator Group and Yale Dermatology Web sites.

TABLE 20 Key Action Statement 5: Clinicians should educate parents of infants with an IH about the condition, including the expected natural history, and its potential for causing complications or disfigurement (grade X, strong recommendation).

Aggregate Evidence Quality	Grade X
Benefits	Promotes parent satisfaction and understanding, may reduce medication errors, may improve clinical outcomes
Risks, harm, cost	May increase parental anxiety because of the need to administer medication; time spent in education, may increase health care costs because of the need for follow-up visits
Benefit-harm assessment	Benefits outweigh harms
Intentional vagueness	None
Role of parental preferences	Essential; shared decision-making regarding the need for treatment is vital
Exclusions	None
Strength	Strong recommendation
Key references	21,22,154

IHs That May Be Problematic

When confronted with a potentially problematic IH (ie, high risk; Table 3; illustrated in Figs 2–4, Supplemental Table 22, and Supplemental Fig 11), primary care clinicians are encouraged to consult promptly with a hemangioma specialist unless they have the experience and knowledge to manage such patients independently. Because IH proliferation may occur early and be unpredictable and because there is a window of opportunity for optimal treatment, caregivers can be advised that consultation should take place in a timely manner. Unfortunately, this does not always occur. Although caregivers first notice lesions by 1 month of age (on average, at 2 weeks) and the ideal time for consultation may be 4 weeks of age, 1 study found that the mean age at presentation to a dermatologist was 5 months, by which time most growth is complete.[21,22]

Recognizing that it may be difficult to obtain an appointment with a hemangioma specialist in a timely manner, caregivers and clinicians may need to advocate on behalf of the infant. In settings where a hemangioma specialist is not readily available, telemedicine triage or consultation, using photographs taken by caregivers or the clinician, can be helpful. In 1 academic center in Spain, teledermatology triage reduced the age at first evaluation of an infant with an IH from 5.9 to 3.5 months.[159]

Once the hemangioma specialist has an opportunity to meet with parents and evaluate the infant, a discussion about management can take place. If medical treatment is recommended, the specialist will educate parents about the medication and its dosing, its possible adverse effects, and the expected duration of treatment. If the medication selected is propranolol, as often is the case, a patient information sheet (such as that developed by the Society for Pediatric Dermatology or that provided in the What Are Hemangiomas? and Propranolol for Hemangiomas sections of the Supplemental Information) or information from the article by Martin et al[160] may be provided. For families unable to travel to see a hemangioma specialist, collaborative care may be considered. The hemangioma specialist can evaluate serial photographs and provide the primary care clinician with guidance on treatment. In this case, the primary care clinician will assume a more active role in parent education.

CHALLENGES TO IMPLEMENTING THIS CPG

Several potential challenges exist to implementing this CPG. The first is the dynamic nature of individual IHs with a period of rapid growth, the degree of which can be difficult to predict, particularly in young infants. There are no surrogate markers or imaging studies that have been shown to reliably predict growth. Hence, frequent

in-person visits or a review of parental photos may be needed, especially in infants younger than 3 to 4 months. However, this may be complicated by the frequency and timing of well-child visits during this period. After the first-week visit, an infant who is well, has regained birth weight, and has parents who are experienced caregivers may not be seen again until 2 months of age. As noted by Tollefson and Frieden,[21] most superficial IHs have accelerated growth between 5 and 7 weeks of age, and 4 weeks of age may be the ideal time for referral if high-risk features are present. Thus, the most dramatic IH growth (and potentially permanent skin changes) may occur during a time when an infant is not scheduled to see a health care provider. Although awareness of this issue does not justify altering the interval of well-child visits for all infants, it heightens the need for more frequent monitoring in those with possible or definite IHs. Prompt evaluation, either in-person or via photographs, is warranted for any infant reported by parents to have a changing birthmark during the first 2 months of life.

A second challenge is the wide heterogeneity of IHs in terms of size, location, patterns of distribution (ie, segmental versus localized), and depth (ie, superficial, mixed, or deep). This heterogeneity, particularly when combined with the unpredictable growth of any given IH, may lead to uncertainty in management (ie, whether to treat or observe). Although this CPG provides guidance regarding risk stratification and growth characteristics, there is no one-size-fits-all approach. If uncertainty exists, consultation with a hemangioma specialist (whether by an in-person visit or photographic triage) can be helpful.

A third challenge is the long-held tenet that IHs are benign and go away. Because of this myth, parents and caregivers are often reassured that the lesion will disappear, and this is accurate in the vast majority of cases. However, there is ample evidence that false reassurance can be given even in high-risk cases; indeed, all hemangioma specialists have seen examples of lost opportunities to intervene and prevent poor outcomes because of lack of or delayed referral. The availability of highly effective treatments for IHs makes it critical that this myth is debunked and that practitioners become more comfortable with the concept of identifying high-risk IHs that require close observation or prompt intervention.

Last, some geographical locations lack access to prompt specialty care from hemangioma specialists. Lack of access can also result in delays in referrals or prompt appointments. Possible solutions could include establishing resources for the photographic triage of cases in which risk stratification is uncertain or in which triage to hasten referral can be augmented by this methodology.

EVIDENCE GAPS AND PROPOSED FUTURE DIRECTIONS

The proportion of IHs in primary care settings that are truly high risk is not known. Even in a referral setting, the proportions needing active intervention vary depending on referral patterns.[3,161] This information would be useful to pediatricians and other primary care providers and should be the subject of future research.

Scoring systems for IH severity have been proposed, and one in particular, the Hemangioma Severity Score, has gained some favor as a triage tool.[162–164] However, more research is needed to ensure that it can accurately be interpreted by primary care physicians and to find scores that capture the vast majority of high-risk IHs requiring specialty care without overreferring.

Other important evidence gaps should be highlighted, including the following:

- How safe is topical timolol as a treatment during early infancy, and which patients being treated with the drug need referral versus which can be observed without referral by the pediatrician?
- Is outpatient in-office cardiovascular monitoring for propranolol truly needed in healthy infants 5 weeks or older? Is blood pressure monitoring necessary, or is measuring heart rate sufficient?
- What is the role of the pediatrician in managing infants placed on β-blocker therapies (both topical and systemic), and are there specific time frames for specialty reevaluation?
- How accurate are primary care physicians in identifying high-risk IHs using parameters such as those outlined in this CPG?
- Are pediatric trainees receiving adequate training in risk stratification and management of IHs?

Some of these questions may be answered by research that is currently underway. Other studies will be needed to identify and remedy remaining gaps. Moreover, because there has been a tremendous accrual of information about IH management, there will need to be periodic updates as new information becomes available (and possibly sooner than the 5 years typical for CPGs). With such ongoing reassessment and revision, the subcommittee hopes this CPG will be viewed as an effective guide to IH triage and management and to minimize poor outcomes from higher-risk IHs. One barrier to a better understanding of IHs and to answering the questions posed here is the imprecision of current diagnostic codes. For example, the *International Classification of Diseases, 10th Revision* code for "hemangioma of the skin and subcutaneous tissues" is not specific to IHs and can include other entities (eg, congenital hemangioma and verrucous hemangioma) that are not IHs. In addition, current diagnostic codes do not contain sufficient detail to permit appreciation of higher-risk features, such as location or multifocality. Advocacy for the creation of a unique and exclusive *International*

Classification of Diseases, 10th Revision code (and appropriate modifiers) for IHs would be an appropriate step in addressing this issue.

Implementation tools for this guideline are available on the AAP Web site at https://www.aap.org/en-us/professional-resources/quality-improvement/Pages/default.aspx (this may leave or stay depending on the Digital Transformation Initiative). A useful resource for clinicians is the AAP Web page, "Diagnosis and Management of Infantile Hemangiomas" (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Infantile-Hemangiomas/Pages/default.aspx).

LEAD AUTHORS

Daniel P. Krowchuk, MD, FAAP
Ilona J. Frieden, MD, FAAP
Anthony J. Mancini MD, FAAP
David H. Darrow, MD, DDS, FAAP
Francine Blei, MD, MBA, FAAP
Arin K. Greene, MD, FAAP
Aparna Annam, DO, FAAP
Cynthia N. Baker, MD, FAAP
Peter C. Frommelt, MD
Amy Hodak, CPMSM
Brian M. Pate, MD, FHM, FAAP
Janice L. Pelletier, MD, FAAP
Deborah Sandrock, MD, FAAP
Stuart T. Weinberg, MD, FAAP
Mary Anne Whelan, MD, PhD, FAAP

SUBCOMMITTEE ON THE MANAGEMENT OF INFANTILE HEMANGIOMAS (OVERSIGHT BY THE COUNCIL ON QUALITY IMPROVEMENT AND PATIENT SAFETY)

Daniel P. Krowchuk, MD, FAAP, Chairperson, General Pediatrics and Adolescent Medicine
Ilona Frieden, MD, FAAP, Vice Chairperson, Pediatric Dermatology
Aparna Annam, DO, FAAP, Pediatric Radiology
Cynthia N. Baker, MD, FAAP, General Pediatrics
Francine Blei, MD, MBA, FAAP, Pediatric Hematology-Oncology
David H. Darrow, MD, DDS, FAAP, Otolaryngology Head and Neck Surgery
Peter C. Frommelt, MD, Pediatric Cardiology
Arin K. Greene, MD, FAAP, Plastic Surgery
Amy Hodak, CPMSM, Family Representative
Anthony J. Mancini, MD, FAAP, Pediatric Dermatology
Brian M. Pate, MD, FHM, FAAP, Implementation Scientist
Janice L. Pelletier, MD, FAAP, General Pediatrics
Deborah Sandrock, MD, FAAP, General Pediatrics
Stuart T. Weinberg, MD, FAAP, Partnership for Policy Implementation Representative
Mary Anne Whelan, MD, PhD, FAAP, Epidemiologist and Methodologist

STAFF

Kymika Okechukwu, MPA, Senior Manager, Evidence-Based Medicine Initiatives

ABBREVIATIONS

AAP: American Academy of Pediatrics
AHRQ: Agency for Healthcare Research and Quality
CPG: clinical practice guideline
ECG: electrocardiography
FDA: Food and Drug Administration
IH: infantile hemangioma
IH-MAG: infantile hemangioma with minimal or arrested growth
KAS: key action statement
LUMBAR: lower body infantile hemangiomas and other cutaneous defects, urogenital anomalies and ulceration, myelopathy, bony deformities, anorectal malformations, and arterial anomalies and renal anomalies
MRA: magnetic resonance angiography
PDL: pulsed-dye laser
PHACE: posterior fossa defects, hemangiomas, cerebrovascular arterial anomalies, cardiovascular anomalies (including coarctation of the aorta), and eye anomalies
RCT: randomized controlled trial
SOE: strength of evidence

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2018-3475

Address correspondence to Daniel P. Krowchuk, MD, FAAP. E-mail: krowchuk@wakehealth.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: Dr Frieden is a member of the Data Monitoring Safety Board for Pfizer and the Scientific Advisory Board for Venthera/Bridge Bio; Dr Mancini has indicated that he has advisory board relationships with Verrica, Valeant, and Pfizer; the other authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Hoeger PH, Harper JI, Baselga E, et al. Treatment of infantile haemangiomas: recommendations of a European expert group. *Eur J Pediatr*. 2015;174(7):855–865
2. Smithson SL, Rademaker M, Adams S, et al. Consensus statement for the treatment of infantile haemangiomas with propranolol. *Australas J Dermatol*. 2017;58(2):155–159
3. Darrow DH, Greene AK, Mancini AJ, Nopper AJ; Section on Dermatology; Section on Otolaryngology–Head and Neck Surgery; Section on Plastic Surgery. Diagnosis and management of infantile hemangioma. *Pediatrics*. 2015;136(4). Available at: www.pediatrics.org/cgi/content/full/136/4/e1060
4. Agency for Healthcare Research and Quality. Effective health care program.

Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm. Accessed February 6, 2018

5. Haggstrom AN, Garzon MC, Baselga E, et al. Risk for PHACE syndrome in infants with large facial hemangiomas. *Pediatrics*. 2010;126(2). Available at: www.pediatrics.org/cgi/content/full/126/2/e418
6. Orlow SJ, Isakoff MS, Blei F. Increased risk of symptomatic hemangiomas of the airway in association with cutaneous hemangiomas in a "beard" distribution. *J Pediatr*. 1997;131(4):643–646
7. Kulungowski AM, Alomari AI, Chawla A, Christison-Lagay ER, Fishman SJ. Lessons from a liver hemangioma registry: subtype classification. *J Pediatr Surg*. 2012;47(1):165–170
8. Rialon KL, Murillo R, Fevurly RD, et al. Risk factors for mortality in patients with multifocal and diffuse hepatic hemangiomas. *J Pediatr Surg*. 2015;50(5):837–841
9. Huang SA, Tu HM, Harney JW, et al. Severe hypothyroidism caused by type 3 iodothyronine deiodinase in infantile hemangiomas. *N Engl J Med*. 2000;343(3):185–189
10. Horii KA, Drolet BA, Frieden IJ, et al; Hemangioma Investigator Group. Prospective study of the frequency of hepatic hemangiomas in infants with multiple cutaneous infantile hemangiomas. *Pediatr Dermatol*. 2011;28(3):245–253
11. Rialon KL, Murillo R, Fevurly RD, et al. Impact of screening for hepatic hemangiomas in patients with multiple cutaneous infantile hemangiomas. *Pediatr Dermatol*. 2015;32(6):808–812
12. Jockin YM, Friedlander SF. Periocular infantile hemangioma. *Int Ophthalmol Clin*. 2010;50(4):15–25
13. Schwartz SR, Blei F, Ceisler E, Steele M, Furlan L, Kodsi S. Risk factors for amblyopia in children with capillary hemangiomas of the eyelids and orbit. *J AAPOS*. 2006;10(3):262–268
14. Chamlin SL, Haggstrom AN, Drolet BA, et al. Multicenter prospective study of ulcerated hemangiomas [published correction appears in *J Pediatr*. 2008;152(4):597]. *J Pediatr*. 2007;151(6):684–689, 689.e1
15. Connelly EA, Viera M, Price C, Waner M. Segmental hemangioma of infancy complicated by life-threatening arterial bleed. *Pediatr Dermatol*. 2009;26(4):469–472
16. Garzon MC, Epstein LG, Heyer GL, et al. PHACE syndrome: consensus-derived diagnosis and care recommendations. *J Pediatr*. 2016;178:24–33.e2
17. Iacobas I, Burrows PE, Frieden IJ, et al. LUMBAR: association between cutaneous infantile hemangiomas of the lower body and regional congenital anomalies. *J Pediatr*. 2010;157(5):795–801.e1–e7
18. Shah SD, Baselga E, McCuaig C, et al. Rebound growth of infantile hemangiomas after propranolol therapy. *Pediatrics*. 2016;137(4):e20151754
19. Bauland CG, Lüning TH, Smit JM, Zeebregts CJ, Spauwen PH. Untreated hemangiomas: growth pattern and residual lesions. *Plast Reconstr Surg*. 2011;127(4):1643–1648
20. Baselga E, Roe E, Coulie J, et al. Risk factors for degree and type of sequelae after involution of untreated hemangiomas of infancy. *JAMA Dermatol*. 2016;152(11):1239–1243
21. Tollefson MM, Frieden IJ. Early growth of infantile hemangiomas: what parents' photographs tell us. *Pediatrics*. 2012;130(2). Available at: www.pediatrics.org/cgi/content/full/130/2/e314
22. Chang LC, Haggstrom AN, Drolet BA, et al; Hemangioma Investigator Group. Growth characteristics of infantile hemangiomas: implications for management. *Pediatrics*. 2008;122(2):360–367
23. Suh KY, Frieden IJ. Infantile hemangiomas with minimal or arrested growth: a retrospective case series. *Arch Dermatol*. 2010;146(9):971–976
24. Luu M, Frieden IJ. Haemangioma: clinical course, complications and management. *Br J Dermatol*. 2013;169(1):20–30
25. Shikhani AH, Jones MM, Marsh BR, Holliday MJ. Infantile subglottic hemangiomas. An update. *Ann Otol Rhinol Laryngol*. 1986;95(4, pt 1):336–347
26. Bitar MA, Moukarbel RV, Zalzal GH. Management of congenital subglottic hemangioma: trends and success over the past 17 years. *Otolaryngol Head Neck Surg*. 2005;132(2):226–231
27. Uthurriague C, Boccara O, Catteau B, et al. Skin patterns associated with upper airway infantile haemangiomas: a retrospective multicentre study. *Acta Derm Venereol*. 2016;96(7):963–966
28. Sherrington CA, Sim DK, Freezer NJ, Robertson CF. Subglottic haemangioma. *Arch Dis Child*. 1997;76(5):458–459
29. Sie KC, McGill T, Healy GB. Subglottic hemangioma: ten years' experience with the carbon dioxide laser. *Ann Otol Rhinol Laryngol*. 1994;103(3):167–172
30. Horii KA, Drolet BA, Baselga E, et al; Hemangioma Investigator Group. Risk of hepatic hemangiomas in infants with large hemangiomas. *Arch Dermatol*. 2010;146(2):201–203
31. Drolet BA, Pope E, Juern AM, et al. Gastrointestinal bleeding in infantile hemangioma: a complication of segmental, rather than multifocal, infantile hemangiomas. *J Pediatr*. 2012;160(6):1021–1026.e3
32. Viswanathan V, Smith ER, Mulliken JB, et al. Infantile hemangiomas involving the neuraxis: clinical and imaging findings. *AJNR Am J Neuroradiol*. 2009;30(5):1005–1013
33. von Noorden GK. Application of basic research data to clinical amblyopia. *Ophthalmology*. 1978;85(5):496–504
34. Dubois J, Milot J, Jaeger BI, McCuaig C, Rousseau E, Powell J. Orbit and eyelid hemangiomas: is there a relationship between location and ocular problems? *J Am Acad Dermatol*. 2006;55(4):614–619
35. Frank RC, Cowan BJ, Harrop AR, Astle WF, McPhalen DF. Visual development in infants: visual complications of periocular haemangiomas. *J Plast Reconstr Aesthet Surg*. 2010;63(1):1–8
36. Yan AC. Pain management for ulcerated hemangiomas. *Pediatr Dermatol*. 2008;25(6):586–589
37. Thomas MW, Burkhart CN, Vaghani SP, Morrell DS, Wagner AM. Failure to thrive in infants with complicated facial hemangiomas. *Pediatr Dermatol*. 2012;29(1):49–52

38. Shin HT, Orlow SJ, Chang MW. Ulcerated haemangioma of infancy: a retrospective review of 47 patients. *Br J Dermatol*. 2007;156(5):1050–1052

39. Frieden IJ, Reese V, Cohen D. PHACE syndrome. The association of posterior fossa brain malformations, hemangiomas, arterial anomalies, coarctation of the aorta and cardiac defects, and eye abnormalities. *Arch Dermatol*. 1996;132(3):307–311

40. Püttgen K, Lucky A, Adams D, et al; Hemangioma Investigator Group. Topical timolol maleate treatment of infantile hemangiomas. *Pediatrics*. 2016;138(3):e20160355

41. Jacobs AH. Strawberry hemangiomas; the natural history of the untreated lesion. *Calif Med*. 1957;86(1):8–10

42. Tanner JL, Dechert MP, Frieden IJ. Growing up with a facial hemangioma: parent and child coping and adaptation. *Pediatrics*. 1998;101 (3, pt 1):446–452

43. Fay A, Nguyen J, Waner M. Conceptual approach to the management of infantile hemangiomas. *J Pediatr*. 2010;157(6):881–888.e1–e5

44. O TM, Scheuermann-Poley C, Tan M, Waner M. Distribution, clinical characteristics, and surgical treatment of lip infantile hemangiomas. *JAMA Facial Plast Surg*. 2013;15(4):292–304

45. Ma EH, Robertson SJ, Chow CW, Bekhor PS. Infantile hemangioma with minimal or arrested growth: further observations on clinical and histopathologic findings of this unique but underrecognized entity. *Pediatr Dermatol*. 2017;34(1):64–71

46. Chinnadurai S, Snyder K, Sathe N, et al. *Diagnosis and Management of Infantile Hemangioma*. Rockville, MD: Agency for Healthcare Research and Quality; 2016

47. Menapace D, Mitkov M, Towbin R, Hogeling M. The changing face of complicated infantile hemangioma treatment. *Pediatr Radiol*. 2016;46(11):1494–1506

48. Bessis D, Bigorre M, Labrèze C. Reticular infantile hemangiomas with minimal or arrested growth associated with lipoatrophy. *J Am Acad Dermatol*. 2015;72(5):828–833

49. Dickie B, Dasgupta R, Nair R, et al. Spectrum of hepatic hemangiomas: management and outcome. *J Pediatr Surg*. 2009;44(1):125–133

50. Rotter A, Samorano LP, de Oliveira Labinas GH, et al. Ultrasonography as an objective tool for assessment of infantile hemangioma treatment with propranolol. *Int J Dermatol*. 2017;56(2):190–194

51. Mamlouk MD, Hess CP. Arterial spin-labeled perfusion for vascular anomalies in the pediatric head and neck. *Clin Imaging*. 2016;40(5):1040–1046

52. Aggarwal N, Tekes A, Bosemani T. Infantile hepatic hemangioma: role of dynamic contrast-enhanced magnetic resonance angiography. *J Pediatr*. 2015;167(4):940–940.e1

53. US Food and Drug Administration. FDA drug safety communications: FDA review results in new warnings about using general anesthetics and sedation drugs in young children and pregnant women. 2016. Available at: www.fda.gov/downloads/Drugs/DrugSafety/UCM533197.pdf. Accessed September 10, 2018

54. American Society of Anesthesiologists. ASA response to the FDA med watch warning - December 16, 2016. 2016. Available at: https://www.asahq.org/advocacy-and-asapac/fda-and-washington-alerts/washington-alerts/2016/12/asa-response-to-the-fda-med-watch. Accessed September 10, 2018

55. Practice advisory on anesthetic care for magnetic resonance imaging: an updated report by the American Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging. *Anesthesiology*. 2015;122(3):495–520

56. Drolet BA, Chamlin SL, Garzon MC, et al. Prospective study of spinal anomalies in children with infantile hemangiomas of the lumbosacral skin. *J Pediatr*. 2010;157(5):789–794

57. Schumacher WE, Drolet BA, Maheshwari M, et al. Spinal dysraphism associated with the cutaneous lumbosacral infantile hemangioma: a neuroradiological review. *Pediatr Radiol*. 2012;42(3):315–320

58. Yu J, Maheshwari M, Foy AB, Calkins CM, Drolet BA. Neonatal lumbosacral ulceration masking lumbosacral and intraspinal hemangiomas associated with occult spinal dysraphism. *J Pediatr*. 2016;175:211–215

59. Léauté-Labrèze C, Dumas de la Roque E, Hubiche T, Boralevi F, Thambo JB, Taïeb A. Propranolol for severe hemangiomas of infancy. *N Engl J Med*. 2008;358(24):2649–2651

60. Léaute-Labrèze C, Boccara O, Degrugillier-Chopinet C, et al. Safety of oral propranolol for the treatment of infantile hemangioma: a systematic review. *Pediatrics*. 2016;138(4):e20160353

61. Drolet BA, Frommelt PC, Chamlin SL, et al. Initiation and use of propranolol for infantile hemangioma: report of a consensus conference. *Pediatrics*. 2013;131(1):128–140

62. Itinteang T, Withers AH, Davis PF, Tan ST. Biology of infantile hemangioma. *Front Surg*. 2014;1:38

63. Dai Y, Hou F, Buckmiller L, et al. Decreased eNOS protein expression in involuting and propranolol-treated hemangiomas. *Arch Otolaryngol Head Neck Surg*. 2012;138(2):177–182

64. Greenberger S, Bischoff J. Infantile hemangioma-mechanism(s) of drug action on a vascular tumor. *Cold Spring Harb Perspect Med*. 2011;1(1):a006460

65. Storch CH, Hoeger PH. Propranolol for infantile haemangiomas: insights into the molecular mechanisms of action. *Br J Dermatol*. 2010;163(2): 269–274

66. Sans V, de la Roque ED, Berge J, et al. Propranolol for severe infantile hemangiomas: follow-up report. *Pediatrics*. 2009;124(3). Available at: www.pediatrics.org/cgi/content/full/124/3/e423

67. Pan WK, Li P, Guo ZT, Huang Q, Gao Y. Propranolol induces regression of hemangioma cells via the down-regulation of the PI3K/Akt/eNOS/VEGF pathway. *Pediatr Blood Cancer*. 2015;62(8):1414–1420

68. Sharifpanah F, Saliu F, Bekhite MM, Wartenberg M, Sauer H. β-adrenergic receptor antagonists inhibit vasculogenesis of embryonic stem cells by downregulation of nitric oxide generation and interference

with VEGF signalling. *Cell Tissue Res*. 2014;358(2):443–452

69. Ji Y, Chen S, Xu C, Li L, Xiang B. The use of propranolol in the treatment of infantile haemangiomas: an update on potential mechanisms of action. *Br J Dermatol*. 2015;172(1):24–32
70. Greene AK, Couto RA. Oral prednisolone for infantile hemangioma: efficacy and safety using a standardized treatment protocol. *Plast Reconstr Surg*. 2011;128(3):743–752
71. Tiwari P, Pandey V, Gangopadhyay AN, Sharma SP, Gupta DK. Role of propranolol in ulcerated haemangioma of head and neck: a prospective comparative study. *Oral Maxillofac Surg*. 2016;20(1):73–77
72. Zaher H, Rasheed H, El-Komy MM, et al. Propranolol versus captopril in the treatment of infantile hemangioma (IH): a randomized controlled trial. *J Am Acad Dermatol*. 2016;74(3):499–505
73. Wu S, Wang B, Chen L, et al. Clinical efficacy of propranolol in the treatment of hemangioma and changes in serum VEGF, bFGF and MMP-9. *Exp Ther Med*. 2015;10(3):1079–1083
74. Aly MM, Hamza AF, Abdel Kader HM, Saafan HA, Ghazy MS, Ragab IA. Therapeutic superiority of combined propranolol with short steroids course over propranolol monotherapy in infantile hemangioma. *Eur J Pediatr*. 2015;174(11):1503–1509
75. Ji Y, Wang Q, Chen S, et al. Oral atenolol therapy for proliferating infantile hemangioma: a prospective study. *Medicine (Baltimore)*. 2016;95(24):e3908
76. Léauté-Labrèze C, Hoeger P, Mazereeuw-Hautier J, et al. A randomized, controlled trial of oral propranolol in infantile hemangioma. *N Engl J Med*. 2015;372(8):735–746
77. Siegel DH, Tefft KA, Kelly T, et al. Stroke in children with posterior fossa brain malformations, hemangiomas, arterial anomalies, coarctation of the aorta and cardiac defects, and eye abnormalities (PHACE) syndrome: a systematic review of the literature. *Stroke*. 2012;43(6):1672–1674
78. Breur JM, de Graaf M, Breugem CC, Pasmans SG. Hypoglycemia as a result of propranolol during treatment of infantile hemangioma: a case report. *Pediatr Dermatol*. 2011;28(2):169–171
79. Holland KE, Frieden IJ, Frommelt PC, Mancini AJ, Wyatt D, Drolet BA. Hypoglycemia in children taking propranolol for the treatment of infantile hemangioma. *Arch Dermatol*. 2010;146(7):775–778
80. Prey S, Voisard JJ, Delarue A, et al. Safety of propranolol therapy for severe infantile hemangioma. *JAMA*. 2016;315(4):413–415
81. Techasatian L, Komwilaisak P, Panombualert S, Uppala R, Jetsrisuparb C. Propranolol was effective in treating cutaneous infantile haemangiomas in Thai children. *Acta Paediatr*. 2016;105(6):e257–e262
82. Stringari G, Barbato G, Zanzucchi M, et al. Propranolol treatment for infantile hemangioma: a case series of sixty-two patients. *Pediatr Med Chir*. 2016;38(2):113
83. Sreekantam S, Preece MA, Vijay S, Raiman J, Santra S. How to use a controlled fast to investigate hypoglycaemia. *Arch Dis Child Educ Pract Ed*. 2017;102(1):28–36
84. Cushing SL, Boucek RJ, Manning SC, Sidbury R, Perkins JA. Initial experience with a multidisciplinary strategy for initiation of propranolol therapy for infantile hemangiomas. *Otolaryngol Head Neck Surg*. 2011;144(1):78–84
85. Ng M, Knuth C, Weisbrod C, Murthy A. Propranolol therapy for problematic infantile hemangioma. *Ann Plast Surg*. 2016;76(3):306–310
86. Chang L, Ye X, Qiu Y, et al. Is propranolol safe and effective for outpatient use for infantile hemangioma? A prospective study of 679 cases from one center in China. *Ann Plast Surg*. 2016;76(5):559–563
87. Liu LS, Sokoloff D, Antaya RJ. Twenty-four-hour hospitalization for patients initiating systemic propranolol therapy for infantile hemangiomas–is it indicated? *Pediatr Dermatol*. 2013;30(5):554–560
88. El Ezzi O, Hohlfeld J, de Buys Roessingh A. Propranolol in infantile haemangioma: simplifying pretreatment monitoring. *Swiss Med Wkly*. 2014;144:w13943
89. Tang LY, Hing JW, Tang JY, et al. Predicting complications with pretreatment testing in infantile haemangioma treated with oral propranolol. *Br J Ophthalmol*. 2016;100(7):902–906
90. Ge J, Zheng J, Zhang L, Yuan W, Zhao H. Oral propranolol combined with topical timolol for compound infantile hemangiomas: a retrospective study. *Sci Rep*. 2016;6:19765
91. Raphael MF, Breugem CC, Vlasveld FA, et al. Is cardiovascular evaluation necessary prior to and during beta-blocker therapy for infantile hemangiomas?: a cohort study. *J Am Acad Dermatol*. 2015;72(3):465–472
92. de Graaf M, Breur JMPJ, Raphaël MF, Vos M, Breugem CC, Pasmans SGMA. Adverse effects of propranolol when used in the treatment of hemangiomas: a case series of 28 infants. *J Am Acad Dermatol*. 2011;65(2):320–327
93. Xu DP, Cao RY, Xue L, Sun NN, Tong S, Wang XK. Treatment of severe infantile hemangiomas with propranolol: an evaluation of the efficacy and effects of cardiovascular parameters in 25 consecutive patients. *J Oral Maxillofac Surg*. 2015;73(3):430–436
94. Street JA, Hemsworth BA, Roach AG, Day MD. Tissue levels of several radiolabelled beta-adrenoceptor antagonists after intravenous administration in rats. *Arch Int Pharmacodyn Ther*. 1979;237(2):180–190
95. Feenstra MG. Functional neuroteratology of drugs acting on adrenergic receptors. *Neurotoxicology*. 1992;13(1):55–63
96. Pitzer M, Schmidt MH, Esser G, Laucht M. Child development after maternal tocolysis with beta-sympathomimetic drugs. *Child Psychiatry Hum Dev*. 2001;31(3):165–182
97. Langley A, Pope E. Propranolol and central nervous system function: potential implications for paediatric patients with infantile haemangiomas. *Br J Dermatol*. 2015;172(1):13–23

98. Bryan BA. Reconsidering the use of propranolol in the treatment of cosmetic infantile hemangiomas. *Angiology: Open Access*. 2013;1:e101

99. Phillips RJ, Penington AJ, Bekhor PS, Crock CM. Use of propranolol for treatment of infantile haemangiomas in an outpatient setting. *J Paediatr Child Health*. 2012;48(10):902–906

100. Gonski K, Wargon O. Retrospective follow up of gross motor development in children using propranolol for treatment of infantile haemangioma at Sydney Children's Hospital. *Australas J Dermatol*. 2014;55(3):209–211

101. Moyakine AV, Hermans DJ, Fuijkschot J, van der Vleuten CJ. Propranolol treatment of infantile hemangiomas does not negatively affect psychomotor development. *J Am Acad Dermatol*. 2015;73(2):341–342

102. Moyakine AV, Kerstjens JM, Spillekom-van Koulil S, van der Vleuten CJ. Propranolol treatment of infantile hemangioma (IH) is not associated with developmental risk or growth impairment at age 4 years. *J Am Acad Dermatol*. 2016;75(1):59–63.e1

103. Chinnadurai S, Fonnesbeck C, Snyder KM, et al. Pharmacologic interventions for infantile hemangioma: a meta-analysis. *Pediatrics*. 2016;137(2):e20153896

104. Frieden IJ, Eichenfield LF, Esterly NB, Geronemus R, Mallory SB; American Academy of Dermatology Guidelines Outcomes Committee. Guidelines of care for hemangiomas of infancy. *J Am Acad Dermatol*. 1997;37(4):631–637

105. Sadan N, Wolach B. Treatment of hemangiomas of infants with high doses of prednisone. *J Pediatr*. 1996;128(1):141–146

106. Bennett ML, Fleischer AB Jr, Chamlin SL, Frieden IJ. Oral corticosteroid use is effective for cutaneous hemangiomas: an evidence-based evaluation. *Arch Dermatol*. 2001;137(9):1208–1213

107. Nieuwenhuis K, de Laat PC, Janmohamed SR, Madern GC, Oranje AP. Infantile hemangioma: treatment with short course systemic corticosteroid therapy as an alternative for propranolol. *Pediatr Dermatol*. 2013;30(1):64–70

108. Sloan GM, Reinisch JF, Nichter LS, Saber WL, Lew K, Morwood DT. Intralesional corticosteroid therapy for infantile hemangiomas. *Plast Reconstr Surg*. 1989;83(3):459–467

109. Chowdri NA, Darzi MA, Fazili Z, Iqbal S. Intralesional corticosteroid therapy for childhood cutaneous hemangiomas. *Ann Plast Surg*. 1994;33(1):46–51

110. Chen MT, Yeong EK, Horng SY. Intralesional corticosteroid therapy in proliferating head and neck hemangiomas: a review of 155 cases. *J Pediatr Surg*. 2000;35(3):420–423

111. Buckmiller LM, Francis CL, Glade RS. Intralesional steroid injection for proliferative parotid hemangiomas. *Int J Pediatr Otorhinolaryngol*. 2008;72(1):81–87

112. Prasetyono TO, Djoenaedi I. Efficacy of intralesional steroid injection in head and neck hemangioma: a systematic review. *Ann Plast Surg*. 2011;66(1):98–106

113. Zarem HA, Edgerton MT. Induced resolution of cavernous hemangiomas following prednisolone therapy. *Plast Reconstr Surg*. 1967;39(1):76–83

114. Kushner BJ. The treatment of periorbital infantile hemangioma with intralesional corticosteroid. *Plast Reconstr Surg*. 1985;76(4):517–526

115. Herlihy EP, Kelly JP, Sidbury R, Perkins JA, Weiss AH. Visual acuity and astigmatism in periocular infantile hemangiomas treated with oral beta-blocker versus intralesional corticosteroid injection. *J AAPOS*. 2016;20(1):30–33

116. Goyal R, Watts P, Lane CM, Beck L, Gregory JW. Adrenal suppression and failure to thrive after steroid injections for periocular hemangioma. *Ophthalmology*. 2004;111(2):389–395

117. Weiss AH. Adrenal suppression after corticosteroid injection of periocular hemangiomas. *Am J Ophthalmol*. 1989;107(5):518–522

118. Shorr N, Seiff SR. Central retinal artery occlusion associated with periocular corticosteroid injection for juvenile hemangioma. *Ophthalmic Surg*. 1986;17(4):229–231

119. Ruttum MS, Abrams GW, Harris GJ, Ellis MK. Bilateral retinal embolization associated with intralesional corticosteroid injection for capillary hemangioma of infancy. *J Pediatr Ophthalmol Strabismus*. 1993;30(1):4–7

120. Egbert JE, Schwartz GS, Walsh AW. Diagnosis and treatment of an ophthalmic artery occlusion during an intralesional injection of corticosteroid into an eyelid capillary hemangioma. *Am J Ophthalmol*. 1996;121(6):638–642

121. Egbert JE, Paul S, Engel WK, Summers CG. High injection pressure during intralesional injection of corticosteroids into capillary hemangiomas. *Arch Ophthalmol*. 2001;119(5):677–683

122. Chan H, McKay C, Adams S, Wargon O. RCT of timolol maleate gel for superficial infantile hemangiomas in 5- to 24-week-olds. *Pediatrics*. 2013;131(6). Available at: www.pediatrics.org/cgi/content/full/131/6/e1739

123. Pope E, Chakkittakandiyil A. Topical timolol gel for infantile hemangiomas: a pilot study. *Arch Dermatol*. 2010;146(5):564–565

124. Chakkittakandiyil A, Phillips R, Frieden IJ, et al. Timolol maleate 0.5% or 0.1% gel-forming solution for infantile hemangiomas: a retrospective, multicenter, cohort study. *Pediatr Dermatol*. 2012;29(1):28–31

125. Chambers CB, Katowitz WR, Katowitz JA, Binenbaum G. A controlled study of topical 0.25% timolol maleate gel for the treatment of cutaneous infantile capillary hemangiomas. *Ophthal Plast Reconstr Surg*. 2012;28(2):103–106

126. Frommelt P, Juern A, Siegel D, et al. Adverse events in young and preterm infants receiving topical timolol for infantile hemangioma. *Pediatr Dermatol*. 2016;33(4):405–414

127. McMahon P, Oza V, Frieden IJ. Topical timolol for infantile hemangiomas: putting a note of caution in "cautiously optimistic". *Pediatr Dermatol*. 2012;29(1):127–130

128. Coppens G, Stalmans I, Zeyen T, Casteels I. The safety and efficacy of glaucoma medication in the pediatric

population. *J Pediatr Ophthalmol Strabismus*. 2009;46(1):12–18

129. Guo S, Ni N. Topical treatment for capillary hemangioma of the eyelid using beta-blocker solution. *Arch Ophthalmol*. 2010;128(2):255–256
130. Ni N, Langer P, Wagner R, Guo S. Topical timolol for periocular hemangioma: report of further study. *Arch Ophthalmol*. 2011;129(3):377–379
131. Moehrle M, Léauté-Labrèze C, Schmidt V, Röcken M, Poets CF, Goelz R. Topical timolol for small hemangiomas of infancy. *Pediatr Dermatol*. 2013;30(2):245–249
132. Yu L, Li S, Su B, et al. Treatment of superficial infantile hemangiomas with timolol: evaluation of short-term efficacy and safety in infants. *Exp Ther Med*. 2013;6(2):388–390
133. Danarti R, Ariwibowo L, Radiono S, Budiyanto A. Topical timolol maleate 0.5% for infantile hemangioma: its effectiveness compared to ultrapotent topical corticosteroids - a single-center experience of 278 cases. *Dermatology*. 2016;232(5):566–571
134. Oranje AP, Janmohamed SR, Madern GC, de Laat PC. Treatment of small superficial haemangioma with timolol 0.5% ophthalmic solution: a series of 20 cases. *Dermatology*. 2011;223(4):330–334
135. Gomulka J, Siegel DH, Drolet BA. Dramatic shift in the infantile hemangioma treatment paradigm at a single institution. *Pediatr Dermatol*. 2013;30(6):751–752
136. Weibel L, Barysch MJ, Scheer HS, et al. Topical timolol for infantile hemangiomas: evidence for efficacy and degree of systemic absorption. *Pediatr Dermatol*. 2016;33(2): 184–190
137. Olson RJ, Bromberg BB, Zimmerman TJ. Apneic spells associated with timolol therapy in a neonate. *Am J Ophthalmol*. 1979;88(1):120–122
138. Burnstine RA, Felton JL, Ginther WH. Cardiorespiratory reaction to timolol maleate in a pediatric patient: a case report. *Ann Ophthalmol*. 1982;14(10):905–906
139. Kiryazov K, Stefova M, Iotova V. Can ophthalmic drops cause central nervous system depression and cardiogenic shock in infants? *Pediatr Emerg Care*. 2013; 29(11):1207–1209
140. Semkova K, Kazandjieva J. Topical timolol maleate for treatment of infantile haemangiomas: preliminary results of a prospective study. *Clin Exp Dermatol*. 2013;38(2):143–146
141. Boos MD, Castelo-Soccio L. Experience with topical timolol maleate for the treatment of ulcerated infantile hemangiomas (IH). *J Am Acad Dermatol*. 2016;74(3):567–570
142. Greene AK. Management of hemangiomas and other vascular tumors. *Clin Plast Surg*. 2011;38(1):45–63
143. Couto RA, Maclellan RA, Zurakowski D, Greene AK. Infantile hemangioma: clinical assessment of the involuting phase and implications for management. *Plast Reconstr Surg*. 2012;130(3):619–624
144. Batta K, Goodyear HM, Moss C, Williams HC, Hiller L, Waters R. Randomised controlled study of early pulsed dye laser treatment of uncomplicated childhood haemangiomas: results of a 1-year analysis. *Lancet*. 2002;360(9332):521–527
145. Mulliken JB, Fishman SJ, Burrows PE. Vascular anomalies. *Curr Probl Surg*. 2000;37(8):517–584
146. Charlesworth R. The toddler: affective development. In: *Understanding Child Development*. 6th ed. Delmar Learning; 1994:304
147. Santrock JW. The self and identity. In: *Child Development*. 7th ed. McGraw-Hill; 1996:378–385
148. Neisser U. Memory development: new questions and old. *Dev Rev*. 2004;24(1):154–158
149. Bowers RE, Graham EA, Tomlinson KM. The natural history of the strawberry nevus. *Arch Dermatol*. 1960;82(5):667–680
150. Laubach HJ, Anderson RR, Luger T, Manstein D. Fractional photothermolysis for involuted infantile hemangioma. *Arch Dermatol*. 2009;145(7):748–750
151. Witman PM, Wagner AM, Scherer K, Waner M, Frieden IJ. Complications following pulsed dye laser treatment of superficial hemangiomas. *Lasers Surg Med*. 2006;38(2):116–123
152. Scheepers JH, Quaba AA. Does the pulsed tunable dye laser have a role in the management of infantile hemangiomas? Observations based on 3 years' experience. *Plast Reconstr Surg*. 1995;95(2):305–312
153. Kessels JP, Hamers ET, Ostertag JU. Superficial hemangioma: pulsed dye laser versus wait-and-see. *Dermatol Surg*. 2013;39(3, pt 1):414–421
154. Liu LS, Sowa A, Antaya RJ. Educating caregivers about the natural history of infantile hemangiomas. *Acta Paediatr*. 2015;104(1):9–11
155. Zweegers J, van der Vleuten CJ. The psychosocial impact of an infantile haemangioma on children and their parents. *Arch Dis Child*. 2012;97(10):922–926
156. Minzer-Conzetti K, Garzon MC, Haggstrom AN, et al. Information about infantile hemangiomas on the Internet: how accurate is it? *J Am Acad Dermatol*. 2007;57(6):998–1004
157. Takahashi K, Mulliken JB, Kozakewich HP, Rogers RA, Folkman J, Ezekowitz RA. Cellular markers that distinguish the phases of hemangioma during infancy and childhood. *J Clin Invest*. 1994;93(6):2357–2364
158. Agency for Healthcare Research and Quality. Treating infantile hemangiomas in children. Available at: https://effectivehealthcare.ahrq.gov/topics/infantile-hemangioma/consumer. Accessed November 27, 2018
159. Bernabeu-Wittel J, Pereyra J, Corb R, Ruiz-Canela J, Tarilonte A M, Conejo-Mir J. Teledermatology for infantile hemangiomas. Comment on: Chang LC, Haggstrom AN, Drolet BA, et al for the Hemangioma Investigator Group. Growth characteristics of infantile hemangiomas: implications for management. Pediatrics. 2008;122:360-367. Available at: http://pediatrics.aappublications.org/content/122/2/360.comments
160. Martin K, Blei F, Chamlin SL, et al. Propranolol treatment of infantile hemangiomas: anticipatory guidance for parents and caretakers [published correction appears in *Pediatr*

Dermatol. 2013;30(2):280]. *Pediatr Dermatol.* 2013;30(1):155–159

161. Munden A, Butschek R, Tom WL, et al. Prospective study of infantile haemangiomas: incidence, clinical characteristics and association with placental anomalies. *Br J Dermatol.* 2014;170(4):907–913
162. Moyakine AV, Herwegen B, van der Vleuten CJM. Use of the Hemangioma Severity Scale to facilitate treatment decisions for infantile hemangiomas. *J Am Acad Dermatol.* 2017;77(5): 868–873
163. Mull JL, Chamlin SL, Lai JS, et al. Utility of the Hemangioma Severity Scale as a triage tool and predictor of need for treatment. *Pediatr Dermatol.* 2017;34(1):78–83
164. Haggstrom AN, Beaumont JL, Lai JS, et al. Measuring the severity of infantile hemangiomas: instrument development and reliability. *Arch Dermatol.* 2012;148(2):197–202

Infantile Hemangiomas Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — Clinical Practice Guideline for the Management of Infantile Hemangiomas
- *ICD-10-CM* Coding Quick Reference for Infantile Hemangiomas

Action Statement Summary

Clinical Practice Guideline for the Management of Infantile Hemangiomas

Key Action Statement 1

Risk stratification

Key Action Statement 1A

Clinicians should classify an IH as high risk if there is evidence of or potential for the following: (1) life-threatening complications, (2) functional impairment or ulceration, (3) structural anomalies (eg, in PHACE syndrome or LUMBAR syndrome), or (4) permanent disfigurement (grade X, strong recommendation).

Key Action Statement 1B

After identifying an IH as high risk, clinicians should facilitate an evaluation by a hemangioma specialist as soon as possible (grade X, strong recommendation).

Key Action Statement 2

Imaging

Key Action Statement 2A

Clinicians should not perform imaging unless the diagnosis of IH is uncertain, there are 5 or more cutaneous IHs, or associated anatomic abnormalities are suspected (grade B, moderate recommendation).

Key Action Statement 2B

Clinicians should perform ultrasonography as the initial imaging modality when the diagnosis of IH is uncertain (grade C, weak recommendation).

Key Action Statement 2C

Clinicians should perform MRI when concerned about associated structural abnormalities (eg, PHACE syndrome or LUMBAR syndrome) (grade B, moderate recommendation).

Key Action Statement 3

Pharmacotherapy

Key Action Statement 3A

Clinicians should use oral propranolol as the first-line agent for IHs requiring systemic treatment (grade A, strong recommendation).

Key Action Statement 3B

Clinicians should dose propranolol between 2 and 3 mg/kg per day unless there are comorbidities (eg, PHACE syndrome) or adverse effects (eg, sleep disturbance) that necessitate a lower dose (grade A, moderate recommendation).

Key Action Statement 3C

Clinicians should counsel that propranolol be administered with or after feeding and that doses be held at times of diminished oral intake or vomiting to reduce the risk of hypoglycemia (grade X, strong recommendation).

Key Action Statement 3D

Clinicians should evaluate patients for and educate caregivers about potential adverse effects of propranolol, including sleep disturbances, bronchial irritation, and clinically symptomatic bradycardia and hypotension (grade X, strong recommendation).

Key Action Statement 3E

Clinicians may prescribe oral prednisolone or prednisone to treat IHs if there are contraindications or an inadequate response to oral propranolol (grade B, moderate recommendation).

Key Action Statement 3F

Clinicians may recommend intralesional injection of triamcinolone and/or betamethasone to treat focal, bulky IHs during proliferation or in certain critical anatomic locations (eg, the lip) (grade B, moderate recommendation).

Key Action Statement 3G

Clinicians may prescribe topical timolol maleate as a therapy for thin and/or superficial IHs (grade B, moderate recommendation).

Key Action Statement 4

Clinicians may recommend surgery and laser therapy as treatment options in managing selected IHs (grade C, moderate recommendation).

Key Action Statement 5

Clinicians should educate parents of infants with an IH about the condition, including the expected natural history, and its potential for causing complications or disfigurement (grade X, strong recommendation).

Coding Quick Reference for Infantile Hemangiomas
ICD-10-CM
D18.00 Hemangioma unspecified site
D18.01 Hemangioma of skin and subcutaneous tissue
D18.02 Hemangioma of intracranial structures
D18.03 Hemangioma of intra-abdominal structures
D18.09 Hemangioma of other sites

Clinical Practice Guideline: Maintenance Intravenous Fluids in Children

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Clinical Practice Guideline: Maintenance Intravenous Fluids in Children

Leonard G. Feld, MD, PhD, MMM, FAAP,[a] Daniel R. Neuspiel, MD, MPH, FAAP,[b] Byron A. Foster, MD, MPH, FAAP,[c] Michael G. Leu, MD, MS, MHS, FAAP,[d] Matthew D. Garber, MD, FHM, FAAP,[e] Kelly Austin, MD, MS, FAAP, FACS,[f] Rajit K. Basu, MD, MS, FCCM,[g,h] Edward E. Conway Jr, MD, MS, FAAP,[i] James J. Fehr, MD, FAAP,[j] Clare Hawkins, MD,[k] Ron L. Kaplan, MD, FAAP,[l] Echo V. Rowe, MD, FAAP,[m] Muhammad Waseem, MD, MS, FAAP, FACEP,[n] Michael L. Moritz, MD, FAAP,[o] SUBCOMMITTEE ON FLUID AND ELECTROLYTE THERAPY

abstract

Maintenance intravenous fluids (IVFs) are used to provide critical supportive care for children who are acutely ill. IVFs are required if sufficient fluids cannot be provided by using enteral administration for reasons such as gastrointestinal illness, respiratory compromise, neurologic impairment, a perioperative state, or being moribund from an acute or chronic illness. Despite the common use of maintenance IVFs, there is high variability in fluid prescribing practices and a lack of guidelines for fluid composition administration and electrolyte monitoring. The administration of hypotonic IVFs has been the standard in pediatrics. Concerns have been raised that this approach results in a high incidence of hyponatremia and that isotonic IVFs could prevent the development of hyponatremia. Our goal in this guideline is to provide an evidence-based approach for choosing the tonicity of maintenance IVFs in most patients from 28 days to 18 years of age who require maintenance IVFs. This guideline applies to children in surgical (postoperative) and medical acute-care settings, including critical care and the general inpatient ward. Patients with neurosurgical disorders, congenital or acquired cardiac disease, hepatic disease, cancer, renal dysfunction, diabetes insipidus, voluminous watery diarrhea, or severe burns; neonates who are younger than 28 days old or in the NICU; and adolescents older than 18 years old are excluded. We specifically address the tonicity of maintenance IVFs in children.

The Key Action Statement of the subcommittee is as follows:

1A: The American Academy of Pediatrics recommends that patients 28 days to 18 years of age requiring maintenance IVFs should receive isotonic solutions with appropriate potassium chloride and dextrose because they significantly decrease the risk of developing hyponatremia (evidence quality: A; recommendation strength: strong)

[a]Retired, Nicklaus Children's Health System, Miami, Florida; [b]Retired, Levine Children's Hospital, Charlotte, North Carolina; [c]Oregon Health and Science University, Portland, Oregon; [d]Department of Pediatric Emergency Medicine, [d]School of Medicine, University of Washington and Seattle Children's Hospital, Seattle, Washington; [e]Department of Pediatrics, College of Medicine – Jacksonville, University of Florida, Jacksonville, Florida; Departments of [f]Surgery and [o]Pediatrics, University of Pittsburgh School of Medicine, Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania; [g]Division of Critical Care Medicine, Children's Healthcare of Atlanta, Atlanta, Georgia; [h]Department of Pediatrics, School of Medicine, Emory University, Atlanta, Georgia; [i]Division of Pediatric Critical Care Medicine, Department of Pediatrics, Jacobi Medical Center, Bronx, New York; Departments of [j]Anesthesiology and Pediatrics, Washington University in St Louis, St Louis, Missouri; [k]Department of Family Medicine, Houston Methodist Hospital, Houston, Texas; [m]Department of Anesthesia, Stanford University School of Medicine, Stanford, California; and [n]Lincoln Medical Center, Bronx, New York

To cite: Feld LG, Neuspiel DR, Foster BA, et al. Clinical Practice Guideline: Maintenance Intravenous Fluids in Children. *Pediatrics*. 2018;142(6):e20183083

INTRODUCTION

Maintenance intravenous fluids (IVFs) are used to provide critical supportive care for children who are acutely ill. IVFs are required if sufficient fluids cannot be provided by using enteral administration for reasons such as gastrointestinal illness, respiratory compromise, neurologic impairment, a perioperative state, or being moribund from an acute or chronic illness. For the purposes of this document, specifying appropriate maintenance IVFs includes the composition of IVF needed to preserve a child's extracellular volume while simultaneously minimizing the risk of developing volume depletion, fluid overload, or electrolyte disturbances, such as hyponatremia or hypernatremia. Because maintenance IVFs may have both potential benefits and harms, they should only be administered when clinically indicated. The administration of hypotonic IVF has been the standard in pediatrics. Concerns have been raised that this approach results in a high incidence of hyponatremia and that isotonic IVF could prevent the development of hyponatremia. Guidelines for maintenance IVF therapy in children have primarily been opinion based, and evidence-based consensus guidelines are lacking.

OBJECTIVE

Despite the common use of maintenance IVFs, there is high variability in fluid prescribing practices and a lack of guidelines for fluid composition and electrolyte monitoring.[1–4] Our goal in this guideline is to provide an evidence-based approach for choosing the tonicity of maintenance IVFs in most patients from 28 days to 18 years of age who require maintenance IVFs. These recommendations do not apply to patients with neurosurgical disorders, congenital or acquired cardiac disease, hepatic disease, cancer, renal dysfunction, diabetes insipidus, voluminous watery diarrhea, or severe burns; neonates who are younger than 28 days old or in the NICU; or adolescents older than 18 years old.

BACKGROUND

Phases of Fluid Therapy

Recent literature has emerged in which researchers describe the context-dependent use of IVFs, which should be prescribed, ordered, dosed, and delivered like any other drug.[5–7] Four distinct physiology-driven time periods exist for children requiring IVFs. The resuscitative phase is the acute presentation window, when IVFs are needed to restore adequate tissue perfusion and prevent or mitigate end-organ injury. The titration phase is the time when IVFs are transitioned from boluses to maintenance; this is a critical window to determine what intravascular repletion has been achieved and the trajectory of fluid gains versus losses in children who are acutely ill. The maintenance phase accounts for fluids administered during the previous 2 stabilization phases and is a time when fluids should be supplied to achieve a precise homeostatic balance between needs and losses. Finally, the convalescent phase reflects the period when exogenous fluid administration is stopped, and the patient returns to intrinsic fluid regulation. The dose of fluid during these 4 phases of fluid therapy needs to be adjusted on the basis of the unique physiologic needs of each patient, and a specific protocoled dose is not able to be applied to all patients.[8,9]

A variety of IVFs are commercially available for use in infants and children. These solutions principally vary by their specific electrolyte composition, the addition of a buffer, and whether they contain glucose (Table 1).[10] The buffer in plasma is bicarbonate, but buffers in commercially available solutions include various concentrations of lactate, acetate, and gluconate. Multiple balanced salt solutions can be compared with normal saline (0.9% saline), which has the same sodium concentration as plasma but has a supraphysiologic chloride concentration.

Effect of Dextrose on Tonicity

Tonicity is used to describe the net vector of force on cells relative to a semipermeable membrane when in solution. Physiologic relevance occurs with tonicity studied in vivo (eg, as IVF is infused intravascularly). Infused isotonic fluids do not result in osmotic shifts; the cells stay the same size. Cellular expansion occurs during immersion in hypotonic fluids as free water, in higher relative abundance in the extracellular environment, and crosses the semipermeable membrane. The converse happens in hypertonic fluid immersion: free water shifts out of the cells, leading to cellular contraction. A distinct but related concept is the concept of osmolality. Osmolality is measured as osmoles of solute per kilogram of solvent. Serum osmolality can be estimated by the following formula:

$$2 \times \mathrm{Na}(\mathrm{mEq}/L) + \mathrm{BUN}\,(\mathrm{mg/dL})/2.8 + \mathrm{glucose}\,(\mathrm{mg/dL})/18$$

Osmolality is distinct from tonicity (effective osmolality) in that tonicity relates to both the effect on a cell of a fluid (dependent on the selective permeability of the membrane) and the osmolality of the fluid. In the plasma, urea affects osmolality but not tonicity because urea moves freely across cell membranes with no effect on tonicity. The tonicity of IVF is primarily affected by the sodium and potassium concentration.

Dextrose (D-glucose) can be added to IVFs (Table 1). Although dextrose affects the osmolarity of IVFs, it is not a significant contributor to the plasma osmotic pressure or tonicity

TABLE 1 Composition of Commonly Used Maintenance IVFs

Fluid	Glucose, g/dL	Sodium	Chloride	Potassium, mEq/L	Calcium	Magnesium	Buffer	Osmolarity,[a] mOsm/L
Human plasma	0.07–0.11	135–145	95–105	3.5–5.3	4.4–5.2	1.6–2.4	23–30 bicarbonate	308[b]
Hypotonic solutions								
D_5 0.2% NaCl	5	34	34	0	0	0	0	78
D_5 0.45% NaCl	5	77	77	0	0	0	0	154
Isotonic and/or near-isotonic solutions								
D_5 0.9% NaCl	5	154	154	0	0	0	0	308
D_5 lactated Ringer	5	130	109	4	3	0	28 lactate	273
PlasmaLyte[c,d]	0	140	98	5	0	3	27 acetate and 23 gluconate	294

[a] The osmolarity calculation excludes the dextrose in the solution because dextrose is rapidly metabolized on infusion.
[b] The osmolality for plasma is 275–295 mOsm/kg.
[c] Multiple electrolytes injection, type 1 *United States Pharmacopeia*, is the generic name for PlasmaLyte.
[d] PlasmaLyte with 5% dextrose is not available in the United States from Baxter Healthcare Corporation in Deerfield, Illinois.

in the absence of uncontrolled diabetes because it is rapidly metabolized after entering the blood stream. Thus, although dextrose will affect the osmolarity of solutions, for patients in whom maintenance IVFs are needed, the dextrose component generally is not believed to affect the tonicity of solutions.

Historical Maintenance IVF Practice and Hyponatremia

Hyponatremia (serum sodium concentration <135 mEq/L) is the most common electrolyte abnormality in patients who are hospitalized, affecting approximately 15% to 30% of children and adults.[11, 12] Patients who are acutely ill frequently have disease states associated with arginine vasopressin (AVP) excess that can impair free-water excretion and place the patient at risk for developing hyponatremia when a source of electrolyte-free water is supplied, as in hypotonic fluids.[10] Nonosmotic stimuli of AVP release include pain, nausea, stress, a postoperative state, hypovolemia, medications, and pulmonary and central nervous system (CNS) disorders, including common childhood conditions such as pneumonia and meningitis.[13–15] These conditions can lead to the syndrome of inappropriate antidiuresis (SIAD) or SIAD-like states, which lead to water retention followed by a physiologic natriuresis in which fluid balance is maintained at the expense of plasma sodium.

Children have historically been administered hypotonic maintenance IVFs.[3,4] This practice is based on theoretical calculations from the 1950s.[16] The water requirement was based on the energy expenditure of healthy children, with 1 mL of fluid provided for each kilocalorie (kcal) expended, or 1500 mL/m^2 per day. The resting energy expenditure in healthy children is vastly different in those with an acute disease and/or illness or after surgery. When using calorimetric methods, energy expenditure in these patients is closer to the basal metabolic rate proposed by Talbot,[17] which averages 50 to 60 kcal/kg per day.[18] The electrolyte concentration of IVFs was estimated to reflect the composition of human and cow milk. The final composition consisted of 3 mEq of sodium and 2 mEq of potassium per 100 kcal metabolized.[16]

Most hyponatremia in patients who are hospitalized is hospital acquired and related to the administration of hypotonic IVFs in the setting of elevated AVP concentrations.[10,11] Studies in which researchers evaluated hospital-acquired hyponatremia have revealed a relationship with the administration of hypotonic IVFs.[11,19,20] The most serious complication of hospital-acquired hyponatremia is hyponatremic encephalopathy, which is a medical emergency that can be fatal or lead to irreversible brain injury if inadequately treated.[21–24] The reports of hospital-acquired hyponatremic encephalopathy have occurred primarily in otherwise healthy children who were receiving hypotonic IVFs, in many cases after minor surgical procedures.[21,23] Patients with hospital-acquired hyponatremia are at particular risk for hyponatremic encephalopathy, which usually develops acutely in less than 48 hours, leaving little time for the brain to adapt. Children are at particularly high risk of developing symptomatic hyponatremia because of their larger brain/skull size ratio.[24] Symptoms of hyponatremia can be nonspecific, including fussiness, headache, nausea, vomiting, confusion, lethargy, and muscle cramps, making prompt diagnosis difficult.

After reports of severe hyponatremia and associated neurologic injury were reported in 1992, a significant debate emerged regarding the appropriateness of administering hypotonic maintenance IVFs to children.[21] In 2003, it was

recommended that isotonic fluids be administered to children who are acutely ill and require maintenance IVFs to prevent the development of hyponatremia.[24] Since then, the Institute for Safe Medical Practices of both the United States[25] and Canada[26] released reports on deaths from severe hyponatremia in patients who were hospitalized and received hypotonic IVFs. The United Kingdom released a national safety alert reporting 4 deaths and 1 near miss from hospital-acquired hyponatremia,[27] and 50 cases of serious injury or child death from hypotonic IVFs were reported in the international literature.[22]

After the recognition of hospital-acquired hyponatremia in patients receiving hypotonic IVFs and recommendations for avoiding them,[24] the use of 0.2% saline has declined with an increase in the use of 0.45% and 0.9% saline.[3,28] There have been concerns raised about the safety of the proposed use of isotonic maintenance IVFs in children who are acutely ill for the prevention of hospital-acquired hyponatremia.[18] Some believe that this approach could lead to complications such as hypernatremia, fluid overload with edema and hypertension, and hyperchloremic acidosis.[29] In the past 15 years, there have been a multitude of clinical trials and systematic reviews in which researchers have attempted to address this debate.[30–35] Authors of textbooks and review articles in the United States continue to recommend hypotonic fluids.[36–38] Conversely, the National Clinical Guideline Centre in the United Kingdom published evidence-based guidelines for IVF therapy in children younger than 16 years old and recommended isotonic IVFs.[34]

METHODS

In April 2016, the American Academy of Pediatrics (AAP) convened a multidisciplinary subcommittee composed of primary care clinicians and experts in the fields of general pediatrics, hospital medicine, emergency medicine, critical care medicine, nephrology, anesthesiology, surgery, and quality improvement. The subcommittee also included a guideline methodologist and/or informatician and an epidemiologist who were skilled in systematic reviews. All panel members declared potential conflicts on the basis of the AAP policy on conflicts of interest and voluntary disclosure. Subcommittee members repeated this process annually and on publication of the guideline. All potential conflicts of interest are listed at the end of this document. The project was funded by the AAP.

The subcommittee initiated its literature review by combining the search strategies in 7 recent systematic reviews of clinical trials of maintenance IVFs in children and adolescents, which consisted of 11 clinical trials involving 1139 patients.[9,33,34,39–42] The subcommittee then used this combined search strategy to discover 7 additional clinical trials of maintenance IVFs involving 1316 children and adolescents (ages 28 days to 18 years) published since 2013 (the last year included in the previous 6 systematic reviews) in the PubMed, Cumulative Index to Nursing and Allied Health Literature, and Cochrane Library databases. All articles that were initially identified were back searched for other relevant publications. Studies published as of March 15, 2016, were included. Three independent reviewers from the subcommittee then critically appraised the full text of each identified article (n = 17) using a structured data collection form that was based on published guidelines for evaluating medical literature.[43,44] These reviews were integrated into an evidence table by the subcommittee epidemiologist (Supplemental Table 3). Forest plots for all included randomized controlled trials (RCTs) in which researchers used random-effects models and Mantel-Haenzel (M-H) statistics with the outcome of hyponatremia are shown in Supplemental Figs 2–4.

To appraise the methodology of the included studies, a risk-of-bias assessment was completed by using the *Cochrane Handbook* risk of bias assessment framework.[45] Using this framework, raters placed a value of low, high, or unclear risk of bias for each article in the areas of selection bias (both random-sequence generation and allocation concealment), performance bias, detection bias, attrition bias, and reporting bias. Two authors independently reviewed each study identified in the systematic review and made an independent judgment. Differences in assessment were resolved via discussion.

The resulting systematic review was used to develop the guideline recommendations by following the Policy Statement from the AAP Steering Committee on Quality Improvement and Management, "Classifying Recommendations for Clinical Practice Guidelines."[46] Decisions and the strength of recommendations were based on a systematic grading of the quality of evidence from the updated literature review by the subcommittee with guidance by the epidemiologist. Expert consensus was used when definitive data were not available. If committee members disagreed with the consensus, they were encouraged to voice their concerns until full agreement was reached. Full agreement was reached on the clinical recommendations below.

Clinical recommendations were entered into Bridge-Wiz 2.1 for AAP software (Building Recommendations in a Developers Guideline Editor), an interactive software tool that is used to lead guideline development

TABLE 2 Key Action Statement 1A

Aggregate Evidence Quality	Grade A
Benefits	More physiologic fluid, less hyponatremia
Risks, harm, cost	Potential harms of hypernatremia, fluid overload, hypertension, hyperchloremic metabolic acidosis, and acute kidney injury have not been found to be of increased risk with isotonic maintenance fluids.
Benefit-harm assessment	Decreased risk of hyponatremia
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Patients with neurosurgical disorders, congenital or acquired cardiac disease, hepatic disease, cancer, renal dysfunction, diabetes insipidus, voluminous watery diarrhea, or severe burns; neonates who are <28 d old or in the NICU; or adolescents >18 y old
Strength	Strong recommendation
Key references	9,33,39–42

teams through a series of questions that are intended to create clear, transparent, and actionable Key Action Statements.[47] The committee was actively involved while the software was used and solicited the inputs of this program, which included strength of evidence and balance of benefits versus harms, and chose which sentences recommended by the program to use as part of the guideline. Bridge-Wiz also integrates the quality of available evidence and a benefit-harm assessment into the final determination of the strength of each recommendation per the guidance in Fig 1.

Before formal approval by the AAP, this guideline underwent a comprehensive review by stakeholders, including AAP councils, committees, and sections; selected outside stakeholder organizations; and individuals who were identified by the subcommittee as experts in the field. All comments were reviewed by the subcommittee and incorporated into the final guideline when appropriate.

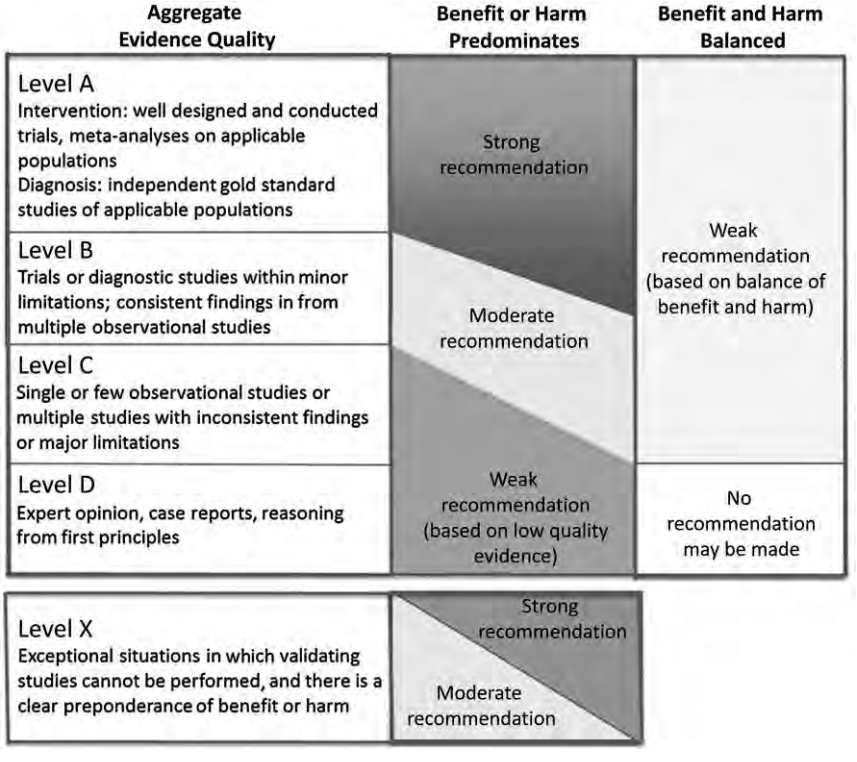


FIGURE 1
AAP rating of evidence and recommendations.

On the basis of the reviewed literature, this guideline applies to children 28 days to 18 years of age in surgical (postoperative) and medical acute-care settings, including critical care and the general inpatient ward. This guideline DOES NOT apply to children with neurosurgical disorders, congenital or acquired cardiac disease, hepatic disease, cancer, renal dysfunction, diabetes insipidus, voluminous watery diarrhea, or severe burns; neonates who are younger than 28 days old or in the NICU; or adolescents older than 18 years old because the majority of the researchers in the prospective studies reviewed in this guideline excluded these subsets of patients or did not include patients with these specific high-risk diagnoses.

RESULTS

Key Action Statement

The Key Action Statement is as follows:

1. Composition of Maintenance IVFs

1A: The AAP recommends that patients 28 days to 18 years of age requiring maintenance IVFs should receive isotonic solutions with appropriate potassium chloride (KCl) and dextrose because they significantly decrease the risk of developing hyponatremia (evidence quality: A; recommendation strength: strong; Table 2).

Isotonic Solutions Versus Hypotonic Solutions

Isotonic fluid has a sodium concentration similar to plasma (135–144 mEq/L). Plasma is approximately 93% aqueous and 7% anhydrous with a sodium concentration in the aqueous phase of plasma of 154 mEq/L and osmolarity of 308 mOsm/L, similar to that of 0.9% sodium chloride (NaCl). Conversely, hypotonic fluid has a sodium concentration lower than that of the aqueous phase of plasma. In the studies evaluated in the formulation of these guidelines, there is some heterogeneity in both the isotonic and hypotonic fluids used. The sodium concentration of isotonic fluids ranged from 131 to 154 mEq/L. Hartmann solution (sodium concentration 131 mEq/L; osmolality 279 mOsm/L) was used in only 46 patients.[48,49] PlasmaLyte (sodium concentration 140 mEq/L; osmolarity 294 mOsm/L) was used in 346 patients.[35] Researchers in the majority of the studies used either 0.9% NaCl (sodium concentration 154 mEq/L; osmolarity 308 mOsm/L) or a fluid of equivalent tonicity. Hypotonic fluids ranged from 30 to 100 mEq/L.[33] Lactated Ringer solution (sodium concentration 130 mEq/L; osmolarity 273 mOsm/L), a slightly hypotonic solution, was not involved in any of the clinical trials. For the purposes of this guideline, isotonic solutions have a sodium concentration similar to PlasmaLyte, or 0.9% NaCl. Recommendations are not made regarding the safety of lactated Ringer solution. Researchers in the majority of studies added dextrose (2.5%–5%) to the intravenous (IV) solution.

The search revealed 17 randomized clinical trials[20,31,32,35,48–60] that met the search criteria, including a total 2455 patients (2313 patients had primary outcome data for analysis in Supplemental Figs 2–4), to help evaluate the question of whether isotonic or hypotonic fluids should be used in children who are hospitalized. Sixteen of the studies revealed that isotonic fluids were superior to hypotonic fluids in preventing hyponatremia. There have also been 7 systematic reviews over the past 11 years in which researchers have synthesized various combinations of the above RCTs.[9,33,34,39–42] The number needed to treat with isotonic fluids to prevent hyponatremia (sodium <135 mEq/L) was 7.5 across all included studies and 27.8 for moderate hyponatremia (sodium <130 mEq/L).

Study appraisal for risk of bias (Supplemental Table 4) revealed the reviewed studies in total to be methodologically sound. Most types of bias were found to be of low risk in all but 2 studies. There was 1 study with 2 bias types of potentially high risk and 11 studies with 1 or more unclear bias areas.

Inclusion and Exclusion Criteria: Rationale for Specific Subgroups

Age

The specific age groups from which data are available from randomized clinical trials range from 1 day (1 trial) to 18 years. Given this broad age range, we specifically evaluated whether there was variability in the outcomes by age, particularly for the lower age range. McNab et al[33] examined this question in their systematic review and found 100 children studied at younger than 1 year of age, 243 children studied between the ages of 1 and 5 years, and 465 children studied at older than 5 years of age. They showed a significant benefit of isotonic IVFs in each age group stratum. There have been 7 additional studies in which researchers have also included children younger than 1 year old, although there are not specific outcome data reported for this age group.[31,32,35,50,51,55,58]

Surgical (Postoperative Patients)

Surgical or postoperative patients have been specifically studied in 7 studies[20,48,49,51,54,56,57] that included 529 patients. McNab[30] showed a pooled risk ratio of 0.48 (95% confidence interval [CI], 0.38–0.60) for the outcome of hyponatremia in favor of isotonic fluids.

Medical (Nonsurgical Patients)

Medical patients are defined here as children who are hospitalized in an acute-care setting with no indication for a surgical operation and no immediate history of a surgical operation. For these patients, there are 4 randomized clinical trials[32,52,55,58] in which researchers enrolled only medical patients and 6 randomized clinical trials[50,51,53,56,57,59] in which researchers enrolled both medical and surgical patients. Some of the mixed studies in which researchers looked at both medical and surgical patients include outcomes for only medical patients, whereas most include combined outcomes for both groups.

Varying Acuity (ICU Versus General Ward)

There are 6 randomized clinical trials[31,49,50,53,56,59] in which researchers enrolled only ICU patients, and all but one[50] revealed a significant difference favoring isotonic IVFs for the prevention of hyponatremia. Researchers in 8 randomized clinical trials enrolled exclusively patients in a general ward setting,[32,51,52,54,55,57,58,60] and those in all but 2[32,57] found a significant reduction in hyponatremia among those receiving isotonic IVFs. McNab et al[35] enrolled patients in both the ICU and general surgical ward, and they were at similar risk for developing hyponatremia.

Exclusion of Specific Populations Not Studied

Patients with neurosurgical disorders, congenital or acquired cardiac disease, hepatic disease,

cancer, renal dysfunction, diabetes insipidus, voluminous watery diarrhea, or severe burns; neonates who were younger than 28 days old or in the NICU (researchers in the majority of prospective studies reviewed in this guideline excluded this subset of patients); and adolescents older than 18 years old were excluded. Patients with congenital or acquired heart disease have been either explicitly excluded from every study listed previously or were not described, so no conclusions may be drawn related to this specific population. Similarly, patients with known liver or renal disease or adrenal insufficiency have also been excluded from most of the studies listed, limiting any conclusions for these patients as well. Neurosurgical patients and those with traumatic brain injury were excluded from most studies. Oncology patients have been included in some of the randomized trials, but no specific subanalysis for them has been completed, and data are not available separately to conduct one. Many patients receiving chemotherapy receive high volumes of fluids to prevent renal injury, and there are reports of clinically significant hyponatremia, which is possibly associated with the fluid type.[61] Further study is needed to evaluate the fluid type, rate, and risk of renal injury and hyponatremia for this population. The committee did not specifically review literature for those with the following care needs: patients with significant renal concentrating defects, such as nephrogenic diabetes insipidus, and patients with voluminous diarrhea or severe burns who may have significant ongoing free-water losses.

Complications

Hyponatremia

The reviewed studies revealed the relative risk of developing mild and moderate hyponatremia (defined as a serum sodium concentration <135 mEq/L and <130 mEq/L, respectively) to be >2 and >5, respectively. The risk related to hyponatremia persisted regardless of age, medical versus surgical status, and intensive care versus general pediatric ward setting. These data strongly reveal an increased risk of hyponatremia when children receive hypotonic versus isotonic IVFs. This association is reinforced by the observations that increased hyponatremia occurs in (1) children with normal sodium at baseline (hospital-acquired hyponatremia) and (2) children who have a low sodium concentration at baseline (hospital-aggravated hyponatremia). This association has been found when using both 0.2% saline (sodium 34 mEq/L) and 0.45% saline (sodium 77 mEq/L). The risk for hyponatremia with hypotonic fluids persisted in the subgroup of patients who received fluids at a restricted rate.[49,54,58,59] A sensitivity analysis in which the Shamim et al[58] study was excluded given the anomalous number of events in both arms revealed no change in the overall estimated relative risk (0.43; 95% CI, 0.35–0.53) compared with that of all the studies included (0.46; 95% CI, 0.37–0.57; Supplemental Fig 2). In the clinical trials in which researchers assessed the possible mechanism for this finding, elevated antidiuretic hormone (ADH) concentration was found to play a putative role.[54]

There is heterogeneity in the design of the above studies in the types of patients enrolled, IVF rate and type, frequency of plasma sodium monitoring, and study duration. Despite this heterogeneity, the increased risk of hyponatremia with hypotonic IVFs is consistent. Some may argue that mild hyponatremia (plasma sodium 130–134 mEq/L) and moderate hyponatremia (plasma sodium 125–129 mEq/L) may not be clinically significant or constitute harm. However, the studies in which researchers evaluated moderate hyponatremia revealed benefits of isotonic versus hypotonic IVFs (Supplemental Figs 2 and 4). Furthermore, hypotonic solutions have been associated with a larger decrease in serum sodium. Also, the true effects of hypotonic IVFs may have been underestimated because many of the studies also included rigorous monitoring of sodium, during which patients were removed from the study if mild hyponatremia developed. Numerous studies of adults have revealed that mild and asymptomatic hyponatremia is associated with deleterious consequences, is an independent risk factor for mortality,[62,63] and leads to increased length of hospitalization and increases in costs of hospitalization.[64,65] Thus, the subcommittee believes that hyponatremia is an appropriate indicator of potential harm.

Hypernatremia

One of the concerns when providing a higher level of sodium in IVFs is the development of hypernatremia (serum sodium >145 mEq/L). This was evaluated in the most recently published systematic review.[33] Those authors identified that there was no evidence of an increased risk of hypernatremia associated with the administration of isotonic fluids, although the quality of evidence was judged to be low, primarily given the low incidence of hypernatremia in the studies included. To be clear, there was not evidence of no risk; the risk is unclear from the meta-analysis results. The estimated risk ratio from that meta-analysis was 1.24 (95% CI, 0.65–2.38), drawn from 9 studies with 937 patients, although 3 studies had no events and did not contribute to the estimate. Researchers in 2 large studies published since the meta-analysis did not find evidence of an increased risk of hypernatremia with isotonic IVFs. In the study by Friedman et al,[32] there was 1 patient in each randomized group (N = 110)

who developed hypernatremia, and in the study by McNab et al,[35] the incidence of hypernatremia was 4% in the isotonic IVF group and 6% in the hypotonic IVF group, with no significant difference noted between the 2 groups (N = 641 with data for analysis). The available data among the meta-analysis discussed above and subsequent large RCTs were unable to be used to demonstrate an increased risk of hypernatremia associated with the use of isotonic IVFs.

Acidosis

A hyperchloremic metabolic acidosis has been associated with 0.9% NaCl when it is used as a resuscitation fluid. Researchers in the majority of studies reviewed in this series did not specifically evaluate the development of acidosis or report on it as a complication. Researchers in 4 studies involving 496 patients evaluated the effect of IVF composition on acid and/or base status,[31,49,54,58] and the majority were not able to demonstrate that 0.9% NaCl resulted in acidosis. Two studies in which researchers compared 0.9% NaCl to 0.45% NaCl involving 357 children found no effect on the development of acidosis based on the change in total carbon dioxide (Tco_2), a measure of plasma bicarbonate, with a low Tco_2 being a surrogate marker for acidosis rather than a low pH.[31,54] Researchers in 1 study compared Hartman solution, which has a base equivalent to 0.45% NaCl, involving 79 patients and found no effect on the development of acidosis based on a change in Tco_2.[49] Researchers in 1 study involving 60 patients compared 0.9% NaCl to 0.18% NaCl and demonstrated a decrease in pH from 7.36 to 7.32 in the 0.9% NaCl group compared with an increase in pH from 7.36 to 7.38 in the 0.18% NaCl group (P = .01), but the effect on Tco_2 was not reported.[58]

Fluid Overload

Children receiving IVFs are at risk for fluid accumulation leading to a positive fluid balance or volume overload. A combination of excessive fluid and sodium can synergistically increase retained volume, a condition that is exacerbated in children with chronic comorbidities (such as systolic cardiac dysfunction [congestive heart failure (CHF)], cirrhotic hepatic failure, chronic kidney disease, and hepatorenal syndrome) and metabolic disturbances (such as hyperaldosteronism and long-term steroid use). Researchers in recent literature, most notably in the critically ill population (adults and children), have attempted to delineate the causative and outcome associations with significant positive fluid accumulation, termed "fluid overload."[66] In the non-ICU population, researchers in only a handful of studies mention an association between fluid tonicity and volume overload (or "weight gain").[20,59,60] Choong et al[20] reported on "overhydration" as estimated by using total weight gain, finding no significant difference between isotonic and hypotonic IVF administration. In the meta-analyses that encompass 12 different RCTs and more than 750 children, neither weight nor net fluid balance is discussed. Increasing scrutiny is being given to fluid management in the critically ill population.[33] To determine any association in patients who are noncritically ill, more evidence is required.

Specific Groups That May Be at Higher Risk for Developing Hyponatremia

Researchers in the RCTs reviewed for this statement excluded many groups of patients who are at particularly high risk for hyponatremia, such as those with congenital or acquired heart disease, liver disease, renal failure or dysfunction, or adrenal insufficiency; neurosurgical patients; and patients taking medication known to impair free-water excretion, such as desmopressin. Data on the efficacy of isotonic fluids to prevent hyponatremia and the potential complications related to isotonic fluids in these patients are lacking. Further studies in which researchers evaluate optimal fluid management in these groups of patients are necessary. Patients with edematous states, such as CHF, cirrhosis, and nephrotic syndrome, have an impaired ability to excrete both free water and sodium and are at risk for both volume overload and hyponatremia. Administering isotonic saline at typical maintenance rates will likely be excessive and risk volume overload, and IVFs should be restricted with close monitoring. Renal diseases can have multiple effects on sodium and water homeostasis; patients with glomerulonephritis may avidly reabsorb sodium, whereas those with tubulopathies may have obligatory urinary sodium losses. Patients with renal failure have a relative inability to excrete free water because of the reduced glomerular filtration rate and simultaneously are unable to produce maximally concentrated urine. Patients with adrenal insufficiency can have renal salt wasting and an impaired ability to excrete free water. Patients with CNS disorders can have multiple conditions that impair water excretion, including SIAD and cerebral salt wasting. Patients receiving certain medications are at particularly high risk for developing hyponatremia, such as desmopressin administered perioperatively for Von Willebrand disease, antiepileptic medications (such as carbamazepine), and chemotherapeutic agents (such as IV cyclophosphamide and vincristine). Isotonic IVFs may be the preferred fluid composition for these disease states, but care is needed in dosing the quantity of fluids, and close

monitoring of both the volume status and electrolytes is required.

Limitations

The subcommittee's recommendation to use isotonic fluids when maintenance IVFs are required does not mean that there are no indications for administering hypotonic fluids or that isotonic fluids will be safe in all patients. Patients with significant renal concentrating defects, such as nephrogenic diabetes insipidus, could develop hypernatremia if they are administered isotonic fluids. Patients with voluminous diarrhea or severe burns may require a hypotonic fluid to keep up with ongoing free-water losses. Hypotonic fluids may also be required to correct hypernatremia. However, for the vast majority of patients, isotonic fluids are the most appropriate maintenance IVF and are the least likely to result in a disorder in serum sodium.

CONCLUSIONS

For the past 60 years, the prescription for maintenance IVFs for infants and children has been a hypotonic fluid. These recommendations were made on theoretical grounds and were not based on clinical trials. Despite this accepted dogma, over the past decade and longer, there have been increasing reports of the deleterious effect of hyponatremia in the acute care setting with the use of the prevailing hypotonic maintenance solutions. Using an evidence-based approach, recommendations for optimal sodium composition of maintenance IVFs are provided to prevent hyponatremia and acute or permanent neurologic impairment related to it. Recommendations are not made regarding the use of an isotonic buffered crystalloid solution versus saline, the optimal rate of fluid therapy, or the need for providing potassium in maintenance fluids. The use of this guideline differentiates the applicability to 2 subgroups of children: (1) The guideline applies to surgical (postoperative) medical patients in a critical care setting and the general inpatient ward. (2) The guideline does not apply to patients with neurosurgical disorders, congenital or acquired cardiac disease, hepatic disease, cancer, renal dysfunction, diabetes insipidus, voluminous watery diarrhea, or severe burns; neonates who are younger than 28 days old or in the NICU; or adolescents older than 18 years of age (Supplemental Fig 5).

This guideline is intended for use primarily by clinicians providing acute care for children and adolescents who require maintenance IVFs. It may be of interest to parents and payers, but it is not intended to be used for reimbursement or to determine insurance coverage. This guideline is not intended to be the sole source of guidance in the use of maintenance IVFs but rather is intended to assist clinicians by providing a framework for clinical decision-making.

The Key Action Statement is as follows:

1A: The AAP recommends that patients 28 days to 18 years of age requiring maintenance IVFs should receive isotonic solutions with appropriate KCl and dextrose because they significantly decrease the risk of developing hyponatremia (evidence quality: A; recommendation strength: strong).

BIOCHEMICAL LABORATORY MONITORING

Although the frequency for biochemical laboratory monitoring was not specifically addressed in the 17 RCTs included in the meta-analysis, researchers in most of the studies obtained serial plasma sodium values, with the first plasma sodium being measured between 6 hours and 12 hours. The incidence of hyponatremia in patients receiving isotonic fluids ranged from 0% to 23%, whereas that of hypotonic fluids ranged from 5% to 100%. This large variability was likely related to the different study designs. Many patients who were hospitalized and received isotonic IVFs will be at risk for hyponatremia if they are receiving IV medications containing free water or are consuming additional free water via the enteral route. For these reasons, clinicians should be aware that even patients receiving isotonic maintenance IVFs are at sufficient risk for developing hyponatremia. If an electrolyte abnormality is discovered, this could provide useful information to adjust maintenance fluid therapy. If patients receiving isotonic maintenance IVFs develop hyponatremia, they should be evaluated to determine if they are receiving other sources of free water or if they may have SIAD and/or an adrenal insufficiency. If hypernatremia develops (plasma sodium >144 mEq/L), patients should be evaluated for renal dysfunction or extrarenal free-water losses.

In patients at high risk for developing electrolyte abnormalities, such as those who have undergone major surgery, those in the ICU, or those with large gastrointestinal losses or receiving diuretics, frequent laboratory monitoring may be necessary. If neurologic symptoms that could be consistent with hyponatremic encephalopathy are present, such as unexplained nausea, vomiting, headache, confusion, or lethargy, electrolytes should be measured.

FUTURE QUALITY-IMPROVEMENT QUESTIONS

Future questions are as follows:

1. How frequently is plasma sodium concentration abnormal, and

is this abnormality clinically significant?

2. Will the widespread use of isotonic maintenance IVFs in the acute-care setting significantly reduce or eliminate hyponatremia- and hyponatremia-related neurologic events?
3. Will the widespread use of 0.9% saline for maintenance IVFs in the acute care setting increase clinically significant metabolic acidosis?
4. Are isotonic-balanced solutions superior to 0.9% saline for the maintenance IVF in the acute-care setting?
5. How frequently should clinicians monitor the serum sodium concentrations when a patient is receiving maintenance IVFs and for patients who are at high risk of sodium abnormalities?

SUBCOMMITTEE ON FLUID AND ELECTROLYTE THERAPY

Leonard G. Feld, MD, PhD, MMM, FAAP – *Chair, Pediatric Nephrology*
Daniel R. Neuspiel, MD, MPH, FAAP – *Pediatric Epidemiologist*
Byron Alexander Foster, MD, MPH, FAAP – *Pediatric Hospitalist*
Matthew D. Garber, MD, FHM, FAAP – *Pediatric Hospitalist; Implementation Scientist*
Michael G. Leu, MD, MS, MHS, FAAP – *Partnership for Policy Implementation*
Rajit K. Basu, MD, MS, FCCM – *Society of Critical Care Medicine, Pediatric Section*
Kelly Austin, MD, MS, FAAP, FACS – *American Pediatric Surgical Association*
Edward E. Conway, Jr, MD, MS, FAAP – *Pediatric Critical Care*
James J. Fehr, MD, FAAP – *Society for Pediatric Anesthesia*
Clare Hawkins, MD – *American Academy of Family Physicians*
Ron L. Kaplan, MD, FAAP – *Pediatric Emergency Medicine*
Echo V. Rowe, MD, FAAP – *Pediatric Anesthesiology and Pain Medicine*
Muhammad Waseem, MD, MS, FAAP, FACEP – *American College of Emergency Physicians*
Michael L. Moritz, MD, FAAP – *Pediatric Nephrology*

STAFF

Kymika Okechukwu, MPA – *Senior Manager, Evidence-Based Medicine Initiatives*

ABBREVIATIONS

AAP: American Academy of Pediatrics
ADH: antidiuretic hormone
AVP: arginine vasopressin
CHF: congestive heart failure
CI: confidence interval
CNS: central nervous system
IV: intravenous
IVF: intravenous fluid
kcal: kilocalorie
KCl: potassium chloride
M-H: Mantel-Haenzel
NaCl: sodium chloride
RCT: randomized controlled trial
SIAD: syndrome of inappropriate antidiuresis
T_{CO_2}: total carbon dioxide

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2018-3083

Address correspondence to Leonard G. Feld, MD, PhD, MMM, FAAP. E-mail: feldllc@gmail.com

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Chawla G, Drummond GB. Textbook coverage of a common topic: fluid management of patients after surgery. *Med Educ*. 2008;42(6):613–618
2. Davies P, Hall T, Ali T, Lakhoo K. Intravenous postoperative fluid prescriptions for children: a survey of practice. *BMC Surg*. 2008;8:10
3. Freeman MA, Ayus JC, Moritz ML. Maintenance intravenous fluid prescribing practices among paediatric residents. *Acta Paediatr*. 2012;101(10):e465–e468
4. Lee JM, Jung Y, Lee SE, et al. Intravenous fluid prescription practices among pediatric residents in Korea. *Korean J Pediatr*. 2013;56(7):282–285
5. Goldstein SL. Fluid management in acute kidney injury. *J Intensive Care Med*. 2014;29(4):183–189
6. Hoste EA, Maitland K, Brudney CS, et al; ADQI XII Investigators Group. Four phases of intravenous fluid therapy: a conceptual model. *Br J Anaesth*. 2014;113(5): 740–747
7. McDermid RC, Raghunathan K, Romanovsky A, Shaw AD, Bagshaw SM. Controversies in fluid therapy: type, dose and toxicity. *World J Crit Care Med*. 2014;3(1):24–33
8. Jackson J, Bolte RG. Risks of intravenous administration of hypotonic fluids for pediatric patients in ED and prehospital settings: let's remove the handle from the pump. *Am J Emerg Med*. 2000;18(3):269–270
9. Wang J, Xu E, Xiao Y. Isotonic versus hypotonic maintenance IV fluids in hospitalized children: a meta-analysis. *Pediatrics*. 2014;133(1):105–113
10. Moritz ML, Ayus JC. Maintenance intravenous fluids in acutely ill patients. *N Engl J Med*. 2015;373(14):1350–1360
11. Carandang F, Anglemyer A, Longhurst CA, et al. Association between

maintenance fluid tonicity and hospital-acquired hyponatremia. *J Pediatr*. 2013;163(6):1646–1651

12. Upadhyay A, Jaber BL, Madias NE. Incidence and prevalence of hyponatremia. *Am J Med*. 2006;119 (7, suppl 1):S30–S35
13. Moritz ML, Ayus JC. Disorders of water metabolism in children: hyponatremia and hypernatremia. *Pediatr Rev*. 2002;23(11):371–380
14. Gerigk M, Gnehm HE, Rascher W. Arginine vasopressin and renin in acutely ill children: implication for fluid therapy. *Acta Paediatr*. 1996;85(5):550–553
15. Judd BA, Haycock GB, Dalton RN, Chantler C. Antidiuretic hormone following surgery in children. *Acta Paediatr Scand*. 1990;79(4):461–466
16. Holliday MA, Segar WE. The maintenance need for water in parenteral fluid therapy. *Pediatrics*. 1957;19(5):823–832
17. Talbot FB. Basal metabolism standards for children. *Am J Dis Child*. 1938;55(3):455–459
18. Hatherill M. Rubbing salt in the wound. *Arch Dis Child*. 2004;89(5):414–418
19. Hoorn EJ, Geary D, Robb M, Halperin ML, Bohn D. Acute hyponatremia related to intravenous fluid administration in hospitalized children: an observational study. *Pediatrics*. 2004;113(5):1279–1284
20. Choong K, Arora S, Cheng J, et al. Hypotonic versus isotonic maintenance fluids after surgery for children: a randomized controlled trial. *Pediatrics*. 2011;128(5):857–866
21. Arieff AI, Ayus JC, Fraser CL. Hyponatraemia and death or permanent brain damage in healthy children. *BMJ*. 1992;304(6836):1218–1222
22. Moritz ML, Ayus JC. Preventing neurological complications from dysnatremias in children. *Pediatr Nephrol*. 2005;20(12):1687–1700
23. Halberthal M, Halperin ML, Bohn D. Lesson of the week: acute hyponatraemia in children admitted to hospital: retrospective analysis of factors contributing to its development and resolution. *BMJ*. 2001;322(7289):780–782
24. Moritz ML, Ayus JC. Prevention of hospital-acquired hyponatremia: a case for using isotonic saline. *Pediatrics*. 2003;111(2):227–230
25. ISMP. Medication safety alert. Plain D5W or hypotonic saline solutions post-op could result in acute hyponatremia and death in healthy children. Available at: ismp.org. Accessed August 14, 2009
26. ISMP Canada. Hospital-acquired acute hyponatremia: two reports of pediatric deaths.*ISMP Canada Saf Bul*. 2009;9(7). Available at: http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2009-7-HospitalAcquiredAcuteHyponatremia.pdf. Accessed July 26, 2018
27. National Patient Safety Agency. Reducing the risk of hyponatraemia when administering intravenous infusions to children. 2007. Available at: www.npsa.nhs.uk/health/alerts. Accessed July 6, 2018
28. Drysdale SB, Coulson T, Cronin N, et al. The impact of the National Patient Safety Agency intravenous fluid alert on iatrogenic hyponatraemia in children. *Eur J Pediatr*. 2010;169(7):813–817
29. Holliday MA, Ray PE, Friedman AL. Fluid therapy for children: facts, fashions and questions. *Arch Dis Child*. 2007;92(6):546–550
30. McNab S. Isotonic vs hypotonic intravenous fluids for hospitalized children. *JAMA*. 2015;314(7):720–721
31. Almeida HI, Mascarenhas MI, Loureiro HC, et al. The effect of NaCl 0.9% and NaCl 0.45% on sodium, chloride, and acid-base balance in a PICU population. *J Pediatr (Rio J)*. 2015;91(5):499–505
32. Friedman JN, Beck CE, DeGroot J, Geary DF, Sklansky DJ, Freedman SB. Comparison of isotonic and hypotonic intravenous maintenance fluids: a randomized clinical trial. *JAMA Pediatr*. 2015;169(5):445–451
33. McNab S, Ware RS, Neville KA, et al. Isotonic versus hypotonic solutions for maintenance intravenous fluid administration in children. *Cochrane Database Syst Rev*. 2014;(12):CD009457
34. National Clinical Guideline Centre (UK). *IV Fluids in Children: Intravenous Fluid Therapy in Children and Young People in Hospital*. London, United Kingdom: National Clinical Guideline Centre; 2015. Available at: www.ncbi.nlm.nih.gov/pubmed/26741016. Accessed July 6, 2018
35. McNab S, Duke T, South M, et al. 140 mmol/L of sodium versus 77 mmol/L of sodium in maintenance intravenous fluid therapy for children in hospital (PIMS): a randomised controlled double-blind trial. *Lancet*. 2015;385(9974):1190–1197. Published online December 1, 2014
36. Siegel NJ, ed. Fluids, electrolytes and acid-base. In: *Rudolph's Pediatrics*. 21st ed. New York, NY: McGraw Hill; 2003:1653–1655
37. Greenbaum LA, ed. Pathophysiology of body fluids and fluid therapy. In: *Nelson's Textbook of Pediatrics*. 17th ed. Philadelphia, PA: WB Saunders; 2004:242–245
38. Powers KS. Dehydration: isonatremic, hyponatremic, and hypernatremic recognition and management. *Pediatr Rev*. 2015;36(7):274–283; quiz 284–285
39. Foster BA, Tom D, Hill V. Hypotonic versus isotonic fluids in hospitalized children: a systematic review and meta-analysis. *J Pediatr*. 2014;165(1):163–169.e2
40. Padua AP, Macaraya JR, Dans LF, Anacleto FE Jr. Isotonic versus hypotonic saline solution for maintenance intravenous fluid therapy in children: a systematic review. *Pediatr Nephrol*. 2015;30(7):1163–1172
41. Yang G, Jiang W, Wang X, Liu W. The efficacy of isotonic and hypotonic intravenous maintenance fluid for pediatric patients: a meta-analysis of randomized controlled trials. *Pediatr Emerg Care*. 2015;31(2):122–126
42. Choong K, Kho ME, Menon K, Bohn D. Hypotonic versus isotonic saline in hospitalised children: a systematic review. *Arch Dis Child*. 2006;91(10):828–835
43. Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA*. 1993;270(21):2598–2601
44. Guyatt GH, Sackett DL, Cook DJ. Users' guides to the medical literature. II.

How to use an article about therapy or prevention. B. What were the results and will they help me in caring for my patients? Evidence-Based Medicine Working Group. *JAMA*. 1994;271(1):59–63

45. Higgins JP, Green S, eds. *Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1.0. Updated March 2011*. London, United Kingdom: The Cochrane Collaboration; 2011. Available at: http://handbook-5-1.cochrane.org/. Accessed July 6, 2018
46. American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877
47. Bridge-Wiz. Guideline quality appraisal. Available at: http://gem.med.yale.edu/BRIDGE-Wiz/BridgeWiz_2.1_AAP.zip. Accessed April 12, 2016
48. Brazel PW, McPhee IB. Inappropriate secretion of antidiuretic hormone in postoperative scoliosis patients: the role of fluid management. *Spine*. 1996;21(6):724–727
49. Coulthard MG, Long DA, Ullman AJ, Ware RS. A randomised controlled trial of Hartmann's solution versus half normal saline in postoperative paediatric spinal instrumentation and craniotomy patients. *Arch Dis Child*. 2012;97(6):491–496
50. Jorro Barón FA, Meregalli CN, Rombola VA, et al. Hypotonic versus isotonic maintenance fluids in critically ill pediatric patients: a randomized controlled trial [in English and Spanish]. *Arch Argent Pediatr*. 2013;111(4):281–287
51. Flores Robles CM, Cuello García CA. A prospective trial comparing isotonic with hypotonic maintenance fluids for prevention of hospital-acquired hyponatraemia. *Paediatr Int Child Health*. 2016;36(3):168–174
52. Kannan L, Lodha R, Vivekanandhan S, Bagga A, Kabra SK, Kabra M. Intravenous fluid regimen and hyponatraemia among children: a randomized controlled trial. *Pediatr Nephrol*. 2010;25(11):2303–2309
53. Montañana PA, Modesto i Alapont V, Ocón AP, López PO, López Prats JL, Toledo Parreño JD. The use of isotonic fluid as maintenance therapy prevents iatrogenic hyponatremia in pediatrics: a randomized, controlled open study. *Pediatr Crit Care Med*. 2008;9(6):589–597
54. Neville KA, Sandeman DJ, Rubinstein A, et al. Prevention of hyponatremia during maintenance intravenous fluid administration: a prospective randomized study of fluid type versus fluid rate. *J Pediatr*. 2010;156(2):313–319.e1–e2
55. Ramanathan S, Kumar P, Mishra K, Dutta AK. Isotonic versus hypotonic parenteral maintenance fluids in very severe pneumonia. *Indian J Pediatr*. 2016;83(1):27–32
56. Rey C, Los-Arcos M, Hernández A, Sánchez A, Díaz JJ, López-Herce J. Hypotonic versus isotonic maintenance fluids in critically ill children: a multicenter prospective randomized study. *Acta Paediatr*. 2011;100(8):1138–1143
57. Saba TG, Fairbairn J, Houghton F, Laforte D, Foster BJ. A randomized controlled trial of isotonic versus hypotonic maintenance intravenous fluids in hospitalized children. *BMC Pediatr*. 2011;11:82
58. Shamim A, Afzal K, Ali SM. Safety and efficacy of isotonic (0.9%) vs. hypotonic (0.18%) saline as maintenance intravenous fluids in children: a randomized controlled trial. *Indian Pediatr*. 2014;51(12):969–974
59. Yung M, Keeley S. Randomised controlled trial of intravenous maintenance fluids. *J Paediatr Child Health*. 2009;45(1–2):9–14
60. Valadão MC S, Piva JP, Santana JC, Garcia PC. Comparison of two maintenance electrolyte solutions in children in the postoperative appendectomy period: a randomized, controlled trial. *J Pediatr (Rio J)*. 2015;91(5):428–434
61. Duke T, Kinney S, Waters K. Hyponatraemia and seizures in oncology patients associated with hypotonic intravenous fluids. *J Paediatr Child Health*. 2005;41(12):685–686
62. Gankam-Kengne F, Ayers C, Khera A, de Lemos J, Maalouf NM. Mild hyponatremia is associated with an increased risk of death in an ambulatory setting. *Kidney Int*. 2013;83(4):700–706
63. Holland-Bill L, Christiansen CF, Heide-Jørgensen U, et al. Hyponatremia and mortality risk: a Danish cohort study of 279508 acutely hospitalized patients. *Eur J Endocrinol*. 2015;173(1):71–81
64. Amin A, Deitelzweig S, Christian R, et al. Evaluation of incremental healthcare resource burden and readmission rates associated with hospitalized hyponatremic patients in the US. *J Hosp Med*. 2012;7(8):634–639
65. Corona G, Giuliani C, Parenti G, et al. The economic burden of hyponatremia: systematic review and meta-analysis. *Am J Med*. 2016;129(8):823–835.e4
66. Alobaidi R, Morgan C, Basu RK, et al. Associations between fluid balance and outcomes in critically ill children: a protocol for a systematic review and meta-analysis. *Can J Kidney Health Dis*. 2017;4:2054358117692560
67. Pemde HK, Dutta AK, Sodani R, Mishra K. Isotonic intravenous maintenance fluid reduces hospital acquired hyponatremia in young children with central nervous system infections. *Indian J Pediatr*. 2015;82(1):13–18

Intravenous Fluids Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — Clinical Practice Guideline: Maintenance Intravenous Fluids in Children
- *ICD-10-CM* Coding Quick Reference for Maintenance Intravenous Fluids

Action Statement Summary

Clinical Practice Guideline: Maintenance Intravenous Fluids in Children

Key Action Statement 1

Composition of Maintenance IVFs

Key Action Statement 1A

The AAP recommends that patients 28 days to 18 years of age requiring maintenance IVFs should receive isotonic solutions with appropriate potassium chloride (KCl) and dextrose because they significantly decrease the risk of developing hyponatremia (evidence quality: A; recommendation strength: strong).

Coding Quick Reference for Maintenance Intravenous Fluids
ICD-10-CM
E86.0 Dehydration

The Diagnosis and Management of Acute Otitis Media

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE

The Diagnosis and Management of Acute Otitis Media

abstract

FREE

This evidence-based clinical practice guideline is a revision of the 2004 acute otitis media (AOM) guideline from the American Academy of Pediatrics (AAP) and American Academy of Family Physicians. It provides recommendations to primary care clinicians for the management of children from 6 months through 12 years of age with uncomplicated AOM.

In 2009, the AAP convened a committee composed of primary care physicians and experts in the fields of pediatrics, family practice, otolaryngology, epidemiology, infectious disease, emergency medicine, and guideline methodology. The subcommittee partnered with the Agency for Healthcare Research and Quality and the Southern California Evidence-Based Practice Center to develop a comprehensive review of the new literature related to AOM since the initial evidence report of 2000. The resulting evidence report and other sources of data were used to formulate the practice guideline recommendations.

The focus of this practice guideline is the appropriate diagnosis and initial treatment of a child presenting with AOM. The guideline provides a specific, stringent definition of AOM. It addresses pain management, initial observation versus antibiotic treatment, appropriate choices of antibiotic agents, and preventive measures. It also addresses recurrent AOM, which was not included in the 2004 guideline. Decisions were made on the basis of a systematic grading of the quality of evidence and benefit-harm relationships.

The practice guideline underwent comprehensive peer review before formal approval by the AAP.

This clinical practice guideline is not intended as a sole source of guidance in the management of children with AOM. Rather, it is intended to assist primary care clinicians by providing a framework for clinical decision-making. It is not intended to replace clinical judgment or establish a protocol for all children with this condition. These recommendations may not provide the only appropriate approach to the management of this problem. *Pediatrics* 2013;131:e964–e999

Allan S. Lieberthal, MD, FAAP, Aaron E. Carroll, MD, MS, FAAP, Tasnee Chonmaitree, MD, FAAP, Theodore G. Ganiats, MD, Alejandro Hoberman, MD, FAAP, Mary Anne Jackson, MD, FAAP, Mark D. Joffe, MD, FAAP, Donald T. Miller, MD, MPH, FAAP, Richard M. Rosenfeld, MD, MPH, FAAP, Xavier D. Sevilla, MD, FAAP, Richard H. Schwartz, MD, FAAP, Pauline A. Thomas, MD, FAAP, and David E. Tunkel, MD, FAAP, FACS

KEY WORDS

acute otitis media, otitis media, otoscopy, otitis media with effusion, watchful waiting, antibiotics, antibiotic prophylaxis, tympanostomy tube insertion, immunization, breastfeeding

ABBREVIATIONS

AAFP—American Academy of Family Physicians
AAP—American Academy of Pediatrics
AHRQ—Agency for Healthcare Research and Quality
AOM—acute otitis media
CI—confidence interval
FDA—US Food and Drug Administration
LAIV—live-attenuated intranasal influenza vaccine
MEE—middle ear effusion
MIC—minimum inhibitory concentration
NNT—number needed to treat
OM—otitis media
OME—otitis media with effusion
OR—odds ratio
PCV7—heptavalent pneumococcal conjugate vaccine
PCV13—13-valent pneumococcal conjugate vaccine
RD—rate difference
SNAP—safety-net antibiotic prescription
TIV—trivalent inactivated influenza vaccine
TM—tympanic membrane
WASP—wait-and-see prescription

(Continued on last page)

Key Action Statement 1A: Clinicians should diagnose acute otitis media (AOM) in children who present with moderate to severe bulging of the tympanic membrane (TM) *or* new onset of otorrhea not due to acute otitis externa. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 1B: Clinicians should diagnose AOM in children who present with mild bulging of the TM *and* recent (less than 48 hours) onset of ear pain (holding, tugging, rubbing of the ear in a nonverbal child) or intense erythema of the TM. Evidence Quality: Grade C. Strength: Recommendation.

Key Action Statement 1C: Clinicians should not diagnose AOM in children who do not have middle ear effusion (MEE) (based on pneumatic otoscopy and/or tympanometry). Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 2: The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 3A: Severe AOM: The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children 6 months and older with severe signs or symptoms (ie, moderate or severe otalgia or otalgia for at least 48 hours or temperature 39°C [102.2°F] or higher). Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 3B: Nonsevere bilateral AOM in young children: The clinician should prescribe antibiotic therapy for bilateral AOM in children 6 months through 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 3C: Nonsevere unilateral AOM in young children: The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for unilateral AOM in children 6 months to 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 3D: Nonsevere AOM in older children: The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for AOM (bilateral or unilateral) in children 24 months or older without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 4A: Clinicians should prescribe amoxicillin for AOM when a decision to treat with antibiotics has been made *and* the child has not received amoxicillin in the past 30 days *or* the child does not have concurrent purulent conjunctivitis *or* the child is not allergic to penicillin. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 4B: Clinicians should prescribe an antibiotic with additional β-lactamase coverage for AOM when a decision to treat with antibiotics has been made, *and* the child has received amoxicillin in the last 30 days *or* has concurrent purulent conjunctivitis, *or* has a history of recurrent AOM unresponsive to amoxicillin. Evidence Quality: Grade C. Strength: Recommendation.

Key Action Statement 4C: Clinicians should reassess the patient if the caregiver reports that the child's symptoms have worsened or failed to respond to the initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 5A: Clinicians should not prescribe prophylactic antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 5B: Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months or 4 episodes in 1 year with 1 episode in the preceding 6 months). Evidence Quality: Grade B. Strength: Option.

Key Action Statement 6A: Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, American Academy of Pediatrics (AAP), and American Academy of Family Physicians (AAFP). Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 6B: Clinicians should recommend annual influenza vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices, AAP, and AAFP. Evidence Quality: Grade B. Strength: Recommendation.

2Key Action Statement 6C: Clinicians should encourage exclusive breastfeeding for at least 6 months. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 6D: Clinicians should encourage avoidance of tobacco smoke exposure. Evidence Quality: Grade C. Strength: Recommendation.

INTRODUCTION

In May 2004, the AAP and AAFP published the "Clinical Practice Guideline: Diagnosis and Management of Acute Otitis Media".[1] The guideline offered 8 recommendations ranked according to level of evidence and benefit-harm relationship. Three of the recommendations—diagnostic criteria, observation, and choice of antibiotics—led to significant discussion, especially among experts in the field of otitis media (OM). Also, at the time the guideline was written, information regarding the heptavalent pneumococcal conjugate vaccine (PCV7) was not yet published. Since completion of the guideline in November 2003 and its publication in May 2004, there has been a significant body of additional literature on AOM.

Although OM remains the most common condition for which antibacterial agents are prescribed for children in the United States[2,3] clinician visits for OM decreased from 950 per 1000 children in 1995–1996 to 634 per 1000 children in 2005–2006. There has been a proportional decrease in antibiotic prescriptions for OM from 760 per 1000 in 1995–1996 to 484 per 1000 in 2005–2006. The percentage of OM visits resulting in antibiotic prescriptions remained relatively stable (80% in 1995–1996; 76% in 2005–2006).[2] Many factors may have contributed to the decrease in visits for OM, including financial issues relating to insurance, such as copayments, that may limit doctor visits, public education campaigns regarding the viral nature of most infectious diseases, use of the PCV7 pneumococcal vaccine, and increased use of the influenza vaccine. Clinicians may also be more attentive to differentiating AOM from OM with effusion (OME), resulting in fewer visits coded for AOM and fewer antibiotic prescriptions written.

Despite significant publicity and awareness of the 2004 AOM guideline, evidence shows that clinicians are hesitant to follow the guideline recommendations. Vernacchio et al[4] surveyed 489 primary care physicians as to their management of 4 AOM scenarios addressed in the 2004 guideline. No significant changes in practice were noted on this survey, compared with a survey administered before the 2004 AOM guideline. Coco[5] used the National Ambulatory Medical Care Survey from 2002 through 2006 to determine the frequency of AOM visits without antibiotics before and after publication of the 2004 guideline. There was no difference in prescribing rates. A similar response to otitis guidelines was found in Italy as in the United States.[6,7] These findings parallel results of other investigations regarding clinician awareness and adherence to guideline recommendations in all specialties, including pediatrics.[8] Clearly, for clinical practice guidelines to be effective, more must be done to improve their dissemination and implementation.

This revision and update of the AAP/AAFP 2004 AOM guideline[1] will evaluate published evidence on the diagnosis and management of uncomplicated AOM and make recommendations based on that evidence. The guideline is intended for primary care clinicians including pediatricians and family physicians, emergency department physicians, otolaryngologists, physician assistants, and nurse practitioners. The scope of the guideline is the diagnosis and management of AOM, including recurrent AOM, in children 6 months through 12 years of age. It applies only to an otherwise healthy child without underlying conditions that may alter the natural course of AOM, including but not limited to the presence of tympanostomy tubes; anatomic abnormalities, including cleft palate; genetic conditions with craniofacial abnormalities, such as Down syndrome; immune deficiencies; and the presence of cochlear implants. Children with OME without AOM are also excluded.

Glossary of Terms

AOM—the rapid onset of signs and symptoms of inflammation in the middle ear[9,10]

Uncomplicated AOM—AOM without otorrhea[1]

Severe AOM—AOM with the presence of moderate to severe otalgia *or* fever equal to or higher than 39°C[9,10]

Nonsevere AOM—AOM with the presence of mild otalgia and a temperature below 39°C[9,10]

Recurrent AOM—3 or more well-documented and separate AOM episodes in the preceding 6 months *or* 4 or more episodes in the preceding 12 months with at least 1 episode in the past 6 months[11,12]

OME—inflammation of the middle ear with liquid collected in the middle ear; the signs and symptoms of acute infection are absent[9]

MEE—liquid in the middle ear without reference to etiology, pathogenesis, pathology, or duration[9]

Otorrhea—discharge from the ear, originating at 1 or more of the following sites: the external auditory canal,

middle ear, mastoid, inner ear, or intracranial cavity

Otitis externa—an infection of the external auditory canal

Tympanometry—measuring acoustic immittance (transfer of acoustic energy) of the ear as a function of ear canal air pressure[13,14]

Number needed to treat (NNT)—the number of patients who need to be treated to prevent 1 additional bad outcome[15]

Initial antibiotic therapy—treatment of AOM with antibiotics that are prescribed at the time of diagnosis with the intent of starting antibiotic therapy as soon as possible after the encounter

Initial observation—initial management of AOM limited to symptomatic relief, with commencement of antibiotic therapy only if the child's condition worsens at any time or does not show clinical improvement within 48 to 72 hours of diagnosis; a mechanism must be in place to ensure follow-up and initiation of antibiotics if the child fails observation

METHODS

Guideline development using an evidence-based approach requires that all evidence related to the guideline is gathered in a systematic fashion, objectively assessed, and then described so readers can easily see the links between the evidence and recommendations made. An evidence-based approach leads to recommendations that are guided by both the quality of the available evidence and the benefit-to-harm ratio that results from following the recommendation. Figure 1 shows the relationship of evidence quality and benefit-harm balance in determining the level of recommendation. Table 1 presents the AAP definitions and implications of different levels of evidence-based recommendations.[16]

In preparing for the 2004 AAP guidelines, the Agency for Healthcare Research and Quality (AHRQ) funded and conducted an exhaustive review of the literature on diagnosis and management of AOM.[17–19] In 2008, the AHRQ and the Southern California Evidence-Based Practice Center began a similar process of reviewing the literature published since the 2001 AHRQ report. The AAP again partnered with AHRQ and the Southern California Evidence-Based Practice Center to develop the evidence report, which served as a major source of data for these practice guideline recommendations.[20,21] New key questions were determined by a technical expert panel. The scope of the new report went beyond the 2001 AHRQ report to include recurrent AOM.

The key questions addressed by AHRQ in the 2010 report were as follows:

1. Diagnosis of AOM: What are the operating characteristics (sensitivity, specificity, and likelihood ratios) of clinical symptoms and otoscopic findings (such as bulging TM) to diagnose uncomplicated AOM and to distinguish it from OME?
2. What has been the effect of the use of heptavalent PCV7 on AOM microbial epidemiology, what organisms (bacterial and viral) are associated with AOM since the introduction of PCV7, and what are the patterns of antimicrobial resistance in AOM since the introduction of PCV7?
3. What is the comparative effectiveness of various treatment options for treating uncomplicated AOM in average risk children?
4. What is the comparative effectiveness of different management options for recurrent OM (uncomplicated) and persistent OM or relapse of AOM?
5. Do treatment outcomes in Questions 3 and 4 differ by characteristics of the condition (AOM), patient, environment, and/or health care delivery system?
6. What adverse effects have been observed for treatments for which outcomes are addressed in Questions 3 and 4?

For the 2010 review, searches of PubMed and the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Education Resources Information Center were conducted by using the same search strategies used for the 2001 report for publications from 1998 through June 2010. Additional terms or conditions not considered in the 2001 review (recurrent OM, new drugs, and heptavalent pneumococcal vaccine) were also included. The Web of Science was also used to search for citations of the 2001 report and its peer-reviewed publications. Titles were screened independently by 2

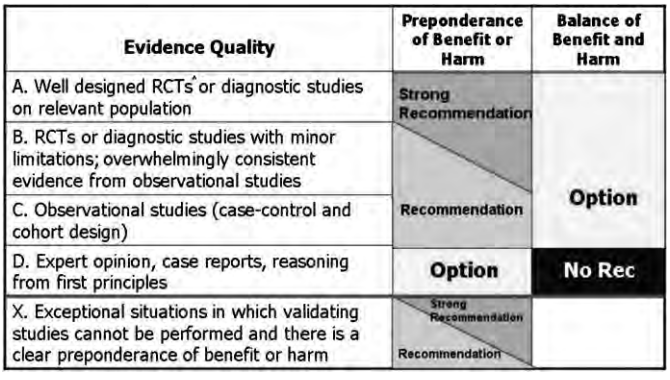


FIGURE 1
Relationship of evidence quality and benefit-harm balance in determining the level of recommendation. RCT, randomized controlled trial.

TABLE 1 Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms, but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No Recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

pediatricians with experience in conducting systematic reviews.

For the question pertaining to diagnosis, efficacy, and safety, the search was primarily for clinical trials. For the question pertaining to the effect of PCV7 on epidemiology and microbiology, the group searched for trials that compared microbiology in the same populations before and after introduction of the vaccine or observational studies that compared microbiology across vaccinated and unvaccinated populations.

In total, the reviewers examined 7646 titles, of which 686 titles were identified for further review. Of those, 72 articles that met the predetermined inclusion and exclusion criteria were reviewed in detail. Investigators abstracted data into standard evidence tables, with accuracy checked by a second investigator. Studies were quality-rated by 2 investigators by using established criteria. For randomized controlled trials, the Jadad criteria were used.[22] QUADAS criteria[23] were used to evaluate the studies that pertained to diagnosis. GRADE criteria were applied to pooled analyses.[24] Data abstracted included parameters necessary to define study groups, inclusion/exclusion criteria, influencing factors, and outcome measures. Some of the data for analysis were abstracted by a biostatistician and checked by a physician reviewer. A sequential resolution strategy was used to match and resolve the screening and review results of the 2 pediatrician reviewers.

For the assessment of treatment efficacy, pooled analyses were performed for comparisons for which 3 or more trials could be identified. Studies eligible for analyses of questions pertaining to treatment efficacy were grouped for comparisons by treatment options. Each comparison consisted of studies that were considered homogeneous across clinical practice. Because some of the key questions were addressed in the 2001 evidence report,[17] studies identified in that report were included with newly identified articles in the 2010 evidence report.[20]

Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendations as well as expert consensus when definitive data were not available. Results of the literature review were presented in evidence tables and published in the final evidence report.[20]

In June 2009, the AAP convened a new subcommittee to review and revise the May 2004 AOM guideline.[1] The subcommittee comprised primary care physicians and experts in the fields of pediatrics, family practice, otolaryngology, epidemiology, infectious disease, emergency medicine, and guideline methodology. All panel members reviewed the AAP policy on conflict of interest and voluntary disclosure and were given an opportunity to present any potential conflicts with the subcommittee's work. All potential conflicts of interest are listed at the end of this document. The project was funded by the AAP. New literature on OM is continually being published. Although the systematic review performed by AHRQ could not be replicated with new literature, members of the Subcommittee on Diagnosis and Management of Acute Otitis Media reviewed additional articles. PubMed was searched by using the single search term "acute otitis media,"

approximately every 6 months from June 2009 through October 2011 to obtain new articles. Subcommittee members evaluated pertinent articles for quality of methodology and importance of results. Selected articles used in the AHRQ review were also reevaluated for their quality. Conclusions were based on the consensus of the subcommittee after the review of newer literature and reevaluation of the AHRQ evidence. Key action statements were generated using BRIDGE-Wiz (Building Recommendations in a Developers Guideline Editor), an interactive software tool that leads guideline development through a series of questions that are intended to create a more actionable set of key action statements.[25] BRIDGE-Wiz also incorporates the quality of available evidence into the final determination of the strength of each recommendation.

After thorough review by the subcommittee for this guideline, a draft was reviewed by other AAP committees and sections, selected outside organizations, and individuals identified by the subcommittee as experts in the field. Additionally, members of the subcommittee were encouraged to distribute the draft to interested parties in their respective specialties. All comments were reviewed by the writing group and incorporated into the final guideline when appropriate.

This clinical practice guideline is not intended as a sole source of guidance in the management of children with AOM. Rather, it is intended to assist clinicians in decision-making. It is not intended to replace clinical judgment or establish a protocol for the care of all children with this condition. These recommendations may not provide the only appropriate approach to the management of children with AOM.

It is AAP policy to review and update evidence-based guidelines every 5 years.

KEY ACTION STATEMENTS

Key Action Statement 1A

Clinicians should diagnose AOM in children who present with moderate to severe bulging of the TM *or* new onset of otorrhea not due to acute otitis externa. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1A

Aggregate evidence quality	Grade B
Benefits	• Identify a population of children most likely to benefit from intervention. • Avoid unnecessary treatment of those without highly certain AOM. • Promote consistency in diagnosis.
Risks, harms, cost	May miss AOM that presents with a combination of mild bulging, intense erythema, or otalgia that may not necessarily represent less severe disease and may also benefit from intervention.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Identification of a population of children with highly certain AOM is beneficial. Accurate, specific diagnosis is helpful to the individual patient. Modification of current behavior of overdiagnosis is a goal. Increased specificity is preferred even as sensitivity is lowered.
Intentional vagueness	By using stringent diagnostic criteria, the TM appearance of less severe illness that might be early AOM has not been addressed.
Role of patient preferences	None
Exclusions	None
Strength	**Recommendation**
Notes	Tympanocentesis studies confirm that using these diagnostic findings leads to high levels of isolation of pathogenic bacteria. Evidence is extrapolated from treatment studies that included tympanocentesis.

Key Action Statement 1B

Clinicians should diagnose AOM in children who present with mild bulging of the TM *and* recent (less than 48 hours) onset of ear pain (holding, tugging, rubbing of the ear in a nonverbal child) or intense erythema of the TM. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1B

Aggregate evidence quality	Grade C
Benefits	Identify AOM in children when the diagnosis is not highly certain.
Risks, harms, cost	Overdiagnosis of AOM. Reduced precision in diagnosis.
Benefits-harms assessment	Benefits greater than harms.
Value judgments	None.
Intentional vagueness	Criteria may be more subjective.
Role of patient preferences	None
Exclusions	None
Strength	**Recommendation**
Notes	Recent onset of ear pain means within the past 48 hours.

Key Action Statement 1C

Clinicians should not diagnose AOM in children who do not have MEE (based on pneumatic otoscopy and/or tympanometry). (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1C

Aggregate evidence quality	Grade B
Benefits	Reduces overdiagnosis and unnecessary treatment. Increases correct diagnosis of other conditions with symptoms that otherwise might be attributed to AOM. Promotes the use of pneumatic otoscopy and tympanometry to improve diagnostic accuracy.
Risks, harms, cost	Cost of tympanometry. Need to acquire or reacquire skills in pneumatic otoscopy and tympanometry for some clinicians.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	AOM is overdiagnosed, often without adequate visualization of the TM. Early AOM without effusion occurs, but the risk of overdiagnosis supersedes that concern.
Intentional vagueness	None
Role of patient preferences	None
Exclusions	Early AOM evidenced by intense erythema of the TM.
Strength	**Recommendation**

Purpose of This Section

There is no gold standard for the diagnosis of AOM. In fact, AOM has a spectrum of signs as the disease develops.[26] Therefore, the purpose of this section is to provide clinicians and researchers with a working clinical definition of AOM and to differentiate AOM from OME. The criteria were chosen to achieve high specificity recognizing that the resulting decreased sensitivity may exclude less severe presentations of AOM.

Changes From AAP/AAFP 2004 AOM Guideline

Accurate diagnosis of AOM is critical to sound clinical decision-making and high-quality research. The 2004 "Clinical Practice Guideline: Diagnosis and Management of AOM"[1] used a 3-part definition for AOM: (1) acute onset of symptoms, (2) presence of MEE, and (3) signs of acute middle ear inflammation. This definition generated extensive discussion and reanalysis of the AOM diagnostic evidence. The 2004 definition lacked precision to exclude cases of OME, and diagnoses of AOM could be made in children with acute onset of symptoms, including severe otalgia and MEE, without other otoscopic findings of inflammation.[27] Furthermore, the use of "uncertain diagnosis" in the 2004 AOM guideline may have permitted diagnoses of AOM without clear visualization of the TM. Earlier studies may have enrolled children who had OME rather than AOM, resulting in the possible classification of such children as improved because their nonspecific symptoms would have abated regardless of therapy.[28–30] Two studies, published in 2011, used stringent diagnostic criteria for diagnosing AOM with much less risk of conclusions based on data from mixed patients.[31,32]

Since publication of the 2004 AOM guideline, a number of studies have been conducted evaluating scales for the presence of symptoms. These studies did not show a consistent correlation of symptoms with the initial diagnosis of AOM, especially in preverbal children.[33–35]

Recent research has used precisely stated stringent criteria of AOM for purposes of the studies.[31,32] The current guideline endorses stringent otoscopic diagnostic criteria as a basis for management decisions (described later). As clinicians use the proposed stringent criteria to diagnose AOM, they should be aware that children with AOM may also present with recent onset of ear pain and intense erythema of the TM as the only otoscopic finding.

Symptoms

Older children with AOM usually present with a history of rapid onset of ear pain. However, in young preverbal children, otalgia as suggested by tugging/rubbing/holding of the ear, excessive crying, fever, or changes in the child's sleep or behavior pattern as noted by the parent are often relatively nonspecific symptoms. A number of studies have attempted to correlate symptom scores with diagnoses of AOM.

A systematic review[36] identified 4 articles that evaluated the accuracy of symptoms.[37–40] Ear pain appeared useful in diagnosing AOM (combined positive likelihood ratio 3.0–7.3, negative likelihood ratio 0.4–0.6); however, it was only present in 50% to 60% of children with AOM. Conclusions from these studies may be limited, because they (1) enrolled children seen by specialists, not likely to represent the whole spectrum of severity of illness; (2) used a clinical diagnosis of AOM based more on symptomatology rather than on tympanocentesis; and (3) included relatively older children.[37,40]

Laine et al[34] used a questionnaire administered to 469 parents who suspected their children, aged 6 to 35 months, had AOM. Of the children, 237 had AOM using strict otoscopic criteria, and 232 had upper respiratory tract infection without AOM. Restless sleep, ear rubbing, fever, and nonspecific respiratory or gastrointestinal

tract symptoms did not differentiate children with or without AOM.

McCormick et al[30] used 2 symptom scores—a 3-item score (OM-3), consisting of symptoms of physical suffering such as ear pain or fever, emotional distress (irritability, poor appetite), and limitation in activity; and a 5-item score (Ear Treatment Group Symptom Questionnaire, 5 Items [ETG-5]), including fever, earache, irritability, decreased appetite, and sleep disturbance—to assess AOM symptoms at the time of diagnosis and daily during the 10-day treatment or observation period. They found both to be a responsive measure of changes in clinical symptoms. The same group[35] also tested a visual scale, Acute Otitis Media-Faces Scale (AOM-FS), with faces similar to the Wong-Baker pain scale.[41] None of the scales were adequately sensitive for making the diagnosis of AOM based on symptoms. The AOM-FS combined with an otoscopy score, OS-8,[30] were presented as a double-sided pocket card. The combination of AOM-FS and OS-8 was more responsive to change than either instrument alone.

Shaikh et al[33,42] validated a 7-item parent-reported symptom score (Acute Otitis Media Severity of Symptom Scale [AOM-SOS]) for children with AOM, following stringent guidance of the US Food and Drug Administration (FDA) on the development of patient-reported outcome scales. Symptoms included ear tugging/rubbing/holding, excessive crying, irritability, difficulty sleeping, decreased activity or appetite, and fever. AOM-SOS was correlated with otoscopic diagnoses (AOM, OME, and normal middle ear status). AOM-SOS changed appropriately in response to clinical change. Its day-to-day responsiveness supports its usefulness in following AOM symptoms over time.

Signs of AOM

Few studies have evaluated the relationship of otoscopic findings in AOM and tympanocentesis. A study by Karma et al[43] is often cited as the best single study of otoscopic findings in AOM. However, the study uses only a symptom-based diagnosis of AOM plus the presence of MEE. Thus, children with acute upper respiratory tract infection symptoms and OME would have been considered to have AOM. There also were significant differences in findings at the 2 centers that participated in the study.

The investigators correlated TM color, mobility, and position with the presence of middle ear fluid obtained by tympanocentesis. At 2 sites in Finland (Tampere and Oulu), 2911 children were followed from 6 months to 2.5 years of age. A single otolaryngologist at Tampere and a single pediatrician at Oulu examined subjects. Color, position, and mobility were recorded. Myringotomy and aspiration were performed if MEE was suspected. AOM was diagnosed if MEE was found and the child had fever, earache, irritability, ear rubbing or tugging, simultaneous other acute respiratory tract symptoms, vomiting, or diarrhea. The presence or absence of MEE was noted, but no analyses of the fluid, including culture, were performed. Pneumatic otoscopic findings were classified as follows: color—hemorrhagic, strongly red, moderately red, cloudy or dull, slightly red, or normal; position—bulging, retracted, or normal; and mobility—distinctly impaired, slightly impaired, or normal.

For this analysis, 11 804 visits were available. For visits with acute symptoms, MEE was found in 84.9% and 81.8% at the 2 sites at which the study was performed. There were significant differences among the results at the 2 centers involved in the study. Table 2 shows specific data for each finding.

The combination of a "cloudy," bulging TM with impaired mobility was the best predictor of AOM using the symptom-based diagnosis in this study. Impaired mobility had the highest sensitivity and specificity (approximately 95% and 85%, respectively). Cloudiness had the next best combination of high sensitivity (~74%) and high specificity (~93%) in this study. Bulging had high specificity (~97%) but lower sensitivity (~51%). A TM that was hemorrhagic, strongly red, or moderately red also correlated with the presence of AOM, and a TM that was only "slightly red" was not helpful diagnostically.

McCormick et al reported that a bulging TM was highly associated with the presence of a bacterial pathogen, with or without a concomitant viral pathogen.[44] In a small study, 31 children (40 ears) underwent myringotomy.[45] Bulging TMs had positive bacterial cultures 75% of the time. The percentage of positive cultures for a pathogen increased to 80% if the color of the TM was yellow. The conclusion is that moderate to severe bulging of the TM represents the most important characteristic in the diagnosis of AOM—a finding that has

TABLE 2 Otoscopic Findings in Children With Acute Symptoms and MEE[a]

TM Finding in Acute Visits With MEE	Group I (Tampere, Finland), %	Group II (Oulo, Finland), %
Color		
Distinctly red	69.8	65.6
Hemorrhagic	81.3	62.9
Strongly red	87.7	68.1
Moderately red	59.8	66.0
Slightly red	39.4	16.7
Cloudy	95.7	80.0
Normal	1.7	4.9
Position		
Bulging	96.0	89
Retracted	46.8	48.6
Normal	32.1	22.2
Mobility		
Distinctly impaired	94.0	78.5
Slightly impaired	59.7	32.8
Normal	2.7	4.8

[a] Totals are greater than 100%, because each ear may have had different findings.[43]

implications for clinical care, research, and education.

The committee recognized that there is a progression from the presence of MEE to the bulging of the TM, and it is often difficult to differentiate this equivocal appearance from the highly certain AOM criteria advocated in this guideline.[26] As such, there is a role for individualized diagnosis and management decisions. Examples of normal, mild bulging, moderate bulging, and severe bulging can be seen in Fig 2.

Distinguishing AOM From OME

OME may occur either as the aftermath of an episode of AOM or as a consequence of eustachian tube dysfunction attributable to an upper respiratory tract infection.[46] However, OME may also precede and predispose to the development of AOM. These 2 forms of OM may be considered segments of a disease continuum.[47] However, because OME does not represent an acute infectious process that benefits from antibiotics, it is of utmost importance for clinicians to become proficient in distinguishing normal middle ear status from OME or AOM. Doing so will avoid unnecessary use of antibiotics, which leads to increased adverse effects of medication and facilitates the development of antimicrobial resistance.

Examination of the TM

Accurate diagnosis of AOM in infants and young children may be difficult. Symptoms may be mild or overlap with those of an upper respiratory tract illness. The TM may be obscured by cerumen, and subtle changes in the TM may be difficult to discern. Additional factors complicating diagnosis may include lack of cooperation from the child; less than optimal diagnostic equipment, including lack of a pneumatic bulb; inadequate instruments for clearing cerumen from the external auditory canal; inadequate assistance for restraining the child; and lack of experience in removing cerumen and performing pneumatic otoscopy.

The pneumatic otoscope is the standard tool used in diagnosing OM. Valuable also is a surgical head, which greatly facilitates cleaning cerumen from an infant's external auditory canal. Cerumen may be removed by using a curette, gentle suction, or irrigation.[48] The pneumatic otoscope should have a light source of sufficient brightness and an air-tight seal that permits application of positive and negative pressure. In general, nondisposable specula achieve a better seal with less pain because of a thicker, smoother edge and better light transmission properties. The speculum size should be chosen to gently seal at the outer portion of the external auditory canal.

Pneumatic otoscopy permits assessment of the contour of the TM (normal, retracted, full, bulging), its color (gray, yellow, pink, amber, white, red, blue), its translucency (translucent, semiopaque, opaque), and its mobility (normal, increased, decreased, absent). The normal TM is translucent, pearly gray, and has a ground-glass appearance (Fig 2A). Specific landmarks can be visualized. They include the short process and the manubrium of the malleus and the pars flaccida, located superiorly. These are easily observed and help to identify the position of the TM. Inward movement of the TM on positive pressure in the external canal and outward movement on negative pressure should occur, especially in the superior posterior quadrant. When the TM is retracted, the short process of the malleus becomes more prominent, and the manubrium appears shortened because of its change in position within the middle ear. Inward motion occurring with positive pressure is restricted or absent, because the TM is frequently as far inward as its range of motion allows. However, outward mobility can be visualized when negative pressure is applied. If the TM does not move perceptibly with applications of gentle positive or negative pressure, MEE is likely. Sometimes, the application of pressure will make an air-fluid interface behind the TM (which is diagnostic of MEE) more evident.[49]

Instruction in the proper evaluation of the child's middle ear status should begin with the first pediatric rotation in medical school and continue throughout postgraduate training.[50]

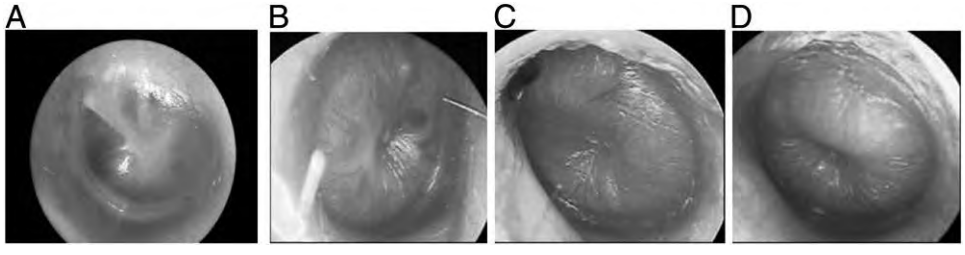


FIGURE 2
A, Normal TM. B, TM with mild bulging. C, TM with moderate bulging. D, TM with severe bulging. Courtesy of Alejandro Hoberman, MD.

Continuing medical education should reinforce the importance of, and retrain the clinician in, the use of pneumatic otoscopy.[51] Training tools include the use of a video-otoscope in residency programs, the use of Web-based educational resources,[49,52] as well as simultaneous or sequential examination of TMs with an expert otoscopist to validate findings by using a double headed or video otoscope. Tools for learning the ear examination can be found in a CD distributed by the Johns Hopkins University School of Medicine and the Institute for Johns Hopkins Nursing,[53] also available at http://www2.aap.org/sections/infectdis/video.cfm,[54] and through a Web-based program, ePROM: Enhancing Proficiency in Otitis Media.[52]

Key Action Statement 2

The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Key Action Statement Profile: KAS 2

Aggregate evidence quality	Grade B
Benefits	Relieves the major symptom of AOM.
Risks, harms, cost	Potential medication adverse effects. Variable efficacy of some modes of treatment.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Treating pain is essential whether or not antibiotics are prescribed.
Intentional vagueness	Choice of analgesic is not specified.
Role of patient preferences	Parents may assist in the decision as to what means of pain relief they prefer.
Exclusions	Topical analgesics in the presence of a perforated TM.
Strength	**Strong Recommendation**

Purpose of This Section

Pain is the major symptom of AOM. This section addresses and updates the literature on treating otalgia.

Changes From AAP/AAFP 2004 AOM Guideline

Only 2 new articles directly address the treatment of otalgia. Both address topical treatment. The 2 new articles are consistent with the 2004 guideline statement. The text of the 2004 guideline is, therefore, reproduced here, with the addition of discussion of the 2 new articles. Table 3 has been updated to include the new references.

Treatment of Otalgia

Many episodes of AOM are associated with pain.[55] Some children with OME also have ear pain. Although pain is a common symptom in these illnesses, clinicians often see otalgia as a peripheral concern not requiring direct attention.[56] Pain associated with AOM can be substantial in the first few days of illness and often persists longer in young children.[57] Antibiotic therapy of AOM does not provide symptomatic relief in the first 24 hours[58–61] and even after 3 to 7 days, there may be persistent pain, fever, or both in 30% of children younger than 2 years.[62] In contrast, analgesics do relieve pain associated with AOM within 24 hours[63] and should be used whether antibiotic therapy is or is not prescribed; they should be continued as long as needed. The AAP published the policy statement "The Assessment and Management of Acute Pain in Infants, Children, and Adolescents"[64] to assist the clinician in addressing pain in the context of illness. The management of pain, especially during the first 24 hours of an episode of AOM, should be addressed regardless of the use of antibiotics.

Various treatments of otalgia have been used, but none has been well studied. The clinician should select a treatment on the basis of a consideration of benefits and risks and, wherever possible, incorporate parent/caregiver and patient preference (Table 3).

TABLE 3 Treatments for Otalgia in AOM

Treatment Modality	Comments
Acetaminophen, ibuprofen[63]	Effective analgesia for mild to moderate pain. Readily available. Mainstay of pain management for AOM.
Home remedies (no controlled studies that directly address effectiveness)	May have limited effectiveness.
Distraction	
External application of heat or cold	
Oil drops in external auditory canal	
Topical agents	
Benzocaine, procaine, lidocaine[65,67,70]	Additional, but brief, benefit over acetaminophen in patients older than 5 y.
Naturopathic agents[68]	Comparable to amethocaine/phenazone drops in patients older than 6 y.
Homeopathic agents[71,72]	No controlled studies that directly address pain.
Narcotic analgesia with codeine or analogs	Effective for moderate or severe pain. Requires prescription; risk of respiratory depression, altered mental status, gastrointestinal tract upset, and constipation.
Tympanostomy/myringotomy[73]	Requires skill and entails potential risk.

Since the 2004 guideline was published, there have been only 2 significant new articles.

Bolt et al reported in 2008 on a double-blind placebo-controlled trial at the Australia Children's Hospital emergency department conducted in 2003–2004.[65] They used a convenience sample of children 3 to 17 years of age diagnosed with AOM in the ED. They excluded children with perforation of the TM, pressure-equalizing tube, allergy to local anesthetic or paracetamol, epilepsy, or liver, renal, or cardiac disease. Sixty-three eligible children were randomized to receive aqueous lidocaine or normal saline ear drops up to 3 times in 24 hours. They demonstrated a statistically significant 50% reduction in reported pain at 10 and 30 minutes but not at 20 minutes after application of topical lidocaine, compared with normal saline. Complications were minimal: 3 children reported some dizziness the next day, and none reported tinnitus. A limitation was that some children had received oral acetaminophen before administration of ear drops.

A Cochrane review of topical analgesia for AOM[66] searched the Cochrane register of controlled trials, randomized controlled trials, or quasi-randomized controlled trials that compared otic preparations to placebo or that compared 2 otic preparations. It included studies of adults and children, without TM perforation. It identified 5 trials in children 3 to 18 years of age. Two (including Bolt et al,[65] discussed above) compared anesthetic drops and placebo at diagnosis of AOM. In both studies, some children also received oral analgesics. Three studies compared anesthetic ear drops with naturopathic herbal drops. Naturopathic drops were favored 15 to 30 minutes after installation, and 1 to 3 days after diagnosis, but the difference was not statistically significant. The Cochrane group concluded that there is limited evidence that ear drops are effective at 30 minutes and unclear if results from these studies are a result of the natural course of illness, placebo effect of receiving treatment, soothing effect of any liquid in the ear, or the drops themselves. Three of the studies included in this review were cited in the 2004 AAP guideline[67–69] and the 1 new paper by Bolt et al.[65]

Key Action Statement 3A

Severe AOM

The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children 6 months and older with severe signs or symptoms (ie, moderate or severe otalgia or otalgia for at least 48 hours, or temperature 39°C [102.2°F] or higher). (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Key Action Statement Profile: KAS 3A

Aggregate evidence quality	Grade B
Benefits	Increased likelihood of more rapid resolution of symptoms. Increased likelihood of resolution of AOM.
Risks, harms, cost	Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	None
Role of patient preference	None
Intentional vagueness	None
Exclusions	None
Strength	**Strong Recommendation**

Key Action Statement 3B

Nonsevere Bilateral AOM in Young Children

The clinician should prescribe antibiotic therapy for bilateral AOM in children younger than 24 months without severe signs or symptoms (ie, mild otalgia for less than 48 hours, temperature less than 39°C [102.2°F]). (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 3B

Aggregate evidence quality	Grade B
Benefits	Increased likelihood of more rapid resolution of symptoms. Increased likelihood of resolution of AOM.
Risks, harms, cost	Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
Benefits-harms assessment	Preponderance of benefit over harm.
Value judgments	None
Role of patient preference	None
Intentional vagueness	None
Exclusions	None
Strength	**Recommendation**

Key Action Statement 3C

Nonsevere Unilateral AOM in Young Children

The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for unilateral AOM in children 6 months to 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours, temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure

follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 3C

Aggregate evidence quality	Grade B
Benefits	Moderately increased likelihood of more rapid resolution of symptoms with initial antibiotics. Moderately increased likelihood of resolution of AOM with initial antibiotics.
Risks, harms, cost	Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
Benefits-harms assessment	Moderate degree of benefit over harm.
Value judgments	Observation becomes an alternative as the benefits and harms approach balance.
Role of patient preference	Joint decision-making with the family is essential before choosing observation.
Intentional vagueness	Joint decision-making is highly variable from family to family
Exclusions	None
Strength	**Recommendation**
Note	In the judgment of 1 Subcommittee member (AH), antimicrobial treatment of these children is preferred because of a preponderance of benefit over harm. AH did not endorse Key Action Statement 3C

Key Action Statement 3D

Nonsevere AOM in Older Children

The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for AOM (bilateral or unilateral) in children 24 months or older without severe signs or symptoms (ie, mild otalgia for less than 48 hours, temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. (Evidence Quality: Grade B, Rec Strength: Recommendation)

Key Action Statement Profile: KAS 3D

Aggregate evidence quality	Grade B
Benefits	*Initial antibiotic treatment*: Slightly increased likelihood of more rapid resolution of symptoms; slightly increased likelihood of resolution of AOM. *Initial observation*: Decreased use of antibiotics; decreased adverse effects of antibiotics; decreased potential for development of bacterial resistance.
Risks, harms, cost	*Initial antibiotic treatment*: Adverse events attributable to antibiotics such as diarrhea, rashes, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. *Initial observation*: Possibility of needing to start antibiotics in 48 to 72 h if the patient continues to have symptoms. Minimal risk of adverse consequences of delayed antibiotic treatment. Potential increased phone calls and doctor visits.
Benefits-harms assessment	Slight degree of benefit of initial antibiotics over harm.
Value judgments	Observation is an option as the benefits and harms approach balance.
Role of patient preference	Joint decision-making with the family is essential before choosing observation.
Intentional vagueness	Joint decision-making is highly variable from family to family.
Exclusions	None
Strength	**Recommendation.**

Purpose of This Section

The purpose of this section is to offer guidance on the initial management of AOM by helping clinicians choose between the following 2 strategies:

1. *Initial antibiotic therapy*, defined as treatment of AOM with antibiotics that are prescribed at the time of diagnosis with the intent of starting antibiotic therapy as soon as possible after the encounter.
2. *Initial observation*, defined as initial management of AOM limited to symptomatic relief, with commencement of antibiotic therapy only if the child's condition worsens at any time or does not show clinical improvement within 48 to 72 hours of diagnosis. A mechanism must be in place to ensure follow-up and initiation of antibiotics if the child fails observation.

This section assumes that the clinician has made an accurate diagnosis of AOM by using the criteria and strategies outlined earlier in this guideline. Another assumption is that a clear distinction is made between the role of analgesics and antibiotics in providing symptomatic relief for children with AOM.

Changes From Previous AOM Guideline

The AOM guideline published by the AAP and AAFP in 2004 proposed, for the first time in North America, an "observation option" for selected children with AOM, building on successful implementation of a similar policy in the state of New York[74] and the use of a similar paradigm in many countries in Europe. A common feature of both approaches was to prioritize initial antibiotic therapy according to diagnostic certainty, with greater reliance on observation when the diagnosis was uncertain. In response to criticism that allowing an "uncertain

diagnosis" might condone incomplete visualization of the TM or allow inappropriate antibiotic use, this category has been eliminated with greater emphasis now placed on maximizing diagnostic accuracy for AOM.

Since the earlier AOM guideline was published, there has been substantial new research on initial management of AOM, including randomized controlled trials of antibiotic therapy versus placebo or no therapy,[31,32,75] immediate versus delayed antibiotic therapy,[30,76,77] or delayed antibiotic with or without a concurrent prescription.[78] The Hoberman and Tähtinen articles are especially important as they used stringent criteria for diagnosing AOM.[31,32] Systematic reviews have been published on delayed antibiotic therapy,[79] the natural history of AOM in untreated children,[57] predictive factors for antibiotic benefits,[62] and the effect of antibiotics on asymptomatic MEE after therapy.[80] Observational studies provide additional data on outcomes of initial observation with delayed antibiotic therapy, if needed,[81] and on the relationship of previous antibiotic therapy for AOM to subsequent acute mastoiditis.[82,83]

In contrast to the earlier AOM guideline,[1] which recommended antibiotic therapy for all children 6 months to 2 years of age with a certain diagnosis, the current guideline indicates a choice between initial antibiotic therapy or initial observation in this age group for children with unilateral AOM and mild symptoms but only after joint decision-making with the parent(s)/caregiver (Table 4). This change is supported by evidence on the safety of observation or delayed prescribing in young children.[30,31,32,75,76,81] A mechanism must be in place to ensure follow-up and begin antibiotics if the child fails observation.

Importance of Accurate Diagnosis

The recommendations for management of AOM assume an accurate diagnosis on the basis of criteria outlined in the diagnosis section of this guideline. Many of the studies since the 2004 AAP/AAFP AOM guideline[1] used more stringent and well-defined AOM diagnostic definitions than were previously used. Bulging of the TM was required for diagnosis of AOM for most of the children enrolled in the most recent studies.[31,32] By using the criteria in this guideline, clinicians will more accurately distinguish AOM from OME. The management of OME can be found in guidelines written by the AAP, AAFP, and American Academy of Otolaryngology-Head and Neck Surgery.[84,85]

TABLE 4 Recommendations for Initial Management for Uncomplicated AOM[a]

Age	Otorrhea With AOM[a]	Unilateral or Bilateral AOM[a] With Severe Symptoms[b]	Bilateral AOM[a] Without Otorrhea	Unilateral AOM[a] Without Otorrhea
6 mo to 2 y	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy or additional observation
≥2 y	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy or additional observation	Antibiotic therapy or additional observation[c]

[a] Applies only to children with well-documented AOM with high certainty of diagnosis (see Diagnosis section).
[b] A toxic-appearing child, persistent otalgia more than 48 h, temperature ≥39°C (102.2°F) in the past 48 h, or if there is uncertain access to follow-up after the visit.
[c] This plan of initial management provides an opportunity for shared decision-making with the child's family for those categories appropriate for additional observation. If observation is offered, a mechanism must be in place to ensure follow-up and begin antibiotics if the child worsens or fails to improve within 48 to 72 h of AOM onset.

Age, Severity of Symptoms, Otorrhea, and Laterality

Rovers et al[62] performed a systematic search for AOM trials that (1) used random allocation of children, (2) included children 0 to 12 years of age with AOM, (3) compared antibiotics with placebo or no treatment, and (4) had pain or fever as an outcome. The original investigators were asked for their original data.

Primary outcome was pain and/or fever (>38°C) at 3 to 7 days. The adverse effects of antibiotics were also analyzed. Baseline predictors were age <2 years versus ≥2 years, bilateral AOM versus unilateral AOM, and the presence versus absence of otorrhea. Statistical methods were used to assess heterogeneity and to analyze the data.

Of the 10 eligible studies, the investigators of 6 studies[30,75,86–89] provided the original data requested, and 4 did not. A total of 1642 patients were included in the 6 studies from which data were obtained. Of the cases submitted, the average age was 3 to 4 years, with 35% of children younger than 2 years. Bilateral AOM was present in 34% of children, and 42% of children had a bulging TM. Otorrhea was present in 21% of children. The antibiotic and control groups were comparable for all characteristics.

The rate difference (RD) for pain, fever, or both between antibiotic and control groups was 13% (NNT = 8). For children younger than 2 years, the RD was 15% (NNT = 7); for those ≥2 years, RD was 11% (NNT = 10). For unilateral AOM, the RD was 6% (NNT = 17); for bilateral AOM, the RD was 20% (NNT = 5). When unilateral AOM was broken into age groups, among those younger than 2 years, the RD was 5% (NNT = 20), and among those ≥2 years, the RD was 7% (NNT = 15). For bilateral AOM in children younger than 2 years, the RD was 25% (NNT = 4); for

bilateral AOM in children ≥2 years, the RD was 12% (NNT = 9). For otorrhea, the RD was 36% (NNT = 3). One child in the control group who developed meningitis had received antibiotics beginning on day 2 because of worsening status. There were no cases of mastoiditis.

In a Cochrane Review, Sanders et al[59] identified 10 studies that met the following criteria: (1) randomized controlled trial, (2) compared antibiotic versus placebo or antibiotic versus observation, (3) age 1 month to 15 years, (4) reported severity and duration of pain, (5) reported adverse events, and (6) reported serious complications of AOM, recurrent attacks, and hearing problems. Studies were analyzed for risk of bias and assessment of heterogeneity. The studies were the same as analyzed by Rovers et al[62] but included the 4 studies for which primary data were not available to Rovers.[60,61,90,91]

The authors' conclusions were that antibiotics produced a small reduction in the number of children with pain 2 to 7 days after diagnosis. They also concluded that most cases spontaneously remitted with no complications (NNT = 16). Antibiotics were most beneficial in children younger than 2 years with bilateral AOM and in children with otorrhea.

Two recent studies only included children younger than 3 years[32] or younger than 2 years.[31] Both included only subjects in whom the diagnosis of AOM was certain. Both studies used improvement of symptoms and improvement in the appearance of the TM in their definitions of clinical success or failure.

Hoberman et al[31] conducted a randomized, double-blind, placebo-controlled study of the efficacy of antimicrobial treatment on AOM. The criteria for AOM were acute symptoms with a score of at least 3 on the AOM-SOS, a validated symptom scale[33,92]; MEE; and moderate or marked bulging of the TM or slight bulging accompanied by either otalgia or marked erythema of the TM. They chose to use high-dose amoxicillin-clavulanate (90 mg/kg/day) as active treatment, because it has the best oral antibiotic coverage for organisms causing AOM. Included in the study were 291 patients 6 to 23 months of age: 144 in the antibiotic group and 147 in the placebo group. The primary outcome measures were the time to resolution of symptoms and the symptom burden over time. The initial resolution of symptoms (ie, the first recording of an AOM-SOS score of 0 or 1) was recorded among the children who received amoxicillin-clavulanate in 35% by day 2, 61% by day 4, and 80% by day 7. Among children who received placebo, an AOM-SOS score of 0 or 1 was recorded in 28% by day 2, 54% by day 4, and 74% by day 7 ($P = .14$ for the overall comparison). For sustained resolution of symptoms (ie, the time to the second of 2 successive recordings of an AOM-SOS score of 0 or 1), the corresponding values were 20% at day 2, 41% at day 4, and 67% at day 7 with amoxicillin-clavulanate, compared with 14%, 36%, and 53% with placebo ($P = .04$ for the overall comparison). The symptom burden (ie, mean AOM-SOS scores) over the first 7 days were lower for the children treated with amoxicillin-clavulanate than for those who received placebo ($P = .02$). Clinical failure at or before the 4- to 5-day visit was defined as "either a lack of substantial improvement in symptoms, a worsening of signs on otoscopic examination, or both," and clinical failure at the 10- to 12-day visit was defined as "the failure to achieve complete or nearly complete resolution of symptoms and of otoscopic signs, without regard to the persistence or resolution of middle ear effusion." Treatment failure occurred by day 4 to 5 in 4% of the antimicrobial treatment group versus 23% in the placebo group ($P < .001$) and at day 10 to 12 in 16% of the antimicrobial treatment group versus 51% in the placebo group (NNT = 2.9, $P < .001$). In a comparison of outcome in unilateral versus bilateral AOM, clinical failure rates by day 10 to 12 in children with unilateral AOM were 9% in those treated with amoxicillin-clavulanate versus 41% in those treated with placebo (RD, 32%; NNT = 3) and 23% vs 60% (RD, 37%; NNT = 3) in those with bilateral AOM. Most common adverse events were diarrhea (25% vs 15% in the treatment versus placebo groups, respectively; $P = .05$) and diaper dermatitis (51% vs 35% in the treatment versus placebo groups, respectively; $P = .008$). One placebo recipient developed mastoiditis. According to these results, antimicrobial treatment of AOM was more beneficial than in previous studies that used less stringent diagnostic criteria.

Tähtinen et al[32] conducted a randomized, double-blind, placebo-controlled, intention-to-treat study of amoxicillin-clavulanate (40 mg/kg/day) versus placebo. Three hundred nineteen patients from 6 to 35 months of age were studied: 161 in the antibiotic group and 158 in the placebo group. AOM definition was the presence of MEE, distinct erythema over a bulging or yellow TM, and acute symptoms such as ear pain, fever, or respiratory symptoms. Compliance was measured by using daily patient diaries and number of capsules remaining at the end of the study. Primary outcome was time to treatment failure defined as a composite of 6 independent components: no improvement in overall condition by day 3, worsening of the child's condition at any time, no improvement in otoscopic signs by day 8, perforation of the TM,

development of severe infection (eg, pneumonia, mastoiditis), and any other reason for stopping the study drug/placebo.

Groups were comparable on multiple parameters. In the treatment group, 135 of 161 patients (84%) were younger than 24 months, and in the placebo group, 124 of 158 patients (78%) were younger than 24 months. Treatment failure occurred in 18.6% of the treatment group and 44.9% in the placebo group (NNT = 3.8, $P < .001$). Rescue treatment was needed in 6.8% of the treatment group and 33.5% of placebo patients ($P < .001$). Contralateral AOM developed in 8.2% and 18.6% of treatment and placebo groups, respectively ($P = .007$). There was no significant difference in use of analgesic or antipyretic medicine, which was used in 84.2% of the amoxicillin-clavulanate group and 85.9% of the placebo group.

Parents of child care attendees on placebo missed more days of work ($P = .005$). Clinical failure rates in children with unilateral AOM were 17.2% in those treated with amoxicillin-clavulanate versus 42.7% in those treated with placebo; for bilateral AOM, clinical failure rates were 21.7% for those treated with amoxicillin-clavulanate versus 46.3% in the placebo group. Reported rates of treatment failure by day 8 were 17.2% in the amoxicillin-clavulanate group versus 42.7% in the placebo group in children with unilateral AOM and 21.7% vs 46.3% among those with bilateral disease.

Adverse events, primarily diarrhea and/or rash, occurred in 52.8% of the treatment group and 36.1% of the placebo group ($P = .003$). Overall condition as evaluated by the parents and otoscopic appearance of the TM showed a benefit of antibiotics over placebo at the end of treatment visit ($P < .001$). Two placebo recipients developed a severe infection; 1 developed pneumococcal bacteremia, and 1 developed radiographically confirmed pneumonia.

Most studies have excluded children with severe illness and all exclude those with bacterial disease other than AOM (pneumonia, mastoiditis, meningitis, streptococcal pharyngitis). Kaleida et al[91] compared myringotomy alone with myringotomy plus antibiotics. Severe AOM was defined as temperature >39°C (102.2°F) or the presence of severe otalgia. Patients with severe AOM in the group that received only myringotomy (without initial antibiotics) had much worse outcomes.

Initial Antibiotic Therapy

The rationale for antibiotic therapy in children with AOM is based on a high prevalence of bacteria in the accompanying MEE.[93] Bacterial and viral cultures of middle ear fluid collected by tympanocentesis from children with AOM showed 55% with bacteria only and 15% with bacteria and viruses. A beneficial effect of antibiotics on AOM was first demonstrated in 1968,[94] followed by additional randomized trials and a meta-analysis[95] showing a 14% increase in absolute rates of clinical improvement. Systematic reviews of the literature published before 2011[21,59,62] revealed increases of clinical improvement with initial antibiotics of 6% to 12%.

Randomized clinical trials using stringent diagnostic criteria for AOM in young children[31,32] show differences in clinical improvement of 26% to 35% favoring initial antibiotic treatment as compared with placebo. Greater benefit of immediate antibiotic therapy was observed for bilateral AOM[62,96] or AOM associated with otorrhea.[62] In most randomized trials,[30,75,77,88,89] antibiotic therapy also decreased the duration of pain, analgesic use, or school absence and parent days missed from work.

Children younger than 2 years with AOM may take longer to improve clinically than older children,[57] and although they are more likely to benefit from antibiotics,[31,32] AOM in many children will resolve without antibiotics.[62] A clinically significant benefit of immediate antibiotic therapy is observed for bilateral AOM,[62,96] *Streptococcus pneumoniae* infection, or AOM associated with otorrhea.[62]

Initial Observation for AOM

In systematic reviews of studies that compare antibiotic therapy for AOM with placebo, a consistent finding has been the overall favorable natural history in control groups (NNT = 8–16).[12,59,62,95] However, randomized trials in these reviews had varying diagnostic criteria that would have permitted inclusion of some children with OME, viral upper respiratory infections, or myringitis, thereby limiting the ability to apply these findings to children with a highly certain AOM diagnosis. In more recent AOM studies[31,32] using stringent diagnostic criteria, approximately half of young children (younger than 2–3 years) experienced clinical success when given placebo, but the effect of antibiotic therapy was substantially greater than suggested by studies without precise diagnosis (NNT = 3–4).

Observation as initial management for AOM in properly selected children does not increase suppurative complications, provided that follow-up is ensured and a rescue antibiotic is given for persistent or worsening symptoms.[17] In contrast, withholding of antibiotics in all children with AOM, regardless of clinical course, would risk a return to the suppurative complications observed in the

preantibiotic era. At the population level, antibiotics halve the risk of mastoiditis after AOM, but the high NNT of approximately 4800 patients to prevent 1 case of mastoiditis precludes a strategy of universal antibiotic therapy as a means to prevent mastoiditis.[83]

The favorable natural history of AOM makes it difficult to demonstrate significant differences in efficacy between antibiotic and placebo when a successful outcome is defined by relief or improvement of presenting signs and symptoms. In contrast, when otoscopic improvement (resolution of TM bulging, intense erythema, or both) is also required for a positive outcome,[31,32] the NNT is 3 to 4, compared with 8 to 16 for symptom improvement alone in older studies that used less precise diagnostic criteria. MEE, however, may persist for weeks or months after an AOM episode and is not a criterion for otoscopic failure.

National guidelines for initial observation of AOM in select children were first implemented in the Netherlands[97] and subsequently in Sweden,[98] Scotland,[99] the United States,[1] the United Kingdom,[100] and Italy.[101] All included observation as an initial treatment option under specified circumstances.

In numerous studies, only approximately one-third of children initially observed received a rescue antibiotic for persistent or worsening AOM,[30,32,76,81,89,102] suggesting that antibiotic use could potentially be reduced by 65% in eligible children. Given the high incidence of AOM, this reduction could help substantially in curtailing antibiotic-related adverse events.

McCormick et al[30] reported on 233 patients randomly assigned to receive immediate antibiotics (amoxicillin, 90 mg/kg/day) or to undergo watchful waiting. Criteria for inclusion were symptoms of ear infection, otoscopic evidence of AOM, and nonsevere AOM based on a 3-item symptom score (OM-3) and TM appearance based on an 8-item scale (OS-8). Primary outcomes were parent satisfaction with AOM care, resolution of AOM symptoms after initial treatment, AOM failure and recurrence, and nasopharyngeal carriage of *S pneumoniae* strains resistant to antibiotics after treatment. The study was confounded by including patients who had received antibiotics in the previous 30 days.

In the watchful waiting group, 66% of children completed the study without antibiotics. There was no difference in parent satisfaction scores at day 12. A 5-item symptom score (ETG-5) was assessed at days 0 to 10 by using patient diaries. Subjects receiving immediate antibiotics resolved their symptoms faster than did subjects who underwent watchful waiting (P = .004). For children younger than 2 years, the difference was greater (P = .008). Otoscopic and tympanogram scores were also lower in the antibiotic group as opposed to the watchful waiting group (P = .02 for otoscopic score, P = .004 for tympanogram). Combining all ages, failure and recurrence rates were lower for the antibiotic group (5%) than for the watchful waiting group (21%) at 12 days. By day 30, there was no difference in failure or recurrence for the antibiotic and watchful waiting groups (23% and 24%, respectively). The association between clinical outcome and intervention group was not significantly different between age groups. Immediate antibiotics resulted in eradication of *S pneumoniae* carriage in the majority of children, but *S pneumoniae* strains cultured from children in the antibiotic group at day 12 were more likely to be multidrug resistant than were strains cultured from children in the watchful waiting group.

The decision not to give initial antibiotic treatment and observe should be a joint decision of the clinician and the parents. In such cases, a system for close follow-up and a means of beginning antibiotics must be in place if symptoms worsen or no improvement is seen in 48 to 72 hours.

Initial observation of AOM should be part of a larger management strategy that includes analgesics, parent information, and provisions for a rescue antibiotic. Education of parents should include an explanation about the self-limited nature of most episodes of AOM, especially in children 2 years and older; the importance of pain management early in the course; and the potential adverse effects of antibiotics. Such an approach can substantially reduce prescription fill rates for rescue antibiotics.[103]

A critical component of any strategy involving initial observation for AOM is the ability to provide a rescue antibiotic if needed. This is often done by using a "safety net" or a "wait-and-see prescription,"[76,102] in which the parent/caregiver is given an antibiotic prescription during the clinical encounter but is instructed to fill the prescription only if the child fails to improve within 2 to 3 days or if symptoms worsen at any time. An alternative approach is not to provide a written prescription but to instruct the parent/caregiver to call or return if the child fails to improve within 2 to 3 days or if symptoms worsen.

In one of the first major studies of observation with a safety-net antibiotic prescription (SNAP), Siegel et al[102] enrolled 194 patients with protocol defined AOM, of whom 175 completed the study. Eligible patients were given a SNAP with instructions to fill the prescription only if symptoms worsened or did not improve in 48 hours. The SNAP was valid for 5 days. Pain medicine was recommended to be taken as needed. A phone interview was conducted 5 to 10 days after diagnosis.

One hundred twenty of 175 families did not fill the prescription. Reasons for filling the prescription (more than 1 reason per patient was acceptable) were as follows: continued pain, 23%; continued fever, 11%; sleep disruption, 6%; missed days of work, 3%; missed days of child care, 3%; and no reason given, 5%. One 16-month-old boy completed observation successfully but 6 weeks later developed AOM in the opposite ear, was treated with antibiotics, and developed postauricular cellulitis.

In a similar study of a "wait-and-see prescription" (WASP) in the emergency department, Spiro et al[76] randomly assigned 283 patients to either a WASP or standard prescription. Clinicians were educated on the 2004 AAP diagnostic criteria and initial treatment options for AOM; however, diagnosis was made at the discretion of the clinician. Patients were excluded if they did not qualify for observation per the 2004 guidelines. The primary outcome was whether the prescription was filled within 3 days of diagnosis. Prescriptions were not filled for 62% and 13% of the WASP and standard prescription patients, respectively ($P < .001$). Reasons for filling the prescription in the WASP group were fever (60%), ear pain (34%), or fussy behavior (6%). No serious adverse events were reported.

Strategies to observe children with AOM who are likely to improve on their own without initial antibiotic therapy reduces common adverse effects of antibiotics, such as diarrhea and diaper dermatitis. In 2 trials, antibiotic therapy significantly increased the absolute rates of diarrhea by 10% to 20% and of diaper rash or dermatitis by 6% to 16%.[31,32] Reduced antibiotic use may also reduce the prevalence of resistant bacterial pathogens. Multidrug-resistant *S pneumoniae* continues to be a significant concern for AOM, despite universal immunization of children in the United States with heptavalent pneumococcal conjugate vaccine.[104,105] In contrast, countries with low antibiotic use for AOM have a low prevalence of resistant nasopharyngeal pathogens in children.[106]

Key Action Statement 4A

Clinicians should prescribe amoxicillin for AOM when a decision to treat with antibiotics has been made *and* the child has not received amoxicillin in the past 30 days *or* the child does not have concurrent purulent conjunctivitis *or* the child is not allergic to penicillin. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4A

Aggregate evidence quality	Grade B
Benefits	Effective antibiotic for most children with AOM. Inexpensive, safe, acceptable taste, narrow antimicrobial spectrum.
Risks, harms, cost	Ineffective against β-lactamase–producing organisms. Adverse effects of amoxicillin.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Better to use a drug that has reasonable cost, has an acceptable taste, and has a narrow antibacterial spectrum.
Intentional vagueness	The clinician must determine whether the patient is truly penicillin allergic.
Role of patient preferences	Should be considered if previous bad experience with amoxicillin.
Exclusions	Patients with known penicillin allergy.
Strength	**Recommendation.**

Key Action Statement 4B

Clinicians should prescribe an antibiotic with additional β-lactamase coverage for AOM when a decision to treat with antibiotics has been made *and* the child has received amoxicillin in the past 30 days *or* has concurrent purulent conjunctivitis *or* has a history of recurrent AOM unresponsive to amoxicillin. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4B

Aggregate evidence quality	Grade C
Benefits	Successful treatment of β-lactamase–producing organisms.
Risks, harms, cost	Cost of antibiotic. Increased adverse effects.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Efficacy is more important than taste.
Intentional vagueness	None.
Role of patient preferences	Concern regarding side effects and taste.
Exclusions	Patients with known penicillin allergy.
Strength	**Recommendation**

Key Action Statement 4C

Clinicians should reassess the patient if the caregiver reports that the child's symptoms have worsened or failed to respond to the initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4C

Aggregate evidence quality	Grade B
Benefits	Identify children who may have AOM caused by pathogens resistant to previous antibiotics.
Risks, harms, cost	Cost. Time for patient and clinician to make change. Potential need for parenteral medication.
Benefit-harm assessment	Preponderance of benefit.
Value judgments	None.
Intentional vagueness	"Reassess" is not defined. The clinician may determine the method of assessment.
Role of patient preferences	Limited.
Exclusions	Appearance of TM improved.
Strength	**Recommendation**

Purpose of This Section

If an antibiotic will be used for treatment of a child with AOM, whether as initial management or after a period of observation, the clinician must choose an antibiotic that will have a high likelihood of being effective against the most likely etiologic bacterial pathogens with considerations of cost, taste, convenience, and adverse effects. This section proposes first- and second-line antibiotics that best meet these criteria while balancing potential benefits and harms.

Changes From AAP/AAFP 2004 AOM Guideline

Despite new data on the effect of PCV7 and updated data on the in vitro susceptibility of bacterial pathogens most likely to cause AOM, the recommendations for the first-line antibiotic remains unchanged from 2004. The current guideline contains revised recommendations regarding penicillin allergy based on new data. The increase of multidrug-resistant strains of pneumococci is noted.

Microbiology

Microorganisms detected in the middle ear during AOM include pathogenic bacteria, as well as respiratory viruses.[107–110] AOM occurs most frequently as a consequence of viral upper respiratory tract infection,[111–113] which leads to eustachian tube inflammation/dysfunction, negative middle ear pressure, and movement of secretions containing the upper respiratory tract infection causative virus and pathogenic bacteria in the nasopharynx into the middle ear cleft. By using comprehensive and sensitive microbiologic testing, bacteria and/or viruses can be detected in the middle ear fluid in up to 96% of AOM cases (eg, 66% bacteria and viruses together, 27% bacteria alone, and 4% virus alone).[114] Studies using less sensitive or less comprehensive microbiologic assays have yielded less positive results for bacteria and much less positive results for viruses.[115–117] The 3 most common bacterial pathogens in AOM are *S pneumoniae*, nontypeable *Haemophilus influenzae*, and *Moraxella catarrhalis*.[111] *Streptococcus pyogenes* (group A β-hemolytic streptococci) accounts for less than 5% of AOM cases. The proportion of AOM cases with pathogenic bacteria isolated from the middle ear fluids varies depending on bacteriologic techniques, transport issues, and stringency of AOM definition. In series of reports from the United States and Europe from 1952–1981 and 1985–1992, the mean percentage of cases with bacterial pathogens isolated from the middle ear fluids was 69% and 72%, respectively.[118] A large series from the University of Pittsburgh Otitis Media Study Group reported bacterial pathogens in 84% of the middle ear fluids from 2807 cases of AOM.[118] Studies that applied more stringent otoscopic criteria and/or use of bedside specimen plating on solid agar in addition to liquid transport media have a reported rate of recovery of pathogenic bacteria from middle ear exudates ranging from 85% to 90%.[119–121] When using appropriate stringent diagnostic criteria, careful specimen handling, and sensitive microbiologic techniques, the vast majority of cases of AOM will involve pathogenic bacteria either alone or in concert with viral pathogens.

Among AOM bacterial pathogens, *S pneumoniae* was the most frequently cultured in earlier reports. Since the debut and routine use of PCV7 in 2000, the ordinal frequency of these 3 major middle ear pathogens has evolved.[105] In the first few years after PCV7 introduction, *H influenzae* became the most frequently isolated middle ear pathogen, replacing *S pneumoniae*.[122,123] Shortly thereafter, a shift to non-PCV7 serotypes of *S pneumoniae* was described.[124] Pichichero et al[104] later reported that 44% of 212 AOM cases seen in 2003–2006 were caused by *H influenzae*, and 28% were caused by *S pneumoniae*, with a high proportion of highly resistant *S pneumoniae*. In that study, a majority (77%) of cases involved recurrent disease or initial treatment failure. A later report[125] with data from 2007 to 2009, 6 to 8 years after the introduction of PCV7 in the United States, showed that PCV7 strains of *S pneumoniae* virtually disappeared from the middle ear fluid of children with AOM who had been vaccinated. However, the frequency of isolation of non-PCV7 serotypes of *S pneumoniae* from the middle ear fluid overall was increased; this has made isolation of *S pneumoniae* and *H influenzae* of children with AOM nearly equal.

In a study of tympanocentesis over 4 respiratory tract illness seasons in a private practice, the percentage of

S pneumoniae initially decreased relative to *H influenzae*. In 2005–2006 (*N* = 33), 48% of bacteria were *S pneumoniae*, and 42% were *H influenzae*. For 2006–2007 (*N* = 37), the percentages were equal at 41%. In 2007–2008 (*N* = 34), 35% were *S pneumoniae*, and 59% were *H influenzae*. In 2008–2009 (*N* = 24), the percentages were 54% and 38%, respectively, with an increase in intermediate and nonsusceptible *S pneumoniae*.[126] Data on nasopharyngeal colonization from PCV7-immunized children with AOM have shown continued presence of *S pneumoniae* colonization. Revai et al[127] showed no difference in *S pneumoniae* colonization rate among children with AOM who have been unimmunized, underimmunized, or fully immunized with PCV7. In a study during a viral upper respiratory tract infection, including mostly PCV7-immunized children (6 months to 3 years of age), *S pneumoniae* was detected in 45.5% of 968 nasopharyngeal swabs, *H influenzae* was detected in 32.4%, and *M catarrhalis* was detected in 63.1%.[128] Data show that nasopharyngeal colonization of children vaccinated with PCV7 increasingly is caused by *S pneumoniae* serotypes not contained in the vaccine.[129–132] With the use of the recently licensed 13-valent pneumococcal conjugate vaccine (PCV13),[133] the patterns of nasopharyngeal colonization and infection with these common AOM bacterial pathogens will continue to evolve.

Investigators have attempted to predict the type of AOM pathogenic bacteria on the basis of clinical severity, but results have not been promising. *S pyogenes* has been shown to occur more commonly in older children[134] and to cause a greater degree of inflammation of the middle ear and TM, a greater frequency of spontaneous rupture of the TM, and more frequent progression to acute mastoiditis compared with other bacterial pathogens.[134–136] As for clinical findings in cases with *S pneumoniae* and nontypeable *H influenzae*, some studies suggest that signs and symptoms of AOM caused by *S pneumoniae* may be more severe (fever, severe earache, bulging TM) than those caused by other pathogens.[44,121,137] These findings were refuted by results of the studies that found AOM caused by nontypeable *H influenzae* to be associated with bilateral AOM and more severe inflammation of the TM.[96,138] Leibovitz et al[139] concluded, in a study of 372 children with AOM caused by *H influenzae* (*N* = 138), *S pneumoniae* (*N* = 64), and mixed *H influenzae* and *S pneumoniae* (*N* = 64), that clinical/otologic scores could not discriminate among various bacterial etiologies of AOM. However, there were significantly different clinical/otologic scores between bacterial culture negative and culture positive cases. A study of middle ear exudates of 82 cases of bullous myringitis has shown a 97% bacteria positive rate, primarily *S pneumoniae*. In contrast to the previous belief, mycoplasma is rarely the causative agent in this condition.[140] Accurate prediction of the bacterial cause of AOM on the basis of clinical presentation, without bacterial culture of the middle ear exudates, is not possible, but specific etiologies may be predicted in some situations. Published evidence has suggested that AOM associated with conjunctivitis (otitis-conjunctivitis syndrome) is more likely caused by nontypeable *H influenzae* than by other bacteria.[141–143]

Bacterial Susceptibility to Antibiotics

Selection of antibiotic to treat AOM is based on the suspected type of bacteria and antibiotic susceptibility pattern, although clinical pharmacology and clinical and microbiologic results and predicted compliance with the drug are also taken into account. Early studies of AOM patients show that 19% of children with *S pneumoniae* and 48% with *H influenzae* cultured on initial tympanocentesis who were not treated with antibiotic cleared the bacteria at the time of a second tympanocentesis 2 to 7 days later.[144] Approximately 75% of children infected with *M catarrhalis* experienced bacteriologic cure even after treatment with amoxicillin, an antibiotic to which it is not susceptible.[145,146]

Antibiotic susceptibility of major AOM bacterial pathogens continues to change, but data on middle ear pathogens have become scanty because tympanocentesis is not generally performed in studies of children with uncomplicated AOM. Most available data come from cases of persistent or recurrent AOM. Current US data from a number of centers indicates that approximately 83% and 87% of isolates of *S pneumoniae* from all age groups are susceptible to regular (40 mg/kg/day) and high-dose amoxicillin (80–90 mg/kg/day divided twice daily), respectively.[130,147–150] Pediatric isolates are smaller in number and include mostly ear isolates collected from recurrent and persistent AOM cases with a high percentage of multidrug-resistant *S pneumoniae*, most frequently nonvaccine serotypes that have recently increased in frequency and importance.[104]

High-dose amoxicillin will yield middle ear fluid levels that exceed the minimum inhibitory concentration (MIC) of all *S pneumoniae* serotypes that are intermediately resistant to penicillin (penicillin MICs, 0.12–1.0 μg/mL), and many but not all highly resistant serotypes (penicillin MICs, ≥2 μg/mL) for a longer period of the dosing interval and has been shown to improve bacteriologic and clinical efficacy

compared with the regular dose.[151–153] Hoberman et al[154] reported superior efficacy of high-dose amoxicillin-clavulanate in eradication of *S pneumoniae* (96%) from the middle ear at days 4 to 6 of therapy compared with azithromycin.

The antibiotic susceptibility pattern for *S pneumoniae* is expected to continue to evolve with the use of PCV13, a conjugate vaccine containing 13 serotypes of *S pneumoniae*.[133,155,156] Widespread use of PCV13 could potentially reduce diseases caused by multidrug-resistant pneumococcal serotypes and diminish the need for the use of higher dose of amoxicillin or amoxicillin-clavulanate for AOM.

Some *H influenzae* isolates produce β-lactamase enzyme, causing the isolate to become resistant to penicillins. Current data from different studies with non-AOM sources and geographic locations that may not be comparable show that 58% to 82% of *H influenzae* isolates are susceptible to regular- and high-dose amoxicillin.[130,147,148,157,158] These data represented a significant decrease in β-lactamase–producing *H influenzae*, compared with data reported in the 2004 AOM guideline.

Nationwide data suggest that 100% of *M catarrhalis* derived from the upper respiratory tract are β-lactamase–positive but remain susceptible to amoxicillin-clavulanate.[159] However, the high rate of spontaneous clinical resolution occurring in children with AOM attributable to *M catarrhalis* treated with amoxicillin reduces the concern for the first-line coverage for this microorganism.[145,146] AOM attributable to *M catarrhalis* rarely progresses to acute mastoiditis or intracranial infections.[102,160,161]

Antibiotic Therapy

High-dose amoxicillin is recommended as the first-line treatment in most patients, although there are a number of medications that are clinically effective (Table 5). The justification for the use of amoxicillin relates to its effectiveness against common AOM bacterial pathogens as well as its safety, low cost, acceptable taste, and narrow microbiologic spectrum.[145,151] In children who have taken amoxicillin in the previous 30 days, those with concurrent conjunctivitis, or those for whom coverage for β-lactamase–positive *H influenzae* and *M catarrhalis* is desired, therapy should be initiated with high-dose amoxicillin-clavulanate (90 mg/kg/day of amoxicillin, with 6.4 mg/kg/day of clavulanate, a ratio of amoxicillin to clavulanate of 14:1, given in 2 divided doses, which is less likely to cause diarrhea than other amoxicillin-clavulanate preparations).[162]

Alternative initial antibiotics include cefdinir (14 mg/kg per day in 1 or 2 doses), cefuroxime (30 mg/kg per day in 2 divided doses), cefpodoxime (10 mg/kg per day in 2 divided doses), or ceftriaxone (50 mg/kg, administered intramuscularly). It is important to note that alternative antibiotics vary in their efficacy against AOM pathogens. For example, recent US data on in vitro susceptibility of *S pneumoniae* to cefdinir and cefuroxime are 70% to 80%, compared with 84% to 92% amoxicillin efficacy.[130,147–149] In vitro efficacy of cefdinir and cefuroxime against *H influenzae* is approximately 98%, compared with 58% efficacy of amoxicillin and nearly 100% efficacy of amoxicillin-clavulanate.[158] A multicenter double tympanocentesis open-label study of

TABLE 5 Recommended Antibiotics for (Initial or Delayed) Treatment and for Patients Who Have Failed Initial Antibiotic Treatment

Initial Immediate or Delayed Antibiotic Treatment		Antibiotic Treatment After 48–72 h of Failure of Initial Antibiotic Treatment	
Recommended First-line Treatment	Alternative Treatment (if Penicillin Allergy)	Recommended First-line Treatment	Alternative Treatment
Amoxicillin (80–90 mg/ kg per day in 2 divided doses)	Cefdinir (14 mg/kg per day in 1 or 2 doses)	Amoxicillin-clavulanate[a] (90 mg/kg per day of amoxicillin, with 6.4 mg/kg per day of clavulanate in 2 divided doses)	Ceftriaxone, 3 d Clindamycin (30–40 mg/kg per day in 3 divided doses), with or without third-generation cephalosporin
or	Cefuroxime (30 mg/kg per day in 2 divided doses)	or	Failure of second antibiotic
Amoxicillin-clavulanate[a] (90 mg/kg per day of amoxicillin, with 6.4 mg/kg per day of clavulanate [amoxicillin to clavulanate ratio, 14:1] in 2 divided doses)	Cefpodoxime (10 mg/kg per day in 2 divided doses)	Ceftriaxone (50 mg IM or IV for 3 d)	Clindamycin (30–40 mg/kg per day in 3 divided doses) plus third-generation cephalosporin
	Ceftriaxone (50 mg IM or IV per day for 1 or 3 d)		Tympanocentesis[b] Consult specialist[b]

IM, intramuscular; IV, intravenous.

[a] May be considered in patients who have received amoxicillin in the previous 30 d or who have the otitis-conjunctivitis syndrome.

[b] Perform tympanocentesis/drainage if skilled in the procedure, or seek a consultation from an otolaryngologist for tympanocentesis/drainage. If the tympanocentesis reveals multidrug-resistant bacteria, seek an infectious disease specialist consultation.

[c] Cefdinir, cefuroxime, cefpodoxime, and ceftriaxone are highly unlikely to be associated with cross-reactivity with penicillin allergy on the basis of their distinct chemical structures. See text for more information.

cefdinir in recurrent AOM attributable to *H influenzae* showed eradication of the organism in 72% of patients.[163]

For penicillin-allergic children, recent data suggest that cross-reactivity among penicillins and cephalosporins is lower than historically reported.[164–167] The previously cited rate of cross-sensitivity to cephalosporins among penicillin-allergic patients (approximately 10%) is likely an overestimate. The rate was based on data collected and reviewed during the 1960s and 1970s. A study analyzing pooled data of 23 studies, including 2400 patients with reported history of penicillin allergy and 39 000 with no penicillin allergic history concluded that many patients who present with a history of penicillin allergy do not have an immunologic reaction to penicillin.[166] The chemical structure of the cephalosporin determines the risk of cross-reactivity between specific agents.[165,168] The degree of cross-reactivity is higher between penicillins and first-generation cephalosporins but is negligible with the second- and third-generation cephalosporins. Because of the differences in the chemical structures, cefdinir, cefuroxime, cefpodoxime, and ceftriaxone are highly unlikely to be associated with cross-reactivity with penicillin.[165] Despite this, the Joint Task Force on Practice Parameters; American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; and Joint Council of Allergy, Asthma and Immunology[169] stated that "cephalosporin treatment of patients with a history of penicillin allergy, selecting out those with severe reaction histories, show a reaction rate of 0.1%." They recommend a cephalosporin in cases without severe and/or recent penicillin allergy reaction history when skin test is not available.

Macrolides, such as erythromycin and azithromycin, have limited efficacy against both *H influenzae* and *S pneumoniae*.[130,147–149] Clindamycin lacks efficacy against *H influenzae*. Clindamycin alone (30–40 mg/kg per day in 3 divided doses) may be used for suspected penicillin-resistant *S pneumoniae*; however, the drug will likely not be effective for the multidrug-resistant serotypes.[130,158,166]

Several of these choices of antibiotic suspensions are barely palatable or frankly offensive and may lead to avoidance behaviors or active rejection by spitting out the suspension. Palatability of antibiotic suspensions has been compared in many studies.[170–172] Specific antibiotic suspensions such as cefuroxime, cefpodoxime, and clindamycin may benefit from adding taste-masking products, such as chocolate or strawberry flavoring agents, to obscure the initial bitter taste and the unpleasant aftertaste.[172,173] In the patient who is persistently vomiting or cannot otherwise tolerate oral medication, even when the taste is masked, ceftriaxone (50 mg/kg, administered intramuscularly in 1 or 2 sites in the anterior thigh, or intravenously) has been demonstrated to be effective for the initial or repeat antibiotic treatment of AOM.[174,175] Although a single injection of ceftriaxone is approved by the US FDA for the treatment of AOM, results of a double tympanocentesis study (before and 3 days after single dose ceftriaxone) by Leibovitz et al[175] suggest that more than 1 ceftriaxone dose may be required to prevent recurrence of the middle ear infection within 5 to 7 days after the initial dose.

Initial Antibiotic Treatment Failure

When antibiotics are prescribed for AOM, clinical improvement should be noted within 48 to 72 hours. During the 24 hours after the diagnosis of AOM, the child's symptoms may worsen slightly. In the next 24 hours, the patient's symptoms should begin to improve. If initially febrile, the temperature should decline within 48 to 72 hours. Irritability and fussiness should lessen or disappear, and sleeping and drinking patterns should normalize.[176,177] If the patient is not improved by 48 to 72 hours, another disease or concomitant viral infection may be present, or the causative bacteria may be resistant to the chosen therapy.

Some children with AOM and persistent symptoms after 48 to 72 hours of initial antibacterial treatment may have combined bacterial and viral infection, which would explain the persistence of ongoing symptoms despite appropriate antibiotic therapy.[109,178,179] Literature is conflicting on the correlation between clinical and bacteriologic outcomes. Some studies report good correlation ranging from 86% to 91%,[180,181] suggesting continued presence of bacteria in the middle ear in a high proportion of cases with persistent symptoms. Others report that middle ear fluid from children with AOM in whom symptoms are persistent is sterile in 42% to 49% of cases.[123,182] A change in antibiotic may not be required in some children with mild persistent symptoms.

In children with persistent, severe symptoms of AOM and unimproved otologic findings after initial treatment, the clinician may consider changing the antibiotic (Table 5). If the child was initially treated with amoxicillin and failed to improve, amoxicillin-clavulanate should be used. Patients who were given amoxicillin-clavulanate or oral third-generation cephalosporins may receive intramuscular ceftriaxone (50 mg/kg). In the treatment of AOM unresponsive to initial antibiotics, a 3-day course of ceftriaxone has been shown to be better than a 1-day regimen.[175]

Although trimethoprim-sulfamethoxazole and erythromycin-sulfisoxazole had been useful as therapy for patients with AOM, pneumococcal surveillance studies have indicated that resistance to these 2 combination agents is substantial.[130,149,183] Therefore, when patients fail to improve while receiving amoxicillin, neither trimethoprim-sulfamethoxazole[184] nor erythromycin-sulfisoxazole is appropriate therapy.

Tympanocentesis should be considered, and culture of middle ear fluid should be performed for bacteriologic diagnosis and susceptibility testing when a series of antibiotic drugs have failed to improve the clinical condition. If tympanocentesis is not available, a course of clindamycin may be used, with or without an antibiotic that covers nontypeable *H influenzae* and *M catarrhalis*, such as cefdinir, cefixime, or cefuroxime.

Because *S pneumoniae* serotype 19A is usually multidrug-resistant and may not be responsive to clindamycin,[104,149] newer antibiotics that are not approved by the FDA for treatment of AOM, such as levofloxacin or linezolid, may be indicated.[185–187] Levofloxacin is a quinolone antibiotic that is not approved by the FDA for use in children. Linezolid is effective against resistant Gram-positive bacteria. It is not approved by the FDA for AOM treatment and is expensive. In children with repeated treatment failures, every effort should be made for bacteriologic diagnosis by tympanocentesis with Gram stain, culture, and antibiotic susceptibility testing of the organism (s) present. The clinician may consider consulting with pediatric medical subspecialists, such as an otolaryngologist for possible tympanocentesis, drainage, and culture and an infectious disease expert, before use of unconventional drugs such as levofloxacin or linezolid.

When tympanocentesis is not available, 1 possible way to obtain information on the middle ear pathogens and their antimicrobial susceptibility is to obtain a nasopharyngeal specimen for bacterial culture. Almost all middle ear pathogens derive from the pathogens colonizing the nasopharynx, but not all nasopharyngeal pathogens enter the middle ear to cause AOM. The positive predictive value of nasopharyngeal culture during AOM (likelihood that bacteria cultured from the nasopharynx is the middle ear pathogen) ranges from 22% to 44% for *S pneumoniae*, 50% to 71% for nontypeable *H influenzae*, and 17% to 19% for *M catarrhalis*. The negative predictive value (likelihood that bacteria not found in the nasopharynx are not AOM pathogens) ranges from 95% to 99% for all 3 bacteria.[188,189] Therefore, if nasopharyngeal culture is negative for specific bacteria, that organism is likely not the AOM pathogen. A negative culture for *S pneumoniae*, for example, will help eliminate the concern for multidrug-resistant bacteria and the need for unconventional therapies, such as levofloxacin or linezolid. On the other hand, if *S pneumoniae* is cultured from the nasopharynx, the antimicrobial susceptibility pattern can help guide treatment.

Duration of Therapy

The optimal duration of therapy for patients with AOM is uncertain; the usual 10-day course of therapy was derived from the duration of treatment of streptococcal pharyngotonsillitis. Several studies favor standard 10-day therapy over shorter courses for children younger than 2 years.[162,190–194] Thus, for children younger than 2 years and children with severe symptoms, a standard 10-day course is recommended. A 7-day course of oral antibiotic appears to be equally effective in children 2 to 5 years of age with mild or moderate AOM. For children 6 years and older with mild to moderate symptoms, a 5- to 7-day course is adequate treatment.

Follow-up of the Patient With AOM

Once the child has shown clinical improvement, follow-up is based on the usual clinical course of AOM. There is little scientific evidence for a routine 10- to 14-day reevaluation visit for all children with an episode of AOM. The physician may choose to reassess some children, such as young children with severe symptoms or recurrent AOM or when specifically requested by the child's parent.

Persistent MEE is common and can be detected by pneumatic otoscopy (with or without verification by tympanometry) after resolution of acute symptoms. Two weeks after successful antibiotic treatment of AOM, 60% to 70% of children have MEE, decreasing to 40% at 1 month and 10% to 25% at 3 months after successful antibiotic treatment.[177,195] The presence of MEE without clinical symptoms is defined as OME. OME must be differentiated clinically from AOM and requires infrequent additional monitoring but not antibiotic therapy. Assurance that OME resolves is particularly important for parents of children with cognitive or developmental delays that may be affected adversely by transient hearing loss associated with MEE. Detailed recommendations for the management of the child with OME can be found in the evidence-based guideline from the AAP/AAFP/American Academy of Otolaryngology-Head and Neck Surgery published in 2004.[84,85]

Key Action Statement 5A

Clinicians should *NOT* prescribe prophylactic antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 5A

Aggregate evidence quality	Grade B
Benefits	No adverse effects from antibiotic. Reduces potential for development of bacterial resistance. Reduced costs.
Risks, harms, cost	Small increase in episodes of AOM.
Benefit-harm assessment	Preponderance of benefit.
Value judgments	Potential harm outweighs the potential benefit.
Intentional vagueness	None.
Role of patient preferences	Limited.
Exclusions	Young children whose only alternative would be tympanostomy tubes.
Strength	**Recommendation**

Key Action Statement 5B

Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months or 4 episodes in 1 year, with 1 episode in the preceding 6 months). (Evidence Quality: Grade B, Rec. Strength: Option)

Key Action Statement Profile: KAS 5B

Aggregate evidence quality	**Grade B**
Benefits	Decreased frequency of AOM. Ability to treat AOM with topical antibiotic therapy.
Risks, harms, cost	Risks of anesthesia or surgery. Cost. Scarring of TM, chronic perforation, cholesteatoma. Otorrhea.
Benefits-harms assessment	Equilibrium of benefit and harm.
Value judgments	None.
Intentional vagueness	Option based on limited evidence.
Role of patient preferences	Joint decision of parent and clinician.
Exclusions	Any contraindication to anesthesia and surgery.
Strength	**Option**

Purpose of This Section

Recurrent AOM has been defined as the occurrence of 3 or more episodes of AOM in a 6-month period or the occurrence of 4 or more episodes of AOM in a 12-month period that includes at least 1 episode in the preceding 6 months.[20] These episodes should be well documented and separate acute infections.[11]

Winter season, male gender, and passive exposure to smoking have been associated with an increased likelihood of recurrence. Half of children younger than 2 years treated for AOM will experience a recurrence within 6 months. Symptoms that last more than 10 days may also predict recurrence.[196]

Changes From AAP/AAFP 2004 AOM Guideline

Recurrent AOM was not addressed in the 2004 AOM guideline. This section addresses the literature on recurrent AOM.

Antibiotic Prophylaxis

Long-term, low-dose antibiotic use, referred to as antibiotic prophylaxis or chemoprophylaxis, has been used to treat children with recurrent AOM to prevent subsequent episodes.[85] A 2006 Cochrane review analyzed 16 studies of long-term antibiotic use for AOM and found such use prevented 1.5 episodes of AOM per year, reducing in half the number of AOM episodes during the period of treatment.[197] Randomized placebo-controlled trials of prophylaxis reported a decrease of 0.09 episodes per month in the frequency of AOM attributable to therapy (approximately 0.5 to 1.5 AOM episodes per year for 95% of children). An estimated 5 children would need to be treated for 1 year to prevent 1 episode of OM. The effect may be more substantial for children with 6 or more AOM episodes in the preceding year.[12]

This decrease in episodes of AOM occurred only while the prophylactic antibiotic was being given. The modest benefit afforded by a 6-month course of antibiotic prophylaxis does not have longer-lasting benefit after cessation of therapy. Teele showed no differences between children who received prophylactic antibiotics compared with those who received placebo in AOM recurrences or persistence of OME.[198]

Antibiotic prophylaxis is not appropriate for children with long-term MEE or for children with infrequent episodes of AOM. The small reduction in frequency of AOM with long-term antibiotic prophylaxis must be weighed against the cost of such therapy; the potential adverse effects of antibiotics, principally allergic reaction and gastrointestinal tract consequences, such as diarrhea; and their contribution to the emergence of bacterial resistance.

Surgery for Recurrent AOM

The use of tympanostomy tubes for treatment of ear disease in general, and for AOM in particular, has been controversial.[199] Most published studies of surgical intervention for OM focus on children with persistent MEE with or without AOM. The literature on surgery for recurrent AOM as defined here is scant. A lack of consensus among otolaryngologists regarding the role of surgery for recurrent AOM was reported in a survey of Canadian otolaryngologists in which 40% reported they would "never," 30% reported they would "sometimes," and 30% reported they would "often or always" place tympanostomy tubes for a hypothetical 2-year-old child with frequent OM without persistent MEE or hearing loss.[200]

Tympanostomy tubes, however, remain widely used in clinical practice for both OME and recurrent OM.[201] Recurrent

AOM remains a common indication for referral to an otolaryngologist.

Three randomized controlled trials have compared the number of episodes of AOM after tympanostomy tube placement or no surgery.[202] Two found significant improvement in mean number of AOM episodes after tympanostomy tubes during a 6-month follow-up period.[203,204] One study randomly assigned children with recurrent AOM to groups receiving placebo, amoxicillin prophylaxis, or tympanostomy tubes and followed them for 2 years.[205] Although prophylactic antibiotics reduced the rate of AOM, no difference in number of episodes of AOM was noted between the tympanostomy tube group and the placebo group over 2 years. A Cochrane review of studies of tympanostomy tubes for recurrent AOM analyzed 2 studies[204,206] that met inclusion criteria and found that tympanostomy tubes reduced the number of episodes of AOM by 1.5 episodes in the 6 months after surgery.[207] Tympanostomy tube insertion has been shown to improve disease-specific quality-of-life measures in children with OM.[208] One multicenter, nonrandomized observational study showed large improvements in a disease-specific quality-of-life instrument that measured psychosocial domains of physical suffering, hearing loss, speech impairment, emotional distress, activity limitations, and caregiver concerns that are associated with ear infections.[209] These benefits of tympanostomy tubes have been demonstrated in mixed populations of children that include children with OME as well as recurrent AOM.

Beyond the cost, insertion of tympanostomy tubes is associated with a small but finite surgical and anesthetic risk. A recent review looking at protocols to minimize operative risk reported no major complications, such as sensorineural hearing loss, vascular injury, or ossicular chain disruption, in 10 000 tube insertions performed primarily by residents, although minor complications such as TM tears or displaced tubes in the middle ear were seen in 0.016% of ears.[210] Long-term sequelae of tympanostomy tubes include TM structural changes including focal atrophy, tympanosclerosis, retraction pockets, and chronic perforation. One meta-analysis found tympanosclerosis in 32% of patients after placement of tympanostomy tubes and chronic perforations in 2.2% of patients who had short-term tubes and 16.6% of patients with long-term tubes.[211]

Adenoidectomy, without myringotomy and/or tympanostomy tubes, did not reduce the number of episodes of AOM when compared with chemoprophylaxis or placebo.[212] Adenoidectomy alone should not be used for prevention of AOM but may have benefit when performed with placement of tympanostomy tubes or in children with previous tympanostomy tube placement in OME.[213]

Prevention of AOM: Key Action Statement 6A

Pneumococcal Vaccine

Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices, AAP, and AAFP. (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Key Action Statement Profile: KAS 6A

Aggregate evidence quality	Grade B
Benefits	Reduced frequency of AOM attributable to vaccine serotypes. Reduced risk of serious pneumococcal systemic disease.
Risks, harms, cost	Potential vaccine side effects. Cost of vaccine.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Potential vaccine adverse effects are minimal.
Intentional vagueness	None.
Role of patient preferences	Some parents may choose to refuse the vaccine.
Exclusions	Severe allergic reaction (eg, anaphylaxis) to any component of pneumococcal vaccine or any diphtheria toxoid-containing vaccine.
Strength	**Strong Recommendation**

Key Action Statement 6B

Influenza Vaccine: Clinicians should recommend annual influenza vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices, AAP, and AAFP. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 6B

Aggregate evidence quality	Grade B
Benefits	Reduced risk of influenza infection. Reduction in frequency of AOM associated with influenza.
Risks, harms, cost	Potential vaccine adverse effects. Cost of vaccine. Requires annual immunization.
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Potential vaccine adverse effects are minimal.
Intentional vagueness	None
Role of patient preferences	Some parents may choose to refuse the vaccine.
Exclusions	See CDC guideline on contraindications (http://www.cdc.gov/flu/professionals/acip/shouldnot.htm).
Strength	**Recommendation**

Key Action Statement 6C

Breastfeeding: Clinicians should encourage exclusive breastfeeding for at least 6 months. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 6C

Aggregate evidence quality	Grade B
Benefits	May reduce the risk of early AOM. Multiple benefits of breastfeeding unrelated to AOM.
Risk, harm, cost	None
Benefit-harm assessment	Preponderance of benefit.
Value judgments	The intervention has value unrelated to AOM prevention.
Intentional vagueness	None
Role of patient preferences	Some parents choose to feed formula.
Exclusions	None
Strength	**Recommendation**

Key Action Statement 6D

Clinicians should encourage avoidance of tobacco smoke exposure. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 6D

Aggregate evidence quality	Grade C
Benefits	May reduce the risk of AOM.
Risks, harms, cost	None
Benefits-harms assessment	Preponderance of benefit.
Value judgments	Avoidance of tobacco exposure has inherent value unrelated to AOM.
Intentional vagueness	None
Role of patient preferences	Many parents/caregivers choose not to stop smoking. Some also remain addicted, and are unable to quit smoking.
Exclusions	None
Strength	**Recommendation**

Purpose of This Section

The 2004 AOM guideline noted data on immunizations, breastfeeding, and lifestyle changes that would reduce the risk of acquiring AOM. This section addresses new data published since 2004.

Changes From AAP/AAFP 2004 AOM Guideline

PCV7 has been in use in the United States since 2000. PCV13 was introduced in the United States in 2010. The 10-valent pneumococcal nontypeable *H influenzae* protein D-conjugate vaccine was recently licensed in Europe for prevention of diseases attributable to *S pneumoniae* and nontypeable *H influenzae*. Annual influenza immunization is now recommended for all children 6 months of age and older in the United States.[214,215] Updated information regarding these vaccines and their effect on the incidence of AOM is reviewed.

The AAP issued a new breastfeeding policy statement in February 2012.[216] This guideline also includes a recommendation regarding tobacco smoke exposure. Bottle propping, pacifier use, and child care are discussed, but no recommendations are made because of limited evidence. The use of xylitol, a possible adjunct to AOM prevention, is discussed; however, no recommendations are made.

Pneumococcal Vaccine

Pneumococcal conjugate vaccines have proven effective in preventing OM caused by pneumococcal serotypes contained in the vaccines. A meta-analysis of 5 studies with AOM as an outcome determined that there is a 29% reduction in AOM caused by all pneumococcal serotypes among children who received PCV7 before 24 months of age.[217] Although the overall benefit seen in clinical trials for all causes of AOM is small (6%–7%),[218–221] observational studies have shown that medical office visits for otitis were reduced by up to 40% comparing years before and after introduction of PCV7.[222–224] Grijvala[223] reported no effect, however, among children first vaccinated at older ages. Poehling et al[225] reported reductions of frequent AOM and PE tube use after introduction of PCV7. The observations by some of greater benefit observed in the community than in clinical trials is not fully understood but may be related to effects of herd immunity or may be attributed to secular trends or changes in AOM diagnosis patterns over time.[223,226–229] In a 2009 Cochrane review,[221] Jansen et al found that the overall reduction in AOM incidence may only be 6% to 7% but noted that even that small rate may have public health relevance. O'Brien et al concurred and noted in addition the potential for cost savings.[230] There is evidence that serotype replacement may reduce the long-term efficacy of pneumococcal conjugate vaccines against AOM,[231] but it is possible that new pneumococcal conjugate vaccines may demonstrate an increased effect on reduction in AOM.[232–234] Data on AOM reduction secondary to the PCV13 licensed in the United States in 2010 are not yet available.

The *H influenzae* protein D-conjugate vaccine recently licensed in Europe has potential benefit of protection against 10 serotypes of *S pneumoniae* and nontypeable *H influenzae*.[221,234]

Influenza Vaccine

Most cases of AOM follow upper respiratory tract infections caused by viruses, including influenza viruses. As many as two-thirds of young children with influenza may have AOM.[235] Investigators have studied the efficacy of trivalent inactivated influenza vaccine (TIV) and live-attenuated intranasal influenza vaccine (LAIV) in preventing AOM. Many studies have demonstrated 30% to 55% efficacy of influenza vaccine in prevention of AOM during the respiratory illness season.[6,235–239] One study reported no benefit of TIV in reducing AOM burden; however, 1 of the 2 respiratory illness seasons during which this study was conducted had a relatively low influenza activity. A pooled analysis[240] of 8 studies comparing LAIV versus TIV or placebo[241–248] showed a higher efficacy of LAIV compared with both placebo and with TIV. Influenza vaccination is now recommended for all children 6 months of age and older in the United States.[214,215]

Breastfeeding

Multiple studies provide evidence that breastfeeding for at least 4 to 6 months reduces episodes of AOM and recurrent AOM.[249–253] Two cohort studies, 1 retrospective study[250] and 1 prospective study,[253] suggest a dose response, with some protection from partial breastfeeding and the greatest protection from exclusive breastfeeding through 6 months of age. In multivariate analysis controlling for exposure to child care settings, the risk of nonrecurrent otitis is 0.61 (95% confidence interval [CI]: 0.4–0.92) comparing exclusive breastfeeding through 6 months of age with no breastfeeding or breastfeeding less than 4 months. In a prospective cohort, Scariatti[253] found a significant dose-response effect. In this study, OM was self-reported by parents. In a systematic review, McNiel et al[254] found that when exclusive breastfeeding was set as the normative standard, the recalculated odds ratios (ORs) revealed the risks of any formula use. For example, any formula use in the first 6 months of age was significantly associated with increased incidence of OM (OR: 1.78; 95% CI: 1.19–2.70; OR: 4.55; 95% CI: 1.64–12.50 in the available studies; pooled OR for any formula in the first 3 months of age, 2.00; 95% CI: 1.40–2.78). A number of studies[255–259] addressed the association of AOM and other infectious illness in infants with duration and exclusivity of breastfeeding, but all had limitations and none had a randomized controlled design. However, taken together, they continue to show a protective effect of exclusive breastfeeding. In all studies, there has been a predominance of white subjects, and child care attendance and smoking exposure may not have been completely controlled. Also, feeding methods were self-reported.

The consistent finding of a lower incidence of AOM and recurrent AOM with increased breastfeeding supports the AAP recommendation to encourage exclusive breastfeeding for the first 6 months of life and to continue for at least the first year and beyond for as long as mutually desired by mother and child.[216]

Lifestyle Changes

In addition to its many other benefits,[260] eliminating exposure to passive tobacco smoke has been postulated to reduce the incidence of AOM in infancy.[252,261–264] Bottles and pacifiers have been associated with AOM. Avoiding supine bottle feeding ("bottle propping") and reducing or eliminating pacifier use in the second 6 months of life may reduce AOM incidence.[265–267] In a recent cohort study, pacifier use was associated with AOM recurrence.[268]

During infancy and early childhood, reducing the incidence of upper respiratory tract infections by altering child care-center attendance patterns can reduce the incidence of recurrent AOM significantly.[249,269]

Xylitol

Xylitol, or birch sugar, is chemically a pentitol or 5-carbon polyol sugar alcohol. It is available as chewing gum, syrup, or lozenges. A 2011 Cochrane review[270] examined the evidence for the use of xylitol in preventing recurrent AOM. A statistically significant 25% reduction in the risk of occurrence of AOM among healthy children at child care centers in the xylitol group compared with the control group (relative risk: 0.75; 95% CI: 0.65 to 0.88; RD: –0.07; 95% CI: –0.12 to –0.03) in the 4 studies met criteria for analysis.[271–274] Chewing gum and lozenges containing xylitol appeared to be more effective than syrup. Children younger than 2 years, those at the greatest risk of having AOM, cannot safely use lozenges or chewing gum. Also, xylitol needs to be given 3 to 5 times a day to be effective. It is not effective for treating AOM and it must be taken daily throughout the respiratory illness season to have an effect. Sporadic or as-needed use is not effective.

Future Research

Despite advances in research partially stimulated by the 2004 AOM guideline, there are still many unanswered clinical questions in the field. Following are possible clinical research questions that still need to be resolved.

Diagnosis

There will probably never be a gold standard for diagnosis of AOM because of the continuum from OME to AOM. Conceivably, new techniques that could be used on the small amount of fluid obtained during tympanocentesis could identify inflammatory markers in addition to the presence of bacteria or viruses. However, performing tympanocentesis studies on children with uncomplicated otitis is likely not feasible because of ethical and other considerations.

Devices that more accurately identify the presence of MEE and bulging that are easier to use than tympanometry during office visits would be welcome, especially in the difficult-to-examine infant. Additional development of inexpensive, easy-to-use video pneumatic otoscopes is still a goal.

Initial Treatment

The recent studies of Hoberman[31] and Tähtinen[32] have addressed clinical and TM appearance by using stringent diagnostic criteria of AOM. However, the outcomes for less stringent diagnostic criteria, a combination of symptoms, MEE, and TM appearance not completely consistent with OME can only be inferred from earlier studies that used less stringent criteria but did not specify outcomes for various grades of findings. Randomized controlled trials on these less certain TM appearances using scales similar to the OS-8 scale[35] could clarify the benefit of initial antibiotics and initial observation for these less certain diagnoses. Such studies must also specify severity of illness, laterality, and otorrhea.

Appropriate end points must be established. Specifically is the appearance of the TM in patients without clinical symptoms at the end of a study significant for relapse, recurrence, or persistent MEE. Such a study would require randomization of patients with unimproved TM appearance to continued observation and antibiotic groups.

The most efficient and acceptable methods of initial observation should continue to be studied balancing the convenience and benefits with the potential risks to the patient.

Antibiotics

Amoxicillin-clavulanate has a broader spectrum than amoxicillin and may be a better initial antibiotic. However, because of cost and adverse effects, the subcommittee has chosen amoxicillin as first-line AOM treatment. Randomized controlled trials comparing the 2 with adequate power to differentiate clinical efficacy would clarify this choice. Stringent diagnostic criteria should be the standard for these studies. Antibiotic comparisons for AOM should now include an observation arm for patients with nonsevere illness to ensure a clinical benefit over placebo. Studies should also have enough patients to show small but meaningful differences.

Although there have been studies on the likelihood of resistant *S pneumoniae* or *H influenzae* in children in child care settings and with siblings younger than 5 years, studies are still needed to determine whether these and other risk factors would indicate a need for different initial treatment than noted in the guideline.

New antibiotics that are safe and effective are needed for use in AOM because of the development of multidrug-resistant organisms. Such new antibiotics must be tested against the currently available medications.

Randomized controlled trials using different durations of antibiotic therapy in different age groups are needed to optimize therapy with the possibility of decreasing duration of antibiotic use. These would need to be performed initially with amoxicillin and amoxicillin-clavulanate but should also be performed for any antibiotic used in AOM. Again, an observation arm should be included in nonsevere illness.

Recurrent AOM

There have been adequate studies regarding prophylactic antibiotic use in recurrent AOM. More and better controlled studies of tympanostomy tube placement would help determine its benefit versus harm.

Prevention

There should be additional development of vaccines targeted at common organisms associated with AOM.[275] Focused epidemiologic studies on the benefit of breastfeeding, specifically addressing AOM prevention, including duration of breastfeeding and partial versus exclusive breastfeeding, would clarify what is now a more general database. Likewise, more focused studies of the effects of lifestyle changes would help clarify their effect on AOM.

Complementary and Alternative Medicine

There are no well-designed randomized controlled trials of the usefulness of complementary and alternative medicine in AOM, yet a large number of families turn to these methods. Although most alternative therapies are relatively inexpensive, some may be costly. Such studies should compare the alternative therapy to observation rather than antibiotics and only use an antibiotic arm if the alternative therapy is shown to be better than observation. Such studies should focus on children with less stringent criteria of AOM but using the same descriptive criteria for the patients as noted above.

DISSEMINATION OF GUIDELINES

An Institute of Medicine Report notes that "Effective multifaceted implementation strategies targeting both individuals and healthcare systems should be employed by implementers to promote adherence to trustworthy [clinical practice guidelines]."[230]

Many studies of the effect of clinical practice guidelines have been performed. In general, the studies show little overt change in practice after a guideline is published. However, as was seen after the 2004 AOM guideline, the number of visits for AOM and the number of prescriptions for antibiotics for AOM had decreased publication. Studies of educational and dissemination methods both at the practicing physician level and especially at the resident level need to be examined.

SUBCOMMITTEE ON DIAGNOSIS AND MANAGEMENT OF ACUTE OTITIS MEDIA

Allan S. Lieberthal, MD, FAAP (Chair, general pediatrician, no conflicts)

Aaron E. Carroll, MD, MS, FAAP (Partnership for Policy Implementation [PPI] Informatician, general academic pediatrician, no conflicts)

Tasnee Chonmaitree, MD, FAAP (pediatric infectious disease physician, no financial conflicts; published research related to AOM)

Theodore G. Ganiats, MD (family physician, American Academy of Family Physicians, no conflicts)

Alejandro Hoberman, MD, FAAP (general academic pediatrician, no financial conflicts; published research related to AOM)

Mary Anne Jackson, MD, FAAP (pediatric infectious disease physician, AAP Committee on Infectious Disease, no conflicts)

Mark D. Joffe, MD, FAAP (pediatric emergency medicine physician, AAP Committee/Section on Pediatric Emergency Medicine, no conflicts)

Donald T. Miller, MD, MPH, FAAP (general pediatrician, no conflicts)

Richard M. Rosenfeld, MD, MPH, FAAP (otolaryngologist, AAP Section on Otolaryngology, Head and Neck Surgery, American Academy of Otolaryngology-Head and Neck Surgery, no financial conflicts; published research related to AOM)

Xavier D. Sevilla, MD, FAAP (general pediatrics, Quality Improvement Innovation Network, no conflicts)

Richard H. Schwartz, MD, FAAP (general pediatrician, no financial conflicts; published research related to AOM)

Pauline A. Thomas, MD, FAAP (epidemiologist, general pediatrician, no conflicts)

David E. Tunkel, MD, FAAP, FACS (otolaryngologist, AAP Section on Otolaryngology, Head and Neck Surgery, periodic consultant to Medtronic ENT)

CONSULTANT

Richard N. Shiffman, MD, FAAP, FACMI (informatician, guideline methodologist, general academic pediatrician, no conflicts)

STAFF

Caryn Davidson, MA

Oversight by the Steering Committee on Quality Improvement and Management, 2009–2012

REFERENCES

1. American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. *Pediatrics*. 2004;113(5):1451–1465
2. Grijalva CG, Nuorti JP, Griffin MR. Antibiotic prescription rates for acute respiratory tract infections in US ambulatory settings. *JAMA*. 2009;302(7):758–766
3. McCaig LF, Besser RE, Hughes JM. Trends in antimicrobial prescribing rates for children and adolescents. *JAMA*. 2002;287(23):3096–3102
4. Vernacchio L, Vezina RM, Mitchell AA. Management of acute otitis media by primary care physicians: trends since the release of the 2004 American Academy of Pediatrics/American Academy of Family Physicians clinical practice guideline. *Pediatrics*. 2007;120(2):281–287
5. Coco A, Vernacchio L, Horst M, Anderson A. Management of acute otitis media after publication of the 2004 AAP and AAFP clinical practice guideline. *Pediatrics*. 2010;125(2):214–220
6. Marchisio P, Mira E, Klersy C, et al. Medical education and attitudes about acute otitis media guidelines: a survey of Italian pediatricians and otolaryngologists. *Pediatr Infect Dis J*. 2009;28(1):1–4
7. Arkins ER, Koehler JM. Use of the observation option and compliance with guidelines in treatment of acute otitis media. *Ann Pharmacother*. 2008;42(5):726–727
8. Flores G, Lee M, Bauchner H, Kastner B. Pediatricians' attitudes, beliefs, and practices regarding clinical practice guidelines: a national survey. *Pediatrics*. 2000;105(3 pt 1):496–501
9. Bluestone CD. Definitions, terminology, and classification. In: Rosenfeld RM, Bluestone CD, eds. *Evidence-Based Otitis Media*. Hamilton, Canada: BC Decker; 2003:120–135
10. Bluestone CD, Klein JO. Definitions, terminology, and classification. In: Bluestone CD, Klein JO, eds. *Otitis Media in Infants and Children*. 4th ed. Hamilton, Canada: BC Decker; 2007:1–19
11. Dowell SF, Marcy MS, Phillips WR, et al. Otitis media: principles of judicious use of antimicrobial agents. *Pediatrics*. 1998;101(suppl):165–171
12. Rosenfeld RM. Clinical pathway for acute otitis media. In: Rosenfeld RM, Bluestone CD, eds. *Evidence-Based Otitis Media*. 2nd ed. Hamilton, Canada: BC Decker; 2003:280–302
13. Carlson LH, Carlson RD. Diagnosis. In: Rosenfeld RM, Bluestone CD, eds. *Evidence-Based Otitis Media*. Hamilton, Canada: BC Decker; 2003: 136–146
14. Bluestone CD, Klein JO. Diagnosis. In: *Otitis Media in Infants and Children*. 4th ed. Hamilton, Canada: BC Decker; 2007:147–212
15. University of Oxford, Centre for Evidence Based Medicine. Available at: www.cebm.net/index.aspx?o=1044. Accessed July 17, 2012
16. American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877
17. Marcy M, Takata G, Shekelle P, et al. *Management of Acute Otitis Media*. Evidence Report/Technology Assessment No. 15. Rockville, MD: Agency for Healthcare Research and Quality; 2000

18. Chan LS, Takata GS, Shekelle P, Morton SC, Mason W, Marcy SM. Evidence assessment of management of acute otitis media: II. Research gaps and priorities for future research. *Pediatrics*. 2001;108(2): 248–254
19. Takata GS, Chan LS, Shekelle P, Morton SC, Mason W, Marcy SM. Evidence assessment of management of acute otitis media: I. The role of antibiotics in treatment of uncomplicated acute otitis media. *Pediatrics*. 2001;108(2):239–247
20. Shekelle PG, Takata G, Newberry SJ, et al. *Management of Acute Otitis Media: Update*. Evidence Report/Technology Assessment No. 198. Rockville, MD: Agency for Healthcare Research and Quality; 2010
21. Coker TR, Chan LS, Newberry SJ, et al. Diagnosis, microbial epidemiology, and antibiotic treatment of acute otitis media in children: a systematic review. *JAMA*. 2010;304(19):2161–2169
22. Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials*. 1996;17(1):1–12
23. Whiting P, Rutjes AW, Reitsma JB, Bossuyt PM, Kleijnen J. The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. *BMC Med Res Methodol*. 2003;3:25
24. Guyatt GH, Oxman AD, Vist GE, et al; GRADE Working Group. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008; 336(7650):924–926
25. Hoffman RN, Michel G, Rosenfeld RM, Davidson C. Building better guidelines with BRIDGE-Wiz: development and evaluation of a software assistant to promote clarity, transparency, and implementability. *J Am Med Inform Assoc*. 2012;19 (1):94–101
26. Kalu SU, Ataya RS, McCormick DP, Patel JA, Revai K, Chonmaitree T. Clinical spectrum of acute otitis media complicating upper respiratory tract viral infection. *Pediatr Infect Dis J*. 2011;30(2):95–99
27. Block SL, Harrison CJ. *Diagnosis and Management of Acute Otitis Media*. 3rd ed. Caddo, OK: Professional Communications; 2005:48–50
28. Wald ER. Acute otitis media: more trouble with the evidence. *Pediatr Infect Dis J*. 2003;22(2):103–104
29. Paradise JL, Rockette HE, Colborn DK, et al. Otitis media in 2253 Pittsburgh-area infants: prevalence and risk factors during the first two years of life. *Pediatrics*. 1997;99(3):318–333
30. McCormick DP, Chonmaitree T, Pittman C, et al. Nonsevere acute otitis media: a clinical trial comparing outcomes of watchful waiting versus immediate antibiotic treatment. *Pediatrics*. 2005;115(6): 1455–1465
31. Hoberman A, Paradise JL, Rockette HE, et al. Treatment of acute otitis media in children under 2 years of age. *N Engl J Med*. 2011;364(2):105–115
32. Tähtinen PA, Laine MK, Huovinen P, Jalava J, Ruuskanen O, Ruohola A. A placebo-controlled trial of antimicrobial treatment for acute otitis media. *N Engl J Med*. 2011;364(2):116–126
33. Shaikh N, Hoberman A, Paradise JL, et al. Development and preliminary evaluation of a parent-reported outcome instrument for clinical trials in acute otitis media. *Pediatr Infect Dis J*. 2009;28(1):5–8
34. Laine MK, Tähtinen PA, Ruuskanen O, Huovinen P, Ruohola A. Symptoms or symptom-based scores cannot predict acute otitis media at otitis-prone age. *Pediatrics*. 2010;125(5). Available at: www.pediatrics.org/cgi/content/full/125/5/e1154
35. Friedman NR, McCormick DP, Pittman C, et al. Development of a practical tool for assessing the severity of acute otitis media. *Pediatr Infect Dis J*. 2006;25(2):101–107
36. Rothman R, Owens T, Simel DL. Does this child have acute otitis media? *JAMA*. 2003; 290(12):1633–1640
37. Niemela M, Uhari M, Jounio-Ervasti K, Luotonen J, Alho OP, Vierimaa E. Lack of specific symptomatology in children with acute otitis media. *Pediatr Infect Dis J*. 1994;13(9):765–768
38. Heikkinen T, Ruuskanen O. Signs and symptoms predicting acute otitis media. *Arch Pediatr Adolesc Med*. 1995;149(1): 26–29
39. Ingvarsson L. Acute otalgia in children—findings and diagnosis. *Acta Paediatr Scand*. 1982;71(5):705–710
40. Kontiokari T, Koivunen P, Niemelä M, Pokka T, Uhari M. Symptoms of acute otitis media. *Pediatr Infect Dis J*. 1998;17(8):676–679
41. Wong DL, Baker CM. Pain in children: comparison of assessment scales. *Pediatr Nurs*. 1988;14(1):9–17
42. Shaikh N, Hoberman A, Paradise JL, et al. Responsiveness and construct validity of a symptom scale for acute otitis media. *Pediatr Infect Dis J*. 2009;28(1):9–12
43. Karma PH, Penttilä MA, Sipilä MM, Kataja MJ. Otoscopic diagnosis of middle ear effusion in acute and non-acute otitis media. I. The value of different otoscopic findings. *Int J Pediatr Otorhinolaryngol*. 1989;17(1):37–49
44. McCormick DP, Lim-Melia E, Saeed K, Baldwin CD, Chonmaitree T. Otitis media: can clinical findings predict bacterial or viral etiology? *Pediatr Infect Dis J*. 2000; 19(3):256–258
45. Schwartz RH, Stool SE, Rodriguez WJ, Grundfast KM. Acute otitis media: toward a more precise definition. *Clin Pediatr (Phila)*. 1981;20(9):549–554
46. Rosenfeld RM. Antibiotic prophylaxis for recurrent acute otitis media. In: Alper CM, Bluestone CD, eds. *Advanced Therapy of Otitis Media*. Hamilton, Canada: BC Decker; 2004
47. Paradise J, Bernard B, Colborn D, Smith C, Rockette H; Pittsburgh-area Child Development/Otitis Media Study Group. Otitis media with effusion: highly prevalent and often the forerunner of acute otitis media during the first year of life [abstract]. *Pediatr Res*. 1993;33:121A
48. Roland PS, Smith TL, Schwartz SR, et al. Clinical practice guideline: cerumen impaction. *Otolaryngol Head Neck Surg*. 2008;139(3 suppl 2):S1–S21
49. Shaikh N, Hoberman A, Kaleida PH, Ploof DL, Paradise JL. Videos in clinical medicine. Diagnosing otitis media—otoscopy and cerumen removal. *N Engl J Med*. 2010; 362(20):e62
50. Pichichero ME. Diagnostic accuracy, tympanocentesis training performance, and antibiotic selection by pediatric residents in management of otitis media. *Pediatrics*. 2002;110(6):1064–1070
51. Kaleida PH, Ploof DL, Kurs-Lasky M, et al. Mastering diagnostic skills: Enhancing Proficiency in Otitis Media, a model for diagnostic skills training. *Pediatrics*. 2009; 124(4). Available at: www.pediatrics.org/cgi/content/full/124/4/e714
52. Kaleida PH, Ploof D. ePROM: Enhancing Proficiency in Otitis Media. Pittsburgh, PA: University of Pittsburgh School of Medicine. Available at: http://pedsed.pitt.edu. Accessed December 31, 2011
53. Innovative Medical Education. *A View Through the Otoscope: Distinguishing Acute Otitis Media from Otitis Media with Effusion*. Paramus, NJ: Innovative Medical Education; 2000
54. American Academy of Pediatrics. Section on Infectious Diseases. A view through the otoscope: distinguishing acute otitis media from otitis media with effusion [video]. Available at: http://www2.aap.org/sections/infectdis/video.cfm. Accessed January 20, 2012
55. Hayden GF, Schwartz RH. Characteristics of earache among children with acute

otitis media. *Am J Dis Child*. 1985;139(7): 721–723

56. Schechter NL. Management of pain associated with acute medical illness. In: Schechter NL, Berde CB, Yaster M, eds. *Pain in Infants, Children, and Adolescents*. Baltimore, MD: Williams & Wilkins; 1993: 537–538
57. Rovers MM, Glasziou P, Appelman CL, et al. Predictors of pain and/or fever at 3 to 7 days for children with acute otitis media not treated initially with antibiotics: a meta-analysis of individual patient data. *Pediatrics*. 2007;119(3):579–585
58. Burke P, Bain J, Robinson D, Dunleavey J. Acute red ear in children: controlled trial of nonantibiotic treatment in children: controlled trial of nonantibiotic treatment in general practice. *BMJ*. 1991;303(6802): 558–562
59. Sanders S, Glasziou PP, DelMar C, Rovers M. Antibiotics for acute otitis media in children [review]. *Cochrane Database Syst Rev*. 2009;(2):1–43
60. van Buchem FL, Dunk JH, van't Hof MA. Therapy of acute otitis media: myringotomy, antibiotics, or neither? A double-blind study in children. *Lancet*. 1981;2(8252): 883–887
61. Thalin A, Densert O, Larsson A, et al. Is penicillin necessary in the treatment of acute otitis media? In: *Proceedings of the International Conference on Acute and Secretory Otitis Media. Part 1*. Amsterdam, Netherlands: Kugler Publications; 1986:441–446
62. Rovers MM, Glasziou P, Appelman CL, et al. Antibiotics for acute otitis media: an individual patient data meta-analysis. *Lancet*. 2006;368(9545):1429–1435
63. Bertin L, Pons G, d'Athis P, et al. A randomized, double-blind, multicentre controlled trial of ibuprofen versus acetaminophen and placebo for symptoms of acute otitis media in children. *Fundam Clin Pharmacol*. 1996;10(4):387–392
64. American Academy of Pediatrics. Committee on Psychosocial Aspects of Child and Family Health; Task Force on Pain in Infants, Children, and Adolescents. The assessment and management of acute pain in infants, children, and adolescents. *Pediatrics*. 2001;108(3): 793–797
65. Bolt P, Barnett P, Babl FE, Sharwood LN. Topical lignocaine for pain relief in acute otitis media: results of a double-blind placebo-controlled randomised trial. *Arch Dis Child*. 2008;93(1):40–44
66. Foxlee R, Johansson AC, Wejfalk J, Dawkins J, Dooley L, Del Mar C. Topical analgesia for acute otitis media. *Cochrane Database Syst Rev*. 2006;(3):CD005657
67. Hoberman A, Paradise JL, Reynolds EA, Urkin J. Efficacy of Auralgan for treating ear pain in children with acute otitis media. *Arch Pediatr Adolesc Med*. 1997; 151(7):675–678
68. Sarrell EM, Mandelberg A, Cohen HA. Efficacy of naturopathic extracts in the management of ear pain associated with acute otitis media. *Arch Pediatr Adolesc Med*. 2001;155(7):796–799
69. Sarrell EM, Cohen HA, Kahan E. Naturopathic treatment for ear pain in children. *Pediatrics*. 2003;111(5 pt 1):e574–e579
70. Adam D, Federspil P, Lukes M, Petrowicz O. Therapeutic properties and tolerance of procaine and phenazone containing ear drops in infants and very young children. *Arzneimittelforschung*. 2009;59(10):504–512
71. Barnett ED, Levatin JL, Chapman EH, et al. Challenges of evaluating homeopathic treatment of acute otitis media. *Pediatr Infect Dis J*. 2000;19(4):273–275
72. Jacobs J, Springer DA, Crothers D. Homeopathic treatment of acute otitis media in children: a preliminary randomized placebo-controlled trial. *Pediatr Infect Dis J*. 2001;20(2):177–183
73. Rosenfeld RM, Bluestone CD. Clinical efficacy of surgical therapy. In: Rosenfeld RM, Bluestone CD, eds. *Evidence-Based Otitis Media. 2003*. Hamilton, Canada: BC Decker; 2003:227–240
74. Rosenfeld RM. Observation option toolkit for acute otitis media. *Int J Pediatr Otorhinolaryngol*. 2001;58(1):1–8
75. Le Saux N, Gaboury I, Baird M, et al. A randomized, double-blind, placebo-controlled noninferiority trial of amoxicillin for clinically diagnosed acute otitis media in children 6 months to 5 years of age. *CMAJ*. 2005;172(3):335–341
76. Spiro DM, Tay KY, Arnold DH, Dziura JD, Baker MD, Shapiro ED. Wait-and-see prescription for the treatment of acute otitis media: a randomized controlled trial. *JAMA*. 2006;296(10):1235–1241
77. Neumark T, Mölstad S, Rosén C, et al. Evaluation of phenoxymethylpenicillin treatment of acute otitis media in children aged 2–16. *Scand J Prim Health Care*. 2007;25(3):166–171
78. Chao JH, Kunkov S, Reyes LB, Lichten S, Crain EF. Comparison of two approaches to observation therapy for acute otitis media in the emergency department. *Pediatrics*. 2008;121(5). Available at: www.pediatrics.org/cgi/content/full/121/5/e1352
79. Spurling GK, Del Mar CB, Dooley L, Foxlee R. Delayed antibiotics for respiratory infections. *Cochrane Database Syst Rev*. 2007;(3):CD004417
80. Koopman L, Hoes AW, Glasziou PP, et al. Antibiotic therapy to prevent the development of asymptomatic middle ear effusion in children with acute otitis media: a meta-analysis of individual patient data. *Arch Otolaryngol Head Neck Surg*. 2008;134(2):128–132
81. Marchetti F, Ronfani L, Nibali SC, Tamburlini G; Italian Study Group on Acute Otitis Media. Delayed prescription may reduce the use of antibiotics for acute otitis media: a prospective observational study in primary care. *Arch Pediatr Adolesc Med*. 2005; 159(7):679–684
82. Ho D, Rotenberg BW, Berkowitz RG. The relationship between acute mastoiditis and antibiotic use for acute otitis media in children. *Arch Otolaryngol Head Neck Surg*. 2008;34(1):45–48
83. Thompson PL, Gilbert RE, Long PF, Saxena S, Sharland M, Wong IC. Effect of antibiotics for otitis media on mastoiditis in children: a retrospective cohort study using the United Kingdom general practice research database. *Pediatrics*. 2009; 123(2):424–430
84. American Academy of Family Physicians; American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Pediatrics Subcommittee on Otitis Media With Effusion. Otitis media with effusion. *Pediatrics*. 2004;113(5):1412–1429
85. Rosenfeld RM, Culpepper L, Doyle KJ, et al; American Academy of Pediatrics Subcommittee on Otitis Media with Effusion; American Academy of Family Physicians; American Academy of Otolaryngology—Head and Neck Surgery. Clinical practice guideline: otitis media with effusion. *Otolaryngol Head Neck Surg*. 2004;130(suppl 5): S95–S118
86. Appelman CL, Claessen JQ, Touw-Otten FW, Hordijk GJ, de Melker RA. Co-amoxiclav in recurrent acute otitis media: placebo controlled study. *BMJ*. 1991;303(6815): 1450–1452
87. Burke P, Bain J, Robinson D, Dunleavey J. Acute red ear in children: controlled trial of nonantibiotic treatment in children: controlled trial of nonantibiotic treatment in general practice. *BMJ*. 1991;303(6802): 558–562
88. van Balen FA, Hoes AW, Verheij TJ, de Melker RA. Primary care based randomized, double blind trial of amoxicillin versus placebo in children aged under 2 years. *BMJ*. 2000;320(7231):350–354

89. Little P, Gould C, Williamson I, Moore M, Warner G, Dunleavey J. Pragmatic randomised controlled trial of two prescribing strategies for childhood acute otitis media. *BMJ*. 2001;322(7282):336–342
90. Mygind N, Meistrup-Larsen K-I, Thomsen J, Thomsen VF, Josefsson K, Sørensen H. Penicillin in acute otitis media: a double-blind placebo-controlled trial. *Clin Otolaryngol Allied Sci*. 1981;6(1):5–13
91. Kaleida PH, Casselbrant ML, Rockette HE, et al. Amoxicillin or myringotomy or both for acute otitis media: results of a randomized clinical trial. *Pediatrics*. 1991;87 (4):466–474
92. Shaikh N, Hoberman A, Paradise JL, et al. Responsiveness and construct validity of a symptom scale for acute otitis media. *Pediatr Infect Dis J*. 2009;28(1):9–12
93. Heikkinen T, Chonmaitree T. Importance of respiratory viruses in acute otitis media. *Clin Microbiol Rev*. 2003;16(2):230–241
94. Halsted C, Lepow ML, Balassanian N, Emmerich J, Wolinsky E. Otitis media. Clinical observations, microbiology, and evaluation of therapy. *Am J Dis Child*. 1968;115(5):542–551
95. Rosenfeld RM, Vertrees J, Carr J, et al. Clinical efficacy of antimicrobials for acute otitis media: meta-analysis of 5,400 children from 33 randomized trials. *J Pediatr*. 1994;124(3):355–367
96. McCormick DP, Chandler SM, Chonmaitree T. Laterality of acute otitis media: different clinical and microbiologic characteristics. *Pediatr Infect Dis J*. 2007;26(7):583–588
97. Appelman CLM, Bossen PC, Dunk JHM, Lisdonk EH, de Melker RA, van Weert HCPM. NHG Standard Otitis Media Acuta (Guideline on acute otitis media of the Dutch College of General Practitioners). *Huisarts Wet*. 1990;33:242–245
98. Swedish Medical Research Council. Treatment for acute inflammation of the middle ear: consensus statement. Stockholm, Sweden: Swedish Medical Research Council; 2000. Available at: http://soapimg.icecube.snowfall.se/strama/Konsensut_ora_eng.pdf. Accessed July 18, 2012
99. Scottish Intercollegiate Guideline Network. Diagnosis and management of childhood otitis media in primary care. Edinburgh, Scotland: Scottish Intercollegiate Guideline Network; 2000. Available at: www.sign.ac.uk/guidelines/fulltext/66/index.html. Accessed July 18, 2012
100. National Institute for Health and Clinical Excellence, Centre for Clinical Practice. Respiratory tract infections—antibiotic prescribing: prescribing of antibiotics for self-limiting respiratory tract infections in adults and children in primary care. NICE Clinical Guideline 69. London, United Kingdom: National Institute for Health and Clinical Excellence; July 2008. Available at: www.nice.org.uk/CG069. Accessed July 18, 2012
101. Marchisio P, Bellussi L, Di Mauro G, et al. Acute otitis media: from diagnosis to prevention. Summary of the Italian guideline. *Int J Pediatr Otorhinolaryngol*. 2010;74(11):1209–1216
102. Siegel RM, Kiely M, Bien JP, et al. Treatment of otitis media with observation and a safety-net antibiotic prescription. *Pediatrics*. 2003;112(3 pt 1):527–531
103. Pshetizky Y, Naimer S, Shvartzman P. Acute otitis media—a brief explanation to parents and antibiotic use. *Fam Pract*. 2003;20(4):417–419
104. Pichichero ME, Casey JR. Emergence of a multiresistant serotype 19A pneumococcal strain not included in the 7-valent conjugate vaccine as an otopathogen in children. *JAMA*. 2007;298(15):1772–1778
105. Pichichero ME, Casey JR. Evolving microbiology and molecular epidemiology of acute otitis media in the pneumococcal conjugate vaccine era. *Pediatr Infect Dis J*. 2007;26(suppl 10):S12–S16
106. Nielsen HUK, Konradsen HB, Lous J, Frimodt-Møller N. Nasopharyngeal pathogens in children with acute otitis media in a low-antibiotic use country. *Int J Pediatr Otorhinolaryngol*. 2004;68(9):1149–1155
107. Pitkäranta A, Virolainen A, Jero J, Arruda E, Hayden FG. Detection of rhinovirus, respiratory syncytial virus, and coronavirus infections in acute otitis media by reverse transcriptase polymerase chain reaction. *Pediatrics*. 1998;102(2 pt 1):291–295
108. Heikkinen T, Thint M, Chonmaitree T. Prevalence of various respiratory viruses in the middle ear during acute otitis media. *N Engl J Med*. 1999;340(4):260–264
109. Chonmaitree T. Acute otitis media is not a pure bacterial disease. *Clin Infect Dis*. 2006;43(11):1423–1425
110. Williams JV, Tollefson SJ, Nair S, Chonmaitree T. Association of human metapneumovirus with acute otitis media. *Int J Pediatr Otorhinolaryngol*. 2006;70(7):1189–1193
111. Chonmaitree T, Heikkinen T. Role of viruses in middle-ear disease. *Ann N Y Acad Sci*. 1997;830:143–157
112. Klein JO, Bluestone CD. Otitis media. In: Feigin RD, Cherry JD, Demmler-Harrison GJ, Kaplan SL, eds. *Textbook of Pediatric Infectious Diseases*. 6th ed. Philadelphia, PA: Saunders; 2009:216–237
113. Chonmaitree T, Revai K, Grady JJ, et al. Viral upper respiratory tract infection and otitis media complication in young children. *Clin Infect Dis*. 2008;46(6):815–823
114. Ruohola A, Meurman O, Nikkari S, et al. Microbiology of acute otitis media in children with tympanostomy tubes: prevalences of bacteria and viruses. *Clin Infect Dis*. 2006; 43(11):1417–1422
115. Ruuskanen O, Arola M, Heikkinen T, Ziegler T. Viruses in acute otitis media: increasing evidence for clinical significance. *Pediatr Infect Dis J*. 1991;10(6):425–427
116. Chonmaitree T. Viral and bacterial interaction in acute otitis media. *Pediatr Infect Dis J*. 2000;19(suppl 5):S24–S30
117. Nokso-Koivisto J, Räty R, Blomqvist S, et al. Presence of specific viruses in the middle ear fluids and respiratory secretions of young children with acute otitis media. *J Med Virol*. 2004;72(2):241–248
118. Bluestone CD, Klein JO. Microbiology. In: Bluestone CD, Klein JO, eds. *Otitis Media in Infants and Children*. 4th ed. Hamilton, Canada: BC Decker; 2007:101–126
119. Del Beccaro MA, Mendelman PM, Inglis AF, et al. Bacteriology of acute otitis media: a new perspective. *J Pediatr*. 1992;120(1): 81–84
120. Block SL, Harrison CJ, Hedrick JA, et al. Penicillin-resistant *Streptococcus pneumoniae* in acute otitis media: risk factors, susceptibility patterns and antimicrobial management. *Pediatr Infect Dis J*. 1995;14 (9):751–759
121. Rodriguez WJ, Schwartz RH. *Streptococcus pneumoniae* causes otitis media with higher fever and more redness of tympanic membranes than *Haemophilus influenzae* or *Moraxella catarrhalis*. *Pediatr Infect Dis J*. 1999;18(10):942–944
122. Block SL, Hedrick J, Harrison CJ, et al. Community-wide vaccination with the heptavalent pneumococcal conjugate significantly alters the microbiology of acute otitis media. *Pediatr Infect Dis J*. 2004;23 (9):829–833
123. Casey JR, Pichichero ME. Changes in frequency and pathogens causing acute otitis media in 1995–2003. *Pediatr Infect Dis J*. 2004;23(9):824–828
124. McEllistrem MC, Adams JM, Patel K, et al. Acute otitis media due to penicillin-nonsusceptible *Streptococcus pneumoniae* before and after the introduction of the pneumococcal conjugate vaccine. *Clin Infect Dis*. 2005;40(12):1738–1744
125. Casey JR, Adlowitz DG, Pichichero ME. New patterns in the otopathogens causing acute otitis media six to eight years after introduction of pneumococcal conjugate vaccine. *Pediatr Infect Dis J*. 2010;29(4): 304–309

126. Grubb MS, Spaugh DC. Microbiology of acute otitis media, Puget Sound region, 2005–2009. *Clin Pediatr (Phila)*. 2010;49(8): 727–730

127. Revai K, McCormick DP, Patel J, Grady JJ, Saeed K, Chonmaitree T. Effect of pneumococcal conjugate vaccine on nasopharyngeal bacterial colonization during acute otitis media. *Pediatrics*. 2006;117(5): 1823–1829

128. Pettigrew MM, Gent JF, Revai K, Patel JA, Chonmaitree T. Microbial interactions during upper respiratory tract infections. *Emerg Infect Dis*. 2008;14(10):1584–1591

129. O'Brien KL, Millar EV, Zell ER, et al. Effect of pneumococcal conjugate vaccine on nasopharyngeal colonization among immunized and unimmunized children in a community-randomized trial. *J Infect Dis*. 2007;196(8):1211–1220

130. Jacobs MR, Bajaksouzian S, Windau A, Good C. Continued emergence of nonvaccine serotypes of *Streptococcus pneumoniae* in Cleveland. *Proceedings of the 49th Interscience Conference on Antimicrobial Agents and Chemotherapy*; 2009:G1-G1556

131. Hoberman A, Paradise JL, Shaikh N, et al. Pneumococcal resistance and serotype 19A in Pittsburgh-area children with acute otitis media before and after introduction of 7-valent pneumococcal polysaccharide vaccine. *Clin Pediatr (Phila)*. 2011;50(2): 114–120

132. Huang SS, Hinrichsen VL, Stevenson AE, et al. Continued impact of pneumococcal conjugate vaccine on carriage in young children. *Pediatrics*. 2009;124(1). Available at: www.pediatrics.org/cgi/content/full/124/1/e1

133. Centers for Disease Control and Prevention (CDC). Licensure of a 13-valent pneumococcal conjugate vaccine (PCV13) and recommendations for use among children—Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR Morb Mortal Wkly Rep*. 2010;59(9):258–261

134. Segal N, Givon-Lavi N, Leibovitz E, Yagupsky P, Leiberman A, Dagan R. Acute otitis media caused by *Streptococcus pyogenes* in children. *Clin Infect Dis*. 2005;41(1):35–41

135. Luntz M, Brodsky A, Nusem S, et al. Acute mastoiditis—the antibiotic era: a multicenter study. *Int J Pediatr Otorhinolaryngol*. 2001;57(1):1–9

136. Nielsen JC. *Studies on the Aetiology of Acute Otitis Media*. Copenhagen, Denmark: Ejnar Mundsgaard Forlag; 1945

137. Palmu AA, Herva E, Savolainen H, Karma P, Mäkelä PH, Kilpi TM. Association of clinical signs and symptoms with bacterial findings in acute otitis media. *Clin Infect Dis*. 2004;38(2):234–242

138. Leibovitz E, Asher E, Piglansky L, et al. Is bilateral acute otitis media clinically different than unilateral acute otitis media? *Pediatr Infect Dis J*. 2007;26(7):589–592

139. Leibovitz E, Satran R, Piglansky L, et al. Can acute otitis media caused by *Haemophilus influenzae* be distinguished from that caused by *Streptococcus pneumoniae? Pediatr Infect Dis J*. 2003;22(6): 509–515

140. Palmu AA, Kotikoski MJ, Kaijalainen TH, Puhakka HJ. Bacterial etiology of acute myringitis in children less than two years of age. *Pediatr Infect Dis J*. 2001;20(6): 607–611

141. Bodor FF. Systemic antibiotics for treatment of the conjunctivitis-otitis media syndrome. *Pediatr Infect Dis J*. 1989;8(5): 287–290

142. Bingen E, Cohen R, Jourenkova N, Gehanno P. Epidemiologic study of conjunctivitis-otitis syndrome. *Pediatr Infect Dis J*. 2005;24(8):731–732

143. Barkai G, Leibovitz E, Givon-Lavi N, Dagan R. Potential contribution by nontypable *Haemophilus influenzae* in protracted and recurrent acute otitis media. *Pediatr Infect Dis J*. 2009;28(6):466–471

144. Howie VM, Ploussard JH. Efficacy of fixed combination antibiotics versus separate components in otitis media. Effectiveness of erythromycin estrolate, triple sulfonamide, ampicillin, erythromycin estolate-triple sulfonamide, and placebo in 280 patients with acute otitis media under two and one-half years of age. *Clin Pediatr (Phila)*. 1972;11(4):205–214

145. Klein JO. Microbiologic efficacy of antibacterial drugs for acute otitis media. *Pediatr Infect Dis J*. 1993;12(12): 973–975

146. Barnett ED, Klein JO. The problem of resistant bacteria for the management of acute otitis media. *Pediatr Clin North Am*. 1995;42(3):509–517

147. Tristram S, Jacobs MR, Appelbaum PC. Antimicrobial resistance in *Haemophilus influenzae*. *Clin Microbiol Rev*. 2007;20(2): 368–389

148. Critchley IA, Jacobs MR, Brown SD, Traczewski MM, Tillotson GS, Janjic N. Prevalence of serotype 19A *Streptococcus pneumoniae* among isolates from U.S. children in 2005≠2006 and activity of faropenem. *Antimicrob Agents Chemother*. 2008;52(7): 2639–2643

149. Jacobs MR, Good CE, Windau AR, et al. Activity of ceftaroline against emerging serotypes of Streptococcus pneumoniae. *Antimicrob Agents Chemother*. 2010;54(6): 2716–2719

150. Jacobs MR. Antimicrobial-resistant *Streptococcus pneumoniae:* trends and management. *Expert Rev Anti Infect Ther*. 2008;6(5):619–635

151. Piglansky L, Leibovitz E, Raiz S, et al. Bacteriologic and clinical efficacy of high dose amoxicillin for therapy of acute otitis media in children. *Pediatr Infect Dis J*. 2003;22(5):405–413

152. Dagan R, Johnson CE, McLinn S, et al. Bacteriologic and clinical efficacy of amoxicillin/clavulanate vs. azithromycin in acute otitis media. *Pediatr Infect Dis J*. 2000;19(2):95–104

153. Dagan R, Hoberman A, Johnson C, et al. Bacteriologic and clinical efficacy of high dose amoxicillin/clavulanate in children with acute otitis media. *Pediatr Infect Dis J*. 2001;20(9):829–837

154. Hoberman A, Dagan R, Leibovitz E, et al. Large dosage amoxicillin/clavulanate, compared with azithromycin, for the treatment of bacterial acute otitis media in children. *Pediatr Infect Dis J*. 2005;24 (6):525–532

155. De Wals P, Erickson L, Poirier B, Pépin J, Pichichero ME. How to compare the efficacy of conjugate vaccines to prevent acute otitis media? *Vaccine*. 2009;27(21): 2877–2883

156. Shouval DS, Greenberg D, Givon-Lavi N, Porat N, Dagan R. Serotype coverage of invasive and mucosal pneumococcal disease in Israeli children younger than 3 years by various pneumococcal conjugate vaccines. *Pediatr Infect Dis J*. 2009;28(4): 277–282

157. Jones RN, Farrell DJ, Mendes RE, Sader HS. Comparative ceftaroline activity tested against pathogens associated with community-acquired pneumonia: results from an international surveillance study. *J Antimicrob Chemother*. 2011;66(suppl 3): iii69–iii80

158. Harrison CJ, Woods C, Stout G, Martin B, Selvarangan R. Susceptibilities of Haemophilus influenzae, Streptococcus pneumoniae, including serotype 19A, and Moraxella catarrhalis paediatric isolates from 2005 to 2007 to commonly used antibiotics. *J Antimicrob Chemother*. 2009;63(3):511–519

159. Doern GV, Jones RN, Pfaller MA, Kugler K. *Haemophilus influenzae* and *Moraxella catarrhalis* from patients with community-acquired respiratory tract infections: antimicrobial susceptibility patterns from the SENTRY antimicrobial Surveillance Program (United States and Canada, 1997).

Antimicrob Agents Chemother. 1999;43(2):385–389

160. Nussinovitch M, Yoeli R, Elishkevitz K, Varsano I. Acute mastoiditis in children: epidemiologic, clinical, microbiologic, and therapeutic aspects over past years. *Clin Pediatr (Phila)*. 2004;43(3):261–267
161. Roddy MG, Glazier SS, Agrawal D. Pediatric mastoiditis in the pneumococcal conjugate vaccine era: symptom duration guides empiric antimicrobial therapy. *Pediatr Emerg Care*. 2007;23(11):779–784
162. Hoberman A, Paradise JL, Burch DJ, et al. Equivalent efficacy and reduced occurrence of diarrhea from a new formulation of amoxicillin/clavulanate potassium (Augmentin) for treatment of acute otitis media in children. *Pediatr Infect Dis J*. 1997;16(5):463–470
163. Arguedas A, Dagan R, Leibovitz E, Hoberman A, Pichichero M, Paris M. A multicenter, open label, double tympanocentesis study of high dose cefdinir in children with acute otitis media at high risk of persistent or recurrent infection. *Pediatr Infect Dis J*. 2006;25(3):211–218
164. Atanasković-Marković M, Velicković TC, Gavrović-Jankulović M, Vucković O, Nestorović B. Immediate allergic reactions to cephalosporins and penicillins and their cross-reactivity in children. *Pediatr Allergy Immunol*. 2005;16(4):341–347
165. Pichichero ME. Use of selected cephalosporins in penicillin-allergic patients: a paradigm shift. *Diagn Microbiol Infect Dis*. 2007;57(suppl 3):13S–18S
166. Pichichero ME, Casey JR. Safe use of selected cephalosporins in penicillin-allergic patients: a meta-analysis. *Otolaryngol Head Neck Surg*. 2007;136(3):340–347
167. DePestel DD, Benninger MS, Danziger L, et al. Cephalosporin use in treatment of patients with penicillin allergies. *J Am Pharm Assoc (2003)*. 2008;48(4):530–540
168. Fonacier L, Hirschberg R, Gerson S. Adverse drug reactions to a cephalosporins in hospitalized patients with a history of penicillin allergy. *Allergy Asthma Proc*. 2005;26(2):135–141
169. Joint Task Force on Practice Parameters; American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; Joint Council of Allergy, Asthma and Immunology. Drug allergy: an updated practice parameter. *Ann Allergy Asthma Immunol*. 2010;105(4):259–273
170. Powers JL, Gooch WM, III, Oddo LP. Comparison of the palatability of the oral suspension of cefdinir vs. amoxicillin/clavulanate potassium, cefprozil and azithromycin in pediatric patients. *Pediatr Infect Dis J*. 2000;19(suppl 12):S174–S180
171. Steele RW, Thomas MP, Bégué RE. Compliance issues related to the selection of antibiotic suspensions for children. *Pediatr Infect Dis J*. 2001;20(1):1–5
172. Steele RW, Russo TM, Thomas MP. Adherence issues related to the selection of antistaphylococcal or antifungal antibiotic suspensions for children. *Clin Pediatr (Phila)*. 2006;45(3):245–250
173. Schwartz RH. Enhancing children's satisfaction with antibiotic therapy: a taste study of several antibiotic suspensions. *Curr Ther Res*. 2000;61(8):570–581
174. Green SM, Rothrock SG. Single-dose intramuscular ceftriaxone for acute otitis media in children. *Pediatrics*. 1993;91(1):23–30
175. Leibovitz E, Piglansky L, Raiz S, Press J, Leiberman A, Dagan R. Bacteriologic and clinical efficacy of one day vs. three day intramuscular ceftriaxone for treatment of nonresponsive acute otitis media in children. *Pediatr Infect Dis J*. 2000;19(11):1040–1045
176. Rosenfeld RM, Kay D. Natural history of untreated otitis media. *Laryngoscope*. 2003;113(10):1645–1657
177. Rosenfeld RM, Kay D. Natural history of untreated otitis media. In: Rosenfeld RM, Bluestone CD, eds. *Evidence-Based Otitis Media*. 2nd ed. Hamilton, Canada: BC Decker; 2003:180–198
178. Arola M, Ziegler T, Ruuskanen O. Respiratory virus infection as a cause of prolonged symptoms in acute otitis media. *J Pediatr*. 1990;116(5):697–701
179. Chonmaitree T, Owen MJ, Howie VM. Respiratory viruses interfere with bacteriologic response to antibiotic in children with acute otitis media. *J Infect Dis*. 1990;162(2):546–549
180. Dagan R, Leibovitz E, Greenberg D, Yagupsky P, Fliss DM, Leiberman A. Early eradication of pathogens from middle ear fluid during antibiotic treatment of acute otitis media is associated with improved clinical outcome. *Pediatr Infect Dis J*. 1998;17(9):776–782
181. Carlin SA, Marchant CD, Shurin PA, Johnson CE, Super DM, Rehmus JM. Host factors and early therapeutic response in acute otitis media. *J Pediatr*. 1991;118(2):178–183
182. Teele DW, Pelton SI, Klein JO. Bacteriology of acute otitis media unresponsive to initial antimicrobial therapy. *J Pediatr*. 1981;98(4):537–539
183. Doern GV, Pfaller MA, Kugler K, Freeman J, Jones RN. Prevalence of antimicrobial resistance among respiratory tract isolates of *Streptococcus pneumoniae* in North America: 1997 results from the SENTRY antimicrobial surveillance program. *Clin Infect Dis*. 1998;27(4):764–770
184. Leiberman A, Leibovitz E, Piglansky L, et al. Bacteriologic and clinical efficacy of trimethoprim-sulfamethoxazole for treatment of acute otitis media. *Pediatr Infect Dis J*. 2001;20(3):260–264
185. Humphrey WR, Shattuck MH, Zielinski RJ, et al. Pharmacokinetics and efficacy of linezolid in a gerbil model of *Streptococcus pneumoniae*-induced acute otitis media. *Antimicrob Agents Chemother*. 2003;47(4):1355–1363
186. Arguedas A, Dagan R, Pichichero M, et al. An open-label, double tympanocentesis study of levofloxacin therapy in children with, or at high risk for, recurrent or persistent acute otitis media. *Pediatr Infect Dis J*. 2006;25(12):1102–1109
187. Noel GJ, Blumer JL, Pichichero ME, et al. A randomized comparative study of levofloxacin versus amoxicillin/clavulanate for treatment of infants and young children with recurrent or persistent acute otitis media. *Pediatr Infect Dis J*. 2008;27(6):483–489
188. Howie VM, Ploussard JH. Simultaneous nasopharyngeal and middle ear exudate culture in otitis media. *Pediatr Digest*. 1971;13:31–35
189. Gehanno P, Lenoir G, Barry B, Bons J, Boucot I, Berche P. Evaluation of nasopharyngeal cultures for bacteriologic assessment of acute otitis media in children. *Pediatr Infect Dis J*. 1996;15(4):329–332
190. Cohen R, Levy C, Boucherat M, Langue J, de La Rocque F. A multicenter, randomized, double-blind trial of 5 versus 10 days of antibiotic therapy for acute otitis media in young children. *J Pediatr*. 1998;133(5):634–639
191. Pessey JJ, Gehanno P, Thoroddsen E, et al. Short course therapy with cefuroxime axetil for acute otitis media: results of a randomized multicenter comparison with amoxicillin/clavulanate. *Pediatr Infect Dis J*. 1999;18(10):854–859
192. Cohen R, Levy C, Boucherat M, et al. Five vs. ten days of antibiotic therapy for acute otitis media in young children. *Pediatr Infect Dis J*. 2000;19(5):458–463
193. Pichichero ME, Marsocci SM, Murphy ML, Hoeger W, Francis AB, Green JL. A prospective observational study of 5-, 7-, and 10-day antibiotic treatment for acute otitis media. *Otolaryngol Head Neck Surg*. 2001;124(4):381–387

194. Kozyrskyj AL, Klassen TP, Moffatt M, Harvey K. Short-course antibiotics for acute otitis media. *Cochrane Database Syst Rev.* 2010; (9):CD001095
195. Shurin PA, Pelton SI, Donner A, Klein JO. Persistence of middle-ear effusion after acute otitis media in children. *N Engl J Med.* 1979;300(20):1121–1123
196. Damoiseaux RA, Rovers MM, Van Balen FA, Hoes AW, de Melker RA. Long-term prognosis of acute otitis media in infancy: determinants of recurrent acute otitis media and persistent middle ear effusion. *Fam Pract.* 2006;23(1):40–45
197. Leach AJ, Morris PS. Antibiotics for the prevention of acute and chronic suppurative otitis media in children. *Cochrane Database Syst Rev.* 2006;(4):CD004401
198. Teele DW, Klein JO, Word BM, et al; Greater Boston Otitis Media Study Group. Antimicrobial prophylaxis for infants at risk for recurrent acute otitis media. *Vaccine.* 2000;19(suppl 1):S140–S143
199. Paradise JL. On tympanostomy tubes: rationale, results, reservations, and recommendations. *Pediatrics.* 1977;60(1):86–90
200. McIsaac WJ, Coyte PC, Croxford R, Asche CV, Friedberg J, Feldman W. Otolaryngologists' perceptions of the indications for tympanostomy tube insertion in children. *CMAJ.* 2000;162(9):1285–1288
201. Casselbrandt ML. Ventilation tubes for recurrent acute otitis media. In: Alper CM, Bluestone CD, eds. *Advanced Therapy of Otitis Media.* Hamilton, Canada: BC Decker; 2004:113–115
202. Shin JJ, Stinnett SS, Hartnick CJ. Pediatric recurrent acute otitis media. In: Shin JJ, Hartnick CJ, Randolph GW, eds. *Evidence-Based Otolaryngology.* New York, NY: Springer; 2008:91–95
203. Gonzalez C, Arnold JE, Woody EA, et al. Prevention of recurrent acute otitis media: chemoprophylaxis versus tympanostomy tubes. *Laryngoscope.* 1986;96(12): 1330–1334
204. Gebhart DE. Tympanostomy tubes in the otitis media prone child. *Laryngoscope.* 1981;91(6):849–866
205. Casselbrant ML, Kaleida PH, Rockette HE, et al. Efficacy of antimicrobial prophylaxis and of tympanostomy tube insertion for prevention of recurrent acute otitis media: results of a randomized clinical trial. *Pediatr Infect Dis J.* 1992;11(4):278–286
206. El-Sayed Y. Treatment of recurrent acute otitis media chemoprophylaxis versus ventilation tubes. *Aust J Otolaryngol.* 1996; 2(4):352–355
207. McDonald S, Langton Hewer CD, Nunez DA. Grommets (ventilation tubes) for recurrent acute otitis media in children. *Cochrane Database Syst Rev.* 2008;(4): CD004741
208. Rosenfeld RM, Bhaya MH, Bower CM, et al. Impact of tympanostomy tubes on child quality of life. *Arch Otolaryngol Head Neck Surg.* 2000;126(5):585–592
209. Witsell DL, Stewart MG, Monsell EM, et al. The Cooperative Outcomes Group for ENT: a multicenter prospective cohort study on the outcomes of tympanostomy tubes for children with otitis media. *Otolaryngol Head Neck Surg.* 2005;132(2):180–188
210. Isaacson G. Six Sigma tympanostomy tube insertion: achieving the highest safety levels during residency training. *Otolaryngol Head Neck Surg.* 2008;139(3):353–357
211. Kay DJ, Nelson M, Rosenfeld RM. Meta-analysis of tympanostomy tube sequelae. *Otolaryngol Head Neck Surg.* 2001;124(4): 374–380
212. Koivunen P, Uhari M, Luotonen J, et al. Adenoidectomy versus chemoprophylaxis and placebo for recurrent acute otitis media in children aged under 2 years: randomised controlled trial. *BMJ.* 2004; 328(7438):487
213. Rosenfeld RM. Surgical prevention of otitis media. *Vaccine.* 2000;19(suppl 1):S134–S139
214. Centers for Disease Control and Prevention (CDC). Prevention and control of influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011. *MMWR Morb Mortal Wkly Rep.* 2011;60(33):1128–1132
215. American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for prevention and control of influenza in children, 2011–2012. *Pediatrics.* 2011;128(4):813–825
216. Section on Breastfeeding. Breastfeeding and the use of human milk. *Pediatrics.* 2012;129(3). Available at: www.pediatrics.org/cgi/content/full/129/3/e827
217. Pavia M, Bianco A, Nobile CG, Marinelli P, Angelillo IF. Efficacy of pneumococcal vaccination in children younger than 24 months: a meta-analysis. *Pediatrics.* 2009; 123(6). Available at: www.pediatrics.org/cgi/content/full/123/6/e1103
218. Eskola J, Kilpi T, Palmu A, et al; Finnish Otitis Media Study Group. Efficacy of a pneumococcal conjugate vaccine against acute otitis media. *N Engl J Med.* 2001;344(6):403–409
219. Black S, Shinefield H, Fireman B, et al; Northern California Kaiser Permanente Vaccine Study Center Group. Efficacy, safety and immunogenicity of heptavalent pneumococcal conjugate vaccine in children. *Pediatr Infect Dis J.* 2000;19(3): 187–195
220. Jacobs MR. Prevention of otitis media: role of pneumococcal conjugate vaccines in reducing incidence and antibiotic resistance. *J Pediatr.* 2002;141(2):287–293
221. Jansen AG, Hak E, Veenhoven RH, Damoiseaux RA, Schilder AG, Sanders EA. Pneumococcal conjugate vaccines for preventing otitis media. *Cochrane Database Syst Rev.* 2009;(2):CD001480
222. Fireman B, Black SB, Shinefield HR, Lee J, Lewis E, Ray P. Impact of the pneumococcal conjugate vaccine on otitis media. *Pediatr Infect Dis J.* 2003;22(1):10–16
223. Grijalva CG, Poehling KA, Nuorti JP, et al. National impact of universal childhood immunization with pneumococcal conjugate vaccine on otitis media. *Pediatr Infect Dis J.* 2006;118(3):865–873
224. Zhou F, Shefer A, Kong Y, Nuorti JP. Trends in acute otitis media-related health care utilization by privately insured young children in the United States, 1997–2004. *Pediatrics.* 2008;121(2):253–260
225. Poehling KA, Szilagyi PG, Grijalva CG, et al. Reduction of frequent otitis media and pressure-equalizing tube insertions in children after introduction of pneumococcal conjugate vaccine. *Pediatrics.* 2007; 119(4):707–715
226. Pelton SI. Prospects for prevention of otitis media. *Pediatr Infect Dis J.* 2007;26 (suppl 10):S20–S22
227. Pelton SI, Leibovitz E. Recent advances in otitis media. *Pediatr Infect Dis J.* 2009;28 (suppl 10):S133–S137
228. De Wals P, Erickson L, Poirier B, Pépin J, Pichichero ME. How to compare the efficacy of conjugate vaccines to prevent acute otitis media? *Vaccine.* 2009;27(21): 2877–2883
229. Plasschaert AI, Rovers MM, Schilder AG, Verheij TJ, Hak E. Trends in doctor consultations, antibiotic prescription, and specialist referrals for otitis media in children: 1995–2003. *Pediatrics.* 2006;117(6): 1879–1886
230. O'Brien MA, Prosser LA, Paradise JL, et al. New vaccines against otitis media: projected benefits and cost-effectiveness. *Pediatrics.* 2009;123(6):1452–1463
231. Hanage WP, Auranen K, Syrjänen R, et al. Ability of pneumococcal serotypes and clones to cause acute otitis media: implications for the prevention of otitis media by conjugate vaccines. *Infect Immun.* 2004; 72(1):76–81
232. Prymula R, Peeters P, Chrobok V, et al. Pneumococcal capsular polysaccharides

conjugated to protein D for prevention of acute otitis media caused by both Streptococcus pneumoniae and non-typable *Haemophilus influenzae*: a randomised double-blind efficacy study. *Lancet*. 2006; 367(9512):740–748

233. Prymula R, Schuerman L. 10-valent pneumococcal nontypeable *Haemophilus influenzae* PD conjugate vaccine: Synflorix. *Expert Rev Vaccines*. 2009;8(11):1479–1500
234. Schuerman L, Borys D, Hoet B, Forsgren A, Prymula R. Prevention of otitis media: now a reality? *Vaccine*. 2009;27(42):5748–5754
235. Heikkinen T, Ruuskanen O, Waris M, Ziegler T, Arola M, Halonen P. Influenza vaccination in the prevention of acute otitis media in children. *Am J Dis Child*. 1991;145(4):445–448
236. Clements DA, Langdon L, Bland C, Walter E. Influenza A vaccine decreases the incidence of otitis media in 6- to 30-month-old children in day care. *Arch Pediatr Adolesc Med*. 1995;149(10):1113–1117
237. Belshe RB, Gruber WC. Prevention of otitis media in children with live attenuated influenza vaccine given intranasally. *Pediatr Infect Dis J*. 2000;19(suppl 5):S66–S71
238. Marchisio P, Cavagna R, Maspes B, et al. Efficacy of intranasal virosomal influenza vaccine in the prevention of recurrent acute otitis media in children. *Clin Infect Dis*. 2002;35(2):168–174
239. Ozgur SK, Beyazova U, Kemaloglu YK, et al. Effectiveness of inactivated influenza vaccine for prevention of otitis media in children. *Pediatr Infect Dis J*. 2006;25(5): 401–404
240. Block SL, Heikkinen T, Toback SL, Zheng W, Ambrose CS. The efficacy of live attenuated influenza vaccine against influenza-associated acute otitis media in children. *Pediatr Infect Dis J*. 2011;30(3):203–207
241. Ashkenazi S, Vertruyen A, Arístegui J, et al; CAIV-T Study Group. Superior relative efficacy of live attenuated influenza vaccine compared with inactivated influenza vaccine in young children with recurrent respiratory tract infections. *Pediatr Infect Dis J*. 2006;25(10):870–879
242. Belshe RB, Edwards KM, Vesikari T, et al; CAIV-T Comparative Efficacy Study Group. Live attenuated versus inactivated influenza vaccine in infants and young children [published correction appears in *N Engl J Med*. 2007;356(12):1283]. *N Engl J Med*. 2007;356(7):685–696
243. Bracco Neto H, Farhat CK, Tregnaghi MW, et al; D153-P504 LAIV Study Group. Efficacy and safety of 1 and 2 doses of live attenuated influenza vaccine in vaccine-naive children. *Pediatr Infect Dis J*. 2009;28(5): 365–371
244. Tam JS, Capeding MR, Lum LC, et al; Pan-Asian CAIV-T Pediatric Efficacy Trial Network. Efficacy and safety of a live attenuated, cold-adapted influenza vaccine, trivalent against culture-confirmed influenza in young children in Asia. *Pediatr Infect Dis J*. 2007;26(7):619–628
245. Vesikari T, Fleming DM, Aristegui JF, et al; CAIV-T Pediatric Day Care Clinical Trial Network. Safety, efficacy, and effectiveness of cold-adapted influenza vaccine-trivalent against community-acquired, culture-confirmed influenza in young children attending day care. *Pediatrics*. 2006;118(6):2298–2312
246. Forrest BD, Pride MW, Dunning AJ, et al. Correlation of cellular immune responses with protection against culture-confirmed influenza virus in young children. *Clin Vaccine Immunol*. 2008;15(7): 1042–1053
247. Lum LC, Borja-Tabora CF, Breiman RF, et al. Influenza vaccine concurrently administered with a combination measles, mumps, and rubella vaccine to young children. *Vaccine*. 2010;28(6):1566–1574
248. Belshe RB, Mendelman PM, Treanor J, et al. The efficacy of live attenuated, cold-adapted, trivalent, intranasal influenzavirus vaccine in children. *N Engl J Med*. 1998;338(20): 1405–1412
249. Daly KA, Giebink GS. Clinical epidemiology of otitis media. *Pediatr Infect Dis J*. 2000; 19(suppl 5):S31–S36
250. Duncan B, Ey J, Holberg CJ, Wright AL, Martinez FD, Taussig LM. Exclusive breastfeeding for at least 4 months protects against otitis media. *Pediatrics*. 1993;91(5): 867–872
251. Duffy LC, Faden H, Wasielewski R, Wolf J, Krystofik D. Exclusive breastfeeding protects against bacterial colonization and day care exposure to otitis media. *Pediatrics*. 1997;100(4). Available at: www.pediatrics.org/cgi/content/full/100/4/e7
252. Paradise JL. Short-course antimicrobial treatment for acute otitis media: not best for infants and young children. *JAMA*. 1997;278(20):1640–1642
253. Scariati PD, Grummer-Strawn LM, Fein SB. A longitudinal analysis of infant morbidity and the extent of breastfeeding in the United States. *Pediatrics*. 1997;99(6). Available at: www.pediatrics.org/cgi/content/full/99/6/e5
254. McNiel ME, Labbok MH, Abrahams SW. What are the risks associated with formula feeding? A re-analysis and review. *Breastfeed Rev*. 2010;18(2):25–32
255. Chantry CJ, Howard CR, Auinger P. Full breastfeeding duration and associated decrease in respiratory tract infection in US children. *Pediatrics*. 2006;117(2):425–432
256. Hatakka K, Piirainen L, Pohjavuori S, Poussa T, Savilahti E, Korpela R. Factors associated with acute respiratory illness in day care children. *Scand J Infect Dis*. 2010;42(9):704–711
257. Ladomenou F, Kafatos A, Tselentis Y, Galanakis E. Predisposing factors for acute otitis media in infancy. *J Infect*. 2010;61(1):49–53
258. Ladomenou F, Moschandreas J, Kafatos A, Tselentis Y, Galanakis E. Protective effect of exclusive breastfeeding against infections during infancy: a prospective study. *Arch Dis Child*. 2010;95(12):1004–1008
259. Duijts L, Jaddoe VW, Hofman A, Moll HA. Prolonged and exclusive breastfeeding reduces the risk of infectious diseases in infancy. *Pediatrics*. 2010;126(1). Available at: www.pediatrics.org/cgi/content/full/126/1/e18
260. Best D; Committee on Environmental Health; Committee on Native American Child Health; Committee on Adolescence. From the American Academy of Pediatrics: technical report—secondhand and prenatal tobacco smoke exposure. *Pediatrics*. 2009;124(5). Available at: www.pediatrics.org/cgi/content/full/124/5/e1017
261. Etzel RA, Pattishall EN, Haley NJ, Fletcher RH, Henderson FW. Passive smoking and middle ear effusion among children in day care. *Pediatrics*. 1992;90(2 pt 1): 228–232
262. Ilicali OC, Keleş N, Değer K, Savaş I. Relationship of passive cigarette smoking to otitis media. *Arch Otolaryngol Head Neck Surg*. 1999;125(7):758–762
263. Wellington M, Hall CB. Pacifier as a risk factor for acute otitis media [letter]. *Pediatrics*. 2002;109(2):351–352, author reply 353
264. Kerstein R. Otitis media: prevention instead of prescription. *Br J Gen Pract*. 2008;58(550):364–365
265. Brown CE, Magnuson B. On the physics of the infant feeding bottle and middle ear sequela: ear disease in infants can be associated with bottle feeding. *Int J Pediatr Otorhinolaryngol*. 2000;54(1):13–20
266. Niemelä M, Pihakari O, Pokka T, Uhari M. Pacifier as a risk factor for acute otitis media: a randomized, controlled trial of parental counseling. *Pediatrics*. 2000;106(3): 483–488

267. Tully SB, Bar-Haim Y, Bradley RL. Abnormal tympanography after supine bottle feeding. *J Pediatr*. 1995;126(6):S105–S111

268. Rovers MM, Numans ME, Langenbach E, Grobbee DE, Verheij TJ, Schilder AG. Is pacifier use a risk factor for acute otitis media? A dynamic cohort study. *Fam Pract*. 2008;25(4):233–236

269. Adderson EE. Preventing otitis media: medical approaches. *Pediatr Ann*. 1998;27(2):101–107

270. Azarpazhooh A, Limeback H, Lawrence HP, Shah PS. Xylitol for preventing acute otitis media in children up to 12 years of age. *Cochrane Database Syst Rev*. 2011;(11):CD007095

271. Hautalahti O, Renko M, Tapiainen T, Kontiokari T, Pokka T, Uhari M. Failure of xylitol given three times a day for preventing acute otitis media. *Pediatr Infect Dis J*. 2007;26(5):423–427

272. Tapiainen T, Luotonen L, Kontiokari T, Renko M, Uhari M. Xylitol administered only during respiratory infections failed to prevent acute otitis media. *Pediatrics*. 2002;109(2). Available at: www.pediatrics.org/cgi/content/full/109/2/e19

273. Uhari M, Kontiokari T, Koskela M, Niemelä M. Xylitol chewing gum in prevention of acute otitis media: double blind randomised trial. *BMJ*. 1996;313(7066):1180–1184

274. Uhari M, Kontiokari T, Niemelä M. A novel use of xylitol sugar in preventing acute otitis media. *Pediatrics*. 1998;102(4 pt 1):879–884

275. O'Brien MA, Prosser LA, Paradise JL, et al. New vaccines against otitis media: projected benefits and cost-effectiveness. *Pediatrics*. 2009;123(6):1452–1463

(Continued from first page)

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

www.pediatrics.org/cgi/doi/10.1542/peds.2012-3488

doi:10.1542/peds.2012-3488

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Otitis Media With Effusion

- *Clinical Practice Guideline*

AMERICAN ACADEMY OF PEDIATRICS

CLINICAL PRACTICE GUIDELINE

American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, and American Academy of Pediatrics Subcommittee on Otitis Media With Effusion

Otitis Media With Effusion

ABSTRACT. The clinical practice guideline on otitis media with effusion (OME) provides evidence-based recommendations on diagnosing and managing OME in children. This is an update of the 1994 clinical practice guideline "Otitis Media With Effusion in Young Children," which was developed by the Agency for Healthcare Policy and Research (now the Agency for Healthcare Research and Quality). In contrast to the earlier guideline, which was limited to children 1 to 3 years old with no craniofacial or neurologic abnormalities or sensory deficits, the updated guideline applies to children aged 2 months through 12 years with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae. The American Academy of Pediatrics, American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery selected a subcommittee composed of experts in the fields of primary care, otolaryngology, infectious diseases, epidemiology, hearing, speech and language, and advanced-practice nursing to revise the OME guideline.

The subcommittee made a strong recommendation that clinicians use pneumatic otoscopy as the primary diagnostic method and distinguish OME from acute otitis media.

The subcommittee made recommendations that clinicians should 1) document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME, 2) distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and more promptly evaluate hearing, speech, language, and need for intervention in children at risk, and 3) manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or diagnosis (if onset is unknown).

The subcommittee also made recommendations that 4) hearing testing be conducted when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME, 5) children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected, and 6) when a child becomes a surgical candidate (tympanostomy tube insertion is the preferred initial procedure). Adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis); repeat surgery consists of adenoidectomy plus myringotomy with or without tubeinsertion. Tonsillectomy alone or myringotomy alone should not be used to treat OME.

The subcommittee made negative recommendations that 1) population-based screening programs for OME not be performed in healthy, asymptomatic children, and 2) because antihistamines and decongestants are ineffective for OME, they should not be used for treatment; antimicrobials and corticosteroids do not have long-term efficacy and should not be used for routine management.

The subcommittee gave as options that 1) tympanometry can be used to confirm the diagnosis of OME and 2) when children with OME are referred by the primary clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery) and provide additional relevant information such as history of acute otitis media and developmental status of the child. The subcommittee made no recommendations for 1) complementary and alternative medicine as a treatment for OME, based on a lack of scientific evidence documenting efficacy, or 2) allergy management as a treatment for OME, based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME. Last, the panel compiled a list of research needs based on limitations of the evidence reviewed.

The purpose of this guideline is to inform clinicians of evidence-based methods to identify, monitor, and manage OME in children aged 2 months through 12 years. The guideline may not apply to children more than 12 years old, because OME is uncommon and the natural history is likely to differ from younger children who experience rapid developmental change. The target population includes children with or without developmental disabilities or underlying conditions that predispose to OME and its sequelae. The guideline is intended for use by providers of health care to children, including primary care and specialist physicians, nurses and nurse practitioners, physician assistants, audiologists, speech-language pathologists, and child-development specialists. The guideline is applicable to any setting in which children with OME would be identified, monitored, or managed.

This guideline is not intended as a sole source of guidance in evaluating children with OME. Rather, it is designed to assist primary care and other clinicians by providing an evidence-based framework for decision-making strategies. It is not intended to replace clinical judgment or establish a protocol for all children with this condition and may not provide the only appropriate approach to diagnosing and managing this problem. *Pediatrics* 2004;113:1412–1429; *acute otitis media, antibacterial, antibiotic.*

This document was approved by the American Academy of Otolaryngology–Head and Neck Surgery Foundation, Inc and the American Academy of Pediatrics, and is published in the May 2004 issue of *Otolaryngology-Head and Neck Surgery* and the May 2004 issue of *Pediatrics*.

ABBREVIATIONS. OME, otitis media with effusion; AOM, acute otitis media; AAP, American Academy of Pediatrics; AHRQ, Agency for Healthcare Research and Quality; EPC, Southern California Evidence-Based Practice Center; CAM, complementary and alternative medicine; HL, hearing level.

Otitis media with effusion (OME) as discussed in this guideline is defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection.[1,2] OME is considered distinct from acute otitis media (AOM), which is defined as a history of acute onset of signs and symptoms, the presence of middle-ear effusion, and signs and symptoms of middle-ear inflammation. Persistent middle-ear fluid from OME results in decreased mobility of the tympanic membrane and serves as a barrier to sound conduction.[3] Approximately 2.2 million diagnosed episodes of OME occur annually in the United States, yielding a combined direct and indirect annual cost estimate of $4.0 billion.[2]

OME may occur spontaneously because of poor eustachian tube function or as an inflammatory response following AOM. Approximately 90% of children (80% of individual ears) have OME at some time before school age,[4] most often between ages 6 months and 4 years.[5] In the first year of life, >50% of children will experience OME, increasing to >60% by 2 years.[6] Many episodes resolve spontaneously within 3 months, but ~30% to 40% of children have recurrent OME, and 5% to 10% of episodes last 1 year or longer.[1,4,7]

The primary outcomes considered in the guideline include hearing loss; effects on speech, language, and learning; physiologic sequelae; health care utilization (medical, surgical); and quality of life.[1,2] The high prevalence of OME, difficulties in diagnosis and assessing duration, increased risk of conductive hearing loss, potential impact on language and cognition, and significant practice variations in management[8] make OME an important condition for the use of up-to-date evidence-based practice guidelines.

METHODS

General Methods and Literature Search

In developing an evidence-based clinical practice guideline on managing OME, the American Academy of Pediatrics (AAP), American Academy of Family Physicians, and American Academy of Otolaryngology-Head and Neck Surgery worked with the Agency for Healthcare Research and Quality (AHRQ) and other organizations. This effort included representatives from each partnering organization along with liaisons from audiology, speech-language pathology, informatics, and advanced-practice nursing. The most current literature on managing children with OME was reviewed, and research questions were developed to guide the evidence-review process.

The AHRQ report on OME from the Southern California Evidence-Based Practice Center (EPC) focused on key questions of natural history, diagnostic methods, and long-term speech, language, and hearing outcomes.[2] Searches were conducted through January 2000 in Medline, Embase, and the Cochrane Library. Additional articles were identified by review of reference listings in proceedings, reports, and other guidelines. The EPC accepted 970 articles for full review after screening 3200 abstracts. The EPC reviewed articles by using established quality criteria[9,10] and included randomized trials, prospective cohorts, and validations of diagnostic tests (validating cohort studies).

The AAP subcommittee on OME updated the AHRQ review with articles identified by an electronic Medline search through April 2003 and with additional material identified manually by subcommittee members. Copies of relevant articles were distributed to the subcommittee for consideration. A specific search for articles relevant to complementary and alternative medicine (CAM) was performed by using Medline and the Allied and Complementary Medicine Database through April 2003. Articles relevant to allergy and OME were identified by using Medline through April 2003. The subcommittee met 3 times over a 1-year period, ending in May 2003, with interval electronic review and feedback on each guideline draft to ensure accuracy of content and consistency with standardized criteria for reporting clinical practice guidelines.[11]

In May 2003, the Guidelines Review Group of the Yale Center for Medical Informatics used the Guideline Elements Model[12] to categorize content of the present draft guideline. Policy statements were parsed into component decision variables and actions and then assessed for decidability and executability. Quality appraisal using established criteria[13] was performed with Guideline Elements Model-Q Online.[14,15] Implementation issues were predicted by using the Implementability Rating Profile, an instrument under development by the Yale Guidelines Review Group (R. Shiffman, MD, written communication, May 2003). OME subcommittee members received summary results and modified an advanced draft of the guideline.

The final draft practice guideline underwent extensive peer review by numerous entities identified by the subcommittee. Comments were compiled and reviewed by the subcommittee cochairpersons. The recommendations contained in the practice guideline are based on the best available published data through April 2003. Where data are lacking, a combination of clinical experience and expert consensus was used. A scheduled review process will occur 5 years from publication or sooner if new compelling evidence warrants earlier consideration.

Classification of Evidence-Based Statements

Guidelines are intended to reduce inappropriate variations in clinical care, produce optimal health outcomes for patients, and minimize harm. The evidence-based approach to guideline development requires that the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The AAP definitions for evidence-based statements[16] are listed in Tables 1 and 2.

Guidelines are never intended to overrule professional judgment; rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a strong recommendation than might be expected with a recommendation. Options offer the most opportunity for practice variability.[17] All clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs regardless of guideline recommendations. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.[16]

Making recommendations about health practices involves value judgments on the desirability of various outcomes associated with management options. Value judgments applied by the OME subcommittee were made in an effort to minimize harm and diminish unnecessary therapy. Emphasis was placed on promptly identifying and managing children at risk for speech, language, or learning problems to maximize opportunities for beneficial outcomes. Direct costs also were considered in the statements concerning diagnosis and screening and to a lesser extent in other statements.

1A. PNEUMATIC OTOSCOPY: CLINICIANS SHOULD USE PNEUMATIC OTOSCOPY AS THE PRIMARY DIAGNOSTIC METHOD FOR OME, AND OME SHOULD BE DISTINGUISHED FROM AOM

This is a strong recommendation based on systematic review of cohort studies and the preponderance of benefit over harm.

TABLE 1. Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means that the subcommittee believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B).* In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means that the subcommittee believes that the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C).* In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians also should generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D)* or that well-done studies (grade A, B, or C)* show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision-making regarding appropriate practice, although they may set boundaries on alternatives; patient preference should have a substantial influencing role.
No Recommendation	No recommendation means that there is both a lack of pertinent evidence (grade D)* and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision-making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

* See Table 2 for the definitions of evidence grades.

TABLE 2. Evidence Quality for Grades of Evidence

Grade	Evidence Quality
A	Well-designed, randomized, controlled trials or diagnostic studies performed on a population similar to the guideline's target population
B	Randomized, controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies
C	Observational studies (case-control and cohort design)
D	Expert opinion, case reports, or reasoning from first principles (bench research or animal studies)

1B. TYMPANOMETRY: TYMPANOMETRY CAN BE USED TO CONFIRM THE DIAGNOSIS OF OME

This option is based on cohort studies and a balance of benefit and harm.

Diagnosing OME correctly is fundamental to proper management. Moreover, OME must be differentiated from AOM to avoid unnecessary antimicrobial use.[18,19]

OME is defined as fluid in the middle ear without signs or symptoms of acute ear infection.[2] The tympanic membrane is often cloudy with distinctly impaired mobility,[20] and an air-fluid level or bubble may be visible in the middle ear. Conversely, diagnosing AOM requires a history of acute onset of signs and symptoms, the presence of middle-ear effusion, and signs and symptoms of middle-ear inflammation. The critical distinguishing feature is that only AOM has acute signs and symptoms. Distinct redness of the tympanic membrane should not be a criterion for prescribing antibiotics, because it has poor predictive value for AOM and is present in ~5% of ears with OME.[20]

The AHRQ evidence report[2] systematically reviewed the sensitivity, specificity, and predictive values of 9 diagnostic methods for OME. Pneumatic otoscopy had the best balance of sensitivity and specificity, consistent with the 1994 guideline.[1] Meta-analysis revealed a pooled sensitivity of 94% (95% confidence interval: 91%–96%) and specificity of 80% (95% confidence interval: 75%–86%) for validated observers using pneumatic otoscopy versus myringotomy as the gold standard. Pneumatic otoscopy therefore should remain the primary method of OME diagnosis, because the instrument is readily available

in practice settings, cost-effective, and accurate in experienced hands. Non–pneumatic otoscopy is not advised for primary diagnosis.

The accuracy of pneumatic otoscopy in routine clinical practice may be less than that shown in published results, because clinicians have varying training and experience.[21,22] When the diagnosis of OME is uncertain, tympanometry or acoustic reflectometry should be considered as an adjunct to pneumatic otoscopy. Tympanometry with a standard 226-Hz probe tone is reliable for infants 4 months old or older and has good interobserver agreement of curve patterns in routine clinical practice.[23,24] Younger infants require specialized equipment with a higher probe tone frequency. Tympanometry generates costs related to instrument purchase, annual calibration, and test administration. Acoustic reflectometry with spectral gradient analysis is a low-cost alternative to tympanometry that does not require an airtight seal in the ear canal; however, validation studies primarily have used children 2 years old or older with a high prevalence of OME.[25–27]

Although no research studies have examined whether pneumatic otoscopy causes discomfort, expert consensus suggests that the procedure does not have to be painful, especially when symptoms of acute infection (AOM) are absent. A nontraumatic examination is facilitated by using a gentle touch, restraining the child properly when necessary, and inserting the speculum only into the outer one third (cartilaginous portion) of the ear canal.[28] The pneumatic bulb should be compressed slightly before insertion, because OME often is associated with a negative middle-ear pressure, which can be assessed more accurately by releasing the already compressed bulb. The otoscope must be fully charged, the bulb (halogen or xenon) bright and luminescent,[29] and the insufflator bulb attached tightly to the head to avoid the loss of an air seal. The window must also be sealed.

Evidence Profile: Pneumatic Otoscopy

- Aggregate evidence quality: A, diagnostic studies in relevant populations.
- Benefit: improved diagnostic accuracy; inexpensive equipment.
- Harm: cost of training clinicians in pneumatic otoscopy.
- Benefits-harms assessment: preponderance of benefit over harm.
- Policy level: strong recommendation.

Evidence Profile: Tympanometry

- Aggregate evidence quality: B, diagnostic studies with minor limitations.
- Benefit: increased diagnostic accuracy beyond pneumatic otoscopy; documentation.
- Harm: acquisition cost, administrative burden, and recalibration.
- Benefits-harms assessment: balance of benefit and harm.
- Policy level: option.

1C. SCREENING: POPULATION-BASED SCREENING PROGRAMS FOR OME ARE NOT RECOMMENDED IN HEALTHY, ASYMPTOMATIC CHILDREN

This recommendation is based on randomized, controlled trials and cohort studies, with a preponderance of harm over benefit.

This recommendation concerns population-based screening programs of all children in a community or a school without regard to any preexisting symptoms or history of disease. This recommendation does not address hearing screening or monitoring of specific children with previous or recurrent OME.

OME is highly prevalent in young children. Screening surveys of healthy children ranging in age from infancy to 5 years old show a 15% to 40% point prevalence of middle-ear effusion.[5,7,30–36] Among children examined at regular intervals for a year, ~50% to 60% of child care center attendees[32] and 25% of school-aged children[37] were found to have a middle-ear effusion at some time during the examination period, with peak incidence during the winter months.

Population-based screening has not been found to influence short-term language outcomes,[33] and its long-term effects have not been evaluated in a randomized, clinical trial. Therefore, the recommendation against screening is based not only on the ability to identify OME but more importantly on a lack of demonstrable benefits from treating children so identified that exceed the favorable natural history of the disease. The New Zealand Health Technology Assessment[38] could not determine whether preschool screening for OME was effective. More recently, the Canadian Task Force on Preventive Health Care[39] reported that insufficient evidence was available to recommend including or excluding routine early screening for OME. Although screening for OME is not inherently harmful, potential risks include inaccurate diagnoses, overtreating self-limited disease, parental anxiety, and the costs of screening and unnecessary treatment.

Population-based screening is appropriate for conditions that are common, can be detected by a sensitive and specific test, and benefit from early detection and treatment.[40] The first 2 requirements are fulfilled by OME, which affects up to 80% of children by school entry[2,5,7] and can be screened easily with tympanometry (see recommendation 1B). Early detection and treatment of OME identified by screening, however, have not been shown to improve intelligence, receptive language, or expressive language.[2,39,41,42] Therefore, population-based screening for early detection of OME in asymptomatic children has not been shown to improve outcomes and is not recommended.

Evidence Profile: Screening

- Aggregate evidence quality: B, randomized, controlled trials with minor limitations and consistent evidence from observational studies.
- Benefit: potentially improved developmental outcomes, which have not been demonstrated in the best current evidence.

- Harm: inaccurate diagnosis (false-positive or false-negative), overtreating self-limited disease, parental anxiety, cost of screening, and/or unnecessary treatment.
- Benefits-harms assessment: preponderance of harm over benefit.
- Policy level: recommendation against.

2. DOCUMENTATION: CLINICIANS SHOULD DOCUMENT THE LATERALITY, DURATION OF EFFUSION, AND PRESENCE AND SEVERITY OF ASSOCIATED SYMPTOMS AT EACH ASSESSMENT OF THE CHILD WITH OME

This recommendation is based on observational studies and strong preponderance of benefit over harm.

Documentation in the medical record facilitates diagnosis and treatment and communicates pertinent information to other clinicians to ensure patient safety and reduce medical errors.[43] Management decisions in children with OME depend on effusion duration and laterality plus the nature and severity of associated symptoms. Therefore, these features should be documented at every medical encounter for OME. Although no studies have addressed documentation for OME specifically, there is room for improvement in documentation of ambulatory care medical records.[44]

Ideally, the time of onset and laterality of OME can be defined through diagnosis of an antecedent AOM, a history of acute onset of signs or symptoms directly referable to fluid in the middle ear, or the presence of an abnormal audiogram or tympanogram closely after a previously normal test. Unfortunately, these conditions are often lacking, and the clinician is forced to speculate on the onset and duration of fluid in the middle ear(s) in a child found to have OME at a routine office visit or school screening audiometry.

In ~40% to 50% of cases of OME, neither the affected children nor their parents or caregivers describe significant complaints referable to a middle-ear effusion.[45,46] In some children, however, OME may have associated signs and symptoms caused by inflammation or the presence of effusion (not acute infection) that should be documented, such as

- Mild intermittent ear pain, fullness, or "popping"
- Secondary manifestations of ear pain in infants, which may include ear rubbing, excessive irritability, and sleep disturbances
- Failure of infants to respond appropriately to voices or environmental sounds, such as not turning accurately toward the sound source
- Hearing loss, even when not specifically described by the child, suggested by seeming lack of attentiveness, behavioral changes, failure to respond to normal conversational-level speech, or the need for excessively high sound levels when using audio equipment or viewing television
- Recurrent episodes of AOM with persistent OME between episodes
- Problems with school performance
- Balance problems, unexplained clumsiness, or delayed gross motor development[47–50]
- Delayed speech or language development

The laterality (unilateral versus bilateral), duration of effusion, and presence and severity of associated symptoms should be documented in the medical record at each assessment of the child with OME. When OME duration is uncertain, the clinician must take whatever evidence is at hand and make a reasonable estimate.

Evidence Profile: Documentation

- Aggregate evidence quality: C, observational studies.
- Benefits: defines severity, duration has prognostic value, facilitates future communication with other clinicians, supports appropriate timing of intervention, and, if consistently unilateral, may identify a problem with specific ear other than OME (eg, retraction pocket or cholesteatoma).
- Harm: administrative burden.
- Benefits-harms assessment: preponderance of benefit over harm.
- Policy level: recommendation.

3. CHILD AT RISK: CLINICIANS SHOULD DISTINGUISH THE CHILD WITH OME WHO IS AT RISK FOR SPEECH, LANGUAGE, OR LEARNING PROBLEMS FROM OTHER CHILDREN WITH OME AND SHOULD EVALUATE HEARING, SPEECH, LANGUAGE, AND NEED FOR INTERVENTION MORE PROMPTLY

This recommendation is based on case series, the preponderance of benefit over harm, and ethical limitations in studying children with OME who are at risk.

The panel defines the child at risk as one who is at increased risk for developmental difficulties (delay or disorder) because of sensory, physical, cognitive, or behavioral factors listed in Table 3. These factors are not caused by OME but can make the child less tolerant of hearing loss or vestibular problems secondary to middle-ear effusion. In contrast the child with OME who is not at risk is otherwise healthy and does not have any of the factors shown in Table 3.

Earlier guidelines for managing OME have applied only to young children who are healthy and exhibit no developmental delays.[1] Studies of the relationship between OME and hearing loss or speech/language development typically exclude children with craniofacial anomalies, genetic syndromes, and other developmental disorders. Therefore, the available literature mainly applies to otherwise healthy children who meet inclusion criteria for randomized,

TABLE 3. Risk Factors for Developmental Difficulties*

Permanent hearing loss independent of OME
Suspected or diagnosed speech and language delay or disorder
Autism-spectrum disorder and other pervasive developmental disorders
Syndromes (eg, Down) or craniofacial disorders that include cognitive, speech, and language delays
Blindness or uncorrectable visual impairment
Cleft palate with or without associated syndrome
Developmental delay

* Sensory, physical, cognitive, or behavioral factors that place children who have OME at an increased risk for developmental difficulties (delay or disorder).

controlled trials. Few, if any, existing studies dealing with developmental sequelae caused by hearing loss from OME can be generalized to children who are at risk.

Children who are at risk for speech or language delay would likely be affected additionally by hearing problems from OME,[51] although definitive studies are lacking. For example, small comparative studies of children or adolescents with Down syndrome[52] or cerebral palsy[53] show poorer articulation and receptive language associated with a history of early otitis media. Large studies are unlikely to be forthcoming because of methodologic and ethical difficulties inherent in studying children who are delayed or at risk for further delays. Therefore, clinicians who manage children with OME should determine whether other conditions coexist that put a child at risk for developmental delay (Table 3) and then take these conditions into consideration when planning assessment and management.

Children with craniofacial anomalies (eg, cleft palate; Down syndrome; Robin sequence; coloboma, heart defect, choanal atresia, retarded growth and development, genital anomaly, and ear defect with deafness [CHARGE] association) have a higher prevalence of chronic OME, hearing loss (conductive and sensorineural), and speech or language delay than do children without these anomalies.[54–57] Other children may not be more prone to OME but are likely to have speech and language disorders, such as those children with permanent hearing loss independent of OME,[58,59] specific language impairment,[60] autism-spectrum disorders,[61] or syndromes that adversely affect cognitive and linguistic development. Some retrospective studies[52,62,63] have found that hearing loss caused by OME in children with cognitive delays, such as Down syndrome, has been associated with lower language levels. Children with language delays or disorders with OME histories perform more poorly on speech-perception tasks than do children with OME histories alone.[64,65]

Children with severe visual impairments may be more susceptible to the effects of OME, because they depend on hearing more than children with normal vision.[51] Any decrease in their most important remaining sensory input for language (hearing) may significantly compromise language development and their ability to interact and communicate with others. All children with severe visual impairments should be considered more vulnerable to OME sequelae, especially in the areas of balance, sound localization, and communication.

Management of the child with OME who is at increased risk for developmental delays should include hearing testing and speech and language evaluation and may include speech and language therapy concurrent with managing OME, hearing aids or other amplification devices for hearing loss independent of OME, tympanostomy tube insertion,[54,63,66,67] and hearing testing after OME resolves to document improvement, because OME can mask a permanent underlying hearing loss and delay detection.[59,68,69]

Evidence Profile: Child at Risk

- Aggregate evidence quality: C, observational studies of children at risk; D, expert opinion on the ability of prompt assessment and management to alter outcomes.
- Benefits: optimizing conditions for hearing, speech, and language; enabling children with special needs to reach their potential; avoiding limitations on the benefits of educational interventions because of hearing problems from OME.
- Harm: cost, time, and specific risks of medications or surgery.
- Benefits-harms assessment: exceptional preponderance of benefits over harm based on subcommittee consensus because of circumstances to date precluding randomized trials.
- Policy level: recommendation.

4. WATCHFUL WAITING: CLINICIANS SHOULD MANAGE THE CHILD WITH OME WHO IS NOT AT RISK WITH WATCHFUL WAITING FOR 3 MONTHS FROM THE DATE OF EFFUSION ONSET (IF KNOWN) OR DIAGNOSIS (IF ONSET IS UNKNOWN)

This recommendation is based on systematic review of cohort studies and the preponderance of benefit over harm.

This recommendation is based on the self-limited nature of most OME, which has been well documented in cohort studies and in control groups of randomized trials.[2,70]

The likelihood of spontaneous resolution of OME is determined by the cause and duration of effusion.[70] For example, ~75% to 90% of residual OME after an AOM episode resolves spontaneously by 3 months.[71–73] Similar outcomes of defined onset during a period of surveillance in a cohort study are observed for OME.[32,37] Another favorable situation involves improvement (not resolution) of newly detected OME defined as change in tympanogram from type B (flat curve) to non-B (anything other than a flat curve). Approximately 55% of children so defined improve by 3 months,[70] but one third will have OME relapse within the next 3 months.[4] Although a type B tympanogram is an imperfect measure of OME (81% sensitivity and 74% specificity versus myringotomy), it is the most widely reported measure suitable for deriving pooled resolution rates.[2,70]

Approximately 25% of newly detected OME of unknown prior duration in children 2 to 4 years old resolves by 3 months when resolution is defined as a change in tympanogram from type B to type A/C1 (peak pressure >200 daPa).[2,70,74–77] Resolution rates may be higher for infants and young children in whom the preexisting duration of effusion is generally shorter, and particularly for those observed prospectively in studies or in the course of well-child care. Documented bilateral OME of 3 months' duration or longer resolves spontaneously after 6 to 12 months in ~30% of children primarily 2 years old or older, with only marginal benefits if observed longer.[70]

Any intervention for OME (medical or surgical) other than observation carries some inherent harm. There is little harm associated with a specified period of observation in the child who is not at risk for speech, language, or learning problems. When observing children with OME, clinicians should inform the parent or caregiver that the child may experience reduced hearing until the effusion resolves, especially if it is bilateral. Clinicians may discuss strategies for optimizing the listening and learning environment until the effusion resolves. These strategies include speaking in close proximity to the child, facing the child and speaking clearly, repeating phrases when misunderstood, and providing preferential classroom seating.[78,79]

The recommendation for a 3-month period of observation is based on a clear preponderance of benefit over harm and is consistent with the original OME guideline intent of avoiding unnecessary surgery.[1] At the discretion of the clinician, this 3-month period of watchful waiting may include interval visits at which OME is monitored by using pneumatic otoscopy, tympanometry, or both. Factors to consider in determining the optimal interval(s) for follow-up include clinical judgment, parental comfort level, unique characteristics of the child and/or his environment, access to a health care system, and hearing levels (HLs) if known.

After documented resolution of OME in all affected ears, additional follow-up is unnecessary.

Evidence Profile: Watchful Waiting

- Aggregate evidence quality: B, systematic review of cohort studies.
- Benefit: avoid unnecessary interventions, take advantage of favorable natural history, and avoid unnecessary referrals and evaluations.
- Harm: delays in therapy for OME that will not resolve with observation; prolongation of hearing loss.
- Benefits-harms assessment: preponderance of benefit over harm.
- Policy level: recommendation.

5. MEDICATION: ANTIHISTAMINES AND DECONGESTANTS ARE INEFFECTIVE FOR OME AND ARE NOT RECOMMENDED FOR TREATMENT; ANTIMICROBIALS AND CORTICOSTEROIDS DO NOT HAVE LONG-TERM EFFICACY AND ARE NOT RECOMMENDED FOR ROUTINE MANAGEMENT

This recommendation is based on systematic review of randomized, controlled trials and the preponderance of harm over benefit.

Therapy for OME is appropriate only if persistent and clinically significant benefits can be achieved beyond spontaneous resolution. Although statistically significant benefits have been demonstrated for some medications, they are short-term and relatively small in magnitude. Moreover, significant adverse events may occur with all medical therapies.

The prior OME guideline[1] found no data supporting antihistamine-decongestant combinations in treating OME. Meta-analysis of 4 randomized trials showed no significant benefit for antihistamines or decongestants versus placebo. No additional studies have been published since 1994 to change this recommendation. Adverse effects of antihistamines and decongestants include insomnia, hyperactivity, drowsiness, behavioral change, and blood-pressure variability.

Long-term benefits of antimicrobial therapy for OME are unproved despite a modest short-term benefit for 2 to 8 weeks in randomized trials.[1,80,81] Initial benefits, however, can become nonsignificant within 2 weeks of stopping the medication.[82] Moreover, ~7 children would need to be treated with antimicrobials to achieve one short-term response.[1] Adverse effects of antimicrobials are significant and may include rashes, vomiting, diarrhea, allergic reactions, alteration of the child's nasopharyngeal flora, development of bacterial resistance,[83] and cost. Societal consequences include direct transmission of resistant bacterial pathogens in homes and child care centers.[84]

The prior OME guideline[1] did not recommend oral steroids for treating OME in children. A later meta-analysis[85] showed no benefit for oral steroid versus placebo within 2 weeks but did show a short-term benefit for oral steroid plus antimicrobial versus antimicrobial alone in 1 of 3 children treated. This benefit became nonsignificant after several weeks in a prior meta-analysis[1] and in a large, randomized trial.[86] Oral steroids can produce behavioral changes, increased appetite, and weight gain.[1] Additional adverse effects may include adrenal suppression, fatal varicella infection, and avascular necrosis of the femoral head.[3] Although intranasal steroids have fewer adverse effects, one randomized trial[87] showed statistically equivalent outcomes at 12 weeks for intranasal beclomethasone plus antimicrobials versus antimicrobials alone for OME.

Antimicrobial therapy with or without steroids has not been demonstrated to be effective in long-term resolution of OME, but in some cases this therapy can be considered an option because of short-term benefit in randomized trials, when the parent or caregiver expresses a strong aversion to impending surgery. In this circumstance, a single course of therapy for 10 to 14 days may be used. The likelihood that the OME will resolve long-term with these regimens is small, and prolonged or repetitive courses of antimicrobials or steroids are strongly not recommended.

Other nonsurgical therapies that are discussed in the OME literature include autoinflation of the eustachian tube, oral or intratympanic use of mucolytics, and systemic use of pharmacologic agents other than antimicrobials, steroids, and antihistamine-decongestants. Insufficient data exist for any of these therapies to be recommended in treating OME.[3]

Evidence Profile: Medication

- Aggregate evidence quality: A, systematic review of well-designed, randomized, controlled trials.

- Benefit: avoid side effects and reduce cost by not administering medications; avoid delays in definitive therapy caused by short-term improvement then relapse.
- Harm: adverse effects of specific medications as listed previously; societal impact of antimicrobial therapy on bacterial resistance and transmission of resistant pathogens.
- Benefits-harms assessment: preponderance of harm over benefit.
- Policy level: recommendation against.

6. HEARING AND LANGUAGE: HEARING TESTING IS RECOMMENDED WHEN OME PERSISTS FOR 3 MONTHS OR LONGER OR AT ANY TIME THAT LANGUAGE DELAY, LEARNING PROBLEMS, OR A SIGNIFICANT HEARING LOSS IS SUSPECTED IN A CHILD WITH OME; LANGUAGE TESTING SHOULD BE CONDUCTED FOR CHILDREN WITH HEARING LOSS

This recommendation is based on cohort studies and the preponderance of benefit over risk.

Hearing Testing

Hearing testing is recommended when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected. Conductive hearing loss often accompanies OME[1,88] and may adversely affect binaural processing,[89] sound localization,[90] and speech perception in noise.[91–94] Hearing loss caused by OME may impair early language acquisition,[95–97] but the child's home environment has a greater impact on outcomes[98]; recent randomized trials[41,99,100] suggest no impact on children with OME who are not at risk as identified by screening or surveillance.

Studies examining hearing sensitivity in children with OME report that average pure-tone hearing loss at 4 frequencies (500, 1000, 2000, and 4000 Hz) ranges from normal hearing to moderate hearing loss (0–55 dB). The 50th percentile is an ~25-dB HL, and ~20% of ears exceed 35-dB HL.[101,102] Unilateral OME with hearing loss results in overall poorer binaural hearing than in infants with normal middle-ear function bilaterally.[103,104] However, based on limited research, there is evidence that children experiencing the greatest conductive hearing loss for the longest periods may be more likely to exhibit developmental and academic sequelae.[1,95,105]

Initial hearing testing for children 4 years old or older can be done in the primary care setting.[106] Testing should be performed in a quiet environment, preferably in a separate closed or sound-proofed area set aside specifically for that purpose. Conventional audiometry with earphones is performed with a fail criterion of more than 20-dB HL at 1 or more frequencies (500, 1000, 2000, and 4000 Hz) in either ear.[106,107] Methods not recommended as substitutes for primary care hearing testing include tympanometry and pneumatic otoscopy,[102] caregiver judgment regarding hearing loss,[108,109] speech audiometry, and tuning forks, acoustic reflectometry, and behavioral observation.[1]

Comprehensive audiologic evaluation is recommended for children who fail primary care testing, are less than 4 years old, or cannot be tested in the primary care setting. Audiologic assessment includes evaluating air-conduction and bone-conduction thresholds for pure tones, speech-detection or speech-recognition thresholds,[102] and measuring speech understanding if possible.[94] The method of assessment depends on the developmental age of the child and might include visual reinforcement or conditioned orienting-response audiometry for infants 6 to 24 months old, play audiometry for children 24 to 48 months old, or conventional screening audiometry for children 4 years old and older.[106] The auditory brainstem response and otoacoustic emission are tests of auditory pathway structural integrity, not hearing, and should not substitute for behavioral pure-tone audiometry.[106]

Language Testing

Language testing should be conducted for children with hearing loss (pure-tone average more than 20-dB HL on comprehensive audiometric evaluation). Testing for language delays is important, because communication is integral to all aspects of human functioning. Young children with speech and language delays during the preschool years are at risk for continued communication problems and later delays in reading and writing.[110–112] In one study, 6% to 8% of children 3 years old and 2% to 13% of kindergartners had language impairment.[113] Language intervention can improve communication and other functional outcomes for children with histories of OME.[114]

Children who experience repeated and persistent episodes of OME and associated hearing loss during early childhood may be at a disadvantage for learning speech and language.[79,115] Although Shekelle et al[2] concluded that there was no evidence to support the concern that OME during the first 3 years of life was related to later receptive or expressive language, this meta-analysis should be interpreted cautiously, because it did not examine specific language domains such as vocabulary and the independent variable was OME and not hearing loss. Other meta-analyses[79,115] have suggested at most a small negative association of OME and hearing loss on children's receptive and expressive language through the elementary school years. The clinical significance of these effects for language and learning is unclear for the child not at risk. For example, in one randomized trial,[100] prompt insertion of tympanostomy tubes for OME did not improve developmental outcomes at 3 years old regardless of baseline hearing. In another randomized trial,[116] however, prompt tube insertion achieved small benefits for children with bilateral OME and hearing loss.

Clinicians should ask the parent or caregiver about specific concerns regarding their child's language development. Children's speech and language can be tested at ages 6 to 36 months by direct engagement of a child and interviewing the parent using the Early Language Milestone Scale.[117] Other approaches require interviewing only the child's parent or caregiver, such

as the MacArthur Communicative Development Inventory[118] and the Language Development Survey.[119] For older children, the Denver Developmental Screening Test II[120] can be used to screen general development including speech and language. Comprehensive speech and language evaluation is recommended for children who fail testing or whenever the child's parent or caregiver expresses concern.[121]

Evidence Profile: Hearing and Language

- Aggregate evidence quality: B, diagnostic studies with minor limitations; C, observational studies.
- Benefit: to detect hearing loss and language delay and identify strategies or interventions to improve developmental outcomes.
- Harm: parental anxiety, direct and indirect costs of assessment, and/or false-positive results.
- Balance of benefit and harm: preponderance of benefit over harm.
- Policy level: recommendation.

7. SURVEILLANCE: CHILDREN WITH PERSISTENT OME WHO ARE NOT AT RISK SHOULD BE REEXAMINED AT 3- TO 6-MONTH INTERVALS UNTIL THE EFFUSION IS NO LONGER PRESENT, SIGNIFICANT HEARING LOSS IS IDENTIFIED, OR STRUCTURAL ABNORMALITIES OF THE EARDRUM OR MIDDLE EAR ARE SUSPECTED

This recommendation is based on randomized, controlled trials and observational studies with a preponderance of benefit over harm.

If OME is asymptomatic and is likely to resolve spontaneously, intervention is unnecessary even if OME persists for more than 3 months. The clinician should determine whether risk factors exist that would predispose the child to undesirable sequelae or predict nonresolution of the effusion. As long as OME persists, the child is at risk for sequelae and must be reevaluated periodically for factors that would prompt intervention.

The 1994 OME guideline[1] recommended surgery for OME persisting 4 to 6 months with hearing loss but requires reconsideration because of later data on tubes and developmental sequelae.[122] For example, selecting surgical candidates using duration-based criteria (eg, OME >3 months or exceeding a cumulative threshold) does not improve developmental outcomes in infants and toddlers who are not at risk.[41,42,99,100] Additionally, the 1994 OME guideline did not specifically address managing effusion without significant hearing loss persisting more than 6 months.

Asymptomatic OME usually resolves spontaneously, but resolution rates decrease the longer the effusion has been present,[36,76,77] and relapse is common.[123] Risk factors that make spontaneous resolution less likely include[124,125]:

- Onset of OME in the summer or fall season
- Hearing loss more than 30-dB HL in the better-hearing ear
- History of prior tympanostomy tubes
- Not having had an adenoidectomy

Children with chronic OME are at risk for structural damage of the tympanic membrane[126] because the effusion contains leukotrienes, prostaglandins, and arachidonic acid metabolites that invoke a local inflammatory response.[127] Reactive changes may occur in the adjacent tympanic membrane and mucosal linings. A relative underventilation of the middle ear produces a negative pressure that predisposes to focal retraction pockets, generalized atelectasis of the tympanic membrane, and cholesteatoma.

Structural integrity is assessed by carefully examining the entire tympanic membrane, which, in many cases, can be accomplished by the primary care clinician using a handheld pneumatic otoscope. A search should be made for retraction pockets, ossicular erosion, and areas of atelectasis or atrophy. If there is any uncertainty that all observed structures are normal, the patient should be examined by using an otomicroscope. All children with these tympanic membrane conditions, regardless of OME duration, should have a comprehensive audiologic evaluation.

Conditions of the tympanic membrane that generally mandate inserting a tympanostomy tube are posterosuperior retraction pockets, ossicular erosion, adhesive atelectasis, and retraction pockets that accumulate keratin debris. Ongoing surveillance is mandatory, because the incidence of structural damage increases with effusion duration.[128]

As noted in recommendation 6, children with persistent OME for 3 months or longer should have their hearing tested. Based on these results, clinicians can identify 3 levels of action based on HLs obtained for the better-hearing ear using earphones or in sound field using speakers if the child is too young for ear-specific testing.

1. HLs of ≥40 dB (at least a moderate hearing loss): A comprehensive audiologic evaluation is indicated if not previously performed. If moderate hearing loss is documented and persists at this level, surgery is recommended, because persistent hearing loss of this magnitude that is permanent in nature has been shown to impact speech, language, and academic performance.[129–131]
2. HLs of 21 to 39 dB (mild hearing loss): A comprehensive audiologic evaluation is indicated if not previously performed. Mild sensorineural hearing loss has been associated with difficulties in speech, language, and academic performance in school,[129,132] and persistent mild conductive hearing loss from OME may have a similar impact. Further management should be individualized based on effusion duration, severity of hearing loss, and parent or caregiver preference and may include strategies to optimize the listening and learning environment (Table 4) or surgery. Repeat hearing testing should be performed in 3 to 6 months if OME persists at follow-up evaluation or tympanostomy tubes have not been placed.
3. HLs of ≤20 dB (normal hearing): A repeat hearing test should be performed in 3 to 6 months if OME persists at follow-up evaluation.

TABLE 4. Strategies for Optimizing the Listening-Learning Environment for Children With OME and Hearing Loss*

Get within 3 feet of the child before speaking.
Turn off competing audio signals such as unnecessary music and television in the background.
Face the child and speak clearly, using visual clues (hands, pictures) in addition to speech.
Slow the rate, raise the level, and enunciate speech directed at the child.
Read to or with the child, explaining pictures and asking questions.
Repeat words, phrases, and questions when misunderstood.
Assign preferential seating in the classroom near the teacher.
Use a frequency-modulated personal- or sound-field-amplification system in the classroom.

* Modified with permission from Roberts et al.[78,79]

In addition to hearing loss and speech or language delay, other factors may influence the decision to intervene for persistent OME. Roberts et al[98,133] showed that the caregiving environment is more strongly related to school outcome than was OME or hearing loss. Risk factors for delays in speech and language development caused by a poor caregiving environment included low maternal educational level, unfavorable child care environment, and low socioeconomic status. In such cases, these factors may be additive to the hearing loss in affecting lower school performance and classroom behavior problems.

Persistent OME may be associated with physical or behavioral symptoms including hyperactivity, poor attention, and behavioral problems in some studies[134–136] and reduced child quality of life.[46] Conversely, young children randomized to early versus late tube insertion for persistent OME showed no behavioral benefits from early surgery.[41,100] Children with chronic OME also have significantly poorer vestibular function and gross motor proficiency when compared with non-OME controls.[48–50] Moreover, vestibular function, behavior, and quality of life can improve after tympanostomy tube insertion.[47,137,138] Other physical symptoms of OME that, if present and persistent, may warrant surgery include otalgia, unexplained sleep disturbance, and coexisting recurrent AOM. Tubes reduce the absolute incidence of recurrent AOM by ~1 episode per child per year, but the relative risk reduction is 56%.[139]

The risks of continued observation of children with OME must be balanced against the risks of surgery. Children with persistent OME examined regularly at 3- to 6-month intervals, or sooner if OME-related symptoms develop, are most likely at low risk for physical, behavioral, or developmental sequelae of OME. Conversely, prolonged watchful waiting of OME is not appropriate when regular surveillance is impossible or when the child is at risk for developmental sequelae of OME because of comorbidities (Table 3). For these children, the risks of anesthesia and surgery (see recommendation 9) may be less than those of continued observation.

Evidence Profile: Surveillance

- Aggregate evidence quality: C, observational studies and some randomized trials.
- Benefit: avoiding interventions that do not improve outcomes.
- Harm: allowing structural abnormalities to develop in the tympanic membrane, underestimating the impact of hearing loss on a child, and/or failing to detect significant signs or symptoms that require intervention.
- Balance of benefit and harm: preponderance of benefit over harm.
- Policy level: recommendation.

8. REFERRAL: WHEN CHILDREN WITH OME ARE REFERRED BY THE PRIMARY CARE CLINICIAN FOR EVALUATION BY AN OTOLARYNGOLOGIST, AUDIOLOGIST, OR SPEECH-LANGUAGE PATHOLOGIST, THE REFERRING CLINICIAN SHOULD DOCUMENT THE EFFUSION DURATION AND SPECIFIC REASON FOR REFERRAL (EVALUATION, SURGERY) AND PROVIDE ADDITIONAL RELEVANT INFORMATION SUCH AS HISTORY OF AOM AND DEVELOPMENTAL STATUS OF THE CHILD

This option is based on panel consensus and a preponderance of benefit over harm.

This recommendation emphasizes the importance of communication between the referring primary care clinician and the otolaryngologist, audiologist, and speech-language pathologist. Parents and caregivers may be confused and frustrated when a recommendation for surgery is made for their child because of conflicting information about alternative management strategies. Choosing among management options is facilitated when primary care physicians and advanced-practice nurses who best know the patient's history of ear problems and general medical status provide the specialist with accurate information. Although there are no studies showing improved outcomes from better documentation of OME histories, there is a clear need for better mechanisms to convey information and expectations from primary care clinicians to consultants and subspecialists.[140–142]

When referring a child for evaluation to an otolaryngologist, the primary care physician should explain the following to the parent or caregiver of the patient:

- Reason for referral: Explain that the child is seeing an otolaryngologist for evaluation, which is likely to include ear examination and audiologic testing, and not necessarily simply to be scheduled for surgery.
- What to expect: Explain that surgery may be recommended, and let the parent know that the otolaryngologist will explain the options, benefits, and risks further.
- Decision-making process: Explain that there are many alternatives for management and that surgical decisions are elective; the parent or caregiver should be encouraged to express to the surgeonany concerns he or she may have about the recommendations made.

When referring a child to an otolaryngologist, audiologist, or speech-language pathologist, the mini-

mum information that should be conveyed in writing includes:

- Duration of OME: State how long fluid has been present.
- Laterality of OME: State whether one or both ears have been affected.
- Results of prior hearing testing or tympanometry.
- Suspected speech or language problems: State whether there had been a delay in speech and language development or whether the parent or a caregiver has expressed concerns about the child's communication abilities, school achievement, or attentiveness.
- Conditions that might exacerbate the deleterious effects of OME: State whether the child has conditions such as permanent hearing loss, impaired cognition, developmental delays, cleft lip or palate, or an unstable or nonsupportive family or home environment.
- AOM history: State whether the child has a history of recurrent AOM.

Additional medical information that should be provided to the otolaryngologist by the primary care clinician includes:

- Parental attitude toward surgery: State whether the parents have expressed a strong preference for or against surgery as a management option.
- Related conditions that might require concomitant surgery: State whether there have been other conditions that might warrant surgery if the child is going to have general anesthesia (eg, nasal obstruction and snoring that might be an indication for adenoidectomy or obstructive breathing during sleep that might mean tonsillectomy is indicated).
- General health status: State whether there are any conditions that might present problems for surgery or administering general anesthesia, such as congenital heart abnormality, bleeding disorder, asthma or reactive airway disease, or family history of malignant hyperthermia.

After evaluating the child, the otolaryngologist, audiologist, or speech-language pathologist should inform the referring physician regarding his or her diagnostic impression, plans for additional assessment, and recommendations for ongoing monitoring and management.

Evidence Profile: Referral

- Aggregate evidence quality: C, observational studies.
- Benefit: better communication and improved decision-making.
- Harm: confidentiality concerns, administrative burden, and/or increased parent or caregiver anxiety.
- Benefits-harms assessment: balance of benefit and harm.
- Policy level: option.

9. SURGERY: WHEN A CHILD BECOMES A SURGICAL CANDIDATE, TYMPANOSTOMY TUBE INSERTION IS THE PREFERRED INITIAL PROCEDURE; ADENOIDECTOMY SHOULD NOT BE PERFORMED UNLESS A DISTINCT INDICATION EXISTS (NASAL OBSTRUCTION, CHRONIC ADENOIDITIS). REPEAT SURGERY CONSISTS OF ADENOIDECTOMY PLUS MYRINGOTOMY, WITH OR WITHOUT TUBE INSERTION. TONSILLECTOMY ALONE OR MYRINGOTOMY ALONE SHOULD NOT BE USED TO TREAT OME

This recommendation is based on randomized, controlled trials with a preponderance of benefit over harm.

Surgical candidacy for OME largely depends on hearing status, associated symptoms, the child's developmental risk (Table 3), and the anticipated chance of timely spontaneous resolution of the effusion. Candidates for surgery include children with OME lasting 4 months or longer with persistent hearing loss or other signs and symptoms, recurrent or persistent OME in children at risk regardless of hearing status, and OME and structural damage to the tympanic membrane or middle ear. Ultimately, the recommendation for surgery must be individualized based on consensus between the primary care physician, otolaryngologist, and parent or caregiver that a particular child would benefit from intervention. Children with OME of any duration who are at risk are candidates for earlier surgery.

Tympanostomy tubes are recommended for initial surgery because randomized trials show a mean 62% relative decrease in effusion prevalence and an absolute decrease of 128 effusion days per child during the next year.[139,143–145] HLs improve by a mean of 6 to 12 dB while the tubes remain patent.[146,147] Adenoidectomy plus myringotomy (without tube insertion) has comparable efficacy in children 4 years old or older[143] but is more invasive, with additional surgical and anesthetic risks. Similarly, the added risk of adenoidectomy outweighs the limited, short-term benefit for children 3 years old or older without prior tubes.[148] Consequently, adenoidectomy is not recommended for initial OME surgery unless a distinct indication exists, such as adenoiditis, postnasal obstruction, or chronic sinusitis.

Approximately 20% to 50% of children who have had tympanostomy tubes have OME relapse after tube extrusion that may require additional surgery.[144,145,149] When a child needs repeat surgery for OME, adenoidectomy is recommended (unless the child has an overt or submucous cleft palate), because it confers a 50% reduction in the need for future operations.[143,150,151] The benefit of adenoidectomy is apparent at 2 years old,[150] greatest for children 3 years old or older, and independent of adenoid size.[143,151,152] Myringotomy is performed concurrent with adenoidectomy. Myringotomy plus adenoidectomy is effective for children 4 years old or older,[143] but tube insertion is advised for younger children, when potential relapse of effusion must be minimized (eg, children at risk) or pronounced inflammation of the tympanic membrane and middle-ear mucosa is present.

Tonsillectomy or myringotomy alone (without adenoidectomy) is not recommended to treat OME. Although tonsillectomy is either ineffective[152] or of limited efficacy,[148,150] the risks of hemorrhage (~2%) and additional hospitalization outweigh any potential benefits unless a distinct indication for tonsillectomy exists. Myringotomy alone, without tube placement or adenoidectomy, is ineffective for chronic OME,[144,145] because the incision closes within several days. Laser-assisted myringotomy extends the ventilation period several weeks,[153] but randomized trials with concurrent controls have not been conducted to establish efficacy. In contrast, tympanostomy tubes ventilate the middle ear for an average of 12 to 14 months.[144,145]

Anesthesia mortality has been reported to be ~1: 50 000 for ambulatory surgery,[154] but the current fatality rate may be lower.[155] Laryngospasm and bronchospasm occur more often in children receiving anesthesia than adults. Tympanostomy tube sequelae are common[156] but are generally transient (otorrhea) or do not affect function (tympanosclerosis, focal atrophy, or shallow retraction pocket). Tympanic membrane perforations, which may require repair, are seen in 2% of children after placement of short-term (grommet-type) tubes and 17% after long-term tubes.[156] Adenoidectomy has a 0.2% to 0.5% incidence of hemorrhage[150,157] and 2% incidence of transient velopharyngeal insufficiency.[148] Other potential risks of adenoidectomy, such as nasopharyngeal stenosis and persistent velopharyngeal insufficiency, can be minimized with appropriate patient selection and surgical technique.

There is a clear preponderance of benefit over harm when considering the impact of surgery for OME on effusion prevalence, HLs, subsequent incidence of AOM, and the need for reoperation after adenoidectomy. Information about adenoidectomy in children less than 4 years old, however, remains limited. Although the cost of surgery and anesthesia is nontrivial, it is offset by reduced OME and AOM after tube placement and by reduced need for reoperation after adenoidectomy. Approximately 8 adenoidectomies are needed to avoid a single instance of tube reinsertion; however, each avoided surgery probably represents a larger reduction in the number of AOM and OME episodes, including those in children who did not require additional surgery.[150]

Evidence Profile: Surgery

- Aggregate evidence quality: B, randomized, controlled trials with minor limitations.
- Benefit: improved hearing, reduced prevalence of OME, reduced incidence of AOM, and less need for additional tube insertion (after adenoidectomy).
- Harm: risks of anesthesia and specific surgical procedures; sequelae of tympanostomy tubes.
- Benefits-harms assessment: preponderance of benefit over harm.
- Policy level: recommendation.

10. CAM: NO RECOMMENDATION IS MADE REGARDING CAM AS A TREATMENT FOR OME

There is no recommendation based on lack of scientific evidence documenting efficacy and an uncertain balance of harm and benefit.

The 1994 OME guideline[1] made no recommendation regarding CAM as a treatment for OME, and no subsequent controlled studies have been published to change this conclusion. The current statement of "no recommendation" is based on the lack of scientific evidence documenting efficacy plus the balance of benefit and harm.

Evidence concerning CAM is insufficient to determine whether the outcomes achieved for OME differ from those achieved by watchful waiting and spontaneous resolution. There are no randomized, controlled trials with adequate sample sizes on the efficacy of CAM for OME. Although many case reports and subjective reviews on CAM treatment of AOM were found, little is published on OME treatment or prevention. Homeopathy[158] and chiropractic treatments[159] were assessed in pilot studies with small numbers of patients that failed to show clinically or statistically significant benefits. Consequently, there is no research base on which to develop a recommendation concerning CAM for OME.

The natural history of OME in childhood (discussed previously) is such that almost any intervention can be "shown" to have helped in an anecdotal, uncontrolled report or case series. The efficacy of CAM or any other intervention for OME can only be shown with parallel-group, randomized, controlled trials with valid diagnostic methods and adequate sample sizes. Unproved modalities that have been claimed to provide benefit in middle-ear disease include osteopathic and chiropractic manipulation, dietary exclusions (such as dairy), herbal and other dietary supplements, acupuncture, traditional Chinese medicine, and homeopathy. None of these modalities, however, have been subjected yet to a published, peer-reviewed, clinical trial.

The absence of any published clinical trials also means that all reports of CAM adverse effects are anecdotal. A systematic review of recent evidence[160] found significant serious adverse effects of unconventional therapies for children, most of which were associated with inadequately regulated herbal medicines. One report on malpractice liability associated with CAM therapies[161] did not address childhood issues specifically. Allergic reactions to echinacea occur but seem to be rare in children.[162] A general concern about herbal products is the lack of any governmental oversight into product quality or purity.[160,163,164] Additionally, herbal products may alter blood levels of allopathic medications, including anticoagulants. A possible concern with homeopathy is the worsening of symptoms, which is viewed as a positive, early sign of homeopathic efficacy. The adverse effects of manipulative therapies (such as chiropractic treatments and osteopathy) in children are difficult to assess because of scant evidence, but a case series of 332 children treated for AOM or OME with chiropractic manipulation did not mention any

side effects.[165] Quadriplegia has been reported, however, after spinal manipulation in an infant with torticollis.[166]

Evidence Profile: CAM

- Aggregate evidence quality: D, case series without controls.
- Benefit: not established.
- Harm: potentially significant depending on the intervention.
- Benefits-harms assessment: uncertain balance of benefit and harm.
- Policy level: no recommendation.

11. ALLERGY MANAGEMENT: NO RECOMMENDATION IS MADE REGARDING ALLERGY MANAGEMENT AS A TREATMENT FOR OME

There is no recommendation based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME.

The 1994 OME guideline[1] made no recommendation regarding allergy management as a treatment for OME, and no subsequent controlled studies have been published to change this conclusion. The current statement of "no recommendation" is based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME plus the balance of benefit and harm.

A linkage between allergy and OME has long been speculated but to date remains unquantified. The prevalence of allergy among OME patients has been reported to range from less than 10% to more than 80%.[167] Allergy has long been postulated to cause OME through its contribution to eustachian tube dysfunction.[168] The cellular response of respiratory mucosa to allergens has been well studied. Therefore, similar to other parts of respiratory mucosa, the mucosa lining the middle-ear cleft is capable of an allergic response.[169,170] Sensitivity to allergens varies among individuals, and atopy may involve neutrophils in type I allergic reactions that enhance the inflammatory response.[171]

The correlation between OME and allergy has been widely reported, but no prospective studies have examined the effects of immunotherapy compared with observation alone or other management options. Reports of OME cure after immunotherapy or food-elimination diets[172] are impossible to interpret without concurrent control groups because of the favorable natural history of most untreated OME. The documentation of allergy in published reports has been defined inconsistently (medical history, physical examination, skin-prick testing, nasal smears, serum immunoglobulin E and eosinophil counts, inflammatory mediators in effusions). Study groups have been drawn primarily from specialist offices, likely lack heterogeneity, and are not representative of general medical practice.

Evidence Profile: Allergy Management

- Aggregate evidence quality: D, case series without controls.
- Benefit: not established.
- Harm: adverse effects and cost of medication, physician evaluation, elimination diets, and desensitization.
- Benefits-harms assessment: balance of benefit and harm.
- Policy level: no recommendation.

RESEARCH NEEDS

Diagnosis

- Further standardize the definition of OME.
- Assess the performance characteristics of pneumatic otoscopy as a diagnostic test for OME when performed by primary care physicians and advanced-practice nurses in the routine office setting.
- Determine the optimal methods for teaching pneumatic otoscopy to residents and clinicians.
- Develop a brief, reliable, objective method for diagnosing OME.
- Develop a classification method for identifying the presence of OME for practical use by clinicians that is based on quantifiable tympanometric characteristics.
- Assess the usefulness of algorithms combining pneumatic otoscopy and tympanometry for detecting OME in clinical practice.
- Conduct additional validating cohort studies of acoustic reflectometry as a diagnostic method for OME, particularly in children less than 2 years old.

Child At Risk

- Better define the child with OME who is at risk for speech, language, and learning problems.
- Conduct large, multicenter, observational cohort studies to identify the child at risk who is most susceptible to potential adverse sequelae of OME.
- Conduct large, multicenter, observational cohort studies to analyze outcomes achieved with alternative management strategies for OME in children at risk.

Watchful Waiting

- Define the spontaneous resolution of OME in infants and young children (existing data are limited primarily to children 2 years old or older).
- Conduct large-scale, prospective cohort studies to obtain current data on the spontaneous resolution of newly diagnosed OME of unknown prior duration (existing data are primarily from the late 1970s and early 1980s).
- Develop prognostic indicators to identify the best candidates for watchful waiting.
- Determine whether the lack of impact from prompt insertion of tympanostomy tubes on speech and language outcomes seen in asymptomatic young children with OME identified by screening or intense surveillance can be generalized to older children with OME or to symptomatic children with OME referred for evaluation.

Medication

- Clarify which children, if any, should receive antimicrobials, steroids, or both for OME.
- Conduct a randomized, placebo-controlled trial on the efficacy of antimicrobial therapy, with or without concurrent oral steroid, in avoiding surgery in children with OME who are surgical candidates and have not received recent antimicrobials.
- Investigate the role of mucosal surface biofilms in refractory or recurrent OME and develop targeted interventions.

Hearing and Language

- Conduct longitudinal studies on the natural history of hearing loss accompanying OME.
- Develop improved methods for describing and quantifying the fluctuations in hearing of children with OME over time.
- Conduct prospective controlled studies on the relation of hearing loss associated with OME to later auditory, speech, language, behavioral, and academic sequelae.
- Develop reliable, brief, objective methods for estimating hearing loss associated with OME.
- Develop reliable, brief, objective methods for estimating speech or language delay associated with OME.
- Evaluate the benefits and administrative burden of language testing by primary care clinicians.
- Agree on the aspects of language that are vulnerable to or affected by hearing loss caused by OME, and reach a consensus on the best tools for measurement.
- Determine whether OME and associated hearing loss place children from special populations at greater risk for speech and language delays.

Surveillance

- Develop better tools for monitoring children with OME that are suitable for routine clinical care.
- Assess the value of new strategies for monitoring OME, such as acoustic reflectometry performed at home by the parent or caregiver, in optimizing surveillance.
- Improve our ability to identify children who would benefit from early surgery instead of prolonged surveillance.
- Promote early detection of structural abnormalities in the tympanic membrane associated with OME that may require surgery to prevent complications.
- Clarify and quantify the role of parent or caregiver education, socioeconomic status, and quality of the caregiving environment as modifiers of OME developmental outcomes.
- Develop methods for minimizing loss to follow-up during OME surveillance.

Surgery

- Define the role of adenoidectomy in children 3 years old or younger as a specific OME therapy.
- Conduct controlled trials on the efficacy of tympanostomy tubes for developmental outcomes in children with hearing loss, other symptoms, or speech and language delay.
- Conduct randomized, controlled trials of surgery versus no surgery that emphasize patient-based outcome measures (quality of life, functional health status) in addition to objective measures (effusion prevalence, HLs, AOM incidence, reoperation).
- Identify the optimal ways to incorporate parent or caregiver preference into surgical decision-making.

CAM

- Conduct randomized, controlled trials on the efficacy of CAM modalities for OME.
- Develop strategies to identify parents or caregivers who use CAM therapies for their child's OME, and encourage surveillance by the primary care clinician.

Allergy Management

- Evaluate the causal role of atopy in OME.
- Conduct randomized, controlled trials on the efficacy of allergy therapy for OME that are generalizable to the primary care setting.

CONCLUSIONS

This evidence-based practice guideline offers recommendations for identifying, monitoring, and managing the child with OME. The guideline emphasizes appropriate diagnosis and provides options for various management strategies including observation, medical intervention, and referral for surgical intervention. These recommendations should provide primary care physicians and other health care providers with assistance in managing children with OME.

Subcommittee on Otitis Media With Effusion
Richard M. Rosenfeld, MD, MPH, Cochairperson
American Academy of Pediatrics
American Academy of Otolaryngology-Head and Neck Surgery
Larry Culpepper, MD, MPH, Cochairperson
American Academy of Family Physicians
Karen J. Doyle, MD, PhD
American Academy of Otolaryngology-Head and Neck Surgery
Kenneth M. Grundfast, MD
American Academy of Otolaryngology-Head and Neck Surgery
Alejandro Hoberman, MD
American Academy of Pediatrics
Margaret A. Kenna, MD
American Academy of Otolaryngology-Head and Neck Surgery
Allan S. Lieberthal, MD
American Academy of Pediatrics
Martin Mahoney, MD, PhD
American Academy of Family Physicians
Richard A. Wahl, MD
American Academy of Pediatrics
Charles R. Woods, Jr, MD, MS
American Academy of Pediatrics

Barbara Yawn, MD, MSc
American Academy of Family Physicians

Consultants
S. Michael Marcy, MD
Richard N. Shiffman, MD

Liaisons
Linda Carlson, MS, CPNP
National Association of Pediatric Nurse Practitioners
Judith Gravel, PhD
American Academy of Audiology
Joanne Roberts, PhD
American Speech-Language-Hearing Association
Staff
Maureen Hannley, PhD
American Academy of Otolaryngology-Head and Neck Surgery
Carla T. Herrerias, MPH
American Academy of Pediatrics
Bellinda K. Schoof, MHA, CPHQ
American Academy of Family Physicians

ACKNOWLEDGMENTS

Dr Marcy serves as a consultant to Abbott Laboratories GlaxoSmithKline (vaccines).

REFERENCES

1. Stool SE, Berg AO, Berman S, et al. *Otitis Media With Effusion in Young Children. Clinical Practice Guideline, Number 12.* AHCPR Publication No. 94-0622. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, US Department of Health and Human Services; 1994
2. Shekelle P, Takata G, Chan LS, et al. *Diagnosis, Natural History, and Late Effects of Otitis Media With Effusion. Evidence Report/Technology Assessment No. 55.* AHRQ Publication No. 03-E023. Rockville, MD: Agency for Healthcare Research and Quality; 2003
3. Williamson I. Otitis media with effusion. *Clin Evid.* 2002;7:469–476
4. Tos M. Epidemiology and natural history of secretory otitis. *Am J Otol.* 1984;5:459–462
5. Paradise JL, Rockette HE, Colborn DK, et al. Otitis media in 2253 Pittsburgh area infants: prevalence and risk factors during the first two years of life. *Pediatrics.* 1997;99:318–333
6. Casselbrant ML, Mandel EM. Epidemiology. In: Rosenfeld RM, Bluestone CD, eds. *Evidence-Based Otitis Media.* 2nd ed. Hamilton, Ontario: BC Decker; 2003:147–162
7. Williamson IG, Dunleavy J, Baine J, Robinson D. The natural history of otitis media with effusion—a three-year study of the incidence and prevalence of abnormal tympanograms in four South West Hampshire infant and first schools. *J Laryngol Otol.* 1994;108:930–934
8. Coyte PC, Croxford R, Asche CV, To T, Feldman W, Friedberg J. Physician and population determinants of rates of middle-ear surgery in Ontario. *JAMA.* 2001;286:2128–2135
9. Tugwell P. How to read clinical journals: III. To learn the clinical course and prognosis of disease. *Can Med Assoc J.* 1981;124:869–872
10. Jaeschke R, Guyatt G, Sackett DL. Users' guides to the medical literature. III. How to use an article about a diagnostic test. A. Are the results of the study valid? Evidence-Based Medicine Working Group. *JAMA.* 1994;271:389–391
11. Shiffman RN, Shekelle P, Overhage JM, Slutsky J, Grimshaw J, Deshpande AM. Standardized reporting of clinical practice guidelines: a proposal from the Conference on Guideline Standardization. *Ann Intern Med.* 2003;139:493–498
12. Shiffman RN, Karras BT, Agrawal A, Chen R, Marenco L, Nath S. GEM: a proposal for a more comprehensive guideline document model using XML. *J Am Med Inform Assoc.* 2000;7:488–498
13. Shaneyfelt TM, Mayo-Smith MF, Rothwangl J. Are guidelines following guidelines? The methodological quality of clinical practice guidelines in the peer-reviewed medical literature. *JAMA.* 1999;281:1900–1905
14. Agrawal A, Shiffman RN. Evaluation of guideline quality using GEM-Q. *Medinfo.* 2001;10:1097–1101
15. Yale Center for Medical Informatics. GEM: The Guideline Elements Model. Available at: http://ycmi.med.yale.edu/GEM/. Accessed December 8, 2003
16. American Academy of Pediatrics, Steering Committee on Quality Improvement and Management. A taxonomy of recommendations for clinical practice guidelines. *Pediatrics*. 2004; In press
17. Eddy DM. *A Manual for Assessing Health Practices and Designing Practice Policies: The Explicit Approach*. Philadelphia, PA: American College of Physicians; 1992
18. Dowell SF, Marcy MS, Phillips WR, Gerber MA, Schwartz B. Otitis media—principles of judicious use of antimicrobial agents. *Pediatrics.* 1998;101:165–171
19. Dowell SF, Butler JC, Giebink GS, et al. Acute otitis media: management and surveillance in an era of pneumococcal resistance—a report from the Drug-Resistant *Streptococcus pneumoniae* Therapeutic Working Group. *Pediatr Infect Dis J.* 1999;18:1–9
20. Karma PH, Penttila MA, Sipila MM, Kataja MJ. Otoscopic diagnosis of middle ear effusion in acute and non-acute otitis media. I. The value of different otoscopic findings. *Int J Pediatr Otorhinolaryngol.* 1989;17:37–49
21. Pichichero ME, Poole MD. Assessing diagnostic accuracy and tympanocentesis skills in the management of otitis media. *Arch Pediatr Adolesc Med.* 2001;155:1137–1142
22. Steinbach WJ, Sectish TC. Pediatric resident training in the diagnosis and treatment of acute otitis media. *Pediatrics.* 2002;109:404–408
23. Palmu A, Puhakka H, Rahko T, Takala AK. Diagnostic value of tympanometry in infants in clinical practice. *Int J Pediatr Otorhinolaryngol.* 1999;49:207–213
24. van Balen FA, Aarts AM, De Melker RA. Tympanometry by general practitioners: reliable? *Int J Pediatr Otorhinolaryngol.* 1999;48:117–123
25. Block SL, Mandel E, McLinn S, et al. Spectral gradient acoustic reflectometry for the detection of middle ear effusion by pediatricians and parents. *Pediatr Infect Dis J.* 1998;17:560–564, 580
26. Barnett ED, Klein JO, Hawkins KA, Cabral HJ, Kenna M, Healy G. Comparison of spectral gradient acoustic reflectometry and other diagnostic techniques for detection of middle ear effusion in children with middle ear disease. *Pediatr Infect Dis J.* 1998;17:556–559, 580
27. Block SL, Pichichero ME, McLinn S, Aronovitz G, Kimball S. Spectral gradient acoustic reflectometry: detection of middle ear effusion by pediatricians in suppurative acute otitis media. *Pediatr Infect Dis J.* 1999;18:741–744
28. Schwartz RH. A practical approach to the otitis prone child. *Contemp Pediatr.* 1987;4:30–54
29. Barriga F, Schwartz RH, Hayden GF. Adequate illumination for otoscopy. Variations due to power source, bulb, and head and speculum design. *Am J Dis Child.* 1986;140:1237–1240
30. Sorenson CH, Jensen SH, Tos M. The post-winter prevalence of middle-ear effusion in four-year-old children, judged by tympanometry. *Int J Pediatr Otorhinolaryngol.* 1981;3:119–128
31. Fiellau-Nikolajsen M. Epidemiology of secretory otitis media. A descriptive cohort study. *Ann Otol Rhinol Laryngol.* 1983;92:172–177
32. Casselbrant ML, Brostoff LM, Cantekin EI, et al. Otitis media with effusion in preschool children. *Laryngoscope.* 1985;95:428–436
33. Zielhuis GA, Rach GH, van den Broek P. Screening for otitis media with effusion in preschool children. *Lancet.* 1989;1:311–314
34. Poulsen G, Tos M. Repetitive tympanometric screenings of two-year-old children. *Scand Audiol.* 1980;9:21–28
35. Tos M, Holm-Jensen S, Sorensen CH. Changes in prevalence of secretory otitis from summer to winter in four-year-old children. *Am J Otol.* 1981;2:324–327
36. Thomsen J, Tos M. Spontaneous improvement of secretory otitis. A long-term study. *Acta Otolaryngol.* 1981;92:493–499
37. Lous J, Fiellau-Nikolajsen M. Epidemiology of middle ear effusion and tubal dysfunction. A one-year prospective study comprising monthly tympanometry in 387 non-selected seven-year-old children. *Int J Pediatr Otorhinolaryngol.* 1981;3:303–317
38. New Zealand Health Technology Assessment. *Screening Programmes for the Detection of Otitis Media With Effusion and Conductive Hearing Loss in Pre-School and New Entrant School Children: A Critical Appraisal of the Literature*. Christchurch, New Zealand: New Zealand Health Technology Assessment; 1998:61
39. Canadian Task Force on Preventive Health Care. Screening for otitis media with effusion: recommendation statement from the Canadian Task Force on Preventive Health Care. *CMAJ.* 2001;165:1092–1093
40. US Preventive Services Task Force. *Guide to Clinical Preventive Services.* 2nd ed. Baltimore, MD: Williams & Wilkins; 1995
41. Paradise JL, Feldman HM, Campbell TF, et al. Effect of early or delayed insertion of tympanostomy tubes for persistent otitis media on

developmental outcomes at the age of three years. *N Engl J Med.* 2001;344:1179–1187
42. Rovers MM, Krabble PF, Straatman H, Ingels K, van der Wilt GJ, Zielhuis GA. Randomized controlled trial of the effect of ventilation tubes (grommets) on quality of life at age 1–2 years. *Arch Dis Child.* 2001;84:45–49
43. Wood DL. Documentation guidelines: evolution, future direction, and compliance. *Am J Med.* 2001;110:332–334
44. Soto CM, Kleinman KP, Simon SR. Quality and correlates of medical record documentation in the ambulatory care setting. *BMC Health Serv Res.* 2002;2:22–35
45. Marchant CD, Shurin PA, Turczyk VA, Wasikowski DE, Tutihasi MA, Kinney SE. Course and outcome of otitis media in early infancy: a prospective study. *J Pediatr.* 1984;104:826–831
46. Rosenfeld RM, Goldsmith AJ, Tetlus L, Balzano A. Quality of life for children with otitis media. *Arch Otolaryngol Head Neck Surg.* 1997;123:1049–1054
47. Casselbrant ML, Furman JM, Rubenstein E, Mandel EM. Effect of otitis media on the vestibular system in children. *Ann Otol Rhinol Laryngol.* 1995;104:620–624
48. Orlin MN, Effgen SK, Handler SD. Effect of otitis media with effusion on gross motor ability in preschool-aged children: preliminary findings. *Pediatrics.* 1997;99:334–337
49. Golz A, Angel-Yeger B, Parush S. Evaluation of balance disturbances in children with middle ear effusion. *Int J Pediatr Otorhinolaryngol.* 1998;43:21–26
50. Casselbrant ML, Redfern MS, Furman JM, Fall PA, Mandel EM. Visual-induced postural sway in children with and without otitis media. *Ann Otol Rhinol Laryngol.* 1998;107:401–405
51. Ruben R. Host susceptibility to otitis media sequelae. In: Rosenfeld RM, Bluestone CD, eds. *Evidence-Based Otitis Media*. 2nd ed. Hamilton, ON, Canada: BC Decker; 2003:505–514
52. Whiteman BC, Simpson GB, Compton WC. Relationship of otitis media and language impairment on adolescents with Down syndrome. *Ment Retard.* 1986;24:353–356
53. van der Vyver M, van der Merwe A, Tesner HE. The effects of otitis media on articulation in children with cerebral palsy. *Int J Rehabil Res.* 1988;11:386–389
54. Paradise JL, Bluestone CD. Early treatment of the universal otitis media of infants with cleft palate. *Pediatrics.* 1974;53:48–54
55. Schwartz DM, Schwartz RH. Acoustic impedance and otoscopic findings in young children with Down's syndrome. *Arch Otolaryngol.* 1978;104:652–656
56. Corey JP, Caldarelli DD, Gould HJ. Otopathology in cranial facial dysostosis. *Am J Otol.* 1987;8:14–17
57. Schonweiler R, Schonweiler B, Schmelzeisen R. Hearing capacity and speech production in 417 children with facial cleft abnormalities [in German]. *HNO.* 1994;42:691–696
58. Ruben RJ, Math R. Serous otitis media associated with sensorineural hearing loss in children. *Laryngoscope.* 1978;88:1139–1154
59. Brookhouser PE, Worthington DW, Kelly WJ. Middle ear disease in young children with sensorineural hearing loss. *Laryngoscope.* 1993;103:371–378
60. Rice ML. Specific language impairments: in search of diagnostic markers and genetic contributions. *Ment Retard Dev Disabil Res Rev.* 1997;3:350–357
61. Rosenhall U, Nordin V, Sandstrom M, Ahlsen G, Gillberg C. Autism and hearing loss. *J Autism Dev Disord.* 1999;29:349–357
62. Cunningham C, McArthur K. Hearing loss and treatment in young Down's syndrome children. *Child Care Health Dev.* 1981;7:357–374
63. Shott SR, Joseph A, Heithaus D. Hearing loss in children with Down syndrome. *Int J Pediatr Otorhinolaryngol.* 2001;61:199–205
64. Clarkson RL, Eimas PD, Marean GC. Speech perception in children with histories of recurrent otitis media. *J Acoust Soc Am.* 1989;85:926–933
65. Groenen P, Crul T, Maassen B, van Bon W. Perception of voicing cues by children with early otitis media with and without language impairment. *J Speech Hear Res.* 1996;39:43–54
66. Hubbard TW, Paradise JL, McWilliams BJ, Elster BA, Taylor FH. Consequences of unremitting middle-ear disease in early life. Otologic, audiologic, and developmental findings in children with cleft palate. *N Engl J Med.* 1985;312:1529–1534
67. Nunn DR, Derkay CS, Darrow DH, Magee W, Strasnick B. The effect of very early cleft palate closure on the need for ventilation tubes in the first years of life. *Laryngoscope.* 1995;105:905–908
68. Pappas DG, Flexer C, Shackelford L. Otological and habilitative management of children with Down syndrome. *Laryngoscope.* 1994;104:1065–1070
69. Vartiainen E. Otitis media with effusion in children with congenital or early-onset hearing impairment. *J Otolaryngol.* 2000;29:221–223
70. Rosenfeld RM, Kay D. Natural history of untreated otitis media. *Laryngoscope.* 2003;113:1645–1657
71. Teele DW, Klein JO, Rosner BA. Epidemiology of otitis media in children. *Ann Otol Rhinol Laryngol Suppl.* 1980;89:5–6
72. Mygind N, Meistrup-Larsen KI, Thomsen J, Thomsen VF, Josefsson K, Sorensen H. Penicillin in acute otitis media: a double-blind, placebo-controlled trial. *Clin Otolaryngol.* 1981;6:5–13
73. Burke P, Bain J, Robinson D, Dunleavey J. Acute red ear in children: controlled trial of nonantibiotic treatment in general practice. *BMJ.* 1991;303:558–562
74. Fiellau-Nikolajsen M, Lous J. Prospective tympanometry in 3-year-old children. A study of the spontaneous course of tympanometry types in a nonselected population. *Arch Otolaryngol.* 1979;105:461–466
75. Fiellau-Nikolajsen M. Tympanometry in 3-year-old children. Type of care as an epidemiological factor in secretory otitis media and tubal dysfunction in unselected populations of 3-year-old children. *ORL J Otorhinolaryngol Relat Spec.* 1979;41:193–205
76. Tos M. Spontaneous improvement of secretory otitis and impedance screening. *Arch Otolaryngol.* 1980;106:345–349
77. Tos M, Holm-Jensen S, Sorensen CH, Mogensen C. Spontaneous course and frequency of secretory otitis in 4-year-old children. *Arch Otolaryngol.* 1982;108:4–10
78. Roberts JE, Zeisel SA. *Ear Infections and Language Development*. Rockville, MD: American Speech-Language-Hearing Association and the National Center for Early Development and Learning; 2000
79. Roberts JE, Rosenfeld RM, Zeisel SA. Otitis media and speech and language: a meta-analysis of prospective studies. *Pediatrics.* 2004;113(3). Available at: www.pediatrics.org/cgi/content/full/113/3/e238
80. Williams RL, Chalmers TC, Stange KC, Chalmers FT, Bowlin SJ. Use of antibiotics in preventing recurrent otitis media and in treating otitis media with effusion. A meta-analytic attempt to resolve the brouhaha. *JAMA.* 1993;270:1344–1351
81. Rosenfeld RM, Post JC. Meta-analysis of antibiotics for the treatment of otitis media with effusion. *Otolaryngol Head Neck Surg.* 1992;106:378–386
82. Mandel EM, Rockette HE, Bluestone CD, Paradise JL, Nozza RJ. Efficacy of amoxicillin with and without decongestant-antihistamine for otitis media with effusion in children. Results of a double-blind, randomized trial. *N Engl J Med.* 1987;316:432–437
83. McCormick AW, Whitney CG, Farley MM, et al. Geographic diversity and temporal trends of antimicrobial resistance in *Streptococcus pneumoniae* in the United States. *Nat Med.* 2003;9:424–430
84. Levy SB. *The Antibiotic Paradox. How the Misuse of Antibiotic Destroys Their Curative Powers*. Cambridge, MA: Perseus Publishing; 2002
85. Butler CC, van der Voort JH. Oral or topical nasal steroids for hearing loss associated with otitis media with effusion in children. *Cochrane Database Syst Rev.* 2002;4:CD001935
86. Mandel EM, Casselbrant ML, Rockette HE, Fireman P, Kurs-Lasky M, Bluestone CD. Systemic steroid for chronic otitis media with effusion in children. *Pediatrics.* 2002;110:1071–1080
87. Tracy JM, Demain JG, Hoffman KM, Goetz DW. Intranasal beclomethasone as an adjunct to treatment of chronic middle ear effusion. *Ann Allergy Asthma Immunol.* 1998;80:198–206
88. Joint Committee on Infant Hearing. Year 2000 position statement: principles and guidelines for early hearing detection and intervention programs. *Am J Audiol.* 2000;9:9–29
89. Pillsbury HC, Grose JH, Hall JW III. Otitis media with effusion in children. Binaural hearing before and after corrective surgery. *Arch Otolaryngol Head Neck Surg.* 1991;117:718–723
90. Besing J, Koehnke J A test of virtual auditory localization. *Ear Hear.* 1995;16:220–229
91. Jerger S, Jerger J, Alford BR, Abrams S. Development of speech intelligibility in children with recurrent otitis media. *Ear Hear.* 1983;4:138–145
92. Gravel JS, Wallace IF. Listening and language at 4 years of age: effects of early otitis media. *J Speech Hear Res.* 1992;35:588–595
93. Schilder AG, Snik AF, Straatman H, van den Broek P. The effect of otitis media with effusion at preschool age on some aspects of auditory perception at school age. *Ear Hear.* 1994;15:224–231
94. Rosenfeld RM, Madell JR, McMahon A. Auditory function in normal-hearing children with middle ear effusion. In: Lim DJ, Bluestone CD, Casselbrant M, Klein JO, Ogra PL, eds. *Recent Advances in Otitis Media: Proceedings of the 6th International Symposium*. Hamilton, ON, Canada: BC Decker; 1996:354–356

95. Friel-Patti S, Finitzo T. Language learning in a prospective study of otitis media with effusion in the first two years of life. *J Speech Hear Res.* 1990;33:188–194
96. Wallace IF, Gravel JS, McCarton CM, Stapells DR, Bernstein RS, Ruben RJ. Otitis media, auditory sensitivity, and language outcomes at one year. *Laryngoscope.* 1988;98:64–70
97. Roberts JE, Burchinal MR, Medley LP, et al. Otitis media, hearing sensitivity, and maternal responsiveness in relation to language during infancy. *J Pediatr.* 1995;126:481–489
98. Roberts JE, Burchinal MR, Zeisel SA. Otitis media in early childhood in relation to children's school-age language and academic skills. *Pediatrics.* 2002;110:696–706
99. Rovers MM, Straatman H, Ingels K, van der Wilt GJ, van den Broek P, Zielhuis GA. The effect of ventilation tubes on language development in infants with otitis media with effusion: a randomized trial. *Pediatrics.* 2000;106(3). Available at: www.pediatrics.org/cgi/content/full/106/3/e42
100. Paradise JL, Feldman HM, Campbell TF, et al. Early versus delayed insertion of tympanostomy tubes for persistent otitis media: developmental outcomes at the age of three years in relation to prerandomization illness patterns and hearing levels. *Pediatr Infect Dis J.* 2003;22:309–314
101. Kokko E. Chronic secretory otitis media in children. A clinical study. *Acta Otolaryngol Suppl.* 1974;327:1–44
102. Fria TJ, Cantekin EI, Eichler JA. Hearing acuity of children with otitis media with effusion. *Arch Otolaryngol.* 1985;111:10–16
103. Gravel JS, Wallace IF. Effects of otitis media with effusion on hearing in the first three years of life. *J Speech Lang Hear Res.* 2000;43:631–644
104. Roberts JE, Burchinal MR, Zeisel S, et al. Otitis media, the caregiving environment, and language and cognitive outcomes at 2 years. *Pediatrics.* 1998;102:346–354
105. Gravel JS, Wallace IF, Ruben RJ. Early otitis media and later educational risk. *Acta Otolaryngol.* 1995;115:279–281
106. Cunningham M, Cox EO; American Academy of Pediatrics, Committee on Practice and Ambulatory Medicine, Section on Otolaryngology and Bronchoesophagology. Hearing assessment in infants and children: recommendations beyond neonatal screening. *Pediatrics.* 2003;111:436–440
107. American Speech-Language-Hearing Association Panel on Audiologic Assessment. *Guidelines for Audiologic Screening*. Rockville, MD: American Speech-Language-Hearing Association; 1996
108. Rosenfeld RM, Goldsmith AJ, Madell JR. How accurate is parent rating of hearing for children with otitis media? *Arch Otolaryngol Head Neck Surg.* 1998;124:989–992
109. Brody R, Rosenfeld RM, Goldsmith AJ, Madell JR. Parents cannot detect mild hearing loss in children. *Otolaryngol Head Neck Surg.* 1999;121:681–686
110. Catts HW, Fey ME, Zhang X, Tomblin JB. Language basis of reading and reading disabilities: evidence from a longitudinal investigation. *Sci Stud Read.* 1999;3:331–362
111. Johnson CJ, Beitchman JH, Young A, et al. Fourteen-year follow-up of children with and without speech/language impairments: speech/language stability and outcomes. *J Speech Lang Hear Res.* 1999;42:744–760
112. Scarborough H, Dobrich W. Development of children with early language delay. *J Speech Hear Res.* 1990;33:70–83
113. Tomblin JB, Records NL, Buckwalter P, Zhang X, Smith E, O'Brien M. Prevalence of specific language impairment in kindergarten children. *J Speech Lang Hear Res.* 1997;40:1245–1260
114. Glade MJ. *Diagnostic and Therapeutic Technology Assessment: Speech Therapy in Patients With a Prior History of Recurrent Acute or Chronic Otitis Media With Effusion*. Chicago, IL: American Medical Association; 1996:1–14
115. Casby MW. Otitis media and language development: a meta-analysis. *Am J Speech Lang Pathol.* 2001;10:65–80
116. Maw R, Wilks J, Harvey I, Peters TJ, Golding J. Early surgery compared with watchful waiting for glue ear and effect on language development in preschool children: a randomised trial. *Lancet.* 1999;353:960–963
117. Coplan J. *Early Language Milestone Scale*. 2nd ed. Austin, TX: PRO-ED; 1983
118. Fenson L, Dale PS, Reznick JS, et al. *MacArthur Communicative Development Inventories. User's Guide and Technical Manual*. San Diego, CA: Singular Publishing Group; 1993
119. Rescoria L. The Language Development Survey: a screening tool for delayed language in toddlers. *J Speech Hear Dis.* 1989;54:587–599
120. Frankenburg WK, Dodds JA, Faucal A, et al. *Denver Developmental Screening Test II*. Denver, CO: University of Colorado Press; 1990
121. Klee T, Pearce K, Carson DK. Improving the positive predictive value of screening for developmental language disorder. *J Speech Lang Hear Res.* 2000;43:821–833
122. Shekelle PG, Ortiz E, Rhodes S, et al. Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? *JAMA.* 2001;286:1461–1467
123. Zielhuis GA, Straatman H, Rach GH, van den Broek P. Analysis and presentation of data on the natural course of otitis media with effusion in children. *Int J Epidemiol.* 1990;19:1037–1044
124. MRC Multi-centre Otitis Media Study Group. Risk factors for persistence of bilateral otitis media with effusion. *Clin Otolaryngol.* 2001;26:147–156
125. van Balen FA, De Melker RA. Persistent otitis media with effusion: can it be predicted? A family practice follow-up study in children aged 6 months to 6 years. *J Fam Pract.* 2000;49:605–611
126. Sano S, Kamide Y, Schachern PA, Paparella MM. Micropathologic changes of pars tensa in children with otitis media with effusion. *Arch Otolaryngol Head Neck Surg.* 1994;120:815–819
127. Yellon RF, Doyle WJ, Whiteside TL, Diven WF, March AR, Fireman P. Cytokines, immunoglobulins, and bacterial pathogens in middle ear effusions. *Arch Otolaryngol Head Neck Surg.* 1995;121:865–869
128. Maw RA, Bawden R. Tympanic membrane atrophy, scarring, atelectasis and attic retraction in persistent, untreated otitis media with effusion and following ventilation tube insertion. *Int J Pediatr Otorhinolaryngol.* 1994;30:189–204
129. Davis JM, Elfenbein J, Schum R, Bentler RA. Effects of mild and moderate hearing impairment on language, educational, and psychosocial behavior of children. *J Speech Hear Disord.* 1986;51:53–62
130. Carney AE, Moeller MP. Treatment efficacy: hearing loss in children. *J Speech Lang Hear Res.* 1998;41:S61–S84
131. Karchmer MA, Allen TE. The functional assessment of deaf and hard of hearing students. *Am Ann Deaf.* 1999;144:68–77
132. Bess FH, Dodd-Murphy J, Parker RA. Children with minimal sensorineural hearing loss: prevalence, educational performance, and functional status. *Ear Hear.* 1998;19:339–354
133. Roberts JE, Burchinal MR, Jackson SC, et al. Otitis media in early childhood in relation to preschool language and school readiness skills among black children. *Pediatrics.* 2000;106:725–735
134. Haggard MP, Birkin JA, Browning GG, Gatehouse S, Lewis S. Behavior problems in otitis media. *Pediatr Infect Dis J.* 1994;13:S43–S50
135. Bennett KE, Haggard MP. Behaviour and cognitive outcomes from middle ear disease. *Arch Dis Child.* 1999;80:28–35
136. Bennett KE, Haggard MP, Silva PA, Stewart IA. Behaviour and developmental effects of otitis media with effusion into the teens. *Arch Dis Child.* 2001;85:91–95
137. Wilks J, Maw R, Peters TJ, Harvey I, Golding J. Randomised controlled trial of early surgery versus watchful waiting for glue ear: the effect on behavioural problems in pre-school children. *Clin Otolaryngol.* 2000;25:209–214
138. Rosenfeld RM, Bhaya MH, Bower CM, et al. Impact of tympanostomy tubes on child quality of life. *Arch Otolaryngol Head Neck Surg.* 2000;126:585–592
139. Rosenfeld RM, Bluestone CD. Clinical efficacy of surgical therapy. In: Rosenfeld RM, Bluestone CD, eds. *Evidence-Based Otitis Media*. 2nd ed. Hamilton, ON, Canada: BC Decker; 2003:227–240
140. Kuyvenhoven MM, De Melker RA. Referrals to specialists. An exploratory investigation of referrals by 13 general practitioners to medical and surgical departments. *Scand J Prim Health Care.* 1990;8:53–57
141. Haldis TA, Blankenship JC. Telephone reporting in the consultant-generalist relationship. *J Eval Clin Pract.* 2002;8:31–35
142. Reichman S. The generalist's patient and the subspecialist. *Am J Manag Care.* 2002;8:79–82
143. Gates GA, Avery CA, Prihoda TJ, Cooper JC Jr. Effectiveness of adenoidectomy and tympanostomy tubes in the treatment of chronic otitis media with effusion. *N Engl J Med.* 1987;317:1444–1451
144. Mandel EM, Rockette HE, Bluestone CD, Paradise JL, Nozza RJ. Myringotomy with and without tympanostomy tubes for chronic otitis media with effusion. *Arch Otolaryngol Head Neck Surg.* 1989;115:1217–1224
145. Mandel EM, Rockette HE, Bluestone CD, Paradise JL, Nozza RJ. Efficacy of myringotomy with and without tympanostomy tubes for chronic otitis media with effusion. *Pediatr Infect Dis J.* 1992;11:270–277
146. University of York Centre for Reviews and Dissemination. The treatment of persistent glue ear in children. *Eff Health Care.* 1992;4:1–16
147. Rovers MM, Straatman H, Ingels K, van der Wilt GJ, van den Broek P, Zielhuis GA. The effect of short-term ventilation tubes versus watchful waiting on hearing in young children with persistent otitis media with effusion: a randomized trial. *Ear Hear.* 2001;22:191–199

148. Paradise JL, Bluestone CD, Colborn DK, et al. Adenoidectomy and adenotonsillectomy for recurrent acute otitis media: parallel randomized clinical trials in children not previously treated with tympanostomy tubes. *JAMA.* 1999;282:945–953
149. Boston M, McCook J, Burke B, Derkay C. Incidence of and risk factors for additional tympanostomy tube insertion in children. *Arch Otolaryngol Head Neck Surg.* 2003;129:293–296
150. Coyte PC, Croxford R, McIsaac W, Feldman W, Friedberg J. The role of adjuvant adenoidectomy and tonsillectomy in the outcome of insertion of tympanostomy tubes. *N Engl J Med.* 2001;344:1188–1195
151. Paradise JL, Bluestone CD, Rogers KD, et al. Efficacy of adenoidectomy for recurrent otitis media in children previously treated with tympanostomy-tube placement. Results of parallel randomized and nonrandomized trials. *JAMA.* 1990;263:2066–2073
152. Maw AR. Chronic otitis media with effusion (glue ear) and adenotonsillectomy: prospective randomised controlled study. *Br Med J (Clin Res Ed).* 1983;287:1586–1588
153. Cohen D, Schechter Y, Slatkine M, Gatt N, Perez R. Laser myringotomy in different age groups. *Arch Otolaryngol Head Neck Surg.* 2001;127: 260–264
154. Holzman RS. Morbidity and mortality in pediatric anesthesia. *Pediatr Clin North Am.* 1994;41:239–256
155. Cottrell JE, Golden S. *Under the Mask: A Guide to Feeling Secure and Comfortable During Anesthesia and Surgery*. New Brunswick, NJ: Rutgers University Press; 2001
156. Kay DJ, Nelson M, Rosenfeld RM. Meta-analysis of tympanostomy tube sequelae. *Otolaryngol Head Neck Surg.* 2001;124:374–380
157. Crysdale WS, Russel D. Complications of tonsillectomy and adenoidectomy in 9409 children observed overnight. *CMAJ.* 1986;135: 1139–1142
158. Harrison H, Fixsen A, Vickers A. A randomized comparison of homeopathic and standard care for the treatment of glue ear in children. *Complement Ther Med.* 1999;7:132–135
159. Sawyer CE, Evans RL, Boline PD, Branson R, Spicer A. A feasibility study of chiropractic spinal manipulation versus sham spinal manipulation for chronic otitis media with effusion in children. *J Manipulative Physiol Ther.* 1999;22:292–298
160. Ernst E. Serious adverse effects of unconventional therapies for children and adolescents: a systematic review of recent evidence. *Eur J Pediatr.* 2003;162:72–80
161. Cohen MH, Eisenberg DM. Potential physician malpractice liability associated with complementary and integrative medical therapies. *Ann Intern Med.* 2002;136:596–603
162. Mullins RJ, Heddle R. Adverse reactions associated with echinacea: the Australian experience. *Ann Allergy Asthma Immunol.* 2002;88:42–51
163. Miller LG, Hume A, Harris IM, et al. White paper on herbal products. American College of Clinical Pharmacy. *Pharmacotherapy.* 2000;20: 877–891
164. Angell M, Kassirer JP. Alternative medicine—the risks of untested and unregulated remedies. *N Engl J Med.* 1998;339:839–841
165. Fallon JM. The role of chiropractic adjustment in the care and treatment of 332 children with otitis media. *J Clin Chiropractic Pediatr.* 1997;2:167–183
166. Shafrir Y, Kaufman BA. Quadriplegia after chiropractic manipulation in an infant with congenital torticollis caused by a spinal cord astrocytoma. *J Pediatr.* 1992;120:266–269
167. Corey JP, Adham RE, Abbass AH, Seligman I. The role of IgE-mediated hypersensitivity in otitis media with effusion. *Am J Otolaryngol.* 1994;15:138–144
168. Bernstein JM. Role of allergy in eustachian tube blockage and otitis media with effusion: a review. *Otolaryngol Head Neck Surg.* 1996;114: 562–568
169. Ishii TM, Toriyama M, Suzuki JI. Histopathological study of otitis media with effusion. *Ann Otol Rhinol Laryngol.* 1980;89(suppl):83–86
170. Hurst DS, Venge P. Evidence of eosinophil, neutrophil, and mast-cell mediators in the effusion of OME patients with and without atopy. *Allergy.* 2000;55:435–441
171. Hurst DS, Venge P. The impact of atopy on neutrophil activity in middle ear effusion from children and adults with chronic otitis media. *Arch Otolaryngol Head Neck Surg.* 2002;128:561–566
172. Hurst DS. Allergy management of refractory serous otitis media. *Otolaryngol Head Neck Surg.* 1990;102:664–669

Otitis Media Clinical Practice Guidelines
Quick Reference Tools

- Action Statement Summary
  — The Diagnosis and Management of Acute Otitis Media
  — Otitis Media With Effusion
- *ICD-10-CM* Coding Quick Reference for Otitis Media
- Bonus Feature
  — Continuum Model for Otitis Media
- AAP Patient Education Handouts
  — *Acute Ear Infections and Your Child*
  — *Middle Ear Fluid and Your Child*

Action Statement Summary

The Diagnosis and Management of Acute Otitis Media

Key Action Statement 1A
Clinicians should diagnose acute otitis media (AOM) in children who present with moderate to severe bulging of the tympanic membrane (TM) *or* new onset of otorrhea not due to acute otitis externa. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 1B
Clinicians should diagnose AOM in children who present with mild bulging of the TM *and* recent (less than 48 hours) onset of ear pain (holding, tugging, rubbing of the ear in a nonverbal child) or intense erythema of the TM. Evidence Quality: Grade C. Strength: Recommendation.

Key Action Statement 1C
Clinicians should not diagnose AOM in children who do not have middle ear effusion (MEE) (based on pneumatic otoscopy and/or tympanometry). Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 2
The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 3A
Severe AOM: The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children 6 months and older with severe signs or symptoms (ie, moderate or severe otalgia or otalgia for at least 48 hours or temperature 39°C [102.2°F] or higher). Evidence Quality: Grade B. Strength: Strong Recommendation.

Key Action Statement 3B
Nonsevere bilateral AOM in young children: The clinician should prescribe antibiotic therapy for bilateral AOM in children 6 months through 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 3C
Nonsevere unilateral AOM in young children: The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for unilateral AOM in children 6 months to 23 months of age without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 3D
Nonsevere AOM in older children: The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for AOM (bilateral or unilateral) in children 24 months or older without severe signs or symptoms (ie, mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 4A
Clinicians should prescribe amoxicillin for AOM when a decision to treat with antibiotics has been made *and* the child has not received amoxicillin in the past 30 days *or* the child does not have concurrent purulent conjunctivitis *or* the child is not allergic to penicillin. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 4B
Clinicians should prescribe an antibiotic with additional β-lactamase coverage for AOM when a decision to treat with antibiotics has been made, *and* the child has received amoxicillin in the last 30 days *or* has concurrent purulent conjunctivitis, *or* has a history of recurrent AOM unresponsive to amoxicillin. Evidence Quality: Grade C. Strength: Recommendation.

Key Action Statement 4C
Clinicians should reassess the patient if the caregiver reports that the child's symptoms have worsened or failed to respond to the initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 5A
Clinicians should not prescribe prophylactic antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM. Evidence Quality: Grade B. Strength: Recommendation.

Key Action Statement 5B
Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months or 4 episodes in 1 year with 1 episode in the preceding 6 months). Evidence Quality: Grade B. Strength: Option.

Key Action Statement 6A
Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices of the Centers for Disease Control and prevention, American Academy of Pediatrics (AAP), and American Academy of Family Physicians (AAFP). Evidence Quality: Grade B. Strength: Strong Recommendation.

Otitis Media With Effusion

1A. Pneumatic Otoscopy
Clinicians should use pneumatic otoscopy as the primary diagnostic method for OME, and OME should be distinguished from AOM.

This is a strong recommendation based on systematic review of cohort studies and the preponderance of benefit over harm.

1B. Tympanometry
Tympanometry can be used to confirm the diagnosis a of OME.

This option is based on cohort studies and a balance of benefit and harm.

1C. Screening
Population-based screening programs for OME are not recommended in healthy, asymptomatic children.

This recommendation is based on randomized, controlled trials and cohort studies, with a preponderance of harm over benefit.

2. Documentation
Clinicians should document the laterality, duration of effusion, and presence and severity of associated symptoms at each assessment of the child with OME.

This recommendation is based on observational studies and strong preponderance of benefit over harm.

3. Child at Risk
Clinicians should distinguish the child with OME who is at risk for speech, language, or learning problems from other children with OME and should evaluate hearing, speech, language, and need for intervention more promptly.

This recommendation is based on case series, the preponderance of benefit over harm, and ethical limitations in studying children with OME who are at risk.

4. Watchful Waiting
Clinicians should manage the child with OME who is not at risk with watchful waiting for 3 months from the date of effusion onset (if known) or diagnosis (if onset is unknown).

This recommendation is based on systematic review of cohort studies and the preponderance of benefit over harm.

5. Medication
Antihistamines and decongestants are ineffective for OME and are not recommended for treatment; antimicrobials and corticosteroids do not have long-term efficacy and are not recommended for routine management.

This recommendation is based on systematic review of randomized, controlled trials and the preponderance of harm over benefit.

6. Hearing and Language
Hearing testing is recommended when OME persists for 3 months or longer or at any time that language delay, learning problems, or a significant hearing loss is suspected in a child with OME; language testing should be conducted for children with hearing loss.

This recommendation is based on cohort studies and the preponderance of benefit over risk.

7. Surveillance
Children with persistent OME who are not at risk should be reexamined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected.

This recommendation is based on randomized, controlled trials and observational studies with a preponderance of benefit over harm.

8. Referral
When children with OME are referred by the primary care clinician for evaluation by an otolaryngologist, audiologist, or speech-language pathologist, the referring clinician should document the effusion duration and specific reason for referral (evaluation, surgery) and provide additional relevant information such as history of AOM and developmental status of the child.

This option is based on panel consensus and a preponderance of benefit over harm.

9. Surgery
When a child becomes a surgical candidate, tympanostomy tube insertion is the preferred initial procedure; adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis). Repeat surgery consists of adenoidectomy plus myringotomy, with or without tube insertion. tonsillectomy alone or myringotomy alone should not be used to treat OME.

This recommendation is based on randomized, controlled trials with a preponderance of benefit over harm.

10. CAM
No recommendation is made regarding CAM as a treatment for OME.

There is no recommendation based on lack of scientific evidence documenting efficacy and an uncertain balance of harm and benefit.

11. Allergy Management
No recommendation is made regarding allergy management as a treatment for OME.

There is no recommendation based on insufficient evidence of therapeutic efficacy or a causal relationship between allergy and OME.

Coding Quick Reference for Otitis Media

ICD-10-CM

H65.01	Acute serous otitis media, right ear
H65.02	Left ear
H65.03	Bilateral
H65.04	Recurrent, right ear
H65.05	Recurrent, left ear
H65.06	Recurrent, bilateral
H65.21	Chronic serous otitis media, right ear
H65.22	Left ear
H65.23	Bilateral
H65.91	Unspecified nonsuppurative otitis media, right ear
H65.92	Left ear
H65.93	Bilateral
H66.001	Acute suppurative otitis media without spontaneous rupture of ear drum, right ear
H66.002	Left ear
H66.003	Bilateral
H66.004	Recurrent, right ear
H66.005	Recurrent, left ear
H66.006	Recurrent, bilateral
H66.011	Acute suppurative otitis media with spontaneous rupture of ear drum, right ear
H66.012	Left ear
H66.013	Bilateral
H66.014	Recurrent, right ear
H66.015	Recurrent, left ear
H66.016	Recurrent, bilateral
H67.1	Otitis media in diseases classified elsewhere, right ear
H67.2	Left ear
H67.3	Bilateral
H66.3X1	Other chronic suppurative otitis media, right ear
H66.3X2	Left ear
H66.3X3	Bilateral

Continuum Model for Otitis Media

*Code selection at any level above **99211** may be based on the complexity of MDM or the total time spent by the physician or other qualified health care professional on the date of the encounter. (Code **99211** is not included due to lack of indication for follow-up by clinical staff.)*

***CPT* Code With Total Physician Time and Vignette**	**MDM (2 of 3 elements required)**		
	Number and Complexity of Problems Addressed	**Amount and/or Complexity of Data Reviewed and Analyzed**	**Risk of Complications and/or Morbidity or Mortality of Patient Management**
99212 (Time: 10–19 min) Follow-up otitis media, uncomplicated	**Minimal:** Follow-up otitis media, evaluation of effusion and hearing	**Limited:** Assessment requiring an independent historian	**Minimal:** Risk associated with diagnostic testing and treatment
99213 (Time: 20–29 min) 2-year-old presents with tugging at her right ear. Afebrile. Mild otitis media.	**Low:** 1 acute, uncomplicated illness or injury	**Limited:** Assessment requiring an independent historian	**Moderate:** Prescription drug management, delayed prescribing
99214 (Time: 30–39 min) Infant presents with fever and cough and suspected third episode of otitis media within 3 months.	**Moderate:** 1 acute illness with systemic symptoms	**Limited:** Assessment requiring an independent historian	**Moderate:** Prescription drug management
99215 (Time: 40–54 min) 6-month-old presents with high fever, vomiting, and irritability. After tests, antipyretics, and fluid, infant is stable.	**High:** 1 acute illness that poses a threat to life or bodily function	**Limited:** Assessment requiring an independent historian or **Moderate:** If 2 or more tests are ordered from an external source and assessment requiring an independent historian	**High:** Decision about hospitalization (Hospitalization discussed with parents and decision made for care at home with strict instructions and close follow-up.)

Abbreviations: *CPT*, *Current Procedural Terminology*; MDM, medical decision-making.

Acute Ear Infections and Your Child

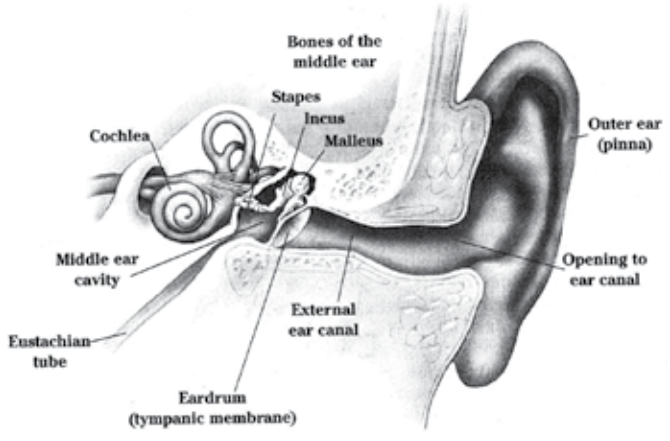
Next to the common cold, an ear infection is the most common childhood illness. In fact, most children have at least one ear infection by the time they are 3 years old. Many ear infections clear up without causing any lasting problems.

The following is information from the American Academy of Pediatrics about the symptoms, treatments, and possible complications of acute *otitis media*, a common infection of the middle ear.

How do ear infections develop?

The ear has 3 parts—the outer ear, middle ear, and inner ear. A narrow channel (eustachian tube) connects the middle ear to the back of the nose. When a child has a cold, nose or throat infection, or allergy, the mucus and fluid can enter the eustachian tube causing a buildup of fluid in the middle ear. If bacteria or a virus infects this fluid, it can cause swelling and pain in the ear. This type of ear infection is called *acute otitis media* (*middle ear inflammation*).

Often after the symptoms of acute otitis media clear up, fluid remains in the ear, creating another kind of ear problem called *otitis media with effusion* (*middle ear fluid*). This condition is harder to detect than acute otitis media because except for the fluid and usually some mild hearing loss, there is often no pain or other symptoms present. This fluid may last several months and, in most cases, disappears on its own. The child's hearing then returns to normal.



Cross-Section of the Ear

Is my child at risk for developing an ear infection?

Risk factors for developing childhood ear infections include

- **Age.** Infants and young children are more likely to get ear infections than older children. The size and shape of an infant's eustachian tube makes it easier for an infection to develop. Ear infections occur most often in children between 6 months and 3 years of age. Also, the younger a child is at the time of the first ear infection, the greater the chance he will have repeated infections.
- **Family history.** Ear infections can run in families. Children are more likely to have repeated middle ear infections if a parent or sibling also had repeated ear infections.
- **Colds.** Colds often lead to ear infections. Children in group child care settings have a higher chance of passing their colds to each other because they are exposed to more viruses from the other children.
- **Tobacco smoke.** Children who breathe in someone else's tobacco smoke have a higher risk of developing health problems, including ear infections.

How can I reduce the risk of an ear infection?

Some things you can do to help reduce your child's risk of getting an ear infection are

- Breastfeed instead of bottle-feed. Breastfeeding may decrease the risk of frequent colds and ear infections.
- Keep your child away from tobacco smoke, especially in your home or car.
- Throw away pacifiers or limit to daytime use, *if your child is older than 1 year*.
- Keep vaccinations up to date. Vaccines against bacteria (such as pneumococcal vaccine) and viruses (such as influenza vaccine) reduce the number of ear infections in children with frequent infections.

What are the symptoms of an ear infection?

Your child may have many symptoms during an ear infection. Talk with your pediatrician about the best way to treat your child's symptoms.

- **Pain.** The most common symptom of an ear infection is pain. Older children can tell you that their ears hurt. Younger children may only seem irritable and cry. You may notice this more during feedings because sucking and swallowing may cause painful pressure changes in the middle ear.
- **Loss of appetite.** Your child may have less of an appetite because of the ear pain.
- **Trouble sleeping.** Your child may have trouble sleeping because of the ear pain.
- **Fever.** Your child may have a temperature ranging from 100°F (normal) to 104°F.

- **Ear drainage.** You might notice yellow or white fluid, possibly blood-tinged, draining from your child's ear. The fluid may have a foul odor and will look different from normal earwax (which is orange-yellow or reddish-brown). Pain and pressure often decrease after this drainage begins, but this doesn't always mean that the infection is going away. If this happens it's not an emergency, but your child will need to see your pediatrician.
- **Trouble hearing.** During and after an ear infection, your child may have trouble hearing for several weeks. This occurs because the fluid behind the eardrum gets in the way of sound transmission. This is usually temporary and clears up after the fluid from the middle ear drains away.

Important: Your doctor *cannot* diagnose an ear infection over the phone; your child's eardrum must be examined by your doctor to confirm fluid buildup and signs of inflammation.

What causes ear pain?

There are other reasons why your child's ears may hurt besides an ear infection. The following can cause ear pain:

- An infection of the skin of the ear canal, often called "swimmer's ear"
- Reduced pressure in the middle ear from colds or allergies
- A sore throat
- Teething or sore gums
- Inflammation of the eardrum alone during a cold (without fluid buildup)

How are ear infections treated?

Because pain is often the first and most uncomfortable symptom of an ear infection, it's important to help comfort your child by giving her pain medicine. Acetaminophen and ibuprofen are over-the-counter (OTC) pain medicines that may help decrease much of the pain. Be sure to use the right dosage for your child's age and size. *Don't give aspirin to your child.* It has been associated with Reye syndrome, a disease that affects the liver and brain. There are also ear drops that may relieve ear pain for a short time. Ask your pediatrician whether these drops should be used. There is no need to use OTC cold medicines (decongestants and antihistamines), because they don't help clear up ear infections.

Not all ear infections require antibiotics. Some children who don't have a high fever and aren't severely ill may be observed without antibiotics. In most cases, pain and fever will improve in the first 1 to 2 days.

If your child is younger than 2 years, has drainage from the ear, has a fever higher than 102.5°F, seems to be in a lot of pain, is unable to sleep, isn't eating, or is acting ill, it's important to call your pediatrician. If your child is older than 2 years and your child's symptoms are mild, you may wait a couple of days to see if she improves.

Your child's ear pain and fever should improve or go away within 3 days of their onset. If your child's condition doesn't improve within 3 days, or worsens at any time, call your pediatrician. Your pediatrician may wish to see your child and may prescribe an antibiotic to take by mouth, if one wasn't given initially. If an antibiotic was already started, your child may need a different antibiotic. Be sure to follow your pediatrician's instructions closely.

If an antibiotic was prescribed, make sure your child finishes the entire prescription. If you stop the medicine too soon, some of the bacteria that caused the ear infection may still be present and cause an infection to start all over again.

As the infection starts to clear up, your child might feel a "popping" in the ears. This is a normal sign of healing. Children with ear infections don't need to stay home if they are feeling well, as long as a child care provider or someone at school can give them their medicine properly, if needed. If your child needs to travel in an airplane, or wants to swim, contact your pediatrician for specific instructions.

What are signs of hearing problems?

Because your child can have trouble hearing without other symptoms of an ear infection, watch for the following changes in behavior (especially during or after a cold):

- Talking more loudly or softly than usual
- Saying "huh?" or "what?" more than usual
- Not responding to sounds
- Having trouble understanding speech in noisy rooms
- Listening with the TV or radio turned up louder than usual

If you think your child may have difficulty hearing, call your pediatrician. Being able to hear and listen to others talk helps a child learn speech and language. This is especially important during the first few years of life.

Are there complications from ear infections?

Although it's very rare, complications from ear infections can develop, including the following:

- An infection of the inner ear that causes dizziness and imbalance (labyrinthitis)
- An infection of the skull behind the ear (mastoiditis)
- Scarring or thickening of the eardrum
- Loss of feeling or movement in the face (facial paralysis)
- Permanent hearing loss

It's normal for children to have several ear infections when they are young—even as many as 2 separate infections within a few months. Most ear infections that develop in children are minor. Recurring ear infections may be a nuisance, but they usually clear up without any lasting problems. With proper care and treatment, ear infections can usually be managed successfully. But, if your child has one ear infection after another for several months, you may want to talk about other treatment options with your pediatrician.

From your doctor

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 66,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site — www.HealthyChildren.org

Middle Ear Fluid and Your Child

The *middle* ear is the space behind the eardrum that is usually filled with air. When a child has middle ear fluid (otitis media with effusion), it means that a watery or mucus-like fluid has collected in the middle ear. *Otitis media* means *middle ear inflammation*, and *effusion* means *fluid*.

Middle ear fluid is **not** the same as an ear infection. An ear infection occurs when middle ear fluid is infected with viruses, bacteria, or both, often during a cold. Children with middle ear fluid have no signs or symptoms of infection. Most children don't have fever or severe pain, but may have mild discomfort or trouble hearing. About 90% of children get middle ear fluid at some time before age 5.

The following is information from the American Academy of Pediatrics about the causes, symptoms, risk reduction, testing, and treatments for middle ear fluid, as well as how middle ear fluid may affect your child's learning.

What causes middle ear fluid?

There is no one cause for middle ear fluid. Often your child's doctor may not know the cause. Middle ear fluid could be caused by

- A past ear infection
- A cold or flu
- Blockage of the eustachian tube (a narrow channel that connects the middle ear to the back of the nose)

What are the symptoms of middle ear fluid?

Many healthy children with middle ear fluid have little or no problems. They usually get better on their own. Often middle ear fluid is found at a regular checkup. Ear discomfort, if present, is usually mild. Your child may be irritable, rub his ears, or have trouble sleeping. Other symptoms include hearing loss, irritability, sleep problems, clumsiness, speech or language problems, and poor school performance. You may notice your child sitting closer to the TV or turning the sound up louder than usual. Sometimes it may seem like your child isn't paying attention to you, especially when at the playground or in a noisy environment.

Talk with your child's doctor if you are concerned about your child's hearing. Keep a record of your child's ear problems. Write down your child's name, child's doctor's name and number, date and type of ear problem or infection, treatment, and results. This may help your child's doctor find the cause of the middle ear fluid.

Can middle ear fluid affect my child's learning?

Some children with middle ear fluid are at risk for delays in speaking or may have problems with learning or schoolwork, especially children with

- Permanent hearing loss not caused by middle ear fluid
- Speech and language delays or disorders
- Developmental delay of social and communication skills disorders (for example, autism spectrum disorders)
- Syndromes that affect cognitive, speech, and language delays (for example, Down syndrome)
- Craniofacial disorders that affect cognitive, speech, and language delays (for example, cleft palate)
- Blindness or visual loss that can't be corrected

If your child is at risk and has ongoing middle ear fluid, her hearing, speech, and language should be checked.

How can I reduce the risk of middle ear fluid?

Children who live with smokers, attend group child care, or use pacifiers have more ear infections. Because some children who have middle ear infections later get middle ear fluid, you may want to

- Keep your child away from tobacco smoke.
- Keep your child away from children who are sick.
- Throw away pacifiers or limit to daytime use, *if your child is older than 1 year.*

Are there special tests to check for middle ear fluid?

Two tests that can check for middle ear fluid are *pneumatic otoscopy* and *tympanometry*. A pneumatic otoscope is the recommended test for middle ear fluid. With this tool, the doctor looks at the eardrum and uses air to see how well the eardrum moves. Tympanometry is another test for middle ear fluid that uses sound to see how well the eardrum moves. An eardrum with fluid behind it doesn't move as well as a normal eardrum. Your child must sit still for both tests; the tests are painless.

Because these tests don't check hearing level, a hearing test may be given, if needed. Hearing tests measure how well your child hears. Although hearing tests don't test for middle ear fluid, they can measure if the fluid is affecting your child's hearing level. The type of hearing test given depends on your child's age and ability to participate.

How can middle ear fluid be treated?

Middle ear fluid can be treated in several ways. Treatment options include observation and tube surgery or adenoid surgery. Because a treatment that works for one child may not work for another, your child's doctor can help you decide which treatment is best for your child and when you should see an ear, nose, and throat (ENT) specialist. If one treatment doesn't work, another treatment can be tried. Ask your child's doctor or ENT specialist about the costs, advantages, and disadvantages of each treatment.

When should middle ear fluid be treated?

Your child is more likely to need treatment for middle ear fluid if she has any of the following:

- Conditions placing her at risk for developmental delays (see "Can middle ear fluid affect my child's learning?")
- Fluid in both ears, especially if present more than 3 months
- Hearing loss or other significant symptoms (see "What are the symptoms of middle ear fluid?")

What treatments are not recommended?

A number of treatments are **not** recommended for young children with middle ear fluid.

- **Medicines** not recommended include antibiotics, decongestants, antihistamines, and steroids (by mouth or in nasal sprays). All of these have side effects and do not cure middle ear fluid.
- **Surgical treatments** not recommended include myringotomy (draining of fluid without placing a tube) and tonsillectomy (removal of the tonsils). If your child's doctor or ENT specialist suggests one of these surgeries, it may be for another medical reason. Ask your doctor why your child needs the surgery.

What about other treatment options?

There is no evidence that complementary and alternative medicine treatments or that treatment for allergies works to decrease middle ear fluid. Some of these treatments may be harmful and many are expensive.

From your doctor

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 66,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site— www.HealthyChildren.org

Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years

- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*

See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE

Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years

abstract

FREE

OBJECTIVE: To update the American Academy of Pediatrics clinical practice guideline regarding the diagnosis and management of acute bacterial sinusitis in children and adolescents.

METHODS: Analysis of the medical literature published since the last version of the guideline (2001).

RESULTS: The diagnosis of acute bacterial sinusitis is made when a child with an acute upper respiratory tract infection (URI) presents with (1) persistent illness (nasal discharge [of any quality] or daytime cough or both lasting more than 10 days without improvement), (2) a worsening course (worsening or new onset of nasal discharge, daytime cough, or fever after initial improvement), or (3) severe onset (concurrent fever [temperature ≥39°C/102.2°F] and purulent nasal discharge for at least 3 consecutive days). Clinicians should not obtain imaging studies of any kind to distinguish acute bacterial sinusitis from viral URI, because they do not contribute to the diagnosis; however, a contrast-enhanced computed tomography scan of the paranasal sinuses should be obtained whenever a child is suspected of having orbital or central nervous system complications. The clinician should prescribe antibiotic therapy for acute bacterial sinusitis in children with severe onset or worsening course. The clinician should either prescribe antibiotic therapy or offer additional observation for 3 days to children with persistent illness. Amoxicillin with or without clavulanate is the first-line treatment of acute bacterial sinusitis. Clinicians should reassess initial management if there is either a caregiver report of worsening (progression of initial signs/symptoms or appearance of new signs/symptoms) or failure to improve within 72 hours of initial management. If the diagnosis of acute bacterial sinusitis is confirmed in a child with worsening symptoms or failure to improve, then clinicians may change the antibiotic therapy for the child initially managed with antibiotic or initiate antibiotic treatment of the child initially managed with observation.

CONCLUSIONS: Changes in this revision include the addition of a clinical presentation designated as "worsening course," an option to treat immediately or observe children with persistent symptoms for 3 days before treating, and a review of evidence indicating that imaging is not necessary in children with uncomplicated acute bacterial sinusitis. *Pediatrics* 2013;132:e262–e280

Ellen R. Wald, MD, FAAP, Kimberly E. Applegate, MD, MS, FAAP, Clay Bordley, MD, FAAP, David H. Darrow, MD, DDS, FAAP, Mary P. Glode, MD, FAAP, S. Michael Marcy, MD, FAAP, Carrie E. Nelson, MD, MS, Richard M. Rosenfeld, MD, FAAP, Nader Shaikh, MD, MPH, FAAP, Michael J. Smith, MD, MSCE, FAAP, Paul V. Williams, MD, FAAP, and Stuart T. Weinberg, MD, FAAP

KEY WORDS

acute bacterial sinusitis, sinusitis, antibiotics, imaging, sinus aspiration

ABBREVIATIONS

AAP—American Academy of Pediatrics
AOM—acute otitis media
CT—computed tomography
PCV-13—13-valent pneumococcal conjugate vaccine
RABS—recurrent acute bacterial sinusitis
RCT—randomized controlled trial
URI—upper respiratory tract infection

www.pediatrics.org/cgi/doi/10.1542/peds.2013-1071

doi:10.1542/peds.2013-1071

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

INTRODUCTION

Acute bacterial sinusitis is a common complication of viral upper respiratory infection (URI) or allergic inflammation. Using stringent criteria to define acute sinusitis, it has been observed that between 6% and 7% of children seeking care for respiratory symptoms has an illness consistent with this definition.[1–4]

This clinical practice guideline is a revision of the clinical practice guideline published by the American Academy of Pediatrics (AAP) in 2001.[5] It has been developed by a subcommittee of the Steering Committee on Quality Improvement and Management that included physicians with expertise in the fields of primary care pediatrics, academic general pediatrics, family practice, allergy, epidemiology and informatics, pediatric infectious diseases, pediatric otolaryngology, radiology, and pediatric emergency medicine. None of the participants had financial conflicts of interest, and only money from the AAP was used to fund the development of the guideline. The guideline will be reviewed in 5 years unless new evidence emerges that warrants revision sooner.

The guideline is intended for use in a variety of clinical settings (eg, office, emergency department, hospital) by clinicians who treat pediatric patients. The data on which the recommendations are based are included in a companion technical report, published in the electronic pages.[6] The Partnership for Policy Implementation has developed a series of definitions using accepted health information technology standards to assist in the implementation of this guideline in computer systems and quality measurement efforts. This document is available at: http://www2.aap.org/informatics/PPI.html.

This revision focuses on the diagnosis and management of acute sinusitis in children between 1 and 18 years of age. It does not apply to children with subacute or chronic sinusitis. Similar to the previous guideline, this document does not consider neonates and children younger than 1 year or children with anatomic abnormalities of the sinuses, immunodeficiencies, cystic fibrosis, or primary ciliary dyskinesia. The most significant areas of change from the 2001 guideline are in the addition of a clinical presentation designated as "worsening course," inclusion of new data on the effectiveness of antibiotics in children with acute sinusitis,[4] and a review of evidence indicating that imaging is not necessary to identify those children who will benefit from antimicrobial therapy.

METHODS

The Subcommittee on Management of Sinusitis met in June 2009 to identify research questions relevant to guideline revision. The primary goal was to update the 2001 report by identifying and reviewing additional studies of pediatric acute sinusitis that have been performed over the past decade.

Searches of PubMed were performed by using the same search term as in the 2001 report. All searches were limited to English-language and human studies. Three separate searches were performed to maximize retrieval of the most recent and highest-quality evidence for pediatric sinusitis. The first limited results to all randomized controlled trials (RCTs) from 1966 to 2009, the second to all meta-analyses from 1966 to 2009, and the third to all pediatric studies (limited to ages <18 years) published since the last technical report (1999–2009). Additionally, the Web of Science was queried to identify studies that cited the original AAP guidelines. This literature search was replicated in July 2010

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed RCTs or diagnostic studies on relevant population	Strong Recommendation	Option
B. RCTs or diagnostic studies with minor limitations;overwhelmingly consistent evidence from observational studies	Recommendation	
C. Observational studies (case-control and cohort design)		
D. Expert opinion, case reports, reasoning from first principles	Option	No Rec
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Strong Recommendation / Recommendation	

FIGURE 1
Levels of recommendations. Rec, recommendation.

and November 2012 to capture recently published studies. The complete results of the literature review are published separately in the technical report.[6] In summary, 17 randomized studies of sinusitis in children were identified and reviewed. Only 3 trials met inclusion criteria. Because of significant heterogeneity among these studies, formal meta-analyses were not pursued.

The results from the literature review were used to guide development of the key action statements included in this document. These action statements were generated by using BRIDGE-Wiz (Building Recommendations in a Developers Guideline Editor, Yale School of Medicine, New Haven, CT), an interactive software tool that leads guideline development through a series of questions that are intended to create a more actionable set of key action statements.[7] BRIDGE-Wiz also incorporates the quality of available evidence into the final determination of the strength of each recommendation.

The AAP policy statement "Classifying Recommendations for Clinical Practice Guidelines" was followed in designating levels of recommendations (Fig 1).[8] Definitions of evidence-based statements are provided in Table 1. This guideline was reviewed by multiple groups in the AAP and 2 external organizations. Comments were compiled and reviewed by the subcommittee, and relevant changes were incorporated into the guideline.

KEY ACTION STATEMENTS

Key Action Statement 1

Clinicians should make a presumptive diagnosis of acute bacterial sinusitis when a child with an acute URI presents with the following:

- **Persistent illness, ie, nasal discharge (of any quality) or daytime cough or both lasting more than 10 days without improvement;**

OR

- **Worsening course, ie, worsening or new onset of nasal discharge, daytime cough, or fever after initial improvement;**

OR

- **Severe onset, ie, concurrent fever (temperature ≥39°C/102.2°F) and purulent nasal discharge for at least 3 consecutive days (Evidence Quality: B; Recommendation).**

KAS Profile 1

Aggregate evidence quality: B	
Benefit	Diagnosis allows decisions regarding management to be made. Children likely to benefit from antimicrobial therapy will be identified.
Harm	Inappropriate diagnosis may lead to unnecessary treatment. A missed diagnosis may lead to persistent infection or complications
Cost	Inappropriate diagnosis may lead to unnecessary cost of antibiotics. A missed diagnosis leads to cost of persistent illness (loss of time from school and work) or cost of caring for complications.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	None.
Role of patient preference	Limited.
Intentional vagueness	None.
Exclusions	Children aged <1 year or older than 18 years and with underlying conditions.
Strength	Recommendation.

TABLE 1 Guideline Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation, but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to one approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

The purpose of this action statement is to guide the practitioner in making a diagnosis of acute bacterial sinusitis on the basis of stringent clinical criteria. To develop criteria to be used in distinguishing episodes of acute bacterial sinusitis from other common respiratory infections, it is helpful to describe the features of an uncomplicated viral URI. Viral URIs are usually characterized by nasal symptoms (discharge and congestion/obstruction) or cough or both. Most often, the nasal discharge begins as clear and watery. Often, however, the quality of nasal discharge changes during the course of the illness. Typically, the nasal discharge becomes thicker and more mucoid and may become purulent (thick, colored, and opaque) for several days. Then the situation reverses, with the purulent discharge becoming mucoid and then clear again or simply resolving. The transition from clear to purulent to clear again occurs in uncomplicated viral URIs without the use of antimicrobial therapy.

Fever, when present in uncomplicated viral URI, tends to occur early in the illness, often in concert with other constitutional symptoms such as headache and myalgias. Typically, the fever and constitutional symptoms disappear in the first 24 to 48 hours, and the respiratory symptoms become more prominent (Fig 2).

The course of most uncomplicated viral URIs is 5 to 7 days.[9–12] As shown in Fig 2, respiratory symptoms usually peak in severity by days 3 to 6 and then begin to improve; however, resolving symptoms and signs may persist in some patients after day 10.[9,10]

Symptoms of acute bacterial sinusitis and uncomplicated viral URI overlap considerably, and therefore it is their persistence without improvement that suggests a diagnosis of acute sinusitis.[9,10,13] Such symptoms include nasal discharge (of any quality: thick or thin, serous, mucoid, or purulent) or daytime cough (which may be worse at night) or both. Bad breath, fatigue, headache, and decreased appetite, although common, are not specific indicators of acute sinusitis.[14] Physical examination findings are also not particularly helpful in distinguishing sinusitis from uncomplicated URIs. Erythema and swelling of the nasal turbinates are nonspecific findings.[14] Percussion of the sinuses is not useful. Transillumination of the sinuses is difficult to perform correctly in children and has been shown to be unreliable.[15,16] Nasopharyngeal cultures do not reliably predict the etiology of acute bacterial sinusitis.[14,16]

Only a minority (~6%–7%) of children presenting with symptoms of URI will meet criteria for persistence.[3,4,11] As a result, before diagnosing acute bacterial sinusitis, it is important for the practitioner to attempt to (1) differentiate between sequential episodes of uncomplicated viral URI (which may seem to coalesce in the mind of the patient or parent) from the onset of acute bacterial sinusitis with persistent symptoms and (2) establish whether the symptoms are clearly not improving.

A worsening course of signs and symptoms, termed "double sickening," in the context of a viral URI is another presentation of acute bacterial sinusitis.[13,17] Affected children experience substantial and acute worsening of respiratory symptoms (nasal discharge or nasal congestion or daytime cough) or a new fever, often on the sixth or seventh day of illness, after initial signs of recovery from an uncomplicated viral URI. Support for this definition comes from studies in children and adults, for whom antibiotic treatment of worsening symptoms after a period of apparent improvement was associated with better outcomes.[4]

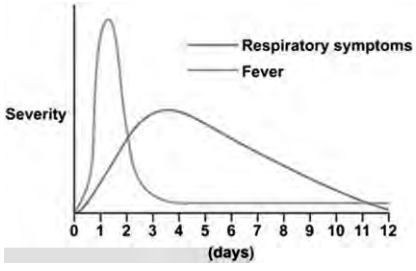


FIGURE 2
Uncomplicated viral URI.

Finally, some children with acute bacterial sinusitis may present with severe onset, ie, concurrent high fever (temperature >39°C) and purulent nasal discharge. These children usually are ill appearing and need to be distinguished from children with uncomplicated viral infections that are unusually severe. If fever is present in uncomplicated viral URIs, it tends to be present early in the illness, usually accompanied by other constitutional symptoms, such as headache and myalgia.[9,13,18] Generally, the constitutional symptoms resolve in the first 48 hours and then the respiratory symptoms become prominent. In most uncomplicated viral infections, including influenza, purulent nasal discharge does not appear for several days. Accordingly, it is the concurrent presentation of high fever and purulent nasal discharge for the first 3 to 4 days of an acute URI that helps to define the severe onset of acute bacterial sinusitis.[13,16,18] This presentation in children is the corollary to acute onset of headache, fever, and facial pain in adults with acute sinusitis.

Allergic and nonallergic rhinitis are predisposing causes of some cases of acute bacterial sinusitis in childhood. In addition, at their onset, these conditions may be mistaken for acute bacterial sinusitis. A family history of atopic conditions, seasonal occurrences, or occurrences with exposure to common allergens and other

allergic diatheses in the index patient (eczema, atopic dermatitis, asthma) may suggest the presence of noninfectious rhinitis. The patient may have complaints of pruritic eyes and nasal mucosa, which will provide a clue to the likely etiology of the condition. On physical examination, there may be a prominent nasal crease, allergic shiners, cobblestoning of the conjunctiva or pharyngeal wall, or pale nasal mucosa as other indicators of the diagnosis.

Key Action Statement 2A

Clinicians should not obtain imaging studies (plain films, contrast-enhanced computed tomography [CT], MRI, or ultrasonography) to distinguish acute bacterial sinusitis from viral URI (Evidence Quality: B; Strong Recommendation).

KAS Profile 2A

Aggregate evidence quality: B; overwhelmingly consistent evidence from observational studies.	
Benefit	Avoids exposure to radiation and costs of studies. Avoids unnecessary therapy for false-positive diagnoses.
Harm	None.
Cost	Avoids cost of imaging.
Benefits-harm assessment	Exclusive benefit.
Value judgments	Concern for unnecessary radiation and costs.
Role of patient preference	Limited. Parents may value a negative study and avoidance of antibiotics as worthy of radiation but panel disagrees.
Intentional vagueness	None.
Exclusions	Patients with complications of sinusitis.
Strength	Strong recommendation.

The purpose of this key action statement is to discourage the practitioner from obtaining imaging studies in children with uncomplicated acute bacterial sinusitis. As emphasized in Key Action Statement 1, acute bacterial sinusitis in children is a diagnosis that is made on the basis of stringent clinical criteria that describe signs, symptoms, and temporal patterns of a URI. Although historically imaging has been used as a confirmatory or diagnostic modality in children suspected to have acute bacterial sinusitis, it is no longer recommended.

The membranes that line the nose are continuous with the membranes (mucosa) that line the sinus cavities, the middle ear, the nasopharynx, and the oropharynx. When an individual experiences a viral URI, there is inflammation of the nasal mucosa and, often, the mucosa of the middle ear and paranasal sinuses as well. The continuity of the mucosa of the upper respiratory tract is responsible for the controversy regarding the usefulness of images of the paranasal sinuses in contributing to a diagnosis of acute bacterial sinusitis.

As early as the 1940s, observations were made regarding the frequency of abnormal sinus radiographs in healthy children without signs or symptoms of current respiratory disease.[19] In addition, several investigators in the 1970s and 1980s observed that children with uncomplicated viral URI had frequent abnormalities of the paranasal sinuses on plain radiographs.[20–22] These abnormalities were the same as those considered to be diagnostic of acute bacterial sinusitis (diffuse opacification, mucosal swelling of at least 4 mm, or an air-fluid level).[16]

As technology advanced and CT scanning of the central nervous system and skull became prevalent, several studies reported on incidental abnormalities of the paranasal sinuses that were observed in children.[23,24] Gwaltney et al[25] showed striking abnormalities (including air-fluid levels) in sinus CT scans of young adults with uncomplicated colds. Manning et al[26] evaluated children undergoing either CT or MRI of the head for indications other than respiratory complaints or suspected sinusitis. Each patient underwent rhinoscopy and otoscopy before imaging and each patient's parent was asked to fill out a questionnaire regarding recent symptoms of URI. Sixty-two percent of patients overall had physical findings or history consistent with an upper respiratory inflammatory process, and 55% of the total group showed some abnormalities on sinus imaging; 33% showed pronounced mucosal thickening or an air-fluid level. Gordts et al[27] made similar observations in children undergoing MRI. Finally, Kristo et al[28] performed MRI in children with URIs and confirmed the high frequency (68%) of major abnormalities seen in the paranasal sinuses.

In summary, when the paranasal sinuses are imaged, either with plain radiographs, contrast-enhanced CT, or MRI in children with uncomplicated URI, the majority of studies will be significantly abnormal with the same kind of findings that are associated with bacterial infection of the sinuses. Accordingly, although normal radiographs or CT or MRI results can ensure that a patient with respiratory symptoms does not have acute bacterial sinusitis, an abnormal image cannot confirm the diagnosis. Therefore, it is not necessary to perform imaging in children with uncomplicated episodes of clinical sinusitis. Similarly, the high likelihood of an abnormal imaging result in a child with an uncomplicated URI indicates that radiographic studies

not be performed in an attempt to eliminate the diagnosis of sinusitis.

Key Action Statement 2B

Clinicians should obtain a contrast-enhanced CT scan of the paranasal sinuses and/or an MRI with contrast whenever a child is suspected of having orbital or central nervous system complications of acute bacterial sinusitis (Evidence Quality: B; Strong Recommendation).

KAS Profile 2B

Aggregate evidence quality: B; overwhelmingly consistent evidence from observational studies.	
Benefit	Determine presence of abscesses, which may require surgical intervention; avoid sequelae because of appropriate aggressive management.
Harm	Exposure to ionizing radiation for CT scans; need for sedation for MRI.
Cost	Direct cost of studies.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Concern for significant complication that may be unrecognized and, therefore, not treated appropriately.
Role of patient preference	Limited.
Intentional vagueness	None.
Exclusions	None.
Strength	Strong recommendation.

The purpose of this key action statement is to have the clinician obtain contrast-enhanced CT images when children are suspected of having serious complications of acute bacterial sinusitis. The most common complication of acute sinusitis involves the orbit in children with ethmoid sinusitis who are younger than 5 years.[29–31] Orbital complications should be suspected when the child presents with a swollen eye, especially if accompanied by proptosis or impaired function of the extraocular muscles. Orbital complications of acute sinusitis have been divided into 5 categories: sympathetic effusion, subperiosteal abscess, orbital cellulitis, orbital abscess, and cavernous sinus thrombosis.[32] Although sympathetic effusion (inflammatory edema) is categorized as an orbital complication, the site of infection remains confined to the sinus cavities; eye swelling is attributable to the impedance of venous drainage secondary to congestion within the ethmoid sinuses. Alternative terms for sympathetic effusion (inflammatory edema) are preseptal or periorbital cellulitis. The remaining "true" orbital complications are best visualized by contrast-enhanced CT scanning.

Intracranial complications of acute sinusitis, which are substantially less common than orbital complications, are more serious, with higher morbidity and mortality than those involving the orbit. Intracranial complications should be suspected in the patient who presents with a very severe headache, photophobia, seizures, or other focal neurologic findings. Intracranial complications include subdural empyema, epidural empyema, venous thrombosis, brain abscess, and meningitis.[29] Typically, patients with intracranial complications of acute bacterial sinusitis are previously healthy adolescent males with frontal sinusitis.[33,34]

There have been no head-to-head comparisons of the diagnostic accuracy of contrast-enhanced CT scanning to MRI with contrast in the evaluation of orbital and intracranial complications of sinusitis in children. In general, the contrast-enhanced CT scan has been the preferred imaging study when complications of sinusitis are suspected.[35,36] However, there are documented cases in which a contrast-enhanced CT scan has not revealed the abnormality responsible for the clinical presentation and the MRI with contrast has, especially for intracranial complications and rarely for orbital complications.[37,38] Accordingly, the most recent appropriateness criteria from the American College of Radiology endorse both MRI with contrast and contrast-enhanced CT as complementary examinations when evaluating potential complications of sinusitis.[35] The availability and speed of obtaining the contrast-enhanced CT are desirable; however, there is increasing concern regarding exposure to radiation. The MRI, although very sensitive, takes longer than the contrast-enhanced CT and often requires sedation in young children (which carries its own risks). In older children and adolescents who may not require sedation, MRI with contrast, if available, may be preferred when intracranial complications are likely. Furthermore, MRI with contrast should be performed when there is persistent clinical concern or incomplete information has been provided by the contrast-enhanced CT scan.

Key Action Statement 3

Initial Management of Acute Bacterial Sinusitis

3A: "Severe onset and worsening course" acute bacterial sinusitis. The clinician should prescribe antibiotic therapy for acute bacterial sinusitis in children with severe onset or worsening course (signs, symptoms, or both) (Evidence Quality: B; Strong Recommendation).

KAS Profile 3A

Aggregate evidence quality: B; randomized controlled trials with limitations.	
Benefit	Increase clinical cures, shorten illness duration, and may prevent suppurative complications in a high-risk patient population.
Harm	Adverse effects of antibiotics.
Cost	Direct cost of therapy.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Concern for morbidity and possible complications if untreated.
Role of patient preference	Limited.
Intentional vagueness	None.
Exclusions	None.
Strength	Strong recommendation.

3B: "Persistent illness." The clinician should either prescribe antibiotic therapy OR offer additional outpatient observation for 3 days to children with persistent illness (nasal discharge of any quality or cough or both for at least 10 days without evidence of improvement) (Evidence Quality: B; Recommendation).

The purpose of this section is to offer guidance on initial management of persistent illness sinusitis by helping clinicians choose between the following 2 strategies:

1. Antibiotic therapy, defined as initial treatment of acute bacterial sinusitis with antibiotics, with the intent of starting antibiotic therapy as soon as possible after the encounter.
2. Additional outpatient observation, defined as initial management of acute bacterial sinusitis limited to continued observation for 3 days, with commencement of antibiotic therapy if either the child does not improve clinically within several days of diagnosis or if there is clinical worsening of the child's condition at any time.

KAS Profile 3B

Aggregate evidence quality: B; randomized controlled trials with limitations.	
Benefit	Antibiotics increase the chance of improvement or cure at 10 to 14 days (number needed to treat, 3–5); additional observation may avoid the use of antibiotics with attendant cost and adverse effects.
Harm	Antibiotics have adverse effects (number needed to harm, 3) and may increase bacterial resistance. Observation may prolong illness and delay start of needed antibiotic therapy.
Cost	Direct cost of antibiotics as well as cost of adverse reactions; indirect costs of delayed recovery when observation is used.
Benefits-harm assessment	Preponderance of benefit (because both antibiotic therapy and additional observation with rescue antibiotic, if needed, are appropriate management).
Value judgments	Role for additional brief observation period for selected children with persistent illness sinusitis, similar to what is recommended for acute otitis media, despite the lack of randomized trials specifically comparing additional observation with immediate antibiotic therapy and longer duration of illness before presentation.
Role of patient preference	Substantial role in shared decision-making that should incorporate illness severity, child's quality of life, and caregiver values and concerns.
Intentional vagueness	None.
Exclusions	Children who are excluded from randomized clinical trials of acute bacterial sinusitis, as defined in the text.
Strength	Recommendation.

In contrast to the 2001 AAP guideline,[5] which recommended antibiotic therapy for all children diagnosed with acute bacterial sinusitis, this guideline allows for additional observation of children presenting with persistent illness (nasal discharge of any quality or daytime cough or both for at least 10 days without evidence of improvement). In both guidelines, however, children presenting with severe or worsening illness (which was not defined explicitly in the 2001 guideline[5]) are to receive antibiotic therapy. The rationale for this approach (Table 2) is discussed below.

Antibiotic Therapy for Acute Bacterial Sinusitis

In the United States, antibiotics are prescribed for 82% of children with acute sinusitis.[39] The rationale for antibiotic therapy of acute bacterial sinusitis is based on the recovery of bacteria in high density ($\geq 10^4$ colony-forming units/mL) in 70% of maxillary sinus aspirates obtained from children with a clinical syndrome characterized by persistent nasal discharge, daytime cough, or both.[16,40] Children who present with severe-onset acute bacterial sinusitis are presumed to have bacterial infection, because a temperature of at least 39°C/102.2°F coexisting for at least 3 consecutive days with purulent nasal discharge is not consistent with the well-documented pattern of acute viral URI. Similarly, children with worsening-course acute bacterial sinusitis have a clinical course that is also not consistent with the steady improvement that characterizes an uncomplicated viral URI.[9,10]

Three RCTs have compared antibiotic therapy with placebo for the initial management of acute bacterial sinusitis in children. Two trials by Wald et al[4,41] found an increase in cure or improvement after antibiotic therapy compared with placebo with a number needed to treat of 3 to 5 children. Most children in these studies had persistent acute bacterial sinusitis, but children with severe or worsening illness were also included. Conversely, Garbutt et al,[42] who studied only children with persistent acute bacterial sinusitis, found no difference in outcomes for antibiotic versus placebo. Another RCT by Kristo et al,[43] often cited as showing no benefit from antibiotics for acute bacterial sinusitis, will not be considered further because of methodologic flaws, including weak entry criteria and inadequate dosing of antibiotic treatment.

The guideline recommends antibiotic therapy for severe or worsening acute bacterial sinusitis because of the benefits revealed in RCTs[4,41] and a theoretically higher risk of suppurative complications than for children who present with persistent symptoms. Orbital and intracranial complications of acute bacterial sinusitis have not been observed in RCTs, even when placebo was administered; however, sample sizes have inadequate power to preclude an increased risk. This risk, however, has caused some investigators to exclude children with severe acute bacterial sinusitis from trial entry.[42]

Additional Observation for Persistent Onset Acute Bacterial Sinusitis

The guideline recommends either antibiotic therapy or an additional brief period of observation as initial management strategies for children with persistent acute bacterial sinusitis because, although there are benefits to antibiotic therapy (number needed to treat, 3–5), some children improve on their own, and the risk of suppurative complications is low.[4,41] Symptoms of persistent acute bacterial sinusitis may be mild and have varying effects on a given child's quality of life, ranging from slight (mild cough, nasal discharge) to significant (sleep disturbance, behavioral changes, school or child care absenteeism). The benefits of antibiotic therapy in some trials[4,41] must also be balanced against an increased risk of adverse events (number need to harm, 3), most often self-limited diarrhea, but also including occasional rash.[4]

Choosing between antibiotic therapy or additional observation for initial management of persistent illness sinusitis presents an opportunity for shared decision-making with families (Table 2). Factors that might influence this decision include symptom severity, the child's quality of life, recent antibiotic use, previous experience or outcomes with acute bacterial sinusitis, cost of antibiotics, ease of administration, caregiver concerns about potential adverse effects of antibiotics, persistence of respiratory symptoms, or development of complications. Values and preferences expressed by the caregiver should be taken into consideration (Table 3).

Children with persistent acute bacterial sinusitis who received antibiotic therapy in the previous 4 weeks, those with concurrent bacterial infection (eg, pneumonia, suppurative cervical adenitis, group A streptococcal pharyngitis, or acute otitis media), those with actual or suspected complications of acute bacterial sinusitis, or those with underlying conditions should generally be managed with antibiotic therapy. The latter group includes children with asthma, cystic fibrosis, immunodeficiency, previous sinus surgery, or anatomic abnormalities of the upper respiratory tract.

Limiting antibiotic use in children with persistent acute bacterial sinusitis who may improve on their own reduces common antibiotic-related adverse events, such as diarrhea, diaper dermatitis, and skin rash. The most recent RCT of acute bacterial sinusitis in children[4] found adverse events of 44% with antibiotic and 14% with placebo.

Limiting antibiotics may also reduce the prevalence of resistant bacterial pathogens. Although this is always a desirable goal, no increase in resistant bacterial species was observed within the group of children treated with a single course of antimicrobial agents (compared with those receiving placebo) in 2 recent large studies of antibiotic versus placebo for children with acute otitis media.[44,45]

Key Action Statement 4

Clinicians should prescribe amoxicillin with or without clavulanate as first-line treatment when a decision has been made to initiate antibiotic treatment of acute bacterial sinusitis (Evidence Quality: B; Recommendation).

KAS Profile 4

Aggregate evidence quality: B; randomized controlled trials with limitations.

Benefit	Increase clinical cures with narrowest spectrum drug; stepwise increase in broadening spectrum as risk factors for resistance increase.
Harm	Adverse effects of antibiotics including development of hypersensitivity.
Cost	Direct cost of antibiotic therapy.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Concerns for not encouraging resistance if possible.
Role of patient preference	Potential for shared decision-making that should incorporate the caregiver's experiences and values.
Intentional vagueness	None.
Exclusions	May include allergy or intolerance.
Strength	Recommendation.

TABLE 2 Recommendations for Initial Use of Antibiotics for Acute Bacterial Sinusitis

Clinical Presentation	Severe Acute Bacterial Sinusitis[a]	Worsening Acute Bacterial Sinusitis[b]	Persistent Acute Bacterial Sinusitis[c]
Uncomplicated acute bacterial sinusitis without coexisting illness	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy or additional observation for 3 days[d]
Acute bacterial sinusitis with orbital or intracranial complications	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy
Acute bacterial sinusitis with coexisting acute otitis media, pneumonia, adenitis, or streptococcal pharyngitis	Antibiotic therapy	Antibiotic therapy	Antibiotic therapy

[a] Defined as temperature ≥39°C and purulent (thick, colored, and opaque) nasal discharge present concurrently for at least 3 consecutive days.

[b] Defined as nasal discharge or daytime cough with sudden worsening of symptoms (manifested by new-onset fever ≥38°C/100.4°F or substantial increase in nasal discharge or cough) after having experienced transient improvement of symptoms.

[c] Defined as nasal discharge (of any quality), daytime cough (which may be worse at night), or both, persisting for >10 days without improvement.

[d] Opportunity for shared decision-making with the child's family; if observation is offered, a mechanism must be in place to ensure follow-up and begin antibiotics if the child worsens at any time or fails to improve within 3 days of observation.

The purpose of this key action statement is to guide the selection of antimicrobial therapy once the diagnosis of acute bacterial sinusitis has been made. The microbiology of acute bacterial sinusitis was determined nearly 30 years ago through direct maxillary sinus aspiration in children with compatible signs and symptoms. The major bacterial pathogens recovered at that time were *Streptococcus pneumoniae* in approximately 30% of children and nontypeable *Haemophilus influenzae* and *Moraxella catarrhalis* in approximately 20% each.[16,40] Aspirates from the remaining 25% to 30% of children were sterile.

Maxillary sinus aspiration is rarely performed at the present time unless the course of the infection is unusually prolonged or severe. Although some authorities have recommended obtaining cultures from the middle meatus to determine the cause of a maxillary sinus infection, there are no data in children with acute bacterial sinusitis that have compared such cultures with cultures of a maxillary sinus aspirate. Furthermore, there are data indicating that the middle meatus in healthy children is commonly colonized with *S pneumoniae*, *H influenzae*, and *M catarrhalis*.[46]

Recent estimates of the microbiology of acute sinusitis have, of necessity, been based primarily on that of acute otitis media (AOM), a condition with relatively easy access to infective fluid through performance of tympanocentesis and one with a similar pathogenesis to acute bacterial sinusitis.[47,48] The 3 most common bacterial pathogens recovered from the middle ear fluid of children with AOM are the same as those that have been associated with acute bacterial sinusitis: *S pneumoniae*, nontypeable *H influenzae*, and *M catarrhalis*.[49] The proportion of each has varied from study to study depending on criteria used for diagnosis of AOM, patient characteristics, and bacteriologic techniques. Recommendations since the year 2000 for the routine use in infants of 7-valent and, more recently, 13-valent pneumococcal conjugate vaccine (PCV-13) have been associated with a decrease in recovery of *S pneumoniae* from ear fluid of children with AOM and a relative increase in the incidence of infections attributable to *H influenzae*.[50] Thus, on the basis of the proportions of bacteria found in middle ear infections, it is estimated that *S pneumoniae* and *H influenzae* are currently each responsible for approximately 30% of cases of acute bacterial sinusitis in children, and *M catarrhalis* is responsible for approximately 10%. These percentages are contingent on the assumption that approximately one-quarter of aspirates of maxillary sinusitis would still be sterile, as reported in earlier studies. *Staphylococcus aureus* is rarely isolated from sinus aspirates in children with acute bacterial sinusitis, and with the exception of acute maxillary sinusitis associated with infections of dental origin,[51] respiratory anaerobes are also rarely recovered.[40,52] Although *S aureus* is a very infrequent cause of acute bacterial sinusitis in children, it is a significant pathogen in the orbital and intracranial complications of sinusitis. The reasons for this discrepancy are unknown.

Antimicrobial susceptibility patterns for *S pneumoniae* vary considerably from community to community. Isolates obtained from surveillance centers nationwide indicate that, at the present time, 10% to 15% of upper respiratory tract isolates of *S pneumoniae* are nonsusceptible to penicillin[53,54]; however, values for penicillin nonsusceptibility as high as 50% to 60% have been reported in some areas.[55,56] Of the organisms that are resistant, approximately half are highly resistant to penicillin and the remaining half are intermediate in resistance. [53,54,56–59] Between 10% and 42% of *H influenzae*[56–59] and close to 100% of *M catarrhalis* are likely to be β-lactamase positive and nonsusceptible to amoxicillin. Because of dramatic geographic variability in the prevalence of β-lactamase–positive *H influenzae*, it is extremely desirable for the practitioner to be familiar with local patterns of susceptibility. Risk factors for the presence of organisms

likely to be resistant to amoxicillin include attendance at child care, receipt of antimicrobial treatment within the previous 30 days, and age younger than 2 years.[50,55,60]

Amoxicillin remains the antimicrobial agent of choice for first-line treatment of uncomplicated acute bacterial sinusitis in situations in which antimicrobial resistance is not suspected. This recommendation is based on amoxicillin's effectiveness, safety, acceptable taste, low cost, and relatively narrow microbiologic spectrum. For children aged 2 years or older with uncomplicated acute bacterial sinusitis that is mild to moderate in degree of severity who do not attend child care and who have not been treated with an antimicrobial agent within the last 4 weeks, amoxicillin is recommended at a standard dose of 45 mg/kg per day in 2 divided doses. In communities with a high prevalence of nonsusceptible *S pneumoniae* (>10%, including intermediate- and high-level resistance), treatment may be initiated at 80 to 90 mg/kg per day in 2 divided doses, with a maximum of 2 g per dose.[55] This high-dose amoxicillin therapy is likely to achieve sinus fluid concentrations that are adequate to overcome the resistance of *S pneumoniae,* which is attributable to alteration in penicillin-binding proteins on the basis of data derived from patients with AOM.[61] If, within the next several years after licensure of PCV-13, a continuing decrease in isolates of *S pneumoniae* (including a decrease in isolates of nonsusceptible *S pneumoniae)* and an increase in β-lactamase–producing *H influenzae* are observed, standard-dose amoxicillin-clavulanate (45 mg/kg per day) may be most appropriate.

Patients presenting with moderate to severe illness as well as those younger than 2 years, attending child care, or who have recently been treated with an antimicrobial may receive high-dose amoxicillin-clavulanate (80–90 mg/kg per day of the amoxicillin component with 6.4 mg/kg per day of clavulanate in 2 divided doses with a maximum of 2 g per dose). The potassium clavulanate levels are adequate to inhibit all β-lactamase–producing *H influenzae* and *M catarrhalis*.[56,59]

A single 50-mg/kg dose of ceftriaxone, given either intravenously or intramuscularly, can be used for children who are vomiting, unable to tolerate oral medication, or unlikely to be adherent to the initial doses of antibiotic.[62–64] The 3 major bacterial pathogens involved in acute bacterial sinusitis are susceptible to ceftriaxone in 95% to 100% of cases.[56,58,59] If clinical improvement is observed at 24 hours, an oral antibiotic can be substituted to complete the course of therapy. Children who are still significantly febrile or symptomatic at 24 hours may require additional parenteral doses before switching to oral therapy.

The treatment of patients with presumed allergy to penicillin has been controversial. However, recent publications indicate that the risk of a serious allergic reaction to second- and third-generation cephalosporins in patients with penicillin or amoxicillin allergy appears to be almost nil and no greater than the risk among patients without such allergy.[65–67] Thus, patients allergic to amoxicillin with a non–type 1 (late or delayed, >72 hours) hypersensitivity reaction can safely be treated with cefdinir, cefuroxime, or cefpodoxime.[66–68] Patients with a history of a serious type 1 immediate or accelerated (anaphylactoid) reaction to amoxicillin can also safely be treated with cefdinir, cefuroxime, or cefpodoxime. In both circumstances, clinicians may wish to determine individual tolerance by referral to an allergist for penicillin and/or cephalosporin skin-testing before initiation of therapy.[66–68] The susceptibility of *S pneumoniae* to cefdinir, cefpodoxime, and cefuroxime varies from 60% to 75%,[56–59] and the susceptibility of *H influenzae* to these agents varies from 85% to 100%.[56,58] In young children (<2 years) with a serious type 1 hypersensitivity to penicillin and moderate or more severe sinusitis, it may be prudent to use a combination of clindamycin (or linezolid) and cefixime to achieve the most comprehensive coverage against both resistant *S pneumoniae* and *H influenzae*. Linezolid has excellent activity against all *S pneumoniae*, including penicillin-resistant strains, but lacks activity against *H influenzae* and *M catarrhalis*. Alternatively, a quinolone, such as levofloxacin, which has a high level of activity against both *S pneumoniae* and *H influenzae*, may be prescribed.[57,58] Although the use of quinolones is usually restricted because of concerns for toxicity, cost, and emerging resistance, their use in this circumstance can be justified.

Pneumococcal and *H influenzae* surveillance studies have indicated that resistance of these organisms to trimethoprim-sulfamethoxazole and azithromycin is sufficient to preclude their use for treatment of acute bacterial sinusitis in patients with penicillin hypersensitivity.[56,58,59,69]

The optimal duration of antimicrobial therapy for patients with acute bacterial sinusitis has not received systematic study. Recommendations based on clinical observations have varied widely, from 10 to 28 days of treatment. An alternative suggestion has been made that antibiotic therapy be continued for 7 days after the patient becomes free of signs and symptoms.[5] This strategy has the advantage of individualizing the treatment of each patient, results in a minimum course of 10 days, and

avoids prolonged antimicrobial therapy in patients who are asymptomatic and therefore unlikely to adhere to the full course of treatment.[5]

Patients who are acutely ill and appear toxic when first seen (see below) can be managed with 1 of 2 options. Consultation can be requested from an otolaryngologist for consideration of maxillary sinus aspiration (with appropriate analgesia/anesthesia) to obtain a sample of sinus secretions for Gram stain, culture, and susceptibility testing so that antimicrobial therapy can be adjusted precisely. Alternatively, inpatient therapy can be initiated with intravenous cefotaxime or ceftriaxone, with referral to an otolaryngologist if the patient's condition worsens or fails to show improvement within 48 hours. If a complication is suspected, management will differ depending on the site and severity.

A recent guideline was published by the Infectious Diseases Society of America for acute bacterial rhinosinusitis in children and adults.[70] Their recommendation for initial empirical antimicrobial therapy for acute bacterial sinusitis in children was amoxicillin-clavulanate based on the concern that there is an increasing prevalence of *H influenzae* as a cause of sinusitis since introduction of the pneumococcal conjugate vaccines and an increasing prevalence of β-lactamase production among these strains. In contrast, this guideline from the AAP allows either amoxicillin or amoxicillin-clavulanate as first-line empirical therapy and is therefore inclusive of the Infectious Diseases Society of America's recommendation. Unfortunately, there are scant data available regarding the precise microbiology of acute bacterial sinusitis in the post–PCV-13 era. Prospective surveillance of nasopharyngeal cultures may be helpful in completely aligning these recommendations in the future.

Key Action Statement 5A

Clinicians should reassess initial management if there is either a caregiver report of worsening (progression of initial signs/symptoms or appearance of new signs/symptoms) OR failure to improve (lack of reduction in all presenting signs/symptoms) within 72 hours of initial management (Evidence Quality: C; Recommendation).

KAS Profile 5A

Aggregate evidence quality: C; observational studies	
Benefits	Identification of patients who may have been misdiagnosed, those at risk of complications, and those who require a change in management.
Harm	Delay of up to 72 hours in changing therapy if patient fails to improve.
Cost	Additional provider and caregiver time and resources.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Use of 72 hours to assess progress may result in excessive classification as treatment failures if premature; emphasis on importance of worsening illness in defining treatment failures.
Role of patient preferences	Caregivers determine whether the severity of the patient's illness justifies the report to clinician of the patient's worsening or failure to improve.
Intentional vagueness	None.
Exclusions	Patients with severe illness, poor general health, complicated sinusitis, immune deficiency, previous sinus surgery, or coexisting bacterial illness.
Strength	Recommendation.

The purpose of this key action statement is to ensure that patients with acute bacterial sinusitis who fail to improve symptomatically after initial management are reassessed to be certain that they have been correctly diagnosed and to consider initiation of alternate therapy to hasten resolution of symptoms and avoid complications. "Worsening" is defined as progression of presenting signs or symptoms of acute bacterial sinusitis or onset of new signs or symptoms. "Failure to improve" is lack of reduction in presenting signs or symptoms of acute bacterial sinusitis by 72 hours after diagnosis and initial management; patients with persistent but improving symptoms do not meet this definition.

The rationale for using 72 hours as the time to assess treatment failure for acute bacterial sinusitis is based on clinical outcomes in RCTs. Wald et al[41] found that 18 of 35 patients (51%) receiving placebo demonstrated symptomatic improvement within 3 days of initiation of treatment; only an additional 3 patients receiving placebo (9%) improved between days 3 and 10. In the same study, 48 of 58 patients (83%) receiving antibiotics were cured or improved within 3 days; at 10 days, the overall rate of improvement was 79%, suggesting that no additional patients improved between days 3 and 10. In a more recent study, 17 of 19 children who ultimately failed initial therapy with either antibiotic or placebo demonstrated failure to improve within 72 hours.[4] Although Garbutt et al[42] did not report the percentage of patients who improved by day 3, they did demonstrate that the majority of improvement in symptoms occurred within

the first 3 days of study entry whether they received active treatment or placebo.

Reporting of either worsening or failure to improve implies a shared responsibility between clinician and caregiver. Although the clinician should educate the caregiver regarding the anticipated reduction in symptoms within 3 days, it is incumbent on the caregiver to appropriately notify the clinician of concerns regarding worsening or failure to improve. Clinicians should emphasize the importance of reassessing those children whose symptoms are worsening whether or not antibiotic therapy was prescribed. Reassessment may be indicated before the 72-hour mark if the patient is substantially worse, because it may indicate the development of complications or a need for parenteral therapy. Conversely, in some cases, caregivers may think that symptoms are not severe enough to justify a change to an antibiotic with a less desirable safety profile or even the time, effort, and resources required for reassessment. Accordingly, the circumstances under which caregivers report back to the clinician and the process by which such reporting occurs should be discussed at the time the initial management strategy is determined.

Key Action Statement 5B

If the diagnosis of acute bacterial sinusitis is confirmed in a child with worsening symptoms or failure to improve in 72 hours, then clinicians may change the antibiotic therapy for the child initially managed with antibiotic OR initiate antibiotic treatment of the child initially managed with observation (Evidence Quality: D; Option based on expert opinion, case reports, and reasoning from first principles).

KAS Profile 5B

Aggregate evidence quality: D; expert opinion and reasoning from first principles.	
Benefit	Prevention of complications, administration of effective therapy.
Harm	Adverse effects of secondary antibiotic therapy.
Cost	Direct cost of medications, often substantial for second-line agents.
Benefits-harm assessment	Preponderance of benefit.
Value judgments	Clinician must determine whether cost and adverse effects associated with change in antibiotic is justified given the severity of illness.
Role of patient preferences	Limited in patients whose symptoms are severe or worsening, but caregivers of mildly affected children who are failing to improve may reasonably defer change in antibiotic.
Intentional vagueness	None.
Exclusions	None.
Strength	Option.

The purpose of this key action statement is to ensure optimal antimicrobial treatment of children with acute bacterial sinusitis whose symptoms worsen or fail to respond to the initial intervention to prevent complications and reduce symptom severity and duration (see Table 4).

Clinicians who are notified by a caregiver that a child's symptoms are worsening or failing to improve should confirm that the clinical diagnosis of acute bacterial sinusitis corresponds to the patient's pattern of illness, as defined in Key Action Statement 1. If caregivers report worsening of symptoms at any time in a patient for whom observation was the initial intervention, the clinician should begin treatment as discussed in Key Action Statement 4. For patients whose symptoms are mild and who have failed to improve but have not worsened, initiation of antimicrobial agents or continued observation (for up to 3 days) is reasonable.

If caregivers report worsening of symptoms after 3 days in a patient initially treated with antimicrobial agents, current signs and symptoms should be reviewed to determine whether acute bacterial sinusitis is still the best diagnosis. If sinusitis is still the best diagnosis, infection with drug-resistant bacteria is probable, and an alternate antimicrobial agent may be administered. Face-to-face reevaluation of the patient is desirable. Once the decision is made to change medications, the clinician should consider the limitations of the initial antibiotic coverage, the anticipated susceptibility of residual bacterial pathogens, and the ability of antibiotics to adequately penetrate the site of infection. Cultures of sinus or nasopharyngeal secretions in patients with initial antibiotic failure have identified a large percentage of bacteria with resistance to the original antibiotic.[71,72] Furthermore, multidrug-resistant *S pneumoniae* and β-lactamase–positive *H influenzae* and *M catarrhalis* are more commonly isolated after previous antibiotic exposure.[73–78] Unfortunately, there are no studies in children that have investigated the microbiology of treatment failure in acute bacterial sinusitis or cure rates using second-line antimicrobial agents. As a result, the likelihood of adequate antibiotic coverage for resistant organisms must be

addressed by extrapolations from studies of acute otitis media in children and sinusitis in adults and by using the results of data generated in vitro. A general guide to management of the child who worsens in 72 hours is shown in Table 4.

NO RECOMMENDATION

Adjuvant Therapy

Potential adjuvant therapy for acute sinusitis might include intranasal corticosteroids, saline nasal irrigation or lavage, topical or oral decongestants, mucolytics, and topical or oral antihistamines. A recent Cochrane review on decongestants, antihistamines, and nasal irrigation for acute sinusitis in children found no appropriately designed studies to determine the effectiveness of these interventions.[79]

Intranasal Steroids

The rationale for the use of intranasal corticosteroids in acute bacterial sinusitis is that an antiinflammatory agent may reduce the swelling around the sinus ostia and encourage drainage, thereby hastening recovery. However, there are limited data on how much inflammation is present, whether the inflammation is responsive to steroids, and whether there are differences in responsivity according to age. Nonetheless, there are several RCTs in adolescents and adults, most of which do show significant differences compared with placebo or active comparator that favor intranasal steroids in the reduction of symptoms and the patient's global assessment of overall improvement.[80–85] Several studies in adults with acute bacterial sinusitis provide data supporting the use of intranasal steroids as either monotherapy or adjuvant therapy to antibiotics.[81,86] Only one study did not show efficacy.[85]

There have been 2 trials of intranasal steroids performed exclusively in children: one comparing intranasal corticosteroids versus an oral decongestant[87] and the other comparing intranasal corticosteroids with placebo.[88] These studies showed a greater rate of complete resolution[87] or greater reduction in symptoms in patients receiving the steroid preparation, although the effects were modest.[88] It is important to note that nearly all of these studies (both those reported in children and adults) suffered from substantial methodologic problems. Examples of these methodologic problems are as follows: (1) variable inclusion criteria for sinusitis, (2) mixed populations of allergic and nonallergic subjects, and (3) different outcome criteria. All of these factors make deriving a clear conclusion difficult. Furthermore, the lack of stringent criteria in selecting the subject population increases the chance that the subjects had viral URIs or even persistent allergies rather than acute bacterial sinusitis.

The intranasal steroids studied to date include budesonide, flunisolide, fluticasone, and mometasone. There is no reason to believe that one steroid would be more effective than another, provided equivalent doses are used.

Potential harm in using nasal steroids in children with acute sinusitis includes the increased cost of therapy, difficulty in effectively administering nasal sprays in young children, nasal irritation and epistaxis, and potential systemic adverse effects of steroid use. Fortunately, no clinically significant steroid adverse effects have been discovered in studies in children.[89–96]

Saline Irrigation

Saline nasal irrigation or lavage (not saline nasal spray) has been used to remove debris from the nasal cavity and temporarily reduce tissue edema (hypertonic saline) to promote drainage from the sinuses. There have been very few RCTs using saline nasal irrigation or lavage in acute sinusitis, and these have had mixed results.[97,98] The 1 study in children showed greater improvement in nasal airflow and quality of life as well as a better rate of improvement in total symptom score when compared with placebo in patients treated with antibiotics and decongestants.[98] There are 2 Cochrane reviews published on the use of saline nasal irrigation in acute sinusitis in adults that showed variable results. One review published in 2007[99] concluded that it is a beneficial adjunct, but the other, published in 2010,[100] concluded that most trials were too small or contained too high a risk of bias to be confident about benefits.

Nasal Decongestants, Mucolytics, and Antihistamines

Data are insufficient to make any recommendations about the use of oral or topical nasal decongestants, mucolytics, or oral or nasal spray antihistamines as adjuvant therapy for acute bacterial sinusitis in children.[79] It is the opinion of the expert panel that antihistamines should not be used for the primary indication of acute bacterial sinusitis in any child, although such therapy might be helpful in reducing typical allergic symptoms in patients with atopy who also have acute sinusitis.

OTHER RELATED CONDITIONS

Recurrence of Acute Bacterial Sinusitis

Recurrent acute bacterial sinusitis (RABS) is an uncommon occurrence in healthy children and must be distinguished from recurrent URIs, exacerbations of allergic rhinitis, and chronic sinusitis. The former is defined by episodes of bacterial infection of the paranasal sinuses lasting fewer than 30 days and separated by intervals of

TABLE 3 Parent Information Regarding Initial Management of Acute Bacterial Sinusitis

How common are sinus infections in children?	Thick, colored, or cloudy mucus from your child's nose frequently occurs with a common cold or viral infection and does not by itself mean your child has sinusitis. In fact, fewer than 1 in 15 children get a true bacterial sinus infection during or after a common cold.
How can I tell if my child has bacterial sinusitis or simply a common cold?	Most colds have a runny nose with mucus that typically starts out clear, becomes cloudy or colored, and improves by about 10 d. Some colds will also include fever (temperature >38°C [100.4°F]) for 1 to 2 days. In contrast, acute bacterial sinusitis is likely when the pattern of illness is persistent, severe, or worsening. 1. *Persistent* sinusitis is the most common type, defined as runny nose (of any quality), daytime cough (which may be worse at night), or both for at least 10 days without improvement. 2. *Severe* sinusitis is present when fever (temperature ≥39°C [102.2°F]) lasts for at least 3 days in a row and is accompanied by nasal mucus that is thick, colored, or cloudy. 3. *Worsening* sinusitis starts with a viral cold, which begins to improve but then worsens when bacteria take over and cause new-onset fever (temperature ≥38°C [100.4°F]) or a substantial increase in daytime cough or runny nose.
If my child has sinusitis, should he or she take an antibiotic?	Children with *persistent* sinusitis may be managed with either an antibiotic or with an additional brief period of observation, allowing the child up to another 3 days to fight the infection and improve on his or her own. The choice to treat or observe should be discussed with your doctor and may be based on your child's quality of life and how much of a problem the sinusitis is causing. In contrast, all children diagnosed with *severe* or *worsening* sinusitis should start antibiotic treatment to help them recover faster and more often.
Why not give all children with acute bacterial sinusitis an immediate antibiotic?	Some episodes of *persistent* sinusitis include relatively mild symptoms that may improve on their own in a few days. In addition, antibiotics can have adverse effects, which may include vomiting, diarrhea, upset stomach, skin rash, allergic reactions, yeast infections, and development of resistant bacteria (that make future infections more difficult to treat).

at least 10 days during which the patient is asymptomatic. Some experts require at least 4 episodes in a calendar year to fulfill the criteria for this condition. Chronic sinusitis is manifest as 90 or more uninterrupted days of respiratory symptoms, such as cough, nasal discharge, or nasal obstruction.

Children with RABS should be evaluated for underlying allergies, particularly allergic rhinitis; quantitative and functional immunologic defect(s), chiefly immunoglobulin A and immunoglobulin G deficiency; cystic fibrosis; gastroesophageal reflux disease; or dysmotile cilia syndrome.[101] Anatomic abnormalities obstructing one or more sinus ostia may be present. These include septal deviation, nasal polyps, or concha bullosa (pneumatization of the middle turbinate); atypical ethmoid cells with compromised drainage; a lateralized middle turbinate; and intrinsic ostiomeatal anomalies.[102] Contrast-enhanced CT, MRI, or endoscopy or all 3 should be performed for detection of obstructive conditions, particularly in children with genetic or acquired craniofacial abnormalities.

The microbiology of RABS is similar to that of isolated episodes of acute bacterial sinusitis and warrants the same treatment.[72] It should be recognized that closely spaced sequential courses of antimicrobial therapy may foster the emergence of antibiotic-resistant bacterial species as the causative agent in recurrent episodes. There are no systematically evaluated options for prevention of RABS in children. In general, the use of prolonged prophylactic antimicrobial therapy should be avoided and is not usually recommended for children with recurrent acute otitis media. However, when there are no recognizable predisposing conditions to remedy in children with RABS, prophylactic antimicrobial agents may be used for several months during the respiratory season. Enthusiasm for this strategy is tempered by concerns regarding the encouragement of bacterial resistance. Accordingly, prophylaxis should only be considered in carefully selected children whose infections have been thoroughly documented.

Influenza vaccine should be administered annually, and PCV-13 should be administered at the recommended ages for all children, including those with RABS. Intranasal steroids and nonsedating antihistamines can be helpful for children with allergic rhinitis, as can antireflux medications for those with gastroesophageal reflux disease. Children with anatomic abnormalities may require endoscopic surgery for removal of or reduction in ostiomeatal obstruction.

The pathogenesis of chronic sinusitis is poorly understood and appears to be multifactorial; however, many of the conditions associated with RABS

TABLE 4 Management of Worsening or Lack of Improvement at 72 Hours

Initial Management	Worse in 72 Hours	Lack of Improvement in 72 Hours
Observation	Initiate amoxicillin with or without clavulanate	Additional observation or initiate antibiotic based on shared decision-making
Amoxicillin	High-dose amoxicillin-clavulanate	Additional observation or high-dose amoxicillin-clavulanate based on shared decision-making
High-dose amoxicillin-clavulanate	Clindamycin[a] and cefixime OR linezolid and cefixime OR levofloxacin	Continued high-dose amoxicillin-clavulanate OR clindamycin[a] and cefixime OR linezolid and cefixime OR levofloxacin

[a] Clindamycin is recommended to cover penicillin-resistant *S pneumoniae*. Some communities have high levels of clindamycin-resistant *S pneumoniae*. In these communities, linezolid is preferred.

have also been implicated in chronic sinusitis, and it is clear that there is an overlap between the 2 syndromes.[101,102] In some cases, there may be episodes of acute bacterial sinusitis superimposed on a chronic sinusitis, warranting antimicrobial therapy to hasten resolution of the acute infection.

Complications of Acute Bacterial Sinusitis

Complications of acute bacterial sinusitis should be diagnosed when the patient develops signs or symptoms of orbital and/or central nervous system (intracranial) involvement. Rarely, complicated acute bacterial sinusitis can result in permanent blindness, other neurologic sequelae, or death if not treated promptly and appropriately. Orbital complications have been classified by Chandler et al.[32] Intracranial complications include epidural or subdural abscess, brain abscess, venous thrombosis, and meningitis.

Periorbital and intraorbital inflammation and infection are the most common complications of acute sinusitis and most often are secondary to acute ethmoiditis in otherwise healthy young children. These disorders are commonly classified in relation to the orbital septum; periorbital or preseptal inflammation involves only the eyelid, whereas postseptal (intraorbital) inflammation involves structures of the orbit. Mild cases of preseptal cellulitis (eyelid <50% closed) may be treated on an outpatient basis with appropriate oral antibiotic therapy (high-dose amoxicillin-clavulanate for comprehensive coverage) for acute bacterial sinusitis and daily follow-up until definite improvement is noted. If the patient does not improve within 24 to 48 hours or if the infection is progressive, it is appropriate to admit the patient to the hospital for antimicrobial therapy. Similarly, if proptosis, impaired visual acuity, or impaired and/or painful extraocular mobility is present on examination, the patient should be hospitalized, and a contrast-enhanced CT should be performed. Consultation with an otolaryngologist, an ophthalmologist, and an infectious disease expert is appropriate for guidance regarding the need for surgical intervention and the selection of antimicrobial agents.

Intracranial complications are most frequently encountered in previously healthy adolescent males with frontal sinusitis.[33,34] In patients with altered mental status, severe headache, or Pott's puffy tumor (osteomyelitis of the frontal bone), neurosurgical consultation should be obtained. A contrast-enhanced CT scan (preferably coronal thin cut) of the head, orbits, and sinuses is essential to confirm intracranial or intraorbital suppurative complications; in such cases, intravenous antibiotics should be started immediately. Alternatively, an MRI may also be desirable in some cases of intracranial abnormality. Appropriate antimicrobial therapy for intraorbital complications include vancomycin (to cover possible methicillin-resistant *S aureus* or penicillin-resistant *S pneumoniae*) and either ceftriaxone, ampicillin-sulbactam, or piperacillin-tazobactam.[103] Given the polymicrobial nature of sinogenic abscesses, coverage for anaerobes (ie, metronidazole) should also be considered for intraorbital complications and should be started in all cases of intracranial complications if ceftriaxone is prescribed.

Patients with small orbital, subperiosteal, or epidural abscesses and minimal ocular and neurologic abnormalities may be managed with intravenous antibiotic treatment for 24 to 48 hours while performing frequent visual and mental status checks.[104] In patients who develop progressive signs and symptoms, such as impaired visual acuity, ophthalmoplegia, elevated intraocular pressure (>20 mm), severe proptosis (>5 mm), altered mental status, headache, or vomiting, as well as those who fail to improve within 24 to 48 hours while receiving antibiotics, prompt surgical intervention and drainage of the abscess should be undertaken.[104] Antibiotics can be tailored to the results of culture and sensitivity studies when they become available.

AREAS FOR FUTURE RESEARCH

Since the publication of the original guideline in 2001, only a small number of high-quality studies of the diagnosis and treatment of acute bacterial sinusitis in children have been published.[5] Ironically, the number of published guidelines on the topic (5) exceeds the number of prospective,

placebo-controlled clinical trials of either antibiotics or ancillary treatments of acute bacterial sinusitis. Thus, as was the case in 2001, there are scant data on which to base recommendations. Accordingly, areas for future research include the following:

Etiology

1. Reexamine the microbiology of acute sinusitis in children in the postpneumococcal conjugate vaccine era and determine the value of using newer polymerase chain reaction–based respiratory testing to document viral, bacterial, and polymicrobial disease.
2. Correlate cultures obtained from the middle meatus of the maxillary sinus of infected children with cultures obtained from the maxillary sinus by puncture of the antrum.
3. Conduct more and larger studies to more clearly define and correlate the clinical findings with the various available diagnostic criteria of acute bacterial sinusitis (eg, sinus aspiration and treatment outcome).
4. Develop noninvasive strategies to accurately diagnose acute bacterial sinusitis in children.
5. Develop imaging technology that differentiates bacterial infection from viral infection or allergic inflammation, preferably without radiation.

Treatment

1. Determine the optimal duration of antimicrobial therapy for children with acute bacterial sinusitis.
2. Evaluate a "wait-and-see prescription" strategy for children with persistent symptom presentation of acute sinusitis.
3. Determine the optimal antimicrobial agent for children with acute bacterial sinusitis, balancing the incentives of choosing narrow-spectrum agents against the known microbiology of the disease and resistance patterns of likely pathogens.
4. Determine the causes and treatment of subacute, recurrent acute, and chronic bacterial sinusitis.
5. Determine the efficacy of prophylaxis with antimicrobial agents to prevent RABS.
6. Determine the effects of bacterial resistance among *S pneumoniae*, *H influenzae*, and *M catarrhalis* on outcome of treatment with antibiotics by the performance of randomized, double-blind, placebo-controlled studies in well-defined populations of patients.
7. Determine the role of adjuvant therapies (antihistamines, nasal corticosteroids, mucolytics, decongestants, nasal irrigation, etc) in patients with acute bacterial sinusitis by the performance of prospective, randomized clinical trials.
8. Determine whether early treatment of acute bacterial sinusitis prevents orbital or central nervous system complications.
9. Determine the role of complementary and alternative medicine strategies in patients with acute bacterial sinusitis by performing systematic, prospective, randomized clinical trials.
10. Develop new bacterial and viral vaccines to reduce the incidence of acute bacterial sinusitis.

SUBCOMMITTEE ON ACUTE SINUSITIS

Ellen R. Wald, MD, FAAP (Chair, Pediatric Infectious Disease Physician: no financial conflicts; published research related to sinusitis)
Kimberly E. Applegate, MD, MS, FAAP (Radiologist, AAP Section on Radiology: no conflicts)
Clay Bordley, MD, MPH, FAAP (Pediatric Emergency and Hospitalist Medicine physician: no conflicts)
David H. Darrow, MD, FAAP (Otolaryngologist, AAP Section on Otolaryngology–Head and Neck Surgery: no conflicts)
Mary P. Glode, MD, FAAP (Pediatric Infectious Disease Physician, AAP Committee on Infectious Disease: no conflicts)
S. Michael Marcy, MD, FAAP (General Pediatrician with Infectious Disease Expertise, AAP Section on Infectious Diseases: no conflicts)
Nader Shaikh, MD, FAAP (General Academic Pediatrician: no financial conflicts; published research related to sinusitis)
Michael J. Smith, MD, MSCE, FAAP (Epidemiologist, Pediatric Infectious Disease Physician: research funding for vaccine clinical trials from Sanofi Pasteur and Novartis)
Paul V. Williams, MD, FAAP (Allergist, AAP Section on Allergy, Asthma, and Immunology: no conflicts)
Stuart T. Weinberg, MD, FAAP (PPI Informatician, General Academic Pediatrician: no conflicts)
Carrie E. Nelson, MD, MS (Family Physician, American Academy of Family Physicians: employed by McKesson Health Solutions)
Richard M. Rosenfeld, MD, MPH, FAAP (Otolaryngologist, AAP Section on Otolaryngology–Head and Neck Surgery, American Academy of Otolaryngology–Head and Neck Surgery: no financial conflicts; published research related to sinusitis)

CONSULTANT

Richard N. Shiffman, MD, FAAP (Informatician, Guideline Methodologist, General Academic Pediatrician: no conflicts)

STAFF

Caryn Davidson, MA

REFERENCES

1. Aitken M, Taylor JA. Prevalence of clinical sinusitis in young children followed up by primary care pediatricians. *Arch Pediatr Adolesc Med.* 1998;152(3):244–248
2. Kakish KS, Mahafza T, Batieha A, Ekteish F, Daoud A. Clinical sinusitis in children attending primary care centers. *Pediatr Infect Dis J.* 2000;19(11):1071–1074
3. Ueda D, Yoto Y. The ten-day mark as a practical diagnostic approach for acute paranasal sinusitis in children. *Pediatr Infect Dis J.* 1996;15(7):576–579

4. Wald ER, Nash D, Eickhoff J. Effectiveness of amoxicillin/clavulanate potassium in the treatment of acute bacterial sinusitis in children. *Pediatrics*. 2009;124(1):9–15
5. American Academy of Pediatrics, Subcommittee on Management of Sinusitis and Committee on Quality Improvement. Clinical practice guideline: management of sinusitis. *Pediatrics*. 2001;108(3):798–808
6. Smith MJ. AAP technical report: evidence for the diagnosis and treatment of acute uncomplicated sinusitis in children: a systematic review. 2013, In press.
7. Shiffman RN, Michel G, Rosenfeld RM, Davidson C. Building better guidelines with BRIDGE-Wiz: development and evaluation of a software assistant to promote clarity, transparency, and implementability. *J Am Med Inform Assoc*. 2012;19(1):94–101
8. American Academy of Pediatrics, Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877
9. Gwaltney JM, Jr, Hendley JO, Simon G, Jordan WS Jr. Rhinovirus infections in an industrial population. II. Characteristics of illness and antibody response. *JAMA*. 1967;202(6):494–500
10. Pappas DE, Hendley JO, Hayden FG, Winther B. Symptom profile of common colds in school-aged children. *Pediatr Infect Dis J*. 2008;27(1):8–11
11. Wald ER, Guerra N, Byers C. Frequency and severity of infections in day care: three-year follow-up. *J Pediatr*. 1991;118(4 pt 1):509–514
12. Wald ER, Guerra N, Byers C. Upper respiratory tract infections in young children: duration of and frequency of complications. *Pediatrics*. 1991;87(2):129–133
13. Meltzer EO, Hamilos DL, Hadley JA, et al. Rhinosinusitis: establishing definitions for clinical research and patient care. *J Allergy Clin Immunol*. 2004;114(6 suppl):155–212
14. Shaikh N, Wald ER. Signs and symptoms of acute sinusitis in children. *Pediatr Infect Dis J*. 2013; in press
15. Wald ER. The diagnosis and management of sinusitis in children: diagnostic considerations. *Pediatr Infect Dis*. 1985;4(6 suppl):S61–S64
16. Wald ER, Milmoe GJ, Bowen A, Ledesma-Medina J, Salamon N, Bluestone CD. Acute maxillary sinusitis in children. *N Engl J Med*. 1981;304(13):749–754
17. Lindbaek M, Hjortdahl P, Johnsen UL. Use of symptoms, signs, and blood tests to diagnose acute sinus infections in primary care: comparison with computed tomography. *Fam Med*. 1996;28(3):183–188
18. Wald ER. Beginning antibiotics for acute rhinosinusitis and choosing the right treatment. *Clin Rev Allergy Immunol*. 2006;30(3):143–152
19. Maresh MM, Washburn AH. Paranasal sinuses from birth to late adolescence. II. Clinical and roentgenographic evidence of infection. *Am J Dis Child*. 1940;60:841–861
20. Glasier CM, Mallory GB, Jr, Steele RW. Significance of opacification of the maxillary and ethmoid sinuses in infants. *J Pediatr*. 1989;114(1):45–50
21. Kovatch AL, Wald ER, Ledesma-Medina J, Chiponis DM, Bedingfield B. Maxillary sinus radiographs in children with nonrespiratory complaints. *Pediatrics*. 1984;73(3):306–308
22. Shopfner CE, Rossi JO. Roentgen evaluation of the paranasal sinuses in children. *Am J Roentgenol Radium Ther Nucl Med*. 1973;118(1):176–186
23. Diament MJ, Senac MO, Jr, Gilsanz V, Baker S, Gillespie T, Larsson S. Prevalence of incidental paranasal sinuses opacification in pediatric patients: a CT study. *J Comput Assist Tomogr*. 1987;11(3):426–431
24. Glasier CM, Ascher DP, Williams KD. Incidental paranasal sinus abnormalities on CT of children: clinical correlation. *AJNR Am J Neuroradiol*. 1986;7(5):861–864
25. Gwaltney JM, Jr, Phillips CD, Miller RD, Riker DK. Computed tomographic study of the common cold. *N Engl J Med*. 1994;330(1):25–30
26. Manning SC, Biavati MJ, Phillips DL. Correlation of clinical sinusitis signs and symptoms to imaging findings in pediatric patients. *Int J Pediatr Otorhinolaryngol*. 1996;37(1):65–74
27. Gordts F, Clement PA, Destryker A, Desprechins B, Kaufman L. Prevalence of sinusitis signs on MRI in a non-ENT paediatric population. *Rhinology*. 1997;35(4):154–157
28. Kristo A, Uhari M, Luotonen J, et al. Paranasal sinus findings in children during respiratory infection evaluated with magnetic resonance imaging. *Pediatrics*. 2003;111(5 pt 1):e586–e589
29. Brook I. Microbiology and antimicrobial treatment of orbital and intracranial complications of sinusitis in children and their management. *Int J Pediatr Otorhinolaryngol*. 2009;73(9):1183–1186
30. Sultesz M, Csakanyi Z, Majoros T, Farkas Z, Katona G. Acute bacterial rhinosinusitis and its complications in our pediatric otolaryngological department between 1997 and 2006. *Int J Pediatr Otorhinolaryngol*. 2009;73(11):1507–1512
31. Wald ER. Periorbital and orbital infections. *Infect Dis Clin North Am*. 2007;21(2):393–408
32. Chandler JR, Langenbrunner DJ, Stevens ER. The pathogenesis of orbital complications in acute sinusitis. *Laryngoscope*. 1970;80(9):1414–1428
33. Kombogiorgas D, Seth R, Modha J, Singh J. Suppurative intracranial complications of sinusitis in adolescence. Single institute experience and review of the literature. *Br J Neurosurg*. 2007;21(6):603–609
34. Rosenfeld EA, Rowley AH. Infectious intracranial complications of sinusitis, other than meningitis in children: 12 year review. *Clin Infect Dis*. 1994;18(5):750–754
35. American College of Radiology. Appropriateness criteria for sinonasal disease. 2009. Available at: www.acr.org/~/media/8172B4DE503149248E64856857674BB5.pdf. Accessed November 6, 2012
36. Triulzi F, Zirpoli S. Imaging techniques in the diagnosis and management of rhinosinusitis in children. *Pediatr Allergy Immunol*. 2007;18(suppl 18):46–49
37. McIntosh D, Mahadevan M. Failure of contrast enhanced computed tomography scans to identify an orbital abscess. The benefit of magnetic resonance imaging. *J Laryngol Otol*. 2008;122(6):639–640
38. Younis RT, Anand VK, Davidson B. The role of computed tomography and magnetic resonance imaging in patients with sinusitis with complications. *Laryngoscope*. 2002;112(2):224–229
39. Shapiro DJ, Gonzales R, Cabana MD, Hersh AL. National trends in visit rates and antibiotic prescribing for children with acute sinusitis. *Pediatrics*. 2011;127(1):28–34
40. Wald ER, Reilly JS, Casselbrant M, et al. Treatment of acute maxillary sinusitis in childhood: a comparative study of amoxicillin and cefaclor. *J Pediatr*. 1984;104(2):297–302
41. Wald ER, Chiponis D, Ledesma-Medina J. Comparative effectiveness of amoxicillin and amoxicillin-clavulanate potassium in acute paranasal sinus infections in children: a double-blind, placebo-controlled trial. *Pediatrics*. 1986;77(6):795–800
42. Garbutt JM, Goldstein M, Gellman E, Shannon W, Littenberg B. A randomized, placebo-controlled trial of antimicrobial treatment for children with clinically diagnosed acute sinusitis. *Pediatrics*. 2001;107(4):619–625

43. Kristo A, Uhari M, Luotonen J, Ilkko E, Koivunen P, Alho OP. Cefuroxime axetil versus placebo for children with acute respiratory infection and imaging evidence of sinusitis: a randomized, controlled trial. *Acta Paediatr*. 2005;94(9): 1208–1213
44. Hoberman A, Paradise JL, Rockette HE, et al. Treatment of acute otitis media in children under 2 years of age. *N Engl J Med*. 2011;364(2):105–115
45. Tahtinen PA, Laine MK, Huovinen P, Jalava J, Ruuskanen O, Ruohola A. A placebo-controlled trial of antimicrobial treatment for acute otitis media. *N Engl J Med*. 2011;364(2):116–126
46. Gordts F, Abu Nasser I, Clement PA, Pierard D, Kaufman L. Bacteriology of the middle meatus in children. *Int J Pediatr Otorhinolaryngol*. 1999;48(2):163–167
47. Parsons DS, Wald ER. Otitis media and sinusitis: similar diseases. *Otolaryngol Clin North Am*. 1996;29(1):11–25
48. Revai K, Dobbs LA, Nair S, Patel JA, Grady JJ, Chonmaitree T. Incidence of acute otitis media and sinusitis complicating upper respiratory tract infection: the effect of age. *Pediatrics*. 2007;119(6). Available at: www.pediatrics.org/cgi/content/full/119/6/e1408
49. Klein JO, Bluestone CD. *Textbook of Pediatric Infectious Diseases*. 6th ed. Philadelphia, PA: Saunders; 2009
50. Casey JR, Adlowitz DG, Pichichero ME. New patterns in the otopathogens causing acute otitis media six to eight years after introduction of pneumococcal conjugate vaccine. *Pediatr Infect Dis J*. 2010;29(4): 304–309
51. Brook I, Gober AE. Frequency of recovery of pathogens from the nasopharynx of children with acute maxillary sinusitis before and after the introduction of vaccination with the 7-valent pneumococcal vaccine. *Int J Pediatr Otorhinolaryngol*. 2007;71(4):575–579
52. Wald ER. Microbiology of acute and chronic sinusitis in children. *J Allergy Clin Immunol*. 1992;90(3 pt 2):452–456
53. Centers for Disease Control and Prevention. Effects of new penicillin susceptibility breakpoints for *Streptococcus pneumoniae*—United States, 2006-2007. *MMWR Morb Mortal Wkly Rep*. 2008;57 (50):1353–1355
54. Centers for Disease Control and Prevention. Active Bacterial Core Surveillance (ABCs): Emerging Infections Program Network. 2011. Available at: www.cdc.gov/abcs/reports-findings/survreports/spneu09.html. Accessed November 6, 2012
55. Garbutt J, St Geme JW, III, May A, Storch GA, Shackelford PG. Developing community-specific recommendations for first-line treatment of acute otitis media: is high-dose amoxicillin necessary? *Pediatrics*. 2004;114(2):342–347
56. Harrison CJ, Woods C, Stout G, Martin B, Selvarangan R. Susceptibilities of *Haemophilus influenzae, Streptococcus pneumoniae*, including serotype 19A, and *Moraxella catarrhalis* paediatric isolates from 2005 to 2007 to commonly used antibiotics. *J Antimicrob Chemother*. 2009; 63(3):511–519
57. Critchley IA, Jacobs MR, Brown SD, Traczewski MM, Tillotson GS, Janjic N. Prevalence of serotype 19A Streptococcus pneumoniae among isolates from U.S. children in 2005-2006 and activity of faropenem. *Antimicrob Agents Chemother*. 2008;52(7):2639–2643
58. Jacobs MR, Good CE, Windau AR, et al. Activity of ceftaroline against recent emerging serotypes of *Streptococcus pneumoniae* in the United States. *Antimicrob Agents Chemother*. 2010;54(6):2716–2719
59. Tristram S, Jacobs MR, Appelbaum PC. Antimicrobial resistance in *Haemophilus influenzae*. *Clin Microbiol Rev*. 2007;20(2): 368–389
60. Levine OS, Farley M, Harrison LH, Lefkowitz L, McGeer A, Schwartz B. Risk factors for invasive pneumococcal disease in children: a population-based case-control study in North America. *Pediatrics*. 1999; 103(3). Available at: www.pediatrics.org/cgi/content/full/103/3/e28
61. Seikel K, Shelton S, McCracken GH Jr. Middle ear fluid concentrations of amoxicillin after large dosages in children with acute otitis media. *Pediatr Infect Dis J*. 1997;16(7):710–711
62. Cohen R, Navel M, Grunberg J, et al. One dose ceftriaxone vs. ten days of amoxicillin/clavulanate therapy for acute otitis media: clinical efficacy and change in nasopharyngeal flora. *Pediatr Infect Dis J*. 1999;18(5):403–409
63. Green SM, Rothrock SG. Single-dose intramuscular ceftriaxone for acute otitis media in children. *Pediatrics*. 1993;91(1): 23–30
64. Leibovitz E, Piglansky L, Raiz S, Press J, Leiberman A, Dagan R. Bacteriologic and clinical efficacy of one day vs. three day intramuscular ceftriaxone for treatment of nonresponsive acute otitis media in children. *Pediatr Infect Dis J*. 2000;19(11): 1040–1045
65. DePestel DD, Benninger MS, Danziger L, et al. Cephalosporin use in treatment of patients with penicillin allergies. *J Am Pharm Assoc*. 2008;48(4):530–540
66. Pichichero ME. A review of evidence supporting the American Academy of Pediatrics recommendation for prescribing cephalosporin antibiotics for penicillin-allergic patients. *Pediatrics*. 2005;115(4): 1048–1057
67. Pichichero ME, Casey JR. Safe use of selected cephalosporins in penicillin-allergic patients: a meta-analysis. *Otolaryngol Head Neck Surg*. 2007;136(3): 340–347
68. Park MA, Koch CA, Klemawesch P, Joshi A, Li JT. Increased adverse drug reactions to cephalosporins in penicillin allergy patients with positive penicillin skin test. *Int Arch Allergy Immunol*. 2010;153(3): 268–273
69. Jacobs MR. Antimicrobial-resistant Streptococcus pneumoniae: trends and management. *Expert Rev Anti Infect Ther*. 2008; 6(5):619–635
70. Chow AW, Benninger MS, Brook I, et al; Infectious Diseases Society of America. IDSA clinical practice guideline for acute bacterial rhinosinusitis in children and adults. *Clin Infect Dis*. 2012;54(8):e72–e112
71. Brook I, Gober AE. Resistance to antimicrobials used for therapy of otitis media and sinusitis: effect of previous antimicrobial therapy and smoking. *Ann Otol Rhinol Laryngol*. 1999;108(7 pt 1):645–647
72. Brook I, Gober AE. Antimicrobial resistance in the nasopharyngeal flora of children with acute maxillary sinusitis and maxillary sinusitis recurring after amoxicillin therapy. *J Antimicrob Chemother*. 2004;53(2):399–402
73. Dohar J, Canton R, Cohen R, Farrell DJ, Felmingham D. Activity of telithromycin and comparators against bacterial pathogens isolated from 1,336 patients with clinically diagnosed acute sinusitis. *Ann Clin Microbiol Antimicrob*. 2004;3(3): 15–21
74. Jacobs MR, Bajaksouzian S, Zilles A, Lin G, Pankuch GA, Appelbaum PC. Susceptibilities of *Streptococcus pneumoniae* and *Haemophilus influenzae* to 10 oral antimicrobial agents based on pharmacodynamic parameters: 1997 U.S. surveillance study. *Antimicrob Agents Chemother*. 1999;43(8):1901–1908
75. Jacobs MR, Felmingham D, Appelbaum PC, Gruneberg RN. The Alexander Project 1998-2000: susceptibility of pathogens isolated from community-acquired respiratory tract infection to commonly used antimicrobial agents. *J Antimicrob Chemother*. 2003;52(2):229–246

76. Lynch JP, III, Zhanel GG. *Streptococcus pneumoniae*: epidemiology and risk factors, evolution of antimicrobial resistance, and impact of vaccines. *Curr Opin Pulm Med.* 2010;16(3):217–225
77. Sahm DF, Jones ME, Hickey ML, Diakun DR, Mani SV, Thornsberry C. Resistance surveillance of *Streptococcus pneumoniae, Haemophilus influenzae* and *Moraxella catarrhalis* isolated in Asia and Europe, 1997-1998. *J Antimicrob Chemother.* 2000; 45(4):457–466
78. Sokol W. Epidemiology of sinusitis in the primary care setting: results from the 1999-2000 respiratory surveillance program. *Am J Med.* 2001;111(suppl 9A):19S–24S
79. Shaikh N, Wald ER, Pi M. Decongestants, antihistamines and nasal irrigation for acute sinusitis in children. *Cochrane Database Syst Rev.* 2010;(12):CD007909
80. Dolor RJ, Witsell DL, Hellkamp AS, Williams JW, Jr, Califf RM, Simel DL. Comparison of cefuroxime with or without intranasal fluticasone for the treatment of rhinosinusitis. The CAFFS Trial: a randomized controlled trial. *JAMA.* 2001;286(24):3097–3105
81. Meltzer EO, Bachert C, Staudinger H. Treating acute rhinosinusitis: comparing efficacy and safety of mometasone furoate nasal spray, amoxicillin, and placebo. *J Allergy Clin Immunol.* 2005;116(6):1289–1295
82. Meltzer EO, Charous BL, Busse WW, Zinreich SJ, Lorber RR, Danzig MR. Added relief in the treatment of acute recurrent sinusitis with adjunctive mometasone furoate nasal spray. The Nasonex Sinusitis Group. *J Allergy Clin Immunol.* 2000;106 (4):630–637
83. Meltzer EO, Orgel HA, Backhaus JW, et al. Intranasal flunisolide spray as an adjunct to oral antibiotic therapy for sinusitis. *J Allergy Clin Immunol.* 1993;92(6):812–823
84. Nayak AS, Settipane GA, Pedinoff A, et al. Effective dose range of mometasone furoate nasal spray in the treatment of acute rhinosinusitis. *Ann Allergy Asthma Immunol.* 2002;89(3):271–278
85. Williamson IG, Rumsby K, Benge S, et al. Antibiotics and topical nasal steroid for treatment of acute maxillary sinusitis: a randomized controlled trial. *JAMA.* 2007; 298(21):2487–2496
86. Zalmanovici A, Yaphe J. Intranasal steroids for acute sinusitis. *Cochrane Database Syst Rev.* 2009;(4):CD005149
87. Yilmaz G, Varan B, Yilmaz T, Gurakan B. Intranasal budesonide spray as an adjunct to oral antibiotic therapy for acute sinusitis in children. *Eur Arch Otorhinolaryngol.* 2000;257(5):256–259
88. Barlan IB, Erkan E, Bakir M, Berrak S, Basaran MM. Intranasal budesonide spray as an adjunct to oral antibiotic therapy for acute sinusitis in children. *Ann Allergy Asthma Immunol.* 1997;78(6):598–601
89. Bruni FM, De Luca G, Venturoli V, Boner AL. Intranasal corticosteroids and adrenal suppression. *Neuroimmunomodulation.* 2009;16 (5):353–362
90. Kim KT, Rabinovitch N, Uryniak T, Simpson B, O'Dowd L, Casty F. Effect of budesonide aqueous nasal spray on hypothalamic-pituitary-adrenal axis function in children with allergic rhinitis. *Ann Allergy Asthma Immunol.* 2004;93(1):61–67
91. Meltzer EO, Tripathy I, Maspero JF, Wu W, Philpot E. Safety and tolerability of fluticasone furoate nasal spray once daily in paediatric patients aged 6-11 years with allergic rhinitis: subanalysis of three randomized, double-blind, placebo-controlled, multicentre studies. *Clin Drug Investig.* 2009;29(2):79–86
92. Murphy K, Uryniak T, Simpson B, O'Dowd L. Growth velocity in children with perennial allergic rhinitis treated with budesonide aqueous nasal spray. *Ann Allergy Asthma Immunol.* 2006;96(5):723–730
93. Ratner PH, Meltzer EO, Teper A. Mometasone furoate nasal spray is safe and effective for 1-year treatment of children with perennial allergic rhinitis. *Int J Pediatr Otorhinolaryngol.* 2009;73(5):651–657
94. Skoner DP, Gentile DA, Doyle WJ. Effect on growth of long-term treatment with intranasal triamcinolone acetonide aqueous in children with allergic rhinitis. *Ann Allergy Asthma Immunol.* 2008;101(4): 431–436
95. Weinstein S, Qaqundah P, Georges G, Nayak A. Efficacy and safety of triamcinolone acetonide aqueous nasal spray in children aged 2 to 5 years with perennial allergic rhinitis: a randomized, double-blind, placebo-controlled study with an open-label extension. *Ann Allergy Asthma Immunol.* 2009;102(4):339–347
96. Zitt M, Kosoglou T, Hubbell J. Mometasone furoate nasal spray: a review of safety and systemic effects. *Drug Saf.* 2007;30(4): 317–326
97. Adam P, Stiffman M, Blake RL Jr. A clinical trial of hypertonic saline nasal spray in subjects with the common cold or rhinosinusitis. *Arch Fam Med.* 1998;7(1):39–43
98. Wang YH, Yang CP, Ku MS, Sun HL, Lue KH. Efficacy of nasal irrigation in the treatment of acute sinusitis in children. *Int J Pediatr Otorhinolaryngol.* 2009;73(12): 1696–1701
99. Harvey R, Hannan SA, Badia L, Scadding G. Nasal saline irrigations for the symptoms of chronic rhinosinusitis. *Cochrane Database Syst Rev.* 2007;(3):CD006394
100. Kassel JC, King D, Spurling GK. Saline nasal irrigation for acute upper respiratory tract infections. *Cochrane Database Syst Rev.* 2010;(3):CD006821
101. Shapiro GG, Virant FS, Furukawa CT, Pierson WE, Bierman CW. Immunologic defects in patients with refractory sinusitis. *Pediatrics.* 1991;87(3):311–316
102. Wood AJ, Douglas RG. Pathogenesis and treatment of chronic rhinosinusitis. *Postgrad Med J.* 2010;86(1016):359–364
103. Liao S, Durand ML, Cunningham MJ. Sinogenic orbital and subperiosteal abscesses: microbiology and methicillin-resistant Staphylococcus aureus incidence. *Otolaryngol Head Neck Surg.* 2010;143(3):392–396
104. Oxford LE, McClay J. Medical and surgical management of subperiosteal orbital abscess secondary to acute sinusitis in children. *Int J Pediatr Otorhinolaryngol.* 2006;70(11):1853–1861

Sinusitis Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years
- *ICD-10-CM* Coding Quick Reference for Sinusitis
- AAP Patient Education Handout
  — *Sinusitis and Your Child*

Action Statement Summary

Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years

Key Action Statement 1

Clinicians should make a presumptive diagnosis of acute bacterial sinusitis when a child with an acute URI presents with the following:

- Persistent illness, ie, nasal discharge (of any quality) or daytime cough or both lasting more than 10 days without improvement;

OR

- Worsening course, ie, worsening or new onset of nasal discharge, daytime cough, or fever after initial improvement;

OR

- Severe onset, ie, concurrent fever (temperature ≥39°C/102.2°F) and purulent nasal discharge for at least 3 consecutive days (Evidence Quality: B; Recommendation).

Key Action Statement 2A

Clinicians should not obtain imaging studies (plain films, contrast-enhanced computed tomography [CT], MRI, or ultrasonography) to distinguish acute bacterial sinusitis from viral URI (Evidence Quality: B; Strong Recommendation).

Key Action Statement 2B

Clinicians should obtain a contrast-enhanced CT scan of the paranasal sinuses and/or an MRI with contrast whenever a child is suspected of having orbital or central nervous system complications of acute bacterial sinusitis (Evidence Quality: B; Strong Recommendation).

Key Action Statement 3

Initial Management of Acute Bacterial Sinusitis

3A: "Severe onset and worsening course" acute bacterial sinusitis. The clinician should prescribe antibiotic therapy for acute bacterial sinusitis in children with severe onset or worsening course (signs, symptoms, or both) (Evidence Quality: B; Strong Recommendation).

3B: "Persistent illness." The clinician should either prescribe antibiotic therapy OR offer additional outpatient observation for 3 days to children with persistent illness (nasal discharge of any quality or cough or both for at least 10 days without evidence of improvement) (Evidence Quality: B; Recommendation).

Key Action Statement 4

Clinicians should prescribe amoxicillin with or without clavulanate as first-line treatment when a decision has been made to initiate antibiotic treatment of acute bacterial sinusitis (Evidence Quality: B; Recommendation).

Key Action Statement 5A

Clinicians should reassess initial management if there is either a caregiver report of worsening (progression of initial signs/symptoms or appearance of new signs/symptoms) OR failure to improve (lack of reduction in all presenting signs/symptoms) within 72 hours of initial management (Evidence Quality: C; Recommendation).

Key Action Statement 5B

If the diagnosis of acute bacterial sinusitis is confirmed in a child with worsening symptoms or failure to improve in 72 hours, then clinicians may change the antibiotic therapy for the child initially managed with antibiotic OR initiate antibiotic treatment of the child initially managed with observation (Evidence Quality: D; Option based on expert opinion, case reports, and reasoning from first principles).

Coding Quick Reference for Sinusitis
ICD-10-CM
J01.00 Acute maxillary sinusitis, unspecified
J01.01 Acute recurrent maxillary sinusitis
J01.10 Acute frontal sinusitis, unspecified
J01.11 Acute recurrent frontal sinusitis
J01.21 Acute recurrent ethmoidal sinusitis
J01.30 Acute sphenoidal sinusitis, unspecified
J01.31 Acute recurrent sphenoidal sinusitis
J01.40 Acute pansinusitis, unspecified
J01.41 Acute recurrent pansinusitis
J01.80 Other acute sinusitis
J01.81 Other acute recurrent sinusitis
J01.90 Acute sinusitis, unspecified
J01.91 Acute recurrent sinusitis, unspecified
J32.9 Sinusitis NOS

Sinusitis and Your Child

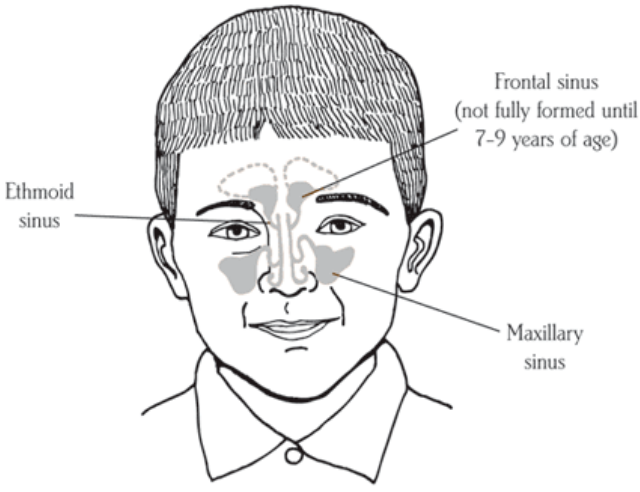
Sinusitis is an inflammation of the lining of the nose and sinuses. It is a very common infection in children.

Viral sinusitis usually accompanies a cold. Allergic sinusitis may accompany allergies such as hay fever. Bacterial sinusitis is a secondary infection caused by the trapping of bacteria in the sinuses during the course of a cold or allergy.

Fluid inside the sinuses

When your child has a viral cold or hay fever, the linings of the nose and sinus cavities swell up and produce more fluid than usual. This is why the nose gets congested and is "runny" during a cold.

Most of the time the swelling disappears by itself as the cold or allergy goes away. However, if the swelling does not go away, the openings that normally allow the sinuses to drain into the back of the nose get blocked and the sinuses fill with fluid. Because the sinuses are blocked and cannot drain properly, bacteria are trapped inside and grow there, causing a secondary infection. Although nose blowing and sniffing may be natural responses to this blockage, when excessive they can make the situation worse by pushing bacteria from the back of the nose into the sinuses.



The linings of the sinuses and the nose always produce some fluid (secretions). This fluid keeps the nose and sinus cavities from becoming too dry and adds moisture to the air that you breathe.

Is it a cold or bacterial sinusitis?

It is often difficult to tell if an illness is just a viral cold or if it is complicated by a bacterial infection of the sinuses.

Generally viral colds have the following characteristics:

- Colds usually last only 5 to 10 days.
- Colds typically start with clear, watery nasal discharge. After a day or 2, it is normal for the nasal discharge to become thicker and white, yellow, or green. After several days, the discharge becomes clear again and dries.
- Colds include a daytime cough that often gets worse at night.
- If a fever is present, it is usually at the beginning of the cold and is generally low grade, lasting for 1 or 2 days.
- Cold symptoms usually peak in severity at 3 or 5 days, then improve and disappear over the next 7 to 10 days.

Signs and symptoms that your child may have bacterial sinusitis include:

- Cold symptoms (nasal discharge, daytime cough, or both) lasting more than 10 days *without improving*
- Thick yellow nasal discharge *and* a fever for at least 3 or 4 days in a row
- A severe headache behind or around the eyes that gets worse when bending over
- Swelling and dark circles around the eyes, especially in the morning
- Persistent bad breath along with cold symptoms (However, this also could be from a sore throat or a sign that your child is not brushing his teeth!)

In very rare cases, a bacterial sinus infection may spread to the eye or the central nervous system (the brain). If your child has the following symptoms, call your pediatrician immediately:

- Swelling and/or redness around the eyes, not just in the morning but all day
- Severe headache and/or pain in the back of the neck
- Persistent vomiting
- Sensitivity to light
- Increasing irritability

Diagnosing bacterial sinusitis

It may be difficult to tell a sinus infection from an uncomplicated cold, especially in the first few days of the illness. Your pediatrician will most likely be able to tell if your child has bacterial sinusitis after examining your child and hearing about the progression of symptoms. In older children, when the diagnosis is uncertain, your pediatrician may order computed tomographic (CT) scans to confirm the diagnosis.

Treating bacterial sinusitis

If your child has bacterial sinusitis, your pediatrician may prescribe an antibiotic for at least 10 days. Once your child is on the medication, symptoms should start to go away over the next 2 to 3 days—the nasal discharge will clear and the cough will improve. *Even though your child may seem better, continue to give the antibiotics for the prescribed length of time. Ending the medications too early could cause the infection to return.*

When a diagnosis of sinusitis is made in children with cold symptoms lasting more than 10 days without improving, some doctors may choose to continue observation for another few days. If your child's symptoms worsen during this time or do not improve after 3 days, antibiotics should be started.

If your child's symptoms show no improvement 2 to 3 days after starting the antibiotics, talk with your pediatrician. Your child might need a different medication or need to be re-examined.

Treating related symptoms of bacterial sinusitis

Headache or sinus pain. To treat headache or sinus pain, try placing a warm washcloth on your child's face for a few minutes at a time. Pain medications such as acetaminophen or ibuprofen may also help. (However, do not give your child aspirin. It has been associated with a rare but potentially fatal disease called Reye syndrome.)

Nasal congestion. If the secretions in your child's nose are especially thick, your pediatrician may recommend that you help drain them with saline nose drops. These are available without a prescription or can be made at home by adding 1/4 teaspoon of table salt to an 8-ounce cup of water. Unless advised by your pediatrician, do not use nose drops that contain medications because they can be absorbed in amounts that can cause side effects.

Placing a cool-mist humidifier in your child's room may help keep your child more comfortable. Clean and dry the humidifier daily to prevent bacteria or mold from growing in it (follow the instructions that came with the humidifier). Hot water vaporizers are not recommended because they can cause scalds or burns.

Remember

If your child has symptoms of a bacterial sinus infection, see your pediatrician. Your pediatrician can properly diagnose and treat the infection and recommend ways to help alleviate the discomfort from some of the symptoms.

From your doctor

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site — www.HealthyChildren.org

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome

- *Clinical Practice Guideline*

CLINICAL PRACTICE GUIDELINE

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome

abstract

FREE

OBJECTIVES: This revised clinical practice guideline, intended for use by primary care clinicians, provides recommendations for the diagnosis and management of the obstructive sleep apnea syndrome (OSAS) in children and adolescents. This practice guideline focuses on uncomplicated childhood OSAS, that is, OSAS associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child who is being treated in the primary care setting.

METHODS: Of 3166 articles from 1999–2010, 350 provided relevant data. Most articles were level II–IV. The resulting evidence report was used to formulate recommendations.

RESULTS AND CONCLUSIONS: The following recommendations are made. (1) All children/adolescents should be screened for snoring. (2) Polysomnography should be performed in children/adolescents with snoring and symptoms/signs of OSAS; if polysomnography is not available, then alternative diagnostic tests or referral to a specialist for more extensive evaluation may be considered. (3) Adenotonsillectomy is recommended as the first-line treatment of patients with adenotonsillar hypertrophy. (4) High-risk patients should be monitored as inpatients postoperatively. (5) Patients should be reevaluated postoperatively to determine whether further treatment is required. Objective testing should be performed in patients who are high risk or have persistent symptoms/signs of OSAS after therapy. (6) Continuous positive airway pressure is recommended as treatment if adenotonsillectomy is not performed or if OSAS persists postoperatively. (7) Weight loss is recommended in addition to other therapy in patients who are overweight or obese. (8) Intranasal corticosteroids are an option for children with mild OSAS in whom adenotonsillectomy is contraindicated or for mild postoperative OSAS. *Pediatrics* 2012;130:576–584

INTRODUCTION

Obstructive sleep apnea syndrome (OSAS) is a common condition in childhood and can result in severe complications if left untreated. In 2002, the American Academy of Pediatrics (AAP) published a practice guideline for the diagnosis and management of childhood OSAS.[1] Since that time, there has been a considerable increase in publications and research on the topic; thus, the guidelines have been revised.

Carole L. Marcus, MBBCh, Lee Jay Brooks, MD, Kari A. Draper, MD, David Gozal, MD, Ann Carol Halbower, MD, Jacqueline Jones, MD, Michael S. Schechter, MD, MPH, Stephen Howard Sheldon, DO, Karen Spruyt, PhD, Sally Davidson Ward, MD, Christopher Lehmann, MD, Richard N. Shiffman, MD

KEY WORDS

snoring, sleep-disordered breathing, adenotonsillectomy, continuous positive airway pressure

ABBREVIATIONS

AAP—American Academy of Pediatrics
AHI—apnea hypopnea index
CPAP—continuous positive airway pressure
OSAS—obstructive sleep apnea syndrome

www.pediatrics.org/cgi/doi/10.1542/peds.2012-1671

doi:10.1542/peds.2012-1671

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

The purposes of this revised clinical practice guideline are to (1) increase the recognition of OSAS by primary care clinicians to minimize delay in diagnosis and avoid serious sequelae of OSAS; (2) evaluate diagnostic techniques; (3) describe treatment options; (4) provide guidelines for follow-up; and (5) discuss areas requiring further research. The recommendations in this statement do not indicate an exclusive course of treatment. Variations, taking into account individual circumstances, may be appropriate.

This practice guideline focuses on uncomplicated childhood OSAS—that is, the OSAS associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child who is being treated in the primary care setting. This guideline specifically excludes infants younger than 1 year of age, patients with central apnea or hypoventilation syndromes, and patients with OSAS associated with other medical disorders, including but not limited to Down syndrome, craniofacial anomalies, neuromuscular disease (including cerebral palsy), chronic lung disease, sickle cell disease, metabolic disease, or laryngomalacia. These important patient populations are too complex to discuss within the scope of this article and require consultation with a pediatric subspecialist.

Additional information providing justification for the key action statements and a detailed review of the literature are provided in the accompanying technical report available online.[2]

METHODS OF GUIDELINE DEVELOPMENT

Details of the methods of guideline development are included in the accompanying technical report.[2] The AAP selected a subcommittee composed of pediatricians and other experts in the fields of sleep medicine, pulmonology, and otolaryngology, as well as experts from epidemiology and pediatric practice to develop an evidence base of literature on this topic. The committee included liaison members from the AAP Section on Otolaryngology-Head and Neck Surgery, American Thoracic Society, American Academy of Sleep Medicine, American College of Chest Physicians, and the National Sleep Foundation. Committee members signed forms disclosing conflicts of interest.

An automated search of the literature on childhood OSAS from 1999 to 2008 was performed by using 5 scientific literature search engines.[2] The medical subject heading terms that were used in all fields were snoring, apnea, sleep-disordered breathing, sleep-related breathing disorders, upper airway resistance, polysomnography, sleep study, adenoidectomy, tonsillectomy, continuous positive airway pressure, obesity, adiposity, hypopnea, hypoventilation, cognition, behavior, and neuropsychology. Reviews, case reports, letters to the editor, and abstracts were not included. Non–English-language articles, animal studies, and studies relating to infants younger than 1 year and to special populations (eg, children with craniofacial anomalies or sickle cell disease) were excluded. In several steps, a total of 3166 hits was reduced to 350 articles, which underwent detailed review.[2] Committee members selectively updated this literature search for articles published from 2008 to 2011 specific to guideline categories. Details of the literature grading system are available in the accompanying technical report.

Since publication of the previous guidelines, there has been an improvement in the quality of OSAS studies in the literature; however, there remain few randomized, blinded, controlled studies. Most studies were questionnaire or polysomnography based. Many studies used standard definitions for pediatric polysomnography scoring, but the interpretation of polysomnography (eg, the apnea hypopnea index [AHI] criterion used for diagnosis or to determine treatment) varied widely. The guideline notes the quality of evidence for each key action statement. Additional details are available in the technical report.

The evidence-based approach to guideline development requires that the evidence in support of each key action statement be identified, appraised, and summarized and that an explicit link between evidence and recommendations be defined. Evidence-based recommendations reflect the quality of evidence and the balance of benefit and harm that is anticipated when the recommendation is followed. The AAP policy statement, "Classifying Recommendations for Clinical Practice Guidelines,"[3] was followed in designating levels of recommendation (see Fig 1 and Table 1).

DEFINITION

This guideline defines OSAS in children as a "disorder of breathing during sleep characterized by prolonged partial upper airway obstruction and/or intermittent complete obstruction (obstructive apnea) that disrupts normal ventilation during sleep and normal sleep patterns,"[4] accompanied by symptoms or signs, as listed in Table 2. Prevalence rates based on level I and II studies range from 1.2% to 5.7%.[5–7] Symptoms include habitual snoring (often with intermittent pauses, snorts, or gasps), disturbed sleep, and daytime neurobehavioral problems. Daytime sleepiness may occur, but is uncommon in young children. OSAS is associated with neurocognitive impairment, behavioral problems, failure to thrive, hypertension, cardiac dysfunction, and systemic inflammation. Risk factors include adenotonsillar hypertrophy, obesity, craniofacial anomalies, and neuromuscular disorders. Only the first 2 risk factors are

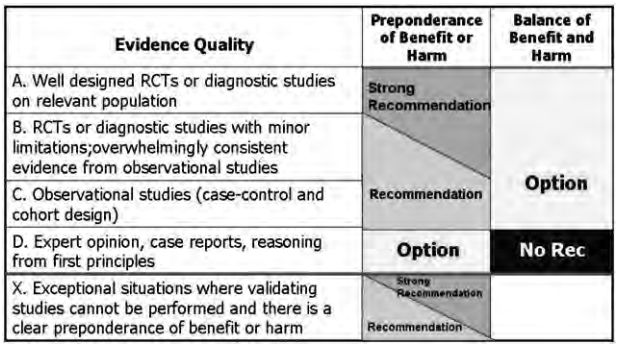


FIGURE 1

Evidence quality. Integrating evidence quality appraisal with an assessment of the anticipated balance between benefits and harms if a policy is carried out leads to designation of a policy as a strong recommendation, recommendation, option, or no recommendation. RCT, randomized controlled trial; Rec, recommendation.

discussed in this guideline. In this guideline, obesity is defined as a BMI >95th percentile for age and gender.[8]

KEY ACTION STATEMENTS

Key Action Statement 1: Screening for OSAS

As part of routine health maintenance visits, clinicians should inquire whether the child or adolescent snores. If the answer is affirmative or if a child or adolescent presents with signs or symptoms of OSAS (Table 2), clinicians should perform a more focused evaluation. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 1

- Aggregate evidence quality: B
- Benefit: Early identification of OSAS is desirable, because it is a high-prevalence condition, and identification and treatment can result in alleviation of current symptoms, improved quality of life, prevention of sequelae, education of parents, and decreased health care utilization.
- Harm: Provider time, patient and parent time.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Panelists believe that identification of a serious medical condition outweighs the time expenditure necessary for screening.
- Role of patient preferences: None.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Almost all children with OSAS snore,[9–11] although caregivers frequently do not volunteer this information at medical visits.[12] Thus, asking about snoring at each health maintenance visit (as well as at other appropriate times, such as when evaluating for tonsillitis) is a sensitive, albeit nonspecific, screening measure that is quick and easy to perform. Snoring is common in children and adolescents; however, OSAS is less common. Therefore, an affirmative answer should be followed by a detailed history and examination to determine whether further evaluation for OSAS is needed (Table 2); this clinical evaluation alone

TABLE 1 Definitions and Recommendation Implications

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	It would be prudent for clinicians to follow a recommendation, but they should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to one approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

TABLE 2 Symptoms and Signs of OSAS

History
Frequent snoring (≥3 nights/wk)
Labored breathing during sleep
Gasps/snorting noises/observed episodes of apnea
Sleep enuresis (especially secondary enuresis)[a]
Sleeping in a seated position or with the neck hyperextended
Cyanosis
Headaches on awakening
Daytime sleepiness
Attention-deficit/hyperactivity disorder
Learning problems
Physical examination
Underweight or overweight
Tonsillar hypertrophy
Adenoidal facies
Micrognathia/retrognathia
High-arched palate
Failure to thrive
Hypertension

[a] Enuresis after at least 6 mo of continence.

does not establish the diagnosis (see technical report). Occasional snoring, for example, with an upper respiratory tract infection, is less of a concern than snoring that occurs at least 3 times a week and is associated with any of the symptoms or signs listed in Table 2.

Key Action Statement 2A: Polysomnography

If a child or adolescent snores on a regular basis and has any of the complaints or findings shown in Table 2, clinicians should either (1) obtain a polysomnogram (Evidence Quality A, Key Action strength: Recommendation) OR (2) refer the patient to a sleep specialist or otolaryngologist for a more extensive evaluation (Evidence quality D, Key Action strength: Option). (Evidence Quality: Grade A for polysomnography; Grade D for specialist referral, Recommendation Strength: Recommendation.)

Evidence Profile KAS 2A: Polysomnography

- Aggregate evidence quality: A
- Benefits: Establish diagnosis and determine severity of OSAS.
- Harm: Expense, time, anxiety/discomfort.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Panelists weighed the value of establishing a diagnosis as more important than the minor potential harms listed.
- Role of patient preferences: Small because of preponderance of evidence that polysomnography is the most accurate way to make a diagnosis.
- Exclusions: See Key Action Statement 2B regarding lack of availability.
- Intentional vagueness: None.
- Strength: Recommendation.

Evidence Profile KAS 2A: Referral

- Aggregate evidence quality: D
- Benefits: Subspecialist may be better able to establish diagnosis and determine severity of OSAS.
- Harm: Expense, time, anxiety/discomfort.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Panelists weighed the value of establishing a diagnosis as more important than the minor potential harms listed.
- Role of patient preferences: Large.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Option.

Although history and physical examination are useful to screen patients and determine which patients need further investigation for OSAS, the sensitivity and specificity of the history and physical examination are poor (see accompanying technical report). Physical examination when the child is awake may be normal, and the size of the tonsils cannot be used to predict the presence of OSAS in an individual child. Thus, objective testing is required. The gold standard test is overnight, attended, in-laboratory polysomnography (sleep study). This is a noninvasive test involving the measurement of a number of physiologic functions overnight, typically including EEG; pulse oximetry; oronasal airflow, abdominal and chest wall movements, partial pressure of carbon dioxide (P_{CO_2}); and video recording.[13] Specific pediatric measuring and scoring criteria should be used.[13] Polysomnography will demonstrate the presence or absence of OSAS. Polysomnography also demonstrates the severity of OSAS, which is helpful in planning treatment and in postoperative short- and long-term management.

Key Action Statement 2B: Alternative Testing

If polysomnography is not available, then clinicians may order alternative diagnostic tests, such as nocturnal video recording, nocturnal oximetry, daytime nap polysomnography, or ambulatory polysomnography. (Evidence Quality: Grade C, Recommendation Strength: Option.)

Evidence Profile KAS 2B

- Aggregate evidence quality: C
- Benefit: Varying positive and negative predictive values for establishing diagnosis.
- Harm: False-negative and false-positive results may underestimate or overestimate severity, expense, time, anxiety/discomfort.
- Benefits-harms assessment: Equilibrium of benefits and harms.
- Value judgments: Opinion of the panel that some objective testing is better than none. Pragmatic decision based on current shortage of pediatric polysomnography facilities (this may change over time).
- Role of patient preferences: Small, if choices are limited by availability;

families may choose to travel to centers where more extensive facilities are available.

- Exclusions: None.
- Intentional vagueness: None.
- Strength: Option.

Although polysomnography is the gold standard for diagnosis of OSAS, there is a shortage of sleep laboratories with pediatric expertise. Hence, polysomnography may not be readily available in certain regions of the country. Alternative diagnostic tests have been shown to have weaker positive and negative predictive values than polysomnography, but nevertheless, objective testing is preferable to clinical evaluation alone. If an alternative test fails to demonstrate OSAS in a patient with a high pretest probability, full polysomnography should be sought.

Key Action Statement 3: Adenotonsillectomy

If a child is determined to have OSAS, has a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery (see Table 3), the clinician should recommend adenotonsillectomy as the first line of treatment. If the child has OSAS but does not have adenotonsillar hypertrophy, other treatment should be considered (see Key Action Statement 6). Clinical judgment is required to determine the benefits of adenotonsillectomy compared with other treatments in obese children with varying degrees of adenotonsillar hypertrophy. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 3

- Aggregate evidence quality: B
- Benefit: Improve OSAS and accompanying symptoms and sequelae.
- Harm: Pain, anxiety, dehydration, anesthetic complications, hemorrhage, infection, postoperative respiratory difficulties, velopharyngeal incompetence, nasopharyngeal stenosis, death.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: The panel sees the benefits of treating OSAS as more beneficial than the low risk of serious consequences.
- Role of patient preferences: Low; continuous positive airway pressure (CPAP) is an option but involves prolonged, long-term treatment as compared with a single, relatively low-risk surgical procedure.
- Exclusions: See Table 3.
- Intentional vagueness: None.
- Strength: Recommendation.

Adenotonsillectomy is very effective in treating OSAS. Adenoidectomy or tonsillectomy alone may not be sufficient, because residual lymphoid tissue may contribute to persistent obstruction. In otherwise healthy children with adenotonsillar hypertrophy, adenotonsillectomy is associated with improvements in symptoms and sequelae of OSAS. Postoperative polysomnography typically shows a major decrease in the number of obstructive events, although some obstructions may still be present. Although obese children may have less satisfactory results, many will be adequately treated with adenotonsillectomy; however, further research is needed to determine which obese children are most likely to benefit from surgery. In this population, the benefits of a 1-time surgical procedure, with a small but real risk of complications, need to be weighed against long-term treatment with CPAP, which is associated with discomfort, disruption of family lifestyle, and risks of poor adherence. Potential complications of adenotonsillectomy are shown in Table 4. Although serious complications (including death) may occur, the rate of these complications is low, and the risks of complications need to be weighed against the consequences of untreated OSAS. In general, a 1-time only procedure with a relatively low morbidity is preferable to lifelong treatment with CPAP; furthermore, the efficacy of CPAP is limited by generally suboptimal adherence. Other treatment options, such as anti-inflammatory medications, weight loss, or tracheostomy, are less effective, are difficult to achieve, or have higher morbidity, respectively.

TABLE 3 Contraindications for Adenotonsillectomy

Absolute contraindications
No adenotonsillar tissue (tissue has been surgically removed)
Relative contraindications
Very small tonsils/adenoid
Morbid obesity and small tonsils/adenoid
Bleeding disorder refractory to treatment
Submucus cleft palate
Other medical conditions making patient medically unstable for surgery

Key Action Statement 4: High-Risk Patients Undergoing Adenotonsillectomy

Clinicians should monitor high-risk patients (Table 5) undergoing adenotonsillectomy as inpatients postoperatively. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

TABLE 4 Risks of Adenotonsillectomy

Minor
Pain
Dehydration attributable to postoperative nausea/vomiting and poor oral intake
Major
Anesthetic complications
Acute upper airway obstruction during induction or emergence from anesthesia
Postoperative respiratory compromise
Hemorrhage
Velopharyngeal incompetence
Nasopharyngeal stenosis
Death

TABLE 5 Risk Factors for Postoperative Respiratory Complications in Children With OSAS Undergoing Adenotonsillectomy

Younger than 3 y of age
Severe OSAS on polysomnography[a]
Cardiac complications of OSAS
Failure to thrive
Obesity
Craniofacial anomalies[b]
Neuromuscular disorders[b]
Current respiratory infection

[a] It is difficult to provide exact polysomnographic criteria for severity, because these criteria will vary depending on the age of the child; additional comorbidities, such as obesity, asthma, or cardiac complications of OSAS; and other polysomnographic criteria that have not been evaluated in the literature, such as the level of hypercapnia and the frequency of desaturation (as compared with lowest oxygen saturation). Nevertheless, on the basis of published studies (primarily Level III, see Technical Report), it is recommended that all patients with a lowest oxygen saturation <80% (either on preoperative polysomnography or during observation in the recovery room postoperatively) or an AHI ≥24/h be observed as inpatients postoperatively as they are at increased risk for postoperative respiratory compromise. Additionally, on the basis of expert consensus, it is recommended that patients with significant hypercapnia on polysomnography (peak P_{CO_2} ≥60 mm Hg) be admitted postoperatively. The committee noted that that most published studies were retrospective and not comprehensive, and therefore these recommendations may change if higher-level studies are published. Clinicians may decide to admit patients with less severe polysomnographic abnormalities based on a constellation of risk factors (age, comorbidities, and additional polysomnographic factors) for a particular individual.

[b] Not discussed in these guidelines.

Evidence Profile KAS 4

- Aggregate evidence quality: B
- Benefit: Effectively manage severe respiratory compromise and avoid death.
- Harm: Expense, time, anxiety.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: The panel believes that early recognition of any serious adverse events is critically important.
- Role of patient preferences: Minimal; this is an important safety issue.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Patients with OSAS may develop respiratory complications, such as worsening of OSAS or pulmonary edema, in the immediate postoperative period. Death attributable to respiratory complications in the immediate postoperative period has been reported in patients with severe OSAS. Identified risk factors are shown in Table 5. High-risk patients should undergo surgery in a center capable of treating complex pediatric patients. They should be hospitalized overnight for close monitoring postoperatively. Children with an acute respiratory infection on the day of surgery, as documented by fever, cough, and/or wheezing, are at increased risk of postoperative complications and, therefore, should be rescheduled or monitored closely postoperatively. Clinicians should decide on an individual basis whether these patients should be rescheduled, taking into consideration the severity of OSAS in the particular patient and keeping in mind that many children with adenotonsillar hypertrophy have chronic rhinorrhea and nasal congestion, even in the absence of viral infections.

Key Action Statement 5: Reevaluation

Clinicians should clinically reassess all patients with OSAS for persisting signs and symptoms after therapy to determine whether further treatment is required. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 5A

- Aggregate evidence quality: B
- Benefit: Determine effects of treatment.
- Harm: Expense, time.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Data show that a significant proportion of children continue to have abnormalities postoperatively; therefore, the panel determined that the benefits of follow-up outweigh the minor inconveniences.
- Role of patient preferences: Minimal; follow-up is good clinical practice.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Clinicians should reassess OSAS-related symptoms and signs (Table 2) after 6 to 8 weeks of therapy to determine whether further evaluation and treatment are indicated. Objective data regarding the timing of the postoperative evaluation are not available. Most clinicians recommend reevaluation 6 to 8 weeks after treatment to allow for healing of the operative site and to allow time for upper airway, cardiac, and central nervous system recovery. Patients who remain symptomatic should undergo objective testing (see Key Action Statement 2) or be referred to a sleep specialist for further evaluation.

Key Action Statement 5B: Reevaluation of High-Risk Patients

Clinicians should reevaluate high-risk patients for persistent OSAS after adenotonsillectomy, including those who had a significantly abnormal baseline polysomnogram, have sequelae of OSAS, are obese, or remain symptomatic after treatment, with an objective test (see Key Action Statement 2) or refer such patients to a sleep specialist. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 5B

- Aggregate evidence quality: B
- Benefit: Determine effects of treatment.
- Harm: Expense, time, anxiety/discomfort.
- Benefits-harms assessment: Preponderance of benefit over harm.

- Value judgments: Given the panel's concerns about the consequences of OSAS and the frequency of postoperative persistence in high-risk groups, the panel believes that the follow-up costs are outweighed by benefits of recognition of persistent OSAS. A minority of panelists believed that all children with OSAS should have follow-up polysomnography because of the high prevalence of persistent postoperative abnormalities on polysomnography, but most panelists believed that persistent polysomnographic abnormalities in uncomplicated children with mild OSAS were usually mild in patients who were asymptomatic after surgery.
- Role of patient preferences: Minimal. Further evaluation is needed to determine the need for further treatment.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Numerous studies have shown that a large proportion of children at high risk continue to have some degree of OSAS postoperatively[10,13,14]; thus, objective evidence is required to determine whether further treatment is necessary.

Key Action Statement 6: CPAP

Clinicians should refer patients for CPAP management if symptoms/signs (Table 2) or objective evidence of OSAS persists after adenotonsillectomy or if adenotonsillectomy is not performed. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Evidence Profile KAS 6

- Aggregate evidence quality: B
- Benefit: Improve OSAS and accompanying symptoms and sequelae.
- Harm: Expense, time, anxiety; parental sleep disruption; nasal and skin adverse effects; possible midface remodeling; extremely rare serious pressure-related complications, such as pneumothorax; poor adherence.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: Panelists believe that CPAP is the most effective treatment of OSAS that persists postoperatively and that the benefits of treatment outweigh the adverse effects. Other treatments (eg, rapid maxillary expansion) may be effective in specially selected patients.
- Role of patient preferences: Other treatments may be effective in specially selected patients.
- Exclusions: Rare patients at increased risk of severe pressure complications.
- Intentional vagueness: None.
- Policy level: Recommendation.

CPAP therapy is delivered by using an electronic device that delivers air at positive pressure via a nasal mask, leading to mechanical stenting of the airway and improved functional residual capacity in the lungs. There is no clear advantage of using bilevel pressure over CPAP.[15] CPAP should be managed by an experienced and skilled clinician with expertise in its use in children. CPAP pressure requirements vary among individuals and change over time; thus, CPAP must be titrated in the sleep laboratory before prescribing the device and periodically readjusted thereafter. Behavioral modification therapy may be required, especially for young children or those with developmental delays. Objective monitoring of adherence, by using the equipment software, is important. If adherence is suboptimal, the clinician should institute measures to improve adherence (such as behavioral modification, or treating side effects of CPAP) and institute alternative treatments if these measures are ineffective.

Key Action Statement 7: Weight Loss

Clinicians should recommend weight loss in addition to other therapy if a child/adolescent with OSAS is overweight or obese. (Evidence Quality: Grade C, Recommendation Strength: Recommendation.)

Evidence Profile KAS 7

- Aggregate evidence quality: C
- Benefit: Improve OSAS and accompanying symptoms and sequelae; non–OSAS-related benefits of weight loss.
- Harm: Hard to achieve and maintain weight loss.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: The panel agreed that weight loss is beneficial for both OSAS and other health issues, but clinical experience suggests that weight loss is difficult to achieve and maintain, and even effective weight loss regimens take time; therefore, additional treatment is required in the interim.
- Role of patient preferences: Strong role for patient and family preference regarding nutrition and exercise.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Recommendation.

Weight loss has been shown to improve OSAS,[16,17] although the degree of weight loss required has not been determined. Because weight loss is a slow and unreliable process, other treatment modalities (such as adenotonsillectomy or CPAP therapy) should be instituted until sufficient weight loss has been achieved and maintained.

Key Action Statement 8: Intranasal Corticosteroids

Clinicians may prescribe topical intranasal corticosteroids for children with mild OSAS in whom adenotonsillectomy is contraindicated or for children with mild postoperative OSAS. (Evidence Quality: Grade B, Recommendation Strength: Option.)

Evidence Profile KAS 8

- Aggregate evidence quality: B
- Benefit: Improves mild OSAS and accompanying symptoms and sequelae.
- Harm: Some subjects may not have an adequate response. It is not known whether therapeutic effect persists long-term; therefore, long-term observation is required. Low risk of steroid-related adverse effects.
- Benefits-harms assessment: Preponderance of benefit over harm.
- Value judgments: The panel agreed that intranasal steroids provide a less invasive treatment than surgery or CPAP and, therefore, may be preferred in some cases despite lower efficacy and lack of data on long-term efficacy.
- Role of patient preferences: Moderate role for patient and family preference if OSAS is mild.
- Exclusions: None.
- Intentional vagueness: None.
- Strength: Option.

Mild OSAS is defined, for this indication, as an AHI <5 per hour, on the basis of studies on intranasal corticosteroids described in the accompanying technical report.[2] Several studies have shown that the use of intranasal steroids decreases the degree of OSAS; however, although OSAS improves, residual OSAS may remain. Furthermore, there is individual variability in response to treatment, and long-term studies have not been performed to determine the duration of improvement. Therefore, nasal steroids are not recommended as a first-line therapy. The response to treatment should be measured objectively after a course of treatment of approximately 6 weeks. Because the long-term effect of this treatment is unknown, the clinician should continue to observe the patient for symptoms of recurrence and adverse effects of corticosteroids.

AREAS FOR FUTURE RESEARCH

A detailed list of research recommendations is provided in the accompanying technical report.[2] There is a great need for further research into the prevalence of OSAS, sequelae of OSAS, best treatment methods, and the role of obesity. In particular, well-controlled, blinded studies, including randomized controlled trials of treatment, are needed to determine the best care for children and adolescents with OSAS.

SUBCOMMITTEE ON OBSTRUCTIVE SLEEP APNEA SYNDROME*

Carole L. Marcus, MBBCh, Chairperson (Sleep Medicine, Pediatric Pulmonologist; Liaison, American Academy of Sleep Medicine; Research Support from Philips Respironics; Affiliated with an academic sleep center; Published research related to OSAS)

Lee J. Brooks, MD (Sleep Medicine, Pediatric Pulmonologist; Liaison, American College of Chest Physicians; No financial conflicts; Affiliated with an academic sleep center; Published research related to OSAS)

Sally Davidson Ward, MD (Sleep Medicine, Pediatric Pulmonologist; No financial conflicts; Affiliated with an academic sleep center; Published research related to OSAS)

Kari A. Draper, MD (General Pediatrician; No conflicts)

David Gozal, MD (Sleep Medicine, Pediatric Pulmonologist; Research support from AstraZeneca; Speaker for Merck Company; Affiliated with an academic sleep center; Published research related to OSAS)

Ann C. Halbower, MD (Sleep Medicine, Pediatric Pulmonologist; Liaison, American Thoracic Society; Research Funding from Resmed; Affiliated with an academic sleep center; Published research related to OSAS)

Jacqueline Jones, MD (Pediatric Otolaryngologist; AAP Section on Otolaryngology-Head and Neck Surgery; Liaison, American Academy of Otolaryngology-Head and Neck Surgery; No financial conflicts; Affiliated with an academic otolaryngologic practice)

Christopher Lehman, MD (Neonatologist, Informatician; No conflicts)

Michael S. Schechter, MD, MPH (Pediatric Pulmonologist; AAP Section on Pediatric Pulmonology; Consultant to Genentech, Inc and Gilead, Inc, not related to Obstructive Sleep Apnea; Research Support from Mpex Pharmaceuticals, Inc, Vertex Pharmaceuticals Incorporated, PTC Therapeutics, Bayer Healthcare, not related to Obstructive Sleep Apnea)

Stephen Sheldon, MD (Sleep Medicine, General Pediatrician; Liaison, National Sleep Foundation; No financial conflicts; Affiliated with an academic sleep center; Published research related to OSAS)

Richard N. Shiffman, MD, MCIS (General pediatrics, Informatician; No conflicts)

Karen Spruyt, PhD (Clinical Psychologist, Child Neuropsychologist, and Biostatistician/Epidemiologist; No financial conflicts; Affiliated with an academic sleep center)

Oversight from the Steering Committee on Quality Improvement and Management, 2009–2012

STAFF

Caryn Davidson, MA

*Areas of expertise are shown in parentheses after each name.

ACKNOWLEDGMENTS

The committee thanks Jason Caboot, June Chan, Mary Currie, Fiona Healy, Maureen Josephson, Sofia Konstantinopoulou, H. Madan Kumar, Roberta Leu, Darius Loghmanee, Rajeev Bhatia, Argyri Petrocheilou, Harsha Vardhan, and Colleen Walsh for assisting with evidence extraction.

REFERENCES

1. Section on Pediatric Pulmonology, Subcommittee on Obstructive Sleep Apnea Syndrome. American Academy of Pediatrics. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics.* 2002;109(4):704–712
2. Marcus CL, Brooks LJ, Davidson C, et al; American Academy of Pediatrics, Subcommittee on Obstructive Sleep Apnea

Syndrome. Technical report: diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. 2012; 130(3):In press

3. American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877
4. American Thoracic Society. Standards and indications for cardiopulmonary sleep studies in children. *Am J Respir Crit Care Med*. 1996;153(2):866–878
5. Bixler EO, Vgontzas AN, Lin HM, et al. Sleep disordered breathing in children in a general population sample: prevalence and risk factors. *Sleep*. 2009;32(6):731–736
6. Li AM, So HK, Au CT, et al. Epidemiology of obstructive sleep apnoea syndrome in Chinese children: a two-phase community study. *Thorax*. 2010;65(11):991–997
7. O'Brien LM, Holbrook CR, Mervis CB, et al. Sleep and neurobehavioral characteristics of 5- to 7-year-old children with parentally reported symptoms of attention-deficit/hyperactivity disorder. *Pediatrics*. 2003; 111(3):554–563
8. Himes JH, Dietz WH; The Expert Committee on Clinical Guidelines for Overweight in Adolescent Preventive Services. Guidelines for overweight in adolescent preventive services: recommendations from an expert committee. *Am J Clin Nutr*. 1994;59(2):307–316
9. Mitchell RB. Adenotonsillectomy for obstructive sleep apnea in children: outcome evaluated by pre- and postoperative polysomnography. *Laryngoscope*. 2007;117(10):1844–1854
10. Suen JS, Arnold JE, Brooks LJ. Adenotonsillectomy for treatment of obstructive sleep apnea in children. *Arch Otolaryngol Head Neck Surg*. 1995;121(5):525–530
11. Nieminen P, Tolonen U, Löppönen H. Snoring and obstructive sleep apnea in children: a 6-month follow-up study. *Arch Otolaryngol Head Neck Surg*. 2000;126(4):481–486
12. Blunden S, Lushington K, Lorenzen B, Wong J, Balendran R, Kennedy D. Symptoms of sleep breathing disorders in children are underreported by parents at general practice visits. *Sleep Breath*. 2003;7(4):167–176
13. Apostolidou MT, Alexopoulos EI, Chaidas K, et al. Obesity and persisting sleep apnea after adenotonsillectomy in Greek children. *Chest*. 2008;134(6):1149–1155
14. Mitchell RB, Kelly J. Outcome of adenotonsillectomy for severe obstructive sleep apnea in children. *Int J Pediatr Otorhinolaryngol*. 2004;68(11):1375–1379
15. Marcus CL, Rosen G, Ward SL, et al. Adherence to and effectiveness of positive airway pressure therapy in children with obstructive sleep apnea. *Pediatrics*. 2006; 117(3). Available at: www.pediatrics.org/cgi/content/full/117/3/e442
16. Verhulst SL, Franckx H, Van Gaal L, De Backer W, Desager K. The effect of weight loss on sleep-disordered breathing in obese teenagers. *Obesity (Silver Spring)*. 2009;17(6):1178–1183
17. Kalra M, Inge T. Effect of bariatric surgery on obstructive sleep apnoea in adolescents. *Paediatr Respir Rev*. 2006;7(4):260–267

Sleep Apnea Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome
- *ICD-10-CM* Coding Quick Reference for Sleep Apnea
- AAP Patient Education Handout
  — *Sleep Apnea and Your Child*

Action Statement Summary

Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome

Key Action Statement 1: Screening for OSAS

As part of routine health maintenance visits, clinicians should inquire whether the child or adolescent snores. If the answer is affirmative or if a child or adolescent presents with signs or symptoms of OSAS (Table 2), clinicians should perform a more focused evaluation. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 2A: Polysomnography

If a child or adolescent snores on a regular basis and has any of the complaints or findings shown in Table 2, clinicians should either (1) obtain a polysomnogram (Evidence Quality A, Key Action strength: Recommendation) OR (2) refer the patient to a sleep specialist or otolaryngologist for a more extensive evaluation (Evidence quality D, Key Action strength: Option). (Evidence Quality: Grade A for polysomnography; Grade D for specialist referral, Recommendation Strength: Recommendation.)

Key Action Statement 2B: Alternative Testing

If polysomnography is not available, then clinicians may order alternative diagnostic tests, such as nocturnal video recording, nocturnal oximetry, daytime nap polysomnography, or ambulatory polysomnography. (Evidence Quality: Grade C, Recommendation Strength: Option.)

Key Action Statement 3: Adenotonsillectomy

If a child is determined to have OSAS, has a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery (see Table 3), the clinician should recommend adenotonsillectomy as the first line of treatment. If the child has OSAS but does not have adenotonsillar hypertrophy, other treatment should be considered (see Key Action Statement 6). Clinical judgment is required to determine the benefits of adenotonsillectomy compared with other treatments in obese children with varying degrees of adenotonsillar hypertrophy. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 4: High-Risk Patients Undergoing Adenotonsillectomy

Clinicians should monitor high-risk patients (Table 5) undergoing adenotonsillectomy as inpatients postoperatively. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 5: Reevaluation

Clinicians should clinically reassess all patients with OSAS for persisting signs and symptoms after therapy to determine whether further treatment is required. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 5B: Reevaluation of High-Risk Patients

Clinicians should reevaluate high-risk patients for persistent OSAS after adenotonsillectomy, including those who had a significantly abnormal baseline polysomnogram, have sequelae of OSAS, are obese, or remain symptomatic after treatment, with an objective test (see Key Action Statement 2) or refer such patients to a sleep specialist. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 6: CPAP

Clinicians should refer patients for CPAP management if symptoms/signs (Table 2) or objective evidence of OSAS persists after adenotonsillectomy or if adenotonsillectomy is not performed. (Evidence Quality: Grade B, Recommendation Strength: Recommendation.)

Key Action Statement 7: Weight Loss

Clinicians should recommend weight loss in addition to other therapy if a child/adolescent with OSAS is overweight or obese. (Evidence Quality: Grade C, Recommendation Strength: Recommendation.)

Key Action Statement 8: Intranasal Corticosteroids

Clinicians may prescribe topical intranasal corticosteroids for children with mild OSAS in whom adenotonsillectomy is contraindicated or for children with mild postoperative OSAS. (Evidence Quality: Grade B, Recommendation Strength: Option.)

Coding Quick Reference for Sleep Apnea	
ICD-10-CM	
G47.30	Sleep apnea, unspecified
G47.31	Primary central sleep apnea
G47.33	Obstructive sleep apnea (adult) (pediatric) _____(Code additional underlying conditions.)
J35.3	Hypertrophy of tonsils with hypertrophy of adenoids
E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.3	Overweight
E66.8	Other obesity
E66.9	Obesity, unspecified
P28.3	Primary sleep apnea of newborn
P28.4	Other apnea of newborn

Sleep Apnea and Your Child

Does your child snore a lot? Does he sleep restlessly? Does he have difficulty breathing, or does he gasp or choke, while he sleeps?

If your child has these symptoms, he may have a condition known as sleep apnea.

Sleep apnea is a common problem that affects an estimated 2% of all children, including many who are undiagnosed.

If not treated, sleep apnea can lead to a variety of problems. These include heart, behavior, learning, and growth problems.

How do I know if my child has sleep apnea?

Symptoms of sleep apnea include

- Frequent snoring
- Problems breathing during the night
- Sleepiness during the day
- Difficulty paying attention
- Behavior problems

If you notice any of these symptoms, let your pediatrician know as soon as possible. Your pediatrician may recommend an overnight sleep study called a *polysomnogram.* Overnight polysomnograms are conducted at hospitals and major medical centers. During the study, medical staff will watch your child sleep. Several sensors will be attached to your child to monitor breathing, oxygenation, and brain waves. An electroencephalogram (EEG) is a test that measures brain waves.

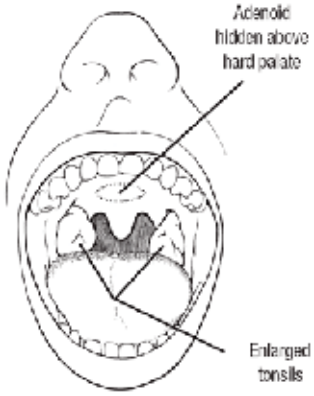
The results of the study will show whether your child suffers from sleep apnea. Other specialists, such as pediatric pulmonologists, otolaryngologists, neurologists, and pediatricians with specialty training in sleep disorders, may help your pediatrician make the diagnosis.

What causes sleep apnea?

Many children with sleep apnea have larger tonsils and adenoids.

Tonsils are the round, reddish masses on each side of your child's throat. They help fight infections in the body. You can only see the adenoid with an x-ray or special mirror. It lies in the space between the nose and throat.

Large tonsils and adenoid may block a child's airway while she sleeps. This causes her to snore and wake up often during the night. However, not every child with large tonsils and adenoid has sleep apnea. A sleep study can tell your doctor whether your child has sleep apnea or if she is simply snoring.



Children born with other medical conditions, such as Down syndrome, cerebral palsy, or craniofacial (skull and face) abnormalities, are at higher risk for sleep apnea. Overweight children are also more likely to suffer from sleep apnea.

How is sleep apnea treated?

The most common way to treat sleep apnea is to remove your child's tonsils and adenoid. This surgery is called a tonsillectomy and adenoidectomy. It is highly effective in treating sleep apnea.

Another effective treatment is nasal continuous positive airway pressure (CPAP), which requires the child to wear a mask while he sleeps. The mask delivers steady air pressure through the child's nose, allowing him to breathe comfortably. Continuous positive airway pressure is usually used in children who do not improve after tonsillectomy and adenoidectomy, or who are not candidates for tonsillectomy and adenoidectomy.

Children who may need additional treatment include children who are overweight or suffering from another complicating condition. Overweight children will improve if they lose weight, but may need to use CPAP until the weight is lost.

Remember

A good night's sleep is important to good health. If your child suffers from the symptoms of sleep apnea, talk with your pediatrician. A proper diagnosis and treatment can mean restful nights and restful days for your child and your family.

From your doctor

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site — www.HealthyChildren.org

Reaffirmation of AAP Clinical Practice Guideline: The Diagnosis and Management of the Initial Urinary Tract Infection in Febrile Infants and Young Children 2–24 Months of Age

- *Reaffirmation of AAP Clinical Practice Guideline*
- *Clinical Practice Guideline*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

CLINICAL PRACTICE GUIDELINE Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Reaffirmation of AAP Clinical Practice Guideline: The Diagnosis and Management of the Initial Urinary Tract Infection in Febrile Infants and Young Children 2–24 Months of Age

SUBCOMMITTEE ON URINARY TRACT INFECTION

FREE

It is the policy of the American Academy of Pediatrics to reassess clinical practice guidelines (CPGs) every 5 years and retire, revise, or reaffirm them. The members of the urinary tract infection (UTI) subcommittee who developed the 2011 UTI CPG[1] have reviewed the literature published since 2011 along with unpublished manuscripts and the status of some clinical trials still in progress. With this article, we reaffirm the 2011 UTI CPG and provide an updated review of the supporting evidence. For the convenience of the reader, we reiterate the 7 Key Action Statements here to obviate the need to consult the 2011 UTI CPG, although interested readers may want to review the text of the guideline[1] and/or its accompanying technical report.[2]

DOI: 10.1542/peds.2016-3026

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they do not have a financial relationship relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

To cite: AAP SUBCOMMITTEE ON URINARY TRACT INFECTION. Reaffirmation of AAP Clinical Practice Guideline: The Diagnosis and Management of the Initial Urinary Tract Infection in Febrile Infants and Young Children 2–24 Months of Age. *Pediatrics.* 2016;138(6):e20163026

ACTION STATEMENT 1

If a clinician decides that a febrile infant with no apparent source for the fever requires antimicrobial therapy to be administered because of ill appearance or another pressing reason, the clinician should ensure that a urine specimen is obtained for both culture and urinalysis before an antimicrobial is administered; the specimen needs to be obtained through catheterization or suprapubic aspiration (SPA), because the diagnosis of UTI cannot be established reliably through culture of urine collected in a bag (evidence quality: A; strong recommendation).

Comment

A key to an accurate diagnosis of UTI is obtaining a sample of urine for culture with minimal contamination before starting antimicrobial

agents. Urine collected in a bag or via a clean catch method is suitable for urinalysis (see Action Statement 2, Option 2), but such specimens (especially urine collected in a bag) are less appropriate for culture. If a culture obtained by bag is positive, the likelihood of a false positive is extremely high, so the result must be confirmed by culturing urine obtained by a more reliable method; if an antimicrobial agent is present in the urine, the opportunity for confirmation is likely to be lost.

Although samples of urine obtained by transurethral catheterization may be contaminated by urethral flora, meticulous technique can reduce this possibility. To avoid contamination, 2 practical steps should be implemented: (1) the first few milliliters obtained by catheter should be discarded (allowed to fall outside of the sterile collecting vessel) and only the subsequent urine cultured; and (2) if the attempt at catheterization is unsuccessful, a new, clean catheter should be used (aided, in girls, by leaving the initial catheter in place as a marker).

ACTION STATEMENT 2

If a clinician assesses a febrile infant with no apparent source for the fever as not being so ill as to require immediate antimicrobial therapy, then the clinician should assess the likelihood of UTI.

Action Statement 2a. If the clinician determines the febrile infant to have a low likelihood of UTI (see text), then clinical follow-up monitoring without testing is sufficient (evidence quality: A; strong recommendation).

Action Statement 2b. If the clinician determines that the febrile infant is not in a low-risk group (see below), then there are 2 choices (evidence quality: A; strong recommendation).

Option 1 is to obtain a urine specimen through catheterization or SPA for culture and urinalysis.

Option 2 is to obtain a urine specimen through the most convenient means and to perform a urinalysis. If the urinalysis results suggest a UTI (positive leukocyte esterase test results or nitrite test or microscopic analysis results for leukocytes or bacteria), then a urine specimen should be obtained through catheterization or SPA and cultured; if urinalysis of fresh (less than 1 hour since void) urine yields negative leukocyte esterase and nitrite results, then it is reasonable to monitor the clinical course without initiating antimicrobial therapy, recognizing that a negative urinalysis does not rule out a UTI with certainty.

Comment

When the patient's degree of illness does not warrant immediate antimicrobial treatment and the risk of UTI is extremely low, the patient may be observed without assessing the urine. (The risk assessment tables in the 2011 UTI CPG have been simplified into algorithm form.[3]) If there is a low but real risk of infection, then either the best possible specimen should be obtained for urinalysis and culture, or a sample of urine obtained by a convenient method and a judgment made about culturing the urine dependent on the findings of the urinalysis or dipstick. A positive urinalysis provides sufficient concern to mandate a properly obtained urine specimen. This 2-step process (Option 2) is not only suitable for office practice but has been demonstrated to be feasible and beneficial in a busy pediatric emergency department, with the catheterization rate decreasing from 63% to fewer than 30% without increasing length of stay or missing UTIs.[4]

ACTION STATEMENT 3

To establish the diagnosis of UTI, clinicians should require both urinalysis results that suggest infection (pyuria and/or bacteriuria) and the presence of at least 50 000 colony-forming units (cfu) per milliliter of a uropathogen cultured from a urine specimen obtained through transurethral catheterization or SPA (evidence quality: C; recommendation).

Comment

The thrust of this key action statement is that the diagnosis of UTI in febrile infants is signaled by the presence of both bacteriuria and pyuria. In general, pyuria without bacteriuria is insufficient to make a diagnosis of UTI because it is nonspecific and occurs in the absence of infection (eg, Kawasaki disease, chemical urethritis, streptococcal infections). Likewise, bacteriuria, without pyuria is attributable to external contamination, asymptomatic bacteriuria, or, rarely, very early infection (before the onset of inflammation). Non–*Escherichia coli* isolates are less frequently associated with pyuria than *E coli*,[5] but the significance of this association is not clear at present. Non–*E coli* uropathogens are of concern because they are more likely to result in scarring than *E coli*,[6] but animal studies demonstrate the host inflammatory response to be what causes scarring rather than the presence of organisms.[7] Moreover, the rate of asymptomatic bacteriuria is sufficient to account for the lack of association with pyuria.

The remaining question is what constitutes "significant" bacteriuria and "significant" pyuria. In 1994,

by using single versus multiple organisms to distinguish true UTI from contamination, 50 000 cfu/mL was proposed as the appropriate threshold for specimens obtained by catheterization,[8] recommended in the 2011 UTI CPG and implemented in the Randomized Intervention for Children with Vesicoureteral Reflux (RIVUR) trial.[9] Lower colony counts are sufficient if the urine specimen is obtained by SPA and, thus, less likely to be contaminated, but most (80%) cases of UTI documented with urine obtained by SPA have 10^5 cfu/mL or more. Colony counts lower than 50 000 cfu/mL are currently being considered for the diagnosis of UTI.[10] If 10 000 cfu/mL coupled with symptoms (eg, fever) and evidence of inflammation (pyuria) proves both sensitive and specific, this threshold would be of particular assistance to clinicians who use laboratories that do not specify colony counts between 10 000 and 100 000 cfu/mL and, thereby, make the criterion of 50 000 cfu/mL difficult to use.

Significant pyuria is ≥10 white blood cells/mm^3 on an "enhanced urinalysis" or ≥5 white blood cells per high power field on a centrifuged specimen of urine or any leukocyte esterase on a dipstick.

ACTION STATEMENT 4

Action Statement 4a. When initiating treatment, the clinician should base the choice of route of administration on practical considerations: initiating treatment orally or parenterally is equally efficacious. The clinician should base the choice of agent on local antimicrobial sensitivity patterns (if available) and should adjust the choice according to sensitivity testing of the isolated uropathogen (evidence quality: A; strong recommendation).

Action Statement 4b. The clinician should choose 7 to 14 days as the duration of antimicrobial therapy (evidence quality B; recommendation).

Comment

Basing the choice of an initial antimicrobial agent on local sensitivity patterns can be difficult because applicable information may not be available. Whether the child has received antimicrobial therapy in the recent past should be considered. This exposure constitutes a risk factor for resistance to the recently prescribed antimicrobial. Further delineation of treatment duration has not been forthcoming, but a randomized controlled trial is currently under way comparing the effectiveness of 5 days versus 10 days of treatment.[11]

Note: The dose of ceftriaxone in Table 2 should be 50 mg/kg, every 24 h.

ACTION STATEMENT 5

Febrile infants with UTIs should undergo renal and bladder ultrasonography (RBUS) (evidence quality: C; recommendation).

Comment

As noted in the 2011 CPG, it is important that the study be a renal and bladder ultrasonogram, not a limited renal ultrasonogram. Ideally, the patient should be well-hydrated for the examination and the bladder should be evaluated while distended. Concern has been raised that RBUS is not effective to detect vesicoureteral reflux (VUR), as it is frequently normal in infants with low-grade VUR and even in some who have high-grade VUR. Moreover, nonspecific RBUS findings, such as mild renal pelvic or ureteral distention, are common and are not necessarily associated with reflux. However, low-grade VUR is generally not considered of concern for renal damage, and most studies (other than the RIVUR trial[9]) have demonstrated continuous antimicrobial prophylaxis (CAP) to lack benefit in this group.[1,2] Although RBUS is not invariably abnormal in infants with grades IV and V VUR, it does identify most, and, of particular importance, an abnormal RBUS is a major risk factor for scarring.[6]

ACTION STATEMENT 6

Action Statement 6a. Voiding cystourethrography (VCUG) should not be performed routinely after the first febrile UTI; VCUG is indicated if RBUS reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy, as well as in other atypical or complex clinical circumstances (evidence quality B; recommendation).

Action Statement 6b. Further evaluation should be conducted if there is a recurrence of febrile UTI (evidence quality: X; recommendation).

Comment

For decades, UTIs in infants were considered harbingers of underlying anatomic and/or physiologic abnormalities, so RBUS and VCUG were recommended to be performed routinely. VUR was a particular concern; CAP was assumed to be effective in preventing UTI and became standard practice when VUR was discovered. In the years leading up to the 2011 guideline, randomized controlled trials of CAP were performed. Authors of the 6 studies published in 2006-2010 graciously provided data to the guideline committee, permitting a meta-analysis of data specifically targeting febrile infants 2 to 24 months of age. CAP was not demonstrated to be effective, so the need to identify VUR by routine voiding cystourethrography was discouraged.[1,2] A recent large trial in the United States, the RIVUR trial,

concluded that CAP was of benefit, but, to prevent 1 UTI recurrence required 5840 doses of antimicrobial and did not reduce the rate of renal scarring.[9]

Since the publication of the 2011 guideline, multiple studies have demonstrated that abnormalities are missed by the selective imaging recommended in the guideline; however, there is no evidence that identifying these missed abnormalities is of sufficient clinical benefit to offset the cost, discomfort, and radiation.[12] Compared with performing the full array of imaging tests, the radiation burden incurred with the application of the guideline has been calculated to be reduced by 93%.[13] Moreover, in population studies, the significance of VUR and the value of treating VUR have been questioned.[14,15]

The authors of the RIVUR trial and its companion study, Careful Urinary Tract Infection Evaluation, have called attention to bowel/bladder dysfunction (BBD) as a major risk factor for UTI recurrences and recognize that, in children who have a UTI recurrence, evaluation for BBD (ie, constipation), rather than for VUR, can be performed by nonspecialists and does not incur high cost, cause discomfort, or require radiation.[16] BBD has long been underappreciated and deserves greater consideration.

ACTION STATEMENT 7

After confirmation of UTI, the clinician should instruct parents or guardians to seek prompt medical evaluation (ideally within 48 hours) for future febrile illnesses to ensure that recurrent infections can be detected and treated promptly (evidence quality: C; recommendation).

Comment

Prompt treatment is of clinical benefit to the child with the acute infection. What has been controversial is the definition of "prompt" and the relationship to renal scarring. A recent study identified that the median time to treatment was shorter in infants who did not incur a scar than in those who did (48 vs 72 hours). The study also noted that the rate of scarring increased minimally between days 1 and 2 and between days 2 and 3 but was much higher thereafter.[17]

SUBCOMMITTEE ON URINARY TRACT INFECTION, 2009-2011

Kenneth B. Roberts, MD, FAAP Chair
Stephen M. Downs, MD, MS, FAAP
S. Maria E. Finnell, MD, MS, FAAP
*Stanley Hellerstein, MD (deceased)
Linda D. Shortliffe, MD
Ellen R. Wald, MD, FAAP, Vice-Chair
J. Michael Zerin, MD

STAFF

Kymika Okechukwu, MPA, Manager, Evidence-Based Practice Initiatives

ABBREVIATIONS

BBD: bowel/bladder dysfunction
CAP: continuous antimicrobial prophylaxis
cfu: colony-forming units
CPG: clinical practice guideline
RBUS: renal and bladder ultrasonography
RIVUR: Randomized Intervention for Children with Vesicoureteral Reflux
SPA: suprapubic aspiration
UTI: urinary tract infection
VCUG: voiding cystourethrography
VUR: vesicoureteral reflux

REFERENCES

1. Roberts KB; Subcommittee on Urinary Tract Infection, Steering Committee on Quality Improvement and Management. Urinary tract infection: clinical practice guideline for the diagnosis and management of the initial UTI in febrile infants and children 2 to 24 months. *Pediatrics*. 2011;128(3):595–610
2. Finnell SM, Carroll AE, Downs SM; Subcommittee on Urinary Tract Infection. Technical report—Diagnosis and management of an initial UTI in febrile infants and young children. *Pediatrics*. 2011;128(3). Available at: www.pediatrics.org/cgi/content/full/128/3/e749 PubMed
3. Roberts KB. Revised AAP Guideline on UTI in Febrile Infants and Young Children. *Am Fam Physician*. 2012;86(10):940–946
4. Lavelle JM, Blackstone MM, Funari MK, et al. Two-step process for ED UTI screening in febrile young children: reducing catheterization rates. *Pediatrics*. 2016;138(1):e20153023
5. Shaikh N, Shope TR, Hoberman A, Vigliotti A, Kurs-Lasky M, Martin JM. Association between uropathogen and pyuria. *Pediatrics*. 2016;138(1):e20160087
6. Shaikh N, Craig JC, Rovers MM, et al. Identification of children and adolescents at risk for renal scarring after a first urinary tract infection: a meta-analysis with individual patient data. *JAMA Pediatr*. 2014;168(10):893–900
7. Glauser MP, Meylan P, Bille J. The inflammatory response and tissue damage. The example of renal scars following acute renal infection. *Pediatr Nephrol*. 1987;1(4):615–622
8. Hoberman A, Wald ER, Reynolds EA, Penchansky L, Charron M. Pyuria and bacteriuria in urine specimens obtained by catheter from young children with fever. *J Pediatr*. 1994;124(4):513–519
9. Hoberman A, Greenfield SP, Mattoo TK, et al; RIVUR Trial Investigators. Antimicrobial prophylaxis for children with vesicoureteral reflux. *N Engl J Med*. 2014;370(25):2367–2376
10. Tullus K. Low urinary bacterial counts: do they count? *Pediatr Nephrol*. 2016;31(2):171–174
11. Hoberman A. The SCOUT study: short course therapy for urinary tract infections in children. Available at: https://clinicaltrials.gov/ct2/show/

NCT01595529. Accessed October 14, 2016

12. Narchi H, Marah M, Khan AA, et al Renal tract abnormalities missed in a historical cohort of your children with UTI if the NICE and AAP imaging guidelines were applied. *J Pediatr Urol*. 2015;11(5):252.e1–7
13. La Scola C, De Mutiis C, Hewitt IK, et al. Different guidelines for imaging after first UTI in febrile infants: yield, cost, and radiation. *Pediatrics*. 2013;131(3). Available at: www.pediatrics.org/cgi/content/full/131/3/e665 PubMed
14. Salo J, Ikäheimo R, Tapiainen T, Uhari M. Childhood urinary tract infections as a cause of chronic kidney disease. *Pediatrics*. 2011;128(5):840–847
15. Craig JC, Williams GJ. Denominators do matter: it's a myth—urinary tract infection does not cause chronic kidney disease. *Pediatrics*. 2011;128(5):984–985
16. Shaikh N, Hoberman A, Keren R, et al. Recurrent urinary tract infections in children with bladder and bowel dysfunction. *Pediatrics*. 2016;137(1):e20152982
17. Shaikh N, Mattoo TK, Keren R, et al. Early antibiotic treatment for pediatric febrile urinary tract infection and renal scarring. *JAMA Pediatr*. 2016;170(9):848–854

CLINICAL PRACTICE GUIDELINE

Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months

SUBCOMMITTEE ON URINARY TRACT INFECTION, STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT

KEY WORDS
urinary tract infection, infants, children, vesicoureteral reflux, voiding cystourethrography

ABBREVIATIONS
SPA—suprapubic aspiration
AAP—American Academy of Pediatrics
UTI—urinary tract infection
RCT—randomized controlled trial
CFU—colony-forming unit
VUR—vesicoureteral reflux
WBC—white blood cell
RBUS—renal and bladder ultrasonography
VCUG—voiding cystourethrography

www.pediatrics.org/cgi/doi/10.1542/peds.2011-1330

doi:10.1542/peds.2011-1330

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

COMPANION PAPERS: Companions to this article can be found on pages 572 and e749, and online at www.pediatrics.org/cgi/doi/10.1542/peds.2011-1818 and www.pediatrics.org/cgi/doi/10.1542/peds.2011-1332.

abstract

FREE

OBJECTIVE: To revise the American Academy of Pediatrics practice parameter regarding the diagnosis and management of initial urinary tract infections (UTIs) in febrile infants and young children.

METHODS: Analysis of the medical literature published since the last version of the guideline was supplemented by analysis of data provided by authors of recent publications. The strength of evidence supporting each recommendation and the strength of the recommendation were assessed and graded.

RESULTS: Diagnosis is made on the basis of the presence of both pyuria and at least 50 000 colonies per mL of a single uropathogenic organism in an appropriately collected specimen of urine. After 7 to 14 days of antimicrobial treatment, close clinical follow-up monitoring should be maintained to permit prompt diagnosis and treatment of recurrent infections. Ultrasonography of the kidneys and bladder should be performed to detect anatomic abnormalities. Data from the most recent 6 studies do not support the use of antimicrobial prophylaxis to prevent febrile recurrent UTI in infants without vesicoureteral reflux (VUR) or with grade I to IV VUR. Therefore, a voiding cystourethrography (VCUG) is not recommended routinely after the first UTI; VCUG is indicated if renal and bladder ultrasonography reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy and in other atypical or complex clinical circumstances. VCUG should also be performed if there is a recurrence of a febrile UTI. The recommendations in this guideline do not indicate an exclusive course of treatment or serve as a standard of care; variations may be appropriate. Recommendations about antimicrobial prophylaxis and implications for performance of VCUG are based on currently available evidence. As with all American Academy of Pediatrics clinical guidelines, the recommendations will be reviewed routinely and incorporate new evidence, such as data from the Randomized Intervention for Children With Vesicoureteral Reflux (RIVUR) study.

CONCLUSIONS: Changes in this revision include criteria for the diagnosis of UTI and recommendations for imaging. *Pediatrics* 2011;128:595–610

INTRODUCTION

Since the early 1970s, occult bacteremia has been the major focus of concern for clinicians evaluating febrile infants who have no recognizable source of infection. With the introduction of effective conjugate vaccines against *Haemophilus influenzae* type b and *Streptococcus pneumoniae* (which have resulted in dramatic decreases in bacteremia and meningitis), there has been increasing appreciation of the urinary tract as the most frequent site of occult and serious bacterial infections. Because the clinical presentation tends to be nonspecific in infants and reliable urine specimens for culture cannot be obtained without invasive methods (urethral catheterization or suprapubic aspiration [SPA]), diagnosis and treatment may be delayed. Most experimental and clinical data support the concept that delays in the institution of appropriate treatment of pyelonephritis increase the risk of renal damage.[1,2]

This clinical practice guideline is a revision of the practice parameter published by the American Academy of Pediatrics (AAP) in 1999.[3] It was developed by a subcommittee of the Steering Committee on Quality Improvement and Management that included physicians with expertise in the fields of academic general pediatrics, epidemiology and informatics, pediatric infectious diseases, pediatric nephrology, pediatric practice, pediatric radiology, and pediatric urology. The AAP funded the development of this guideline; none of the participants had any financial conflicts of interest. The guideline was reviewed by multiple groups within the AAP (7 committees, 1 council, and 9 sections) and 5 external organizations in the United States and Canada. The guideline will be reviewed and/or revised in 5 years, unless new evidence emerges that warrants revision sooner. The guideline is intended for use in a variety of clinical settings (eg, office, emergency department, or hospital) by clinicians who treat infants and young children. This text is a summary of the analysis. The data on which the recommendations are based are included in a companion technical report.[4]

Like the 1999 practice parameter, this revision focuses on the diagnosis and management of initial urinary tract infections (UTIs) in febrile infants and young children (2–24 months of age) who have no obvious neurologic or anatomic abnormalities known to be associated with recurrent UTI or renal damage. (For simplicity, in the remainder of this guideline the phrase "febrile infants" is used to indicate febrile infants and young children 2–24 months of age.) The lower and upper age limits were selected because studies on infants with unexplained fever generally have used these age limits and have documented that the prevalence of UTI is high (~5%) in this age group. In those studies, fever was defined as temperature of at least 38.0°C (≥100.4°F); accordingly, this definition of fever is used in this guideline. Neonates and infants less than 2 months of age are excluded, because there are special considerations in this age group that may limit the application of evidence derived from the studies of 2- to 24-month-old children. Data are insufficient to determine whether the evidence generated from studies of infants 2 to 24 months of age applies to children more than 24 months of age.

METHODS

To provide evidence for the guideline, 2 literature searches were conducted, that is, a surveillance of Medline-listed literature over the past 10 years for significant changes since the guideline was published and a systematic review of the literature on the effectiveness of prophylactic antimicrobial therapy to prevent recurrence of febrile UTI/pyelonephritis in children with vesicoureteral reflux (VUR). The latter was based on the new and growing body of evidence questioning the effectiveness of antimicrobial prophylaxis to prevent recurrent febrile UTI in children with VUR. To explore this particular issue, the literature search was expanded to include trials published since 1993 in which antimicrobial prophylaxis was compared with no treatment or placebo treatment for children with VUR. Because all except 1 of the recent randomized controlled trials (RCTs) of the effectiveness of prophylaxis included children more than 24 months of age and some did not provide specific data according to grade of VUR, the authors of the 6 RCTs were contacted; all provided raw data from their studies specifically addressing infants 2 to 24 months of age, according to grade of VUR. Meta-analysis of these data was performed.

Results from the literature searches and meta-analyses were provided to committee members. Issues were raised and discussed until consensus was reached regarding recommendations. The quality of evidence supporting each recommendation and the strength of the recommendation were assessed by the committee member most experienced in informatics and epidemiology and were graded according to AAP policy[5] (Fig 1).

The subcommittee formulated 7 recommendations, which are presented in the text in the order in which a clinician would use them when evaluating and treating a febrile infant, as well as in algorithm form in the Appendix. This clinical practice guideline is not intended to be a sole source of guidance for the treatment of febrile infants with UTIs. Rather, it is intended to assist clinicians in decision-making. It is not intended to replace clinical judgment or to

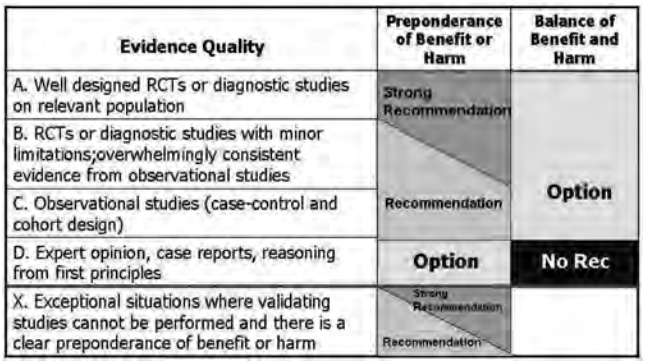


FIGURE 1
AAP evidence strengths.

establish an exclusive protocol for the care of all children with this condition.

DIAGNOSIS

Action Statement 1

If a clinician decides that a febrile infant with no apparent source for the fever requires antimicrobial therapy to be administered because of ill appearance or another pressing reason, the clinician should ensure that a urine specimen is obtained for both culture and urinalysis before an antimicrobial agent is administered; the specimen needs to be obtained through catheterization or SPA, because the diagnosis of UTI cannot be established reliably through culture of urine collected in a bag (evidence quality: A; strong recommendation).

When evaluating febrile infants, clinicians make a subjective assessment of the degree of illness or toxicity, in addition to seeking an explanation for the fever. This clinical assessment determines whether antimicrobial therapy should be initiated promptly and affects the diagnostic process regarding UTI. If the clinician determines that the degree of illness warrants immediate antimicrobial therapy, then a urine specimen suitable for culture should be obtained through catheterization or SPA before antimicrobial agents are administered, because the antimicrobial agents commonly prescribed in such situations would almost certainly obscure the diagnosis of UTI.

SPA has been considered the standard method for obtaining urine that is uncontaminated by perineal flora. Variable success rates for obtaining urine have been reported (23%–90%).[6–8] When ultrasonographic guidance is used, success rates improve.[9,10] The technique has limited risks, but technical expertise and experience are required, and many parents and physicians perceive the procedure as unacceptably invasive, compared with catheterization. However, there may be no acceptable alternative to SPA for boys with moderate or severe phimosis or girls with tight labial adhesions.

Urine obtained through catheterization for culture has a sensitivity of 95% and a specificity of 99%, compared with that obtained through SPA.[7,11,12] The techniques required for catheterization and SPA are well described.[13] When catheterization or SPA is being attempted, the clinician should have a sterile container ready to collect a urine specimen, because the preparation for the procedure may stimulate the child to void. Whether the urine is obtained through catheterization or is voided, the first few drops should be allowed to fall outside the sterile container, because they may be contaminated by bacteria in the distal urethra.

Cultures of urine specimens collected in a bag applied to the perineum have an unacceptably high false-positive rate and are valid only when they yield negative results.[6,14–16] With a prevalence of UTI of 5% and a high rate of false-positive results (specificity: ~63%), a "positive" culture result for urine collected in a bag would be a false-positive result 88% of the time. For febrile boys, with a prevalence of UTI of 2%, the rate of false-positive results is 95%; for circumcised boys, with a prevalence of UTI of 0.2%, the rate of false-positive results is 99%. Therefore, in cases in which antimicrobial therapy will be initiated, catheterization or SPA is required to establish the diagnosis of UTI.

- Aggregate quality of evidence: A (diagnostic studies on relevant populations).
- Benefits: A missed diagnosis of UTI can lead to renal scarring if left untreated; overdiagnosis of UTI can lead to overtreatment and unnecessary and expensive imaging. Once antimicrobial therapy is initiated, the opportunity to make a definitive diagnosis is lost; multiple studies of antimicrobial therapy have shown that the urine may be rapidly sterilized.
- Harms/risks/costs: Catheterization is invasive.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: Once antimicrobial therapy has begun, the opportunity to make a definitive diagnosis is lost. Therefore, it is important to have the most-accurate test for UTI performed initially.
- Role of patient preferences: There is no evidence regarding patient preferences for bag versus catheterized urine. However, bladder tap has

been shown to be more painful than urethral catheterization.

- Exclusions: None.
- Intentional vagueness: The basis of the determination that antimicrobial therapy is needed urgently is not specified, because variability in clinical judgment is expected; considerations for individual patients, such as availability of follow-up care, may enter into the decision, and the literature provides only general guidance.
- Policy level: Strong recommendation.

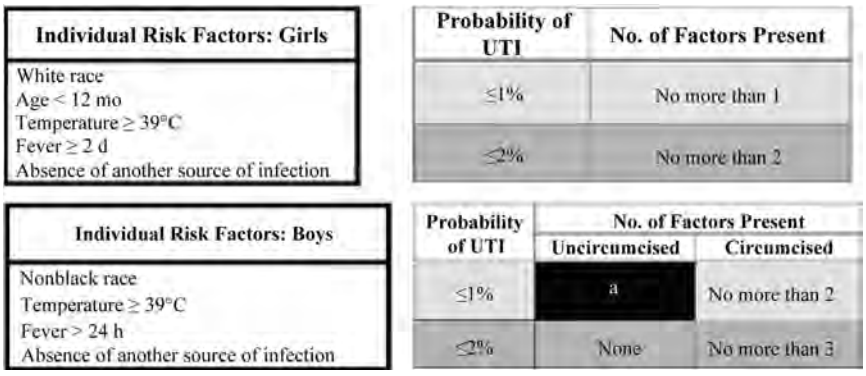


FIGURE 2

Probability of UTI Among Febrile Infant Girls[28] and Infant Boys[30] According to Number of Findings Present. [a]Probability of UTI exceeds 1% even with no risk factors other than being uncircumcised.

Action Statement 2

If a clinician assesses a febrile infant with no apparent source for the fever as not being so ill as to require immediate antimicrobial therapy, then the clinician should assess the likelihood of UTI (see below for how to assess likelihood).

Action Statement 2a

If the clinician determines the febrile infant to have a low likelihood of UTI (see text), then clinical follow-up monitoring without testing is sufficient (evidence quality: A; strong recommendation).

Action Statement 2b

If the clinician determines that the febrile infant is not in a low-risk group (see below), then there are 2 choices (evidence quality: A; strong recommendation). Option 1 is to obtain a urine specimen through catheterization or SPA for culture and urinalysis. Option 2 is to obtain a urine specimen through the most convenient means and to perform a urinalysis. If the urinalysis results suggest a UTI (positive leukocyte esterase test results or nitrite test or microscopic analysis results positive for leukocytes or bacteria), then a urine specimen should be obtained through catheterization or SPA and cultured; if urinalysis of fresh (<1 hour since void) urine yields negative leukocyte esterase and nitrite test results, then it is reasonable to monitor the clinical course without initiating antimicrobial therapy, recognizing that negative urinalysis results do not rule out a UTI with certainty.

If the clinician determines that the degree of illness does not require immediate antimicrobial therapy, then the likelihood of UTI should be assessed. As noted previously, the overall prevalence of UTI in febrile infants who have no source for their fever evident on the basis of history or physical examination results is approximately 5%,[17,18] but it is possible to identify groups with higher-than-average likelihood and some with lower-than-average likelihood. The prevalence of UTI among febrile infant girls is more than twice that among febrile infant boys (relative risk: 2.27). The rate for uncircumcised boys is 4 to 20 times higher than that for circumcised boys, whose rate of UTI is only 0.2% to 0.4%.[19–24] The presence of another, clinically obvious source of infection reduces the likelihood of UTI by one-half.[25]

In a survey asking, "What yield is required to warrant urine culture in febrile infants?," the threshold was less than 1% for 10.4% of academicians and 11.7% for practitioners[26]; when the threshold was increased to 1% to 3%, 67.5% of academicians and 45.7% of practitioners considered the yield sufficiently high to warrant urine culture. Therefore, attempting to operationalize "low likelihood" (ie, below a threshold that warrants a urine culture) does not produce an absolute percentage; clinicians will choose a threshold depending on factors such as their confidence that contact will be maintained through the illness (so that a specimen can be obtained at a later time) and comfort with diagnostic uncertainty. Fig 2 indicates the number of risk factors associated with threshold probabilities of UTI of at least 1% and at least 2%.

In a series of studies, Gorelick, Shaw, and colleagues[27–29] derived and validated a prediction rule for febrile infant girls on the basis of 5 risk factors, namely, white race, age less than 12 months, temperature of at least 39°C, fever for at least 2 days, and absence of another source of infection. This prediction rule, with sensitivity of 88% and specificity of 30%, permits some infant girls to be considered in a low-likelihood group (Fig 2). For example, of girls with no identifiable source of infection, those who are nonwhite and more than 12 months of age with a recent onset (<2 days) of low-

grade fever (<39°C) have less than a 1% probability of UTI; each additional risk factor increases the probability. It should be noted, however, that some of the factors (eg, duration of fever) may change during the course of the illness, excluding the infant from a low-likelihood designation and prompting testing as described in action statement 2a.

As demonstrated in Fig 2, the major risk factor for febrile infant boys is whether they are circumcised. The probability of UTI can be estimated on the basis of 4 risk factors, namely, nonblack race, temperature of at least 39°C, fever for more than 24 hours, and absence of another source of infection.[4,30]

If the clinician determines that the infant does not require immediate antimicrobial therapy and a urine specimen is desired, then often a urine collection bag affixed to the perineum is used. Many clinicians think that this collection technique has a low contamination rate under the following circumstances: the patient's perineum is properly cleansed and rinsed before application of the collection bag, the urine bag is removed promptly after urine is voided into the bag, and the specimen is refrigerated or processed immediately. Even if contamination from the perineal skin is minimized, however, there may be significant contamination from the vagina in girls or the prepuce in uncircumcised boys, the 2 groups at highest risk of UTI. A "positive" culture result from a specimen collected in a bag cannot be used to document a UTI; confirmation requires culture of a specimen collected through catheterization or SPA. Because there may be substantial delay waiting for the infant to void and a second specimen, obtained through catheterization, may be necessary if the urinalysis suggests the possibility of UTI, many clinicians prefer to obtain a definitive urine specimen through catheterization initially.

- Aggregate quality of evidence: A (diagnostic studies on relevant populations).
- Benefits: Accurate diagnosis of UTI can prevent the spread of infection and renal scarring; avoiding overdiagnosis of UTI can prevent overtreatment and unnecessary and expensive imaging.
- Harms/risks/costs: A small proportion of febrile infants, considered at low likelihood of UTI, will not receive timely identification and treatment of their UTIs.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: There is a risk of UTI sufficiently low to forestall further evaluation.
- Role of patient preferences: The choice of option 1 or option 2 and the threshold risk of UTI warranting obtaining a urine specimen may be influenced by parents' preference to avoid urethral catheterization (if a bag urine sample yields negative urinalysis results) versus timely evaluation (obtaining a definitive specimen through catheterization).
- Exclusions: Because it depends on a range of patient- and physician-specific considerations, the precise threshold risk of UTI warranting obtaining a urine specimen is left to the clinician but is below 3%.
- Intentional vagueness: None.
- Policy level: Strong recommendation.

TABLE 1 Sensitivity and Specificity of Components of Urinalysis, Alone and in Combination

Test	Sensitivity (Range), %	Specificity (Range), %
Leukocyte esterase test	83 (67–94)	78 (64–92)
Nitrite test	53 (15–82)	98 (90–100)
Leukocyte esterase or nitrite test positive	93 (90–100)	72 (58–91)
Microscopy, WBCs	73 (32–100)	81 (45–98)
Microscopy, bacteria	81 (16–99)	83 (11–100)
Leukocyte esterase test, nitrite test, or microscopy positive	99.8 (99–100)	70 (60–92)

Action Statement 3

To establish the diagnosis of UTI, clinicians should require *both* urinalysis results that suggest infection (pyuria and/or bacteriuria) *and* the presence of at least 50 000 colony-forming units (CFUs) per mL of a uropathogen cultured from a urine specimen obtained through catheterization or SPA (evidence quality: C; recommendation).

Urinalysis

General Considerations

Urinalysis cannot substitute for urine culture to document the presence of UTI but needs to be used in conjunction with culture. Because urine culture results are not available for at least 24 hours, there is considerable interest in tests that may predict the results of the urine culture and enable presumptive therapy to be initiated at the first encounter. Urinalysis can be performed on any specimen, including one collected from a bag applied to the perineum. However, the specimen must be fresh (<1 hour after voiding with maintenance at room temperature or <4 hours after voiding with refrigeration), to ensure sensitivity and specificity of the urinalysis. The tests that have received the most attention are biochemical analyses of leukocyte esterase and nitrite through a rapid dipstick method and urine microscopic examination for white blood cells (WBCs) and bacteria (Table 1).

Urine dipsticks are appealing, because they provide rapid results, do not require microscopy, and are eligible for a waiver under the Clinical Laboratory Improvement Amendments. They indicate the presence of leukocyte esterase (as a surrogate marker for pyuria) and urinary nitrite (which is converted from dietary nitrates in the presence of most Gram-negative enteric bacteria in the urine). The conversion of dietary nitrates to nitrites by bacteria requires approximately 4 hours in the bladder.[31] The performance characteristics of both leukocyte esterase and nitrite tests vary according to the definition used for positive urine culture results, the age and symptoms of the population being studied, and the method of urine collection.

Nitrite Test

A nitrite test is not a sensitive marker for children, particularly infants, who empty their bladders frequently. Therefore, negative nitrite test results have little value in ruling out UTI. Moreover, not all urinary pathogens reduce nitrate to nitrite. The test is helpful when the result is positive, however, because it is highly specific (ie, there are few false-positive results).[32]

Leukocyte Esterase Test

The sensitivity of the leukocyte esterase test is 94% when it used in the context of clinically suspected UTI. Overall, the reported sensitivity in various studies is lower (83%), because the results of leukocyte esterase tests were related to culture results without exclusion of individuals with asymptomatic bacteriuria. The absence of leukocyte esterase in the urine of individuals with asymptomatic bacteriuria is an advantage of the test, rather than a limitation, because it distinguishes individuals with asymptomatic bacteriuria from those with true UTI.

The specificity of the leukocyte esterase test (average: 72% [range: 64%–92%]) generally is not as good as the sensitivity, which reflects the nonspecificity of pyuria in general. Accordingly, positive leukocyte esterase test results should be interpreted with caution, because false-positive results are common. With numerous conditions other than UTI, including fever resulting from other conditions (eg, streptococcal infections or Kawasaki disease), and after vigorous exercise, WBCs may be found in the urine. Therefore, a finding of pyuria by no means confirms that an infection of the urinary tract is present.

The absence of pyuria in children with true UTIs is rare, however. It is theoretically possible if a febrile child is assessed before the inflammatory response has developed, but the inflammatory response to a UTI produces both fever and pyuria; therefore, children who are being evaluated because of fever should already have WBCs in their urine. More likely explanations for significant bacteriuria in culture in the absence of pyuria include contaminated specimens, insensitive criteria for pyuria, and asymptomatic bacteriuria. In most cases, when true UTI has been reported to occur in the absence of pyuria, the definition of pyuria has been at fault. The standard method of assessing pyuria has been centrifugation of the urine and microscopic analysis, with a threshold of 5 WBCs per high-power field (~25 WBCs per μL). If a counting chamber is used, however, the finding of at least 10 WBCs per μL in uncentrifuged urine has been demonstrated to be more sensitive[33] and performs well in clinical situations in which the standard method does not, such as with very young infants.[34]

An important cause of bacteriuria in the absence of pyuria is asymptomatic bacteriuria. Asymptomatic bacteriuria often is associated with school-aged and older girls,[35] but it can be present during infancy. In a study of infants 2 to 24 months of age, 0.7% of afebrile girls had 3 successive urine cultures with 10^5 CFUs per mL of a single uropathogen.[26] Asymptomatic bacteriuria can be easily confused with true UTI in a febrile infant but needs to be distinguished, because studies suggest that antimicrobial treatment may do more harm than good.[36] The key to distinguishing true UTI from asymptomatic bacteriuria is the presence of pyuria.

Microscopic Analysis for Bacteriuria

The presence of bacteria in a fresh, Gram-stained specimen of uncentrifuged urine correlates with 10^5 CFUs per mL in culture.[37] An "enhanced urinalysis," combining the counting chamber assessment of pyuria noted previously with Gram staining of drops of uncentrifuged urine, with a threshold of at least 1 Gram-negative rod in 10 oil immersion fields, has greater sensitivity, specificity, and positive predictive value than does the standard urinalysis[33] and is the preferred method of urinalysis when appropriate equipment and personnel are available.

Automated Urinalysis

Automated methods to perform urinalysis are now being used in many hospitals and laboratories. Image-based systems use flow imaging analysis technology and software to classify particles in uncentrifuged urine specimens rapidly.[38] Results correlate well with manual methods, especially for red blood cells, WBCs, and squamous epithelial cells. In the future, this may be the most common method by which urinalysis is performed in laboratories.

Culture

The diagnosis of UTI is made on the basis of quantitative urine culture results in addition to evidence of pyuria and/or bacteriuria. Urine specimens should be processed as expediently as

possible. If the specimen is not processed promptly, then it should be refrigerated to prevent the growth of organisms that can occur in urine at room temperature; for the same reason, specimens that require transportation to another site for processing should be transported on ice. A properly collected urine specimen should be inoculated on culture medium that will allow identification of urinary tract pathogens.

Urine culture results are considered positive or negative on the basis of the number of CFUs that grow on the culture medium.[36] Definition of significant colony counts with regard to the method of collection considers that the distal urethra and periurethral area are commonly colonized by the same bacteria that may cause UTI; therefore, a low colony count may be present in a specimen obtained through voiding or catheterization when bacteria are not present in bladder urine. Definitions of positive and negative culture results are operational and not absolute. The time the urine resides in the bladder (bladder incubation time) is an important determinant of the magnitude of the colony count. The concept that more than 100 000 CFUs per mL indicates a UTI was based on morning collections of urine from adult women, with comparison of specimens from women without symptoms and women considered clinically to have pyelonephritis; the transition range, in which the proportion of women with pyelonephritis exceeded the proportion of women without symptoms, was 10 000 to 100 000 CFUs per mL.[39] In most instances, an appropriate threshold to consider bacteriuria "significant" in infants and children is the presence of at least 50 000 CFUs per mL of a single urinary pathogen.[40] (Organisms such as *Lactobacillus* spp, coagulase-negative staphylococci, and *Corynebacterium* spp are not considered clinically relevant urine isolates for otherwise healthy, 2- to 24-month-old children.) Reducing the threshold from 100 000 CFUs per mL to 50 000 CFUs per mL would seem to increase the sensitivity of culture at the expense of decreased specificity; however, because the proposed criteria for UTI now include evidence of pyuria in addition to positive culture results, infants with "positive" culture results alone will be recognized as having asymptomatic bacteriuria rather than a true UTI. Some laboratories report growth only in the following categories: 0 to 1000, 1000 to 10 000, 10 000 to 100 000, and more than 100 000 CFUs per mL. In such cases, results in the 10 000 to 100 000 CFUs per mL range need to be evaluated in context, such as whether the urinalysis findings support the diagnosis of UTI and whether the organism is a recognized uropathogen.

Alternative culture methods, such as dipslides, may have a place in the office setting; sensitivity is reported to be in the range of 87% to 100%, and specificity is reported to be 92% to 98%, but dipslides cannot specify the organism or antimicrobial sensitivities.[41] Practices that use dipslides should do so in collaboration with a certified laboratory for identification and sensitivity testing or, in the absence of such results, may need to perform "test of cure" cultures after 24 hours of treatment.

- Aggregate quality of evidence: C (observational studies).
- Benefits: Accurate diagnosis of UTI can prevent the spread of infection and renal scarring; avoiding overdiagnosis of UTI can prevent overtreatment and unnecessary and expensive imaging. These criteria reduce the likelihood of overdiagnosis of UTI in infants with asymptomatic bacteriuria or contaminated specimens.
- Harms/risks/costs: Stringent diagnostic criteria may miss a small number of UTIs.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: Treatment of asymptomatic bacteriuria may be harmful.
- Role of patient preferences: We assume that parents prefer no action in the absence of a UTI (avoiding false-positive results) over a very small chance of missing a UTI.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Recommendation.

MANAGEMENT

Action Statement 4

Action Statement 4a

When initiating treatment, the clinician should base the choice of route of administration on practical considerations. Initiating treatment orally or parenterally is equally efficacious. The clinician should base the choice of agent on local antimicrobial sensitivity patterns (if available) and should adjust the choice according to sensitivity testing of the isolated uropathogen (evidence quality: A; strong recommendation).

Action Statement 4b

The clinician should choose 7 to 14 days as the duration of antimicrobial therapy (evidence quality: B; recommendation).

The goals of treatment of acute UTI are to eliminate the acute infection, to prevent complications, and to reduce the likelihood of renal damage. Most children can be treated orally.[42–44] Patients whom clinicians judge to be "toxic" or who are unable to retain oral intake (including medications) should receive an antimicrobial agent parenter-

TABLE 2 Some Empiric Antimicrobial Agents for Parenteral Treatment of UTI

Antimicrobial Agent	Dosage
Ceftriaxone	75 mg/kg, every 24 h
Cefotaxime	150 mg/kg per d, divided every 6–8 h
Ceftazidime	100–150 mg/kg per d, divided every 8 h
Gentamicin	7.5 mg/kg per d, divided every 8 h
Tobramycin	5 mg/kg per d, divided every 8 h
Piperacillin	300 mg/kg per d, divided every 6–8 h

TABLE 3 Some Empiric Antimicrobial Agents for Oral Treatment of UTI

Antimicrobial Agent	Dosage
Amoxicillin-clavulanate	20–40 mg/kg per d in 3 doses
Sulfonamide	
Trimethoprim-sulfamethoxazole	6–12 mg/kg trimethoprim and 30-60 mg/kg sulfamethoxazole per d in 2 doses
Sulfisoxazole	120–150 mg/kg per d in 4 doses
Cephalosporin	
Cefixime	8 mg/kg per d in 1 dose
Cefpodoxime	10 mg/kg per d in 2 doses
Cefprozil	30 mg/kg per d in 2 doses
Cefuroxime axetil	20–30 mg/kg per d in 2 doses
Cephalexin	50–100 mg/kg per d in 4 doses

ally (Table 2) until they exhibit clinical improvement, generally within 24 to 48 hours, and are able to retain orally administered fluids and medications. In a study of 309 febrile infants with UTIs, only 3 (1%) were deemed too ill to be assigned randomly to either parenteral or oral treatment.[42] Parenteral administration of an antimicrobial agent also should be considered when compliance with obtaining an antimicrobial agent and/or administering it orally is uncertain. The usual choices for oral treatment of UTIs include a cephalosporin, amoxicillin plus clavulanic acid, or trimethoprim-sulfamethoxazole (Table 3). It is essential to know local patterns of susceptibility of coliforms to antimicrobial agents, particularly trimethoprim-sulfamethoxazole and cephalexin, because there is substantial geographic variability that needs to be taken into account during selection of an antimicrobial agent before sensitivity results are available. Agents that are excreted in the urine but do not achieve therapeutic concentrations in the bloodstream, such as nitrofurantoin, should not be used to treat febrile infants with UTIs, because parenchymal and serum antimicrobial concentrations may be insufficient to treat pyelonephritis or urosepsis.

Whether the initial route of administration of the antimicrobial agent is oral or parenteral (then changed to oral), the total course of therapy should be 7 to 14 days. The committee attempted to identify a single, preferred, evidence-based duration, rather than a range, but data comparing 7, 10, and 14 days directly were not found. There is evidence that 1- to 3-day courses for febrile UTIs are inferior to courses in the recommended range; therefore, the minimal duration selected should be 7 days.

- Aggregate quality of evidence: A/B (RCTs).
- Benefits: Adequate treatment of UTI can prevent the spread of infection and renal scarring. Outcomes of short courses (1–3 d) are inferior to those of 7- to 14-d courses.
- Harms/risks/costs: There are minimal harm and minor cost effects of antimicrobial choice and duration of therapy.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: Adjusting antimicrobial choice on the basis of available data and treating according to best evidence will minimize cost and consequences of failed or unnecessary treatment.
- Role of patient preferences: It is assumed that parents prefer the most-effective treatment and the least amount of medication that ensures effective treatment.
- Exclusions: None.
- Intentional vagueness: No evidence distinguishes the benefit of treating 7 vs 10 vs 14 days, and the range is allowable.
- Policy level: Strong recommendation/recommendation.

Action Statement 5

Febrile infants with UTIs should undergo renal and bladder ultrasonography (RBUS) (evidence quality: C; recommendation).

The purpose of RBUS is to detect anatomic abnormalities that require further evaluation, such as additional imaging or urologic consultation. RBUS also provides an evaluation of the renal parenchyma and an assessment of renal size that can be used to monitor renal growth. The yield of actionable findings is relatively low.[45,46] Widespread application of prenatal ultrasonography clearly has reduced the prevalence of previously unsuspected obstructive uropathy in infants, but the consequences of prenatal screening with respect to the risk of renal abnormalities in infants with UTIs have not yet been well defined. There is considerable variability in the timing and quality of prenatal ultrasonograms, and the report of "normal" ultrasonographic results cannot necessarily be relied on to dismiss completely the possibility of a structural abnormality unless the study was a detailed anatomic survey (with measurements), was performed during the third tri-

mester, and was performed and interpreted by qualified individuals.[47]

The timing of RBUS depends on the clinical situation. RBUS is recommended during the first 2 days of treatment to identify serious complications, such as renal or perirenal abscesses or pyonephrosis associated with obstructive uropathy when the clinical illness is unusually severe or substantial clinical improvement is not occurring. For febrile infants with UTIs who demonstrate substantial clinical improvement, however, imaging does not need to occur early during the acute infection and can even be misleading; animal studies demonstrate that *Escherichia coli* endotoxin can produce dilation during acute infection, which could be confused with hydronephrosis, pyonephrosis, or obstruction.[48] Changes in the size and shape of the kidneys and the echogenicity of renal parenchyma attributable to edema also are common during acute infection. The presence of these abnormalities makes it inappropriate to consider RBUS performed early during acute infection to be a true baseline study for later comparisons in the assessment of renal growth.

Nuclear scanning with technetium-labeled dimercaptosuccinic acid has greater sensitivity for detection of acute pyelonephritis and later scarring than does either RBUS or voiding cystourethrography (VCUG). The scanning is useful in research, because it ensures that all subjects in a study have pyelonephritis to start with and it permits assessment of later renal scarring as an outcome measure. The findings on nuclear scans rarely affect acute clinical management, however, and are not recommended as part of routine evaluation of infants with their first febrile UTI. The radiation dose to the patient during dimercaptosuccinic acid scanning is generally low (~1 mSv),[49] although it may be increased in children with reduced renal function. The radiation dose from dimercaptosuccinic acid is additive with that of VCUG when both studies are performed.[50] The radiation dose from VCUG depends on the equipment that is used (conventional versus pulsed digital fluoroscopy) and is related directly to the total fluoroscopy time. Moreover, the total exposure for the child will be increased when both acute and follow-up studies are obtained. The lack of exposure to radiation is a major advantage of RBUS, even with recognition of the limitations of this modality that were described previously.

- Aggregate quality of evidence: C (observational studies).
- Benefits: RBUS in this population will yield abnormal results in ~15% of cases, and 1% to 2% will have abnormalities that would lead to action (eg, additional evaluation, referral, or surgery).
- Harms/risks/costs: Between 2% and 3% will be false-positive results, leading to unnecessary and invasive evaluations.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: The seriousness of the potentially correctable abnormalities in 1% to 2%, coupled with the absence of physical harm, was judged sufficiently important to tip the scales in favor of testing.
- Role of patient preferences: Because ultrasonography is noninvasive and poses minimal risk, we assume that parents will prefer RBUS over taking even a small risk of missing a serious and correctable condition.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Recommendation.

Action Statement 6

Action Statement 6a

VCUG should not be performed routinely after the first febrile UTI; VCUG is indicated if RBUS reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy, as well as in other atypical or complex clinical circumstances (evidence quality B; recommendation).

Action Statement 6b

Further evaluation should be conducted if there is a recurrence of febrile UTI (evidence quality: X; recommendation).

For the past 4 decades, the strategy to protect the kidneys from further damage after an initial UTI has been to detect childhood genitourinary abnormalities in which recurrent UTI could increase renal damage. The most common of these is VUR, and VCUG is used to detect this. Management included continuous antimicrobial administration as prophylaxis and surgical intervention if VUR was persistent or recurrences of infection were not prevented with an antimicrobial prophylaxis regimen; some have advocated surgical intervention to correct high-grade reflux even when infection has not recurred. However, it is clear that there are a significant number of infants who develop pyelonephritis in whom VUR cannot be demonstrated, and the effectiveness of antimicrobial prophylaxis for patients who have VUR has been challenged in the past decade. Several studies have suggested that prophylaxis does not confer the desired benefit of preventing recurrent febrile UTI.[51–55] If prophylaxis is, in fact, not beneficial and VUR is not required for development of pyelonephritis, then the rationale for performing VCUG routinely after an initial febrile UTI must be questioned.

RCTs of the effectiveness of prophylaxis performed to date generally included children more than 24 months of age, and some did not provide complete data according to grade of VUR. These 2 factors have compromised meta-analyses. To ensure direct comparisons, the committee contacted the 6 researchers who had conducted the most recent RCTs and requested raw data from their studies.[51–56] All complied, which permitted the creation of a data set with data for 1091 infants 2 to 24 months of age according to grade of VUR. A χ^2 analysis (2-tailed) and a formal meta-analysis did not detect a statistically significant benefit of prophylaxis in preventing recurrence of febrile UTI/pyelonephritis in infants without reflux or those with grades I, II, III, or IV VUR (Table 4 and Fig 3). Only 5 infants with grade V VUR were included in the RCTs; therefore, data for those infants are not included in Table 4 or Fig 3.

The proportion of infants with high-grade VUR among all infants with febrile UTIs is small. Data adapted from current studies (Table 5) indicate that, of a hypothetical cohort of 100 infants with febrile UTIs, only 1 has grade V VUR; 99 do not. With a practice of waiting for a second UTI to perform VCUG, only 10 of the 100 would need to undergo the procedure and the 1 with grade V VUR would be identified. (It also is possible that the 1 infant with grade V VUR might have been identified after the first UTI on the basis of abnormal RBUS results that prompted VCUG to be performed.) Data to quantify additional potential harm to an infant who is not revealed to have high-grade VUR until a second UTI are not precise but suggest that the increment is insufficient to justify routinely subjecting all infants with an initial febrile UTI to VCUG (Fig 4). To minimize any harm incurred by that infant, attempts have been made to identify, at the time of the initial UTI, those who have the greatest likelihood of having high-grade VUR. Unfortunately, there are no clinical or laboratory indicators that have been demonstrated to identify infants with high-grade VUR. Indications for VCUG have been proposed on the basis of consensus in the absence of data[57]; the predictive value of any of the indications for VCUG proposed in this manner is not known.

TABLE 4 Recurrences of Febrile UTI/Pyelonephritis in Infants 2 to 24 Months of Age With and Without Antimicrobial Prophylaxis, According to Grade of VUR

Reflux Grade	Prophylaxis		No Prophylaxis		*P*
	No. of Recurrences	Total *N*	No. of Recurrences	Total *N*	
None	7	210	11	163	.15
I	2	37	2	35	1.00
II	11	133	10	124	.95
III	31	140	40	145	.29
IV	16	55	21	49	.14

The level of evidence supporting routine imaging with VCUG was deemed insufficient at the time of the 1999 practice parameter to receive a recommendation, but the consensus of the subcommittee was to "strongly encourage" imaging studies. The position of the current subcommittee reflects the new evidence demonstrating antimicrobial prophylaxis not to be effective as presumed previously. Moreover, prompt diagnosis and effective treatment of a febrile UTI recurrence may be of greater importance regardless of whether VUR is present or the child is receiving antimicrobial prophylaxis. A national study (the Randomized Intervention for Children With Vesicoureteral Reflux study) is currently in progress to identify the effects of a prophylactic antimicrobial regimen for children 2 months to 6 years of age who have experienced a UTI, and it is anticipated to provide additional important data[58] (see Areas for Research).

Action Statement 6a

- Aggregate quality of evidence: B (RCTs).
- Benefits: This avoids, for the vast majority of febrile infants with UTIs, radiation exposure (of particular concern near the ovaries in girls), expense, and discomfort.
- Harms/risks/costs: Detection of a small number of cases of high-grade reflux and correctable abnormalities is delayed.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: The risks associated with radiation (plus the expense and discomfort of the procedure) for the vast majority of infants outweigh the risk of delaying the detection of the few with correctable abnormalities until their second UTI.
- Role of patient preferences: The judgment of parents may come into play, because VCUG is an uncomfortable procedure involving radiation exposure. In some cases, parents may prefer to subject their children to the procedure even when the chance of benefit is both small and uncertain. Antimicrobial prophylaxis seems to be ineffective in preventing recurrence of febrile UTI/pyelonephritis for the vast majority of infants. Some parents may want to avoid VCUG even after the second UTI. Because the benefit of identifying high-grade reflux is still in some doubt, these preferences should be considered. It is the judgment of the committee that VCUG is indicated after the second UTI.
- Exclusions: None.

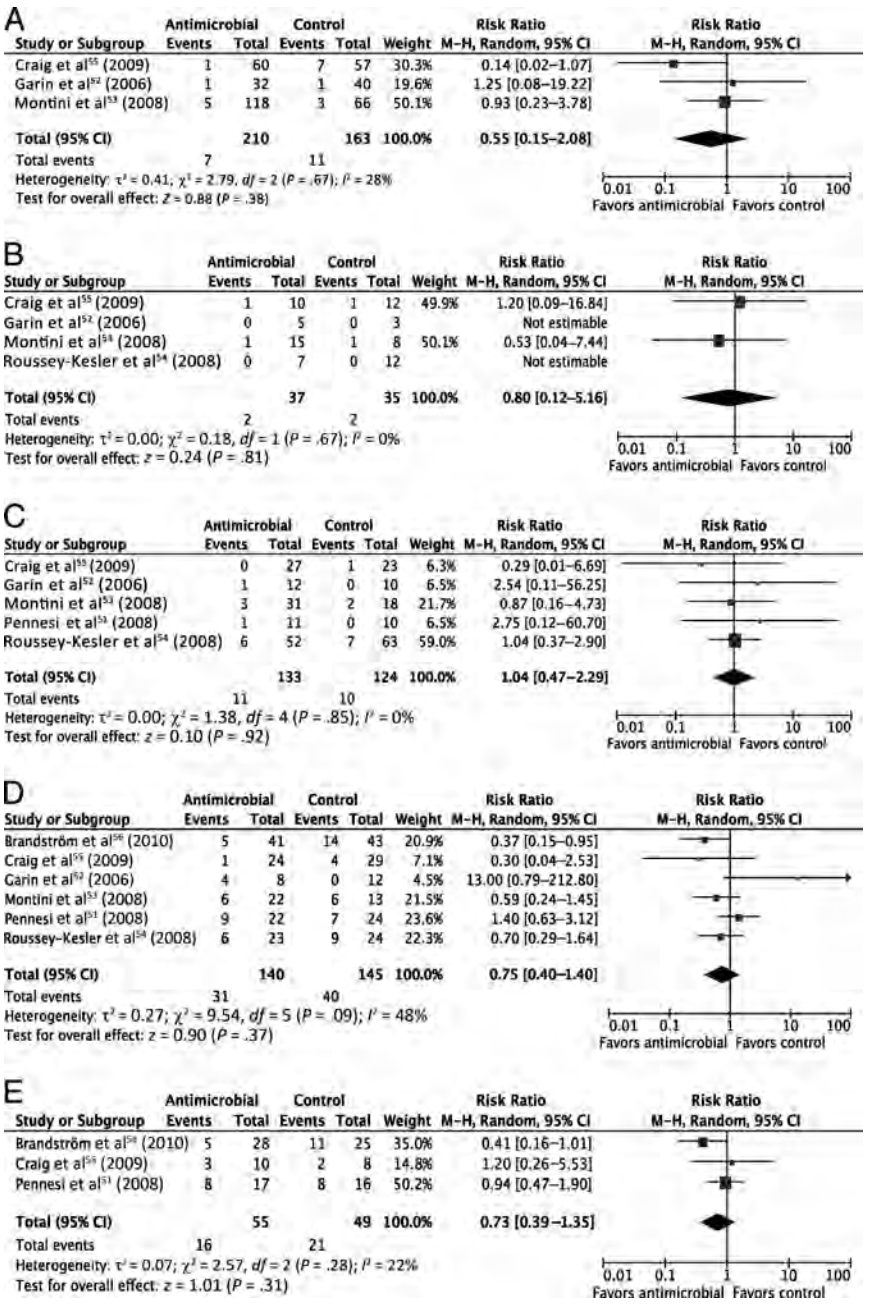


FIGURE 3

A, Recurrences of febrile UTI/pyelonephritis in 373 infants 2 to 24 months of age without VUR, with and without antimicrobial prophylaxis (based on 3 studies; data provided by Drs Craig, Garin, and Montini). B, Recurrences of febrile UTI/pyelonephritis in 72 infants 2 to 24 months of age with grade I VUR, with and without antimicrobial prophylaxis (based on 4 studies; data provided by Drs Craig, Garin, Montini, and Roussey-Kesler). C, Recurrences of febrile UTI/pyelonephritis in 257 infants 2 to 24 months of age with grade II VUR, with and without antimicrobial prophylaxis (based on 5 studies; data provided by Drs Craig, Garin, Montini, Pennesi, and Roussey-Kesler). D, Recurrences of febrile UTI/pyelonephritis in 285 infants 2 to 24 months of age with grade III VUR, with and without antimicrobial prophylaxis (based on 6 studies; data provided by Drs Brandström, Craig, Garin, Montini, Pennesi, and Roussey-Kesler). E, Recurrences of febrile UTI/pyelonephritis in 104 infants 2 to 24 months of age with grade IV VUR, with and without antimicrobial prophylaxis (based on 3 studies; data provided by Drs Brandström, Craig, and Pennesi). M-H indicates Mantel-Haenszel; CI, confidence interval.

TABLE 5 Rates of VUR According to Grade in Hypothetical Cohort of Infants After First UTI and After Recurrence

	Rate, %	
	After First UTI ($N = 100$)	After Recurrence ($N = 10$)
No VUR	65	26
Grades I–III VUR	29	56
Grade IV VUR	5	12
Grade V VUR	1	6

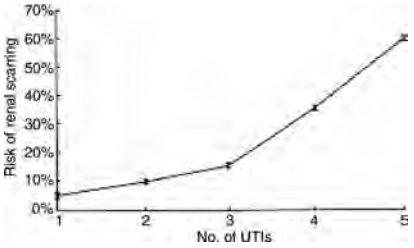


FIGURE 4

Relationship between renal scarring and number of bouts of pyelonephritis. Adapted from Jodal.[59]

- Intentional vagueness: None.
- Policy level: Recommendation.

Action Statement 6b

- Aggregate quality of evidence: X (exceptional situation).
- Benefits: VCUG after a second UTI should identify infants with very high-grade reflux.
- Harms/risks/costs: VCUG is an uncomfortable, costly procedure that involves radiation, including to the ovaries of girls.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: The committee judged that patients with high-grade reflux and other abnormalities may benefit from interventions to prevent further scarring. Further studies of treatment for grade V VUR are not underway and are unlikely in the near future, because the condition is uncommon and randomization of treatment in this group generally has been considered unethical.

- Role of patient preferences: As mentioned previously, the judgment of parents may come into play, because VCUG is an uncomfortable procedure involving radiation exposure. In some cases, parents may prefer to subject their children to the procedure even when the chance of benefit is both small and uncertain. The benefits of treatment of VUR remain unproven, but the point estimates suggest a small potential benefit. Similarly, parents may want to avoid VCUG even after the second UTI. Because the benefit of identifying high-grade reflux is still in some doubt, these preferences should be considered. It is the judgment of the committee that VCUG is indicated after the second UTI.
- Exclusions: None.
- Intentional vagueness: Further evaluation will likely start with VCUG but may entail additional studies depending on the findings. The details of further evaluation are beyond the scope of this guideline.
- Policy level: Recommendation.

Action Statement 7

After confirmation of UTI, the clinician should instruct parents or guardians to seek prompt medical evaluation (ideally within 48 hours) for future febrile illnesses, to ensure that recurrent infections can be detected and treated promptly (evidence quality: C; recommendation).

Early treatment limits renal damage better than late treatment,[1,2] and the risk of renal scarring increases as the number of recurrences increase (Fig 4).[59] For these reasons, all infants who have sustained a febrile UTI should have a urine specimen obtained at the onset of subsequent febrile illnesses, so that a UTI can be diagnosed and treated promptly.

- Aggregate quality of evidence: C (observational studies).
- Benefits: Studies suggest that early treatment of UTI reduces the risk of renal scarring.
- Harms/risks/costs: There may be additional costs and inconvenience to parents with more-frequent visits to the clinician for evaluation of fever.
- Benefit-harms assessment: Preponderance of benefit over harm.
- Value judgments: None.
- Role of patient preferences: Parents will ultimately make the judgment to seek medical care.
- Exclusions: None.
- Intentional vagueness: None.
- Policy level: Recommendation.

CONCLUSIONS

The committee formulated 7 key action statements for the diagnosis and treatment of infants and young children 2 to 24 months of age with UTI and unexplained fever. Strategies for diagnosis and treatment depend on whether the clinician determines that antimicrobial therapy is warranted immediately or can be delayed safely until urine culture and urinalysis results are available. Diagnosis is based on the presence of pyuria and at least 50 000 CFUs per mL of a single uropathogen in an appropriately collected specimen of urine; urinalysis alone does not provide a definitive diagnosis. After 7 to 14 days of antimicrobial treatment, close clinical follow-up monitoring should be maintained, with evaluation of the urine during subsequent febrile episodes to permit prompt diagnosis and treatment of recurrent infections. Ultrasonography of the kidneys and bladder should be performed to detect anatomic abnormalities that require further evaluation (eg, additional imaging or urologic consultation). Routine VCUG after the first UTI is not recommended; VCUG is indicated if RBUS reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy, as well as in other atypical or complex clinical circumstances. VCUG also should be performed if there is a recurrence of febrile UTI.

AREAS FOR RESEARCH

One of the major values of a comprehensive literature review is the identification of areas in which evidence is lacking. The following 8 areas are presented in an order that parallels the previous discussion.

1. The relationship between UTIs in infants and young children and reduced renal function in adults has been established but is not well characterized in quantitative terms. The ideal prospective cohort study from birth to 40 to 50 years of age has not been conducted and is unlikely to be conducted. Therefore, estimates of undesirable outcomes in adulthood, such as hypertension and end-stage renal disease, are based on the mathematical product of probabilities at several steps, each of which is subject to bias and error. Other attempts at decision analysis and thoughtful literature review have recognized the same limitations. Until recently, imaging tools available for assessment of the effects of UTIs have been insensitive. With the imaging techniques now available, it may be possible to identify the relationship of scarring to renal impairment and hypertension.
2. The development of techniques that would permit an alternative to invasive sampling and culture would be valuable for general use. Special attention should be given to infant girls and uncircumcised boys, because urethral catheterization may

be difficult and can produce contaminated specimens and SPA now is not commonly performed. Incubation time, which is inherent in the culture process, results in delayed treatment or presumptive treatment on the basis of tests that lack the desired sensitivity and specificity to replace culture.

3. The role of VUR (and therefore of VCUG) is incompletely understood. It is recognized that pyelonephritis (defined through cortical scintigraphy) can occur in the absence of VUR (defined through VCUG) and that progressive renal scarring (defined through cortical scintigraphy) can occur in the absence of demonstrated VUR.[52,53] The presumption that antimicrobial prophylaxis is of benefit for individuals with VUR to prevent recurrences of UTI or the development of renal scars is not supported by the aggregate of data from recent studies and currently is the subject of the Randomized Intervention for Children With Vesicoureteral Reflux study.[58]
4. Although the effectiveness of antimicrobial prophylaxis for the prevention of UTI has not been demonstrated, the concept has biological plausibility. Virtually all antimicrobial agents used to treat or to prevent infections of the urinary tract are excreted in the urine in high concentrations. Barriers to the effectiveness of antimicrobial prophylaxis are adherence to a daily regimen, adverse effects associated with the various agents, and the potential for emergence of antimicrobial resistance. To overcome these issues, evidence of effectiveness with a well-tolerated, safe product would be required, and parents would need sufficient education to understand the value and importance of adherence. A urinary antiseptic, rather than an antimicrobial agent, would be particularly desirable, because it could be taken indefinitely without concern that bacteria would develop resistance. Another possible strategy might be the use of probiotics.
5. Better understanding of the genome (human and bacterial) may provide insight into risk factors (VUR and others) that lead to increased scarring. Blood specimens will be retained from children enrolled in the Randomized Intervention for Children With Vesicoureteral Reflux study, for future examination of genetic determinants of VUR, recurrent UTI, and renal scarring.[58] VUR is recognized to "run in families,"[60,61] and multiple investigators are currently engaged in research to identify a genetic basis for VUR. Studies may also be able to distinguish the contribution of congenital dysplasia from acquired scarring attributable to UTI.
6. One of the factors used to assess the likelihood of UTI in febrile infants is race. Data regarding rates among Hispanic individuals are limited and would be useful for prediction rules.
7. This guideline is limited to the initial management of the first UTI in febrile infants 2 to 24 months of age. Some of the infants will have recurrent UTIs; some will be identified as having VUR or other abnormalities. Further research addressing the optimal course of management in specific situations would be valuable.
8. The optimal duration of antimicrobial treatment has not been determined. RCTs of head-to-head comparisons of various duration would be valuable, enabling clinicians to limit antimicrobial exposure to what is needed to eradicate the offending uropathogen.

LEAD AUTHOR
Kenneth B. Roberts, MD

SUBCOMMITTEE ON URINARY TRACT INFECTION, 2009–2011
Kenneth B. Roberts, MD, Chair
Stephen M. Downs, MD, MS
S. Maria E. Finnell, MD, MS
Stanley Hellerstein, MD
Linda D. Shortliffe, MD
Ellen R. Wald, MD
J. Michael Zerin, MD

OVERSIGHT BY THE STEERING COMMITTEE ON QUALITY IMPROVEMENT AND MANAGEMENT, 2009–2011

STAFF
Caryn Davidson, MA

ACKNOWLEDGMENTS

The committee gratefully acknowledges the generosity of the researchers who graciously shared their data to permit the data set with data for 1091 infants aged 2 to 24 months according to grade of VUR to be compiled, that is, Drs Per Brandström, Jonathan Craig, Eduardo Garin, Giovanni Montini, Marco Pennesi, and Gwenaelle Roussey-Kesler.

REFERENCES

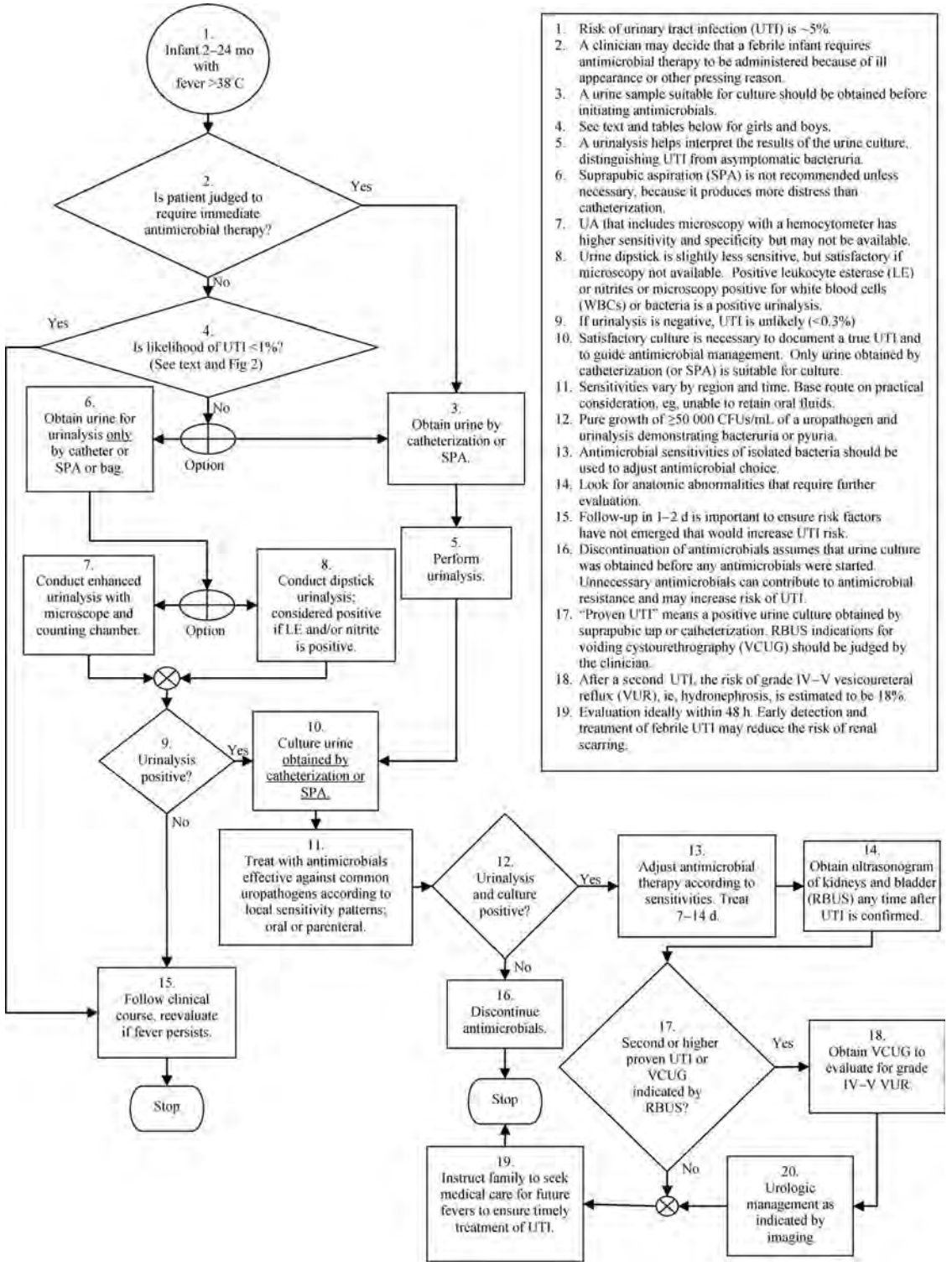
1. Winter AL, Hardy BE, Alton DJ, Arbus GS, Churchill BM. Acquired renal scars in children. *J Urol*. 1983;129(6):1190–1194
2. Smellie JM, Poulton A, Prescod NP. Retrospective study of children with renal scarring associated with reflux and urinary infection. *BMJ*. 1994;308(6938):1193–1196
3. American Academy of Pediatrics, Committee on Quality Improvement, Subcommittee on Urinary Tract Infection. Practice parameter: the diagnosis, treatment, and evaluation of the initial urinary tract infection in febrile infants and young children. *Pediatrics*. 1999;103(4):843–852
4. Finnell SM, Carroll AE, Downs SM, et al. Technical report: diagnosis and management of an initial urinary tract infection in febrile infants and young children. *Pediatrics*. 2011;128(3):e749
5. American Academy of Pediatrics, Steering Committee on Quality Improvement and Management. Classifying recommenda-

tions for clinical practice guidelines. *Pediatrics*. 2004;114(3):874–877

6. Leong YY, Tan KW. Bladder aspiration for diagnosis of urinary tract infection in infants and young children. *J Singapore Paediatr Soc*. 1976;18(1):43–47
7. Pryles CV, Atkin MD, Morse TS, Welch KJ. Comparative bacteriologic study of urine obtained from children by percutaneous suprapubic aspiration of the bladder and by catheter. *Pediatrics*. 1959;24(6):983–991
8. Djojohadipringgo S, Abdul Hamid RH, Thahir S, Karim A, Darsono I. Bladder puncture in newborns: a bacteriological study. *Paediatr Indones*. 1976;16(11–12):527–534
9. Gochman RF, Karasic RB, Heller MB. Use of portable ultrasound to assist urine collection by suprapubic aspiration. *Ann Emerg Med*. 1991;20(6):631–635
10. Buys H, Pead L, Hallett R, Maskell R. Suprapubic aspiration under ultrasound guidance in children with fever of undiagnosed cause. *BMJ*. 1994;308(6930):690–692
11. Kramer MS, Tange SM, Drummond KN, Mills EL. Urine testing in young febrile children: a risk-benefit analysis. *J Pediatr*. 1994;125(1):6–13
12. Bonadio WA. Urine culturing technique in febrile infants. *Pediatr Emerg Care*. 1987;3(2):75–78
13. Lohr J. *Pediatric Outpatient Procedures*. Philadelphia, PA: Lippincott; 1991
14. Taylor CM, White RH. The feasibility of screening preschool children for urinary tract infection using dipslides. *Int J Pediatr Nephrol*. 1983;4(2):113–114
15. Sørensen K, Lose G, Nathan E. Urinary tract infections and diurnal incontinence in girls. *Eur J Pediatr*. 1988;148(2):146–147
16. Shannon F, Sepp E, Rose G. The diagnosis of bacteriuria by bladder puncture in infancy and childhood. *Aust Pediatr J*. 1969;5(2):97–100
17. Hoberman A, Chao HP, Keller DM, Hickey R, Davis HW, Ellis D. Prevalence of urinary tract infection in febrile infants. *J Pediatr*. 1993;123(1):17–23
18. Haddon RA, Barnett PL, Grimwood K, Hogg GG. Bacteraemia in febrile children presenting to a paediatric emergency department. *Med J Aust*. 1999;170(10):475–478
19. Wiswell TE, Roscelli JD. Corroborative evidence for the decreased incidence of urinary tract infections in circumcised male infants. *Pediatrics*. 1986;78(1):96–99
20. To T, Agha M, Dick PT, Feldman W. Cohort study on circumcision of newborn boys and subsequent risk of urinary-tract infection. *Lancet*. 1998;352(9143):1813–1816
21. Wiswell TE, Hachey WE. Urinary tract infections and the uncircumcised state: an update. *Clin Pediatr (Phila)*. 1993;32(3):130–134
22. Wiswell TE, Smith FR, Bass JW. Decreased incidence of urinary tract infections in circumcised male infants. *Pediatrics*. 1985;75(5):901–903
23. Ginsburg CM, McCracken GH Jr. Urinary tract infections in young infants. *Pediatrics*. 1982;69(4):409–412
24. Craig JC, Knight JF, Sureshkumar P, Mantz E, Roy LP. Effect of circumcision on incidence of urinary tract infection in preschool boys. *J Pediatr*. 1996;128(1):23–27
25. Levine DA, Platt SL, Dayan PS, et al. Risk of serious bacterial infection in young febrile infants with respiratory syncytial virus infections. *Pediatrics*. 2004;113(6):1728–1734
26. Roberts KB, Charney E, Sweren RJ, et al. Urinary tract infection in infants with unexplained fever: a collaborative study. *J Pediatr*. 1983;103(6):864–867
27. Gorelick MH, Hoberman A, Kearney D, Wald E, Shaw KN. Validation of a decision rule identifying febrile young girls at high risk for urinary tract infection. *Pediatr Emerg Care*. 2003;19(3):162–164
28. Gorelick MH, Shaw KN. Clinical decision rule to identify febrile young girls at risk for urinary tract infection. *Arch Pediatr Adolesc Med*. 2000;154(4):386–390
29. Shaw KN, Gorelick M, McGowan KL, Yakscoe NM, Schwartz JS. Prevalence of urinary tract infection in febrile young children in the emergency department. *Pediatrics*. 1998;102(2). Available at: www.pediatrics.org/cgi/content/full/102/2/e16
30. Shaikh N, Morone NE, Lopez J, et al. Does this child have a urinary tract infection? *JAMA*. 2007;298(24):2895–2904
31. Powell HR, McCredie DA, Ritchie MA. Urinary nitrite in symptomatic and asymptomatic urinary infection. *Arch Dis Child*. 1987;62(2):138–140
32. Kunin CM, DeGroot JE. Sensitivity of a nitrite indicator strip method in detecting bacteriuria in preschool girls. *Pediatrics*. 1977;60(2):244–245
33. Hoberman A, Wald ER, Reynolds EA, Penchansky L, Charron M. Is urine culture necessary to rule out urinary tract infection in young febrile children? *Pediatr Infect Dis J*. 1996;15(4):304–309
34. Herr SM, Wald ER, Pitetti RD, Choi SS. Enhanced urinalysis improves identification of febrile infants ages 60 days and younger at low risk for serious bacterial illness. *Pediatrics*. 2001;108(4):866–871
35. Kunin C. A ten-year study of bacteriuria in schoolgirls: final report of bacteriologic, urologic, and epidemiologic findings. *J Infect Dis*. 1970;122(5):382–393
36. Kemper K, Avner E. The case against screening urinalyses for asymptomatic bacteriuria in children. *Am J Dis Child*. 1992;146(3):343–346
37. Wald E. Genitourinary tract infections: cystitis and pyelonephritis. In: Feigin R, Cherry JD, Demmler GJ, Kaplan SL, eds. *Textbook of Pediatric Infectious Diseases*. 5th ed. Philadelphia, PA: Saunders; 2004:541–555
38. Mayo S, Acevedo D, Quiñones-Torrelo C, Canós I, Sancho M. Clinical laboratory automated urinalysis: comparison among automated microscopy, flow cytometry, two test strips analyzers, and manual microscopic examination of the urine sediments. *J Clin Lab Anal*. 2008;22(4):262–270
39. Kass E. Asymptomatic infections of the urinary tract. *Trans Assoc Am Phys*. 1956;69:56–64
40. Hoberman A, Wald ER, Reynolds EA, Penchansky L, Charron M. Pyuria and bacteriuria in urine specimens obtained by catheter from young children with fever. *J Pediatr*. 1994;124(4):513–519
41. Downs SM. Technical report: urinary tract infections in febrile infants and young children. *Pediatrics*. 1999;103(4). Available at: www.pediatrics.org/cgi/content/full/103/4/e54
42. Hoberman A, Wald ER, Hickey RW, et al. Oral versus initial intravenous therapy for urinary tract infections in young febrile children. *Pediatrics*. 1999;104(1):79–86
43. Hodson EM, Willis NS, Craig JC. Antibiotics for acute pyelonephritis in children. *Cochrane Database Syst Rev*. 2007;(4):CD003772
44. Bloomfield P, Hodson EM, Craig JC. Antibiotics for acute pyelonephritis in children. *Cochrane Database Syst Rev*. 2005;(1):CD003772
45. Hoberman A, Charron M, Hickey RW, Baskin M, Kearney DH, Wald ER. Imaging studies after a first febrile urinary tract infection in young children. *N Engl J Med*. 2003;348(3):195–202
46. Jahnukainen T, Honkinen O, Ruuskanen O, Mertsola J. Ultrasonography after the first febrile urinary tract infection in children. *Eur J Pediatr*. 2006;165(8):556–559
47. Economou G, Egginton J, Brookfield D. The importance of late pregnancy scans for renal tract abnormalities. *Prenat Diagn*. 1994;14(3):177–180
48. Roberts J. Experimental pyelonephritis in the monkey, part III: pathophysiology of ure-

teral malfunction induced by bacteria. *Invest Urol*. 1975;13(2):117–120

49. Smith T, Evans K, Lythgoe MF, Anderson PJ, Gordon I. Radiation dosimetry of technetium-99m-DMSA in children. *J Nucl Med*. 1996;37(8):1336–1342
50. Ward VL. Patient dose reduction during voiding cystourethrography. *Pediatr Radiol*. 2006;36(suppl 2):168–172
51. Pennesi M, Travan L, Peratoner L, et al. Is antibiotic prophylaxis in children with vesicoureteral reflux effective in preventing pyelonephritis and renal scars? A randomized, controlled trial. *Pediatrics*. 2008; 121(6). Available at: www.pediatrics.org/cgi/content/full/121/6/e1489
52. Garin EH, Olavarria F, Garcia Nieto V, Valenciano B, Campos A, Young L. Clinical significance of primary vesicoureteral reflux and urinary antibiotic prophylaxis after acute pyelonephritis: a multicenter, randomized, controlled study. *Pediatrics*. 2006;117(3): 626–632
53. Montini G, Rigon L, Zucchetta P, et al. Prophylaxis after first febrile urinary tract infection in children? A multicenter, randomized, controlled, noninferiority trial. *Pediatrics*. 2008;122(5):1064–1071
54. Roussey-Kesler G, Gadjos V, Idres N, et al. Antibiotic prophylaxis for the prevention of recurrent urinary tract infection in children with low grade vesicoureteral reflux: results from a prospective randomized study. *J Urol*. 2008;179(2):674–679
55. Craig J, Simpson J, Williams G. Antibiotic prophylaxis and recurrent urinary tract infection in children. *N Engl J Med*. 2009; 361(18):1748–1759
56. Brandström P, Esbjorner E, Herthelius M, Swerkersson S, Jodal U, Hansson S. The Swedish Reflux Trial in Children, part III: urinary tract infection pattern. *J Urol*. 2010; 184(1):286–291
57. National Institute for Health and Clinical Excellence. *Urinary Tract Infection in Children: Diagnosis, Treatment, and Long-term Management: NICE Clinical Guideline 54*. London, England: National Institute for Health and Clinical Excellence; 2007. Available at: www.nice.org.uk/nicemedia/live/11819/36032/36032.pdf. Accessed March 14, 2011
58. Keren R, Carpenter MA, Hoberman A, et al. Rationale and design issues of the Randomized Intervention for Children With Vesicoureteral Reflux (RIVUR) study. *Pediatrics*. 2008;122(suppl 5):S240–S250
59. Jodal U. The natural history of bacteriuria in childhood. *Infect Dis Clin North Am*. 1987; 1(4):713–729
60. Eccles MR, Bailey RR, Abbott GD, Sullivan MJ. Unravelling the genetics of vesicoureteric reflux: a common familial disorder. *Hum Mol Genet*. 1996;5(Spec No.):1425–1429
61. Scott JE, Swallow V, Coulthard MG, Lambert HJ, Lee RE. Screening of newborn babies for familial ureteric reflux. *Lancet*. 1997; 350(9075):396–400



APPENDIX
Clinical practice guideline algorithm.

Urinary Tract Infection Clinical Practice Guideline Quick Reference Tools

- Action Statement Summary
  — Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months
- *ICD-10-CM* Coding Quick Reference for Urinary Tract Infection
- AAP Patient Education Handout
  — *Urinary Tract Infections in Young Children*

Action Statement Summary

Urinary Tract Infection: Clinical Practice Guideline for the Diagnosis and Management of the Initial UTI in Febrile Infants and Children 2 to 24 Months

Action Statement 1

If a clinician decides that a febrile infant with no apparent source for the fever requires antimicrobial therapy to be administered because of ill appearance or another pressing reason, the clinician should ensure that a urine specimen is obtained for both culture and urinalysis before an antimicrobial agent is administered; the specimen needs to be obtained through catheterization or SPA, because the diagnosis of UTI cannot be established reliably through culture of urine collected in a bag (evidence quality: A; strong recommendation).

Action Statement 2

If a clinician assesses a febrile infant with no apparent source for the fever as not being so ill as to require immediate antimicrobial therapy, then the clinician should assess the likelihood of UTI (see below for how to assess likelihood).

Action Statement 2a

If the clinician determines the febrile infant to have a low likelihood of UTI (see text), then clinical follow-up monitoring without testing is sufficient (evidence quality: A; strong recommendation).

Action Statement 2b

If the clinician determines that the febrile infant is not in a low-risk group (see below), then there are 2 choices (evidence quality: A; strong recommendation). Option 1 is to obtain a urine specimen through catheterization or SPA for culture and urinalysis. Option 2 is to obtain a urine specimen through the most convenient means and to perform a urinalysis. If the urinalysis results suggest a UTI (positive leukocyte esterase test results or nitrite test or microscopic analysis results positive for leukocytes or bacteria), then a urine specimen should be obtained through catheterization or SPA and cultured; if urinalysis of fresh (<1 hour since void) urine yields negative leukocyte esterase and nitrite test results, then it is reasonable to monitor the clinical course without initiating antimicrobial therapy, recognizing that negative urinalysis results do not rule out a UTI with certainty.

Action Statement 3

To establish the diagnosis of UTI, clinicians should require *both* urinalysis results that suggest infection (pyuria and/or bacteriuria) *and* the presence of at least 50 000 colony-forming units (CFUs) per mL of a uropathogen cultured from a urine specimen obtained through catheterization or SPA (evidence quality: C; recommendation).

Action Statement 4a

When initiating treatment, the clinician should base the choice of route of administration on practical considerations. Initiating treatment orally or parenterally is equally efficacious. The clinician should base the choice of agent on local antimicrobial sensitivity patterns (if available) and should adjust the choice according to sensitivity testing of the isolated uropathogen (evidence quality: A; strong recommendation).

Action Statement 4b

The clinician should choose 7 to 14 days as the duration of antimicrobial therapy (evidence quality: B; recommendation).

Action Statement 5

Febrile infants with UTIs should undergo renal and bladder ultrasonography (RBUS) (evidence quality: C; recommendation).

Action Statement 6a

VCUG should not be performed routinely after the first febrile UTI; VCUG is indicated if RBUS reveals hydronephrosis, scarring, or other findings that would suggest either high-grade VUR or obstructive uropathy, as well as in other atypical or complex clinical circumstances (evidence quality B; recommendation).

Action Statement 6b

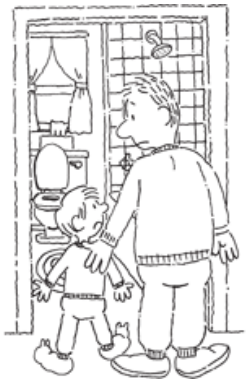
Further evaluation should be conducted if there is a recurrence of febrile UTI (evidence quality: X; recommendation).

Action Statement 7

After confirmation of UTI, the clinician should instruct parents or guardians to seek prompt medical evaluation (ideally within 48 hours) for future febrile illnesses, to ensure that recurrent infections can be detected and treated promptly (evidence quality: C; recommendation).

Coding Quick Reference for Urinary Tract Infection
ICD-10-CM
N39.0 Urinary tract infection, site not specified
P39.3 Neonatal urinary tract infection

Urinary Tract Infections in Young Children



Urinary tract infections (UTIs) are common in young children. These infections can lead to serious health problems. UTIs may go untreated because the symptoms may not be obvious to the child or the parents. The following is information from the American Academy of Pediatrics about UTIs—what they are, how children get them, and how they are treated.

The urinary tract

The urinary tract makes and stores urine. It is made up of the kidneys, ureters, bladder, and urethra (see illustration on the next page). The kidneys produce urine. Urine travels from the kidneys down 2 narrow tubes called the ureters to the bladder. The bladder is a thin muscular bag that stores urine until it is time to empty urine out of the body. When it is time to empty the bladder, a muscle at the bottom of the bladder relaxes. Urine then flows out of the body through a tube called the urethra. The opening of the urethra is at the end of the penis in boys and above the vaginal opening in girls.

Urinary tract infections

Normal urine has no germs (bacteria). However, bacteria can get into the urinary tract from 2 sources: (1) the skin around the rectum and genitals and (2) the bloodstream from other parts of the body. Bacteria may cause infections in any or all parts of the urinary tract, including the following:

- Urethra (called urethritis)
- Bladder (called cystitis)
- Kidneys (called pyelonephritis)

UTIs are common in infants and young children. The frequency of UTIs in girls is much greater than in boys. About 3% of girls and 1% of boys will have a UTI by 11 years of age. A young child with a high fever and no other symptoms has a 1 in 20 chance of having a UTI. Uncircumcised boys have more UTIs than those who have been circumcised.

Symptoms

Symptoms of UTIs may include the following:

- Fever
- Pain or burning during urination
- Need to urinate more often, or difficulty getting urine out
- Urgent need to urinate, or wetting of underwear or bedding by a child who knows how to use the toilet
- Vomiting, refusal to eat
- Abdominal pain
- Side or back pain
- Foul-smelling urine
- Cloudy or bloody urine
- Unexplained and persistent irritability in an infant
- Poor growth in an infant

Diagnosis

If your child has symptoms of a UTI, your child's doctor will do the following:

- Ask about your child's symptoms.
- Ask about any family history of urinary tract problems.
- Ask about what your child has been eating and drinking.
- Examine your child.
- Get a urine sample from your child.

Your child's doctor will need to test your child's urine to see if there are bacteria or other abnormalities.

Ways urine is collected

Urine must be collected and analyzed to determine if there is a bacterial infection. Older children are asked to urinate into a container.

There are 3 ways to collect urine from a young child:

1. The preferred method is to place a small tube, called a catheter, through the urethra into the bladder. Urine flows through the tube into a special urine container.
2. Another method is to insert a needle through the skin of the lower abdomen to draw urine from the bladder. This is called needle aspiration.
3. If your child is very young or not yet toilet trained, the child's doctor may place a plastic bag over the genitals to collect the urine. Since bacteria on the skin can contaminate the urine and give a false test result, this method is used only to screen for infection. If an infection seems to be present, the doctor will need to collect urine through 1 of the first 2 methods in order to determine if bacteria are present.

Your child's doctor will discuss with you the best way to collect your child's urine.

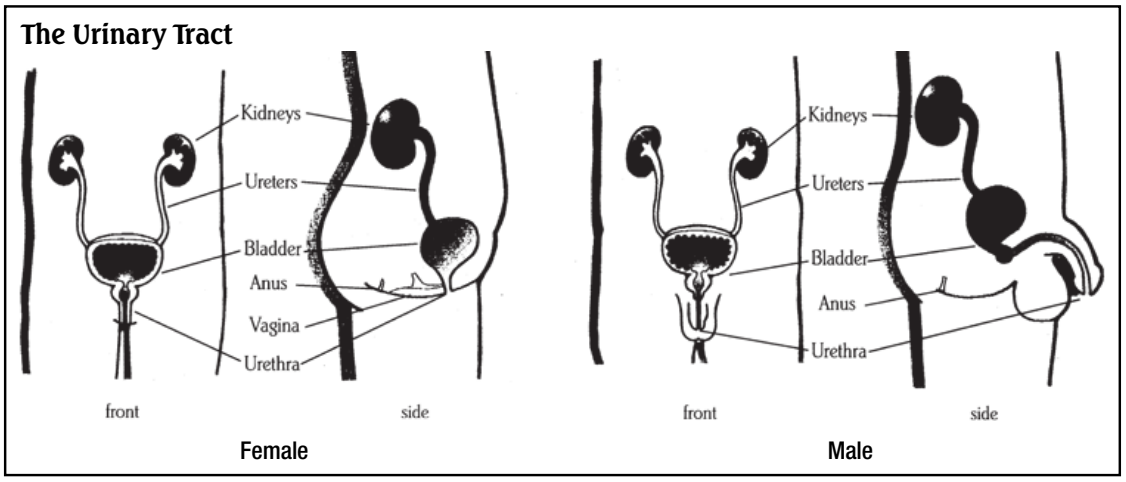
Treatment

UTIs are treated with antibiotics. The way your child receives the antibiotic depends on the severity and type of infection. Antibiotics are usually given by mouth, as liquid or pills. If your child has a fever or is vomiting and is unable to keep fluids down, the antibiotics may be put directly into a vein or injected into a muscle.

UTIs need to be treated right away to

- Get rid of the infection.
- Prevent the spread of the infection outside of the urinary tract.
- Reduce the chances of kidney damage.

Infants and young children with UTIs usually need to take antibiotics for 7 to 14 days, sometimes longer. Make sure your child takes all the medicine your child's doctor prescribes. Do not stop giving your child the medicine until the child's doctor says the treatment is finished, even if your child feels better. UTIs can return if not fully treated.



Follow-up

If the UTI occurs early in life, your child's doctor will probably want to make sure the urinary tract is normal with a kidney and bladder ultrasound. This test uses sound waves to examine the bladder and kidneys.

In addition, your child's doctor may want to make sure that the urinary tract is functioning normally and is free of any damage. Several tests are available to do this, including the following:

Voiding cystourethrogram (VCUG). A catheter is placed into the urethra and the bladder is filled with a liquid that can be seen on x-rays. This test shows whether the urine is flowing back from the bladder toward the kidneys instead of all of it coming out through the urethra as it should.

Nuclear scans. Radioactive material is injected into a vein to see if the kidneys are normal. There are many kinds of nuclear scans, each giving different information about the kidneys and bladder. The radioactive material gives no more radiation than any other kind of x-ray.

Remember

UTIs are common and most are easy to treat. Early diagnosis and prompt treatment are important because untreated or repeated infections can cause long-term medical problems. Children who have had one UTI are more likely to have another. Be sure to see your child's doctor early if your child has had a UTI in the past and has fever. Talk with your child's doctor if you suspect that your child might have a UTI.

From your doctor

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

The American Academy of Pediatrics is an organization of 66,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.

American Academy of Pediatrics
Web site — www.HealthyChildren.org

SECTION 2

Endorsed Clinical Practice Guidelines

The American Academy of Pediatrics endorses and accepts as its policy the following guidelines from other organizations.

AUTISM SPECTRUM DISORDER

Screening and Diagnosis of Autism

Quality Standards Subcommittee of the American Academy of Neurology and the Child Neurology Society

ABSTRACT. Autism is a common disorder of childhood, affecting 1 in 500 children. Yet, it often remains unrecognized and undiagnosed until or after late preschool age because appropriate tools for routine developmental screening and screening specifically for autism have not been available. Early identification of children with autism and intensive, early intervention during the toddler and preschool years improves outcome for most young children with autism. This practice parameter reviews the available empirical evidence and gives specific recommendations for the identification of children with autism. This approach requires a dual process: (1) routine developmental surveillance and screening specifically for autism to be performed on all children to first identify those at risk for any type of atypical development, and to identify those specifically at risk for autism; and (2) to diagnose and evaluate autism, to differentiate autism from other developmental disorders. (8/00, reaffirmed 10/03, 7/06, 7/10, 8/14)

CARDIOVASCULAR HEALTH

Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report

National Heart, Lung, and Blood Institute

INTRODUCTION (EXCERPT). Atherosclerotic cardiovascular disease (CVD) remains the leading cause of death in North Americans, but manifest disease in childhood and adolescence is rare. By contrast, risk factors and risk behaviors that accelerate the development of atherosclerosis begin in childhood, and there is increasing evidence that risk reduction delays progression toward clinical disease. In response, the former director of the National Heart, Lung, and Blood Institute (NHLBI), Dr Elizabeth Nabel, initiated development of cardiovascular health guidelines for pediatric care providers based on a formal evidence review of the science with an integrated format addressing all the major cardiovascular risk factors simultaneously. An expert panel was appointed to develop the guidelines in the fall of 2006. (10/12)

CEREBRAL PALSY

Diagnostic Assessment of the Child With Cerebral Palsy

Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society

ABSTRACT. ***Objective.*** The Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society develop practice parameters as strategies for patient management based on analysis of evidence. For this parameter the authors reviewed available evidence on the assessment of a child suspected of having cerebral palsy (CP), a nonprogressive disorder of posture or movement due to a lesion of the developing brain.

Methods. Relevant literature was reviewed, abstracted, and classified. Recommendations were based on a four-tiered scheme of evidence classification.

Results. CP is a common problem, occurring in about 2 to 2.5 per 1,000 live births. In order to establish that a brain abnormality exists in children with CP that may, in turn, suggest an etiology and prognosis, neuroimaging is recommended with MRI preferred to CT (Level A). Metabolic and genetic studies should not be routinely obtained in the evaluation of the child with CP (Level B). If the clinical history or findings on neuroimaging do not determine a specific structural abnormality or if there are additional and atypical features in the history or clinical examination, metabolic and genetic testing should be considered (Level C). Detection of a brain malformation in a child with CP warrants consideration of an underlying genetic or metabolic etiology. Because the incidence of cerebral infarction is high in children with hemiplegic CP, diagnostic testing for coagulation disorders should be considered (Level B). However, there is insufficient evidence at present to be precise as to what studies should be ordered. An EEG is not recommended unless there are features suggestive of epilepsy or a specific epileptic syndrome (Level A). Because children with CP may have associated deficits of mental retardation, ophthalmologic and hearing impairments, speech and language disorders, and oral-motor dysfunction, screening for these conditions should be part of the initial assessment (Level A).

Conclusions. Neuroimaging results in children with CP are commonly abnormal and may help determine the etiology. Screening for associated conditions is warranted as part of the initial evaluation. (3/04, reaffirmed 7/07)

CERUMEN IMPACTION

Cerumen Impaction

American Academy of Otolaryngology—Head and Neck Surgery Foundation

ABSTRACT. This update of the 2008 American Academy of Otolaryngology—Head and Neck Surgery Foundation cerumen impaction clinical practice guideline provides evidence-based recommendations on managing cerumen impaction. Cerumen impaction is defined as an accumulation of cerumen that causes symptoms, prevents assessment of the ear, or both. Changes from the prior guideline include

- a consumer added to the development group;
- new evidence (3 guidelines, 5 systematic reviews, and 6 randomized controlled trials);
- enhanced information on patient education and counseling;
- a new algorithm to clarify action statement relationships;
- expanded action statement profiles to explicitly state quality improvement opportunities, confidence in the evidence, intentional vagueness, and differences of opinion;
- an enhanced external review process to include public comment and journal peer review; and
- new key action statements on managing cerumen impaction that focus on primary prevention, contraindicated intervention, and referral and coordination of care. (1/17)

CONGENITAL MUSCULAR DYSTROPHY

Evidence-based Guideline Summary: Evaluation, Diagnosis, and Management of Congenital Muscular Dystrophy. Report of the Guideline Development Subcommittee of the American Academy of Neurology and the Practice Issues Review Panel of the American Association of Neuromuscular & Electrodiagnostic Medicine

American Academy of Neurology and American Association of Neuromuscular & Electrodiagnostic Medicine

ABSTRACT. ***Objective.*** To delineate optimal diagnostic and therapeutic approaches to congenital muscular dystrophy (CMD) through a systematic review and analysis of the currently available literature.

Methods. Relevant, peer-reviewed research articles were identified using a literature search of the MEDLINE, EMBASE, and Scopus databases. Diagnostic and therapeutic data from these articles were extracted and analyzed in accordance with the American Academy of Neurology classification of evidence schemes for diagnostic, prognostic, and therapeutic studies. Recommendations were linked to the strength of the evidence, other related literature, and general principles of care.

Results. The geographic and ethnic backgrounds, clinical features, brain imaging studies, muscle imaging studies, and muscle biopsies of children with suspected CMD help predict subtype-specific diagnoses. Genetic testing can confirm some subtype-specific diagnoses, but not all causative genes for CMD have been described. Seizures and respiratory complications occur in specific subtypes. There is insufficient evidence to determine the efficacy of various treatment interventions to optimize respiratory, orthopedic, and nutritional outcomes, and more data are needed regarding complications.

Recommendations. Multidisciplinary care by experienced teams is important for diagnosing and promoting the health of children with CMD. Accurate assessment of clinical presentations and genetic data will help in identifying the correct subtype-specific diagnosis in many cases. Multiorgan system complications occur frequently; surveillance and prompt interventions are likely to be beneficial for affected children. More research is needed to fill gaps in knowledge regarding this category of muscular dystrophies. (3/15, reaffirmed 7/18)

DEPRESSION

Guidelines for Adolescent Depression in Primary Care (GLAD-PC): Part I. Practice Preparation, Identification, Assessment, and Initial Management

Rachel A. Zuckerbrot, MD; Amy Cheung, MD; Peter S. Jensen, MD; Ruth E.K. Stein, MD; Danielle Laraque, MD; and GLAD-PC Steering Group

ABSTRACT. ***Objectives***. To update clinical practice guidelines to assist primary care (PC) clinicians in the management of adolescent depression. This part of the updated guidelines is used to address practice preparation, identification, assessment, and initial management of adolescent depression in PC settings.

Methods. By using a combination of evidence- and consensus-based methodologies, guidelines were developed by an expert steering committee in 2 phases as informed by (1) current scientific evidence (published and unpublished) and (2) draft revision and iteration among the steering committee, which included experts, clinicians, and youth and families with lived experience.

Results. Guidelines were updated for youth aged 10 to 21 years and correspond to initial phases of adolescent depression management in PC, including the identification of at-risk youth, assessment and diagnosis, and initial management. The strength of each recommendation and its evidence base are summarized. The practice preparation, identification, assessment, and initial management section of the guidelines include recommendations for (1) the preparation of the PC practice for improved care of adolescents with depression; (2) annual universal screening of youth 12 and over at health maintenance visits; (3) the identification of depression in youth who are at high risk; (4) systematic assessment procedures by using reliable depression scales, patient and caregiver interviews, and *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* criteria; (5) patient and family psychoeducation; (6) the establishment of relevant links in the community; and (7) the establishment of a safety plan.

Conclusions. This part of the guidelines is intended to assist PC clinicians in the identification and initial management of adolescents with depression in an era of great clinical need and shortage of mental health specialists, but they cannot replace clinical judgment; these guidelines are not meant to be the sole source of guidance for depression management in adolescents. Additional research that addresses the identification and initial management of youth with depression in PC is needed, including empirical testing of these guidelines. (2/18)

Guidelines for Adolescent Depression in Primary Care (GLAD-PC): Part II. Treatment and Ongoing Management

Amy H. Cheung, MD; Rachel A. Zuckerbrot, MD; Peter S. Jensen, MD; Danielle Laraque, MD; Ruth E.K. Stein, MD; and GLAD-PC Steering Group

ABSTRACT. ***Objectives***. To update clinical practice guidelines to assist primary care (PC) in the screening and assessment of depression. In this second part of the updated guidelines, we address treatment and ongoing management of adolescent depression in the PC setting.

Methods. By using a combination of evidence- and consensus-based methodologies, the guidelines were updated in 2 phases as informed by (1) current scientific evidence (published and unpublished) and (2) revision and iteration among the steering committee, including youth and families with lived experience.

Results. These updated guidelines are targeted for youth aged 10 to 21 years and offer recommendations for the management of adolescent depression in PC, including (1) active monitoring of mildly depressed youth, (2) treatment with evidence-based medication and psychotherapeutic approaches in cases of moderate and/or severe depression, (3) close monitoring of side effects, (4) consultation and comanagement of care with mental health specialists, (5) ongoing tracking of outcomes, and (6) specific steps to be taken in instances of partial or no improvement after an initial treatment has begun. The strength of each recommendation and the grade of its evidence base are summarized.

Conclusions. The Guidelines for Adolescent Depression in Primary Care cannot replace clinical judgment, and they should not be the sole source of guidance for adolescent depression management. Nonetheless, the guidelines may assist PC clinicians in the management of depressed adolescents in an era of great clinical need and a shortage of mental health specialists. Additional research concerning the management of depressed youth in PC is needed, including the usability, feasibility, and sustainability of guidelines, and determination of the extent to which the guidelines actually improve outcomes of depressed youth. (2/18)

DUCHENNE MUSCULAR DYSTROPHY

Practice Guideline Update Summary: Corticosteroid Treatment of Duchenne Muscular Dystrophy

David Gloss, MD, MPH&TM; Richard T. Moxley III, MD; Stephen Ashwal, MD; and Maryam Oskoui, MD, for the American Academy of Neurology Guideline Development Subcommittee

ABSTRACT. ***Objective.*** To update the 2005 American Academy of Neurology (AAN) guideline on corticosteroid treatment of Duchenne muscular dystrophy (DMD).

Methods. We systematically reviewed the literature from January 2004 to July 2014 using the AAN classification scheme for therapeutic articles and predicated recommendations on the strength of the evidence.

Results. Thirty-four studies met inclusion criteria.

Recommendations. In children with DMD, prednisone should be offered for improving strength (Level B) and pulmonary function (Level B). Prednisone may be offered for improving timed motor function (Level C), reducing the need for scoliosis surgery (Level C), and delaying cardiomyopathy onset by 18 years of age (Level C). Deflazacort may be offered for improving strength and timed motor function and delaying age at loss of ambulation by 1.4–2.5 years (Level C). Deflazacort may be offered for improving pulmonary function, reducing the need for scoliosis surgery, delaying cardiomyopathy onset, and increasing survival at 5–15 years of follow-up (Level C for each). Deflazacort and prednisone may be equivalent in improving motor function (Level C). Prednisone may be associated with greater weight gain in the first years of treatment than deflazacort (Level C).

Deflazacort may be associated with a greater risk of cataracts than prednisone (Level C). The preferred dosing regimen of prednisone is 0.75 mg/kg/d (Level B). Over 12 months, prednisone 10 mg/kg/weekend is equally effective (Level B), with no long-term data available. Prednisone 0.75 mg/kg/d is associated with significant risk of weight gain, hirsutism, and cushingoid appearance (Level B). *Neurology*® 2016;86:465–472 (2/16, reaffirmed 1/19)

DYSPLASIA OF THE HIP

Guideline on Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age: Evidence-based Clinical Practice Guideline
American Academy of Orthopaedic Surgeons

OVERVIEW. This clinical practice guideline is based upon a systematic review of published articles related to the detection and early management of hip instability and dysplasia in typically developing children less than 6 months of age. This guideline provides practice recommendations for the early screening and detection of hip instability and dysplasia and also highlights gaps in the published literature that should stimulate additional research. This guideline is intended towards appropriately trained practitioners involved in the early examination and assessment of typically developing children for hip instability and dysplasia. (9/14)

FOOD ALLERGY

Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel
National Institute of Allergy and Infectious Diseases

ABSTRACT. Food allergy is an important public health problem that affects children and adults and may be increasing in prevalence. Despite the risk of severe allergic reactions and even death, there is no current treatment for food allergy: the disease can only be managed by allergen avoidance or treatment of symptoms. The diagnosis and management of food allergy also may vary from one clinical practice setting to another. Finally, because patients frequently confuse nonallergic food reactions, such as food intolerance, with food allergies, there is an unfounded belief among the public that food allergy prevalence is higher than it truly is. In response to these concerns, the National Institute of Allergy and Infectious Diseases, working with 34 professional organizations, federal agencies, and patient advocacy groups, led the development of clinical guidelines for the diagnosis and management of food allergy. These Guidelines are intended for use by a wide variety of health care professionals, including family practice physicians, clinical specialists, and nurse practitioners. The Guidelines include a consensus definition for food allergy, discuss comorbid conditions often associated with food allergy, and focus on both IgE-mediated and non-IgE-mediated reactions to food. Topics addressed include the epidemiology, natural history, diagnosis, and management of food allergy, as well as the management of severe symptoms and anaphylaxis. These Guidelines provide 43 concise clinical recommendations and additional guidance on points of current controversy in patient management. They also identify gaps in the current scientific knowledge to be addressed through future research. (12/10)

HEMORRHAGE

An Evidence-based Prehospital Guideline for External Hemorrhage Control
American College of Surgeons Committee on Trauma

ABSTRACT. This report describes the development of an evidence-based guideline for external hemorrhage control in the prehospital setting. This project included a systematic review of the literature regarding the use of tourniquets and hemostatic agents for management of life-threatening extremity and junctional hemorrhage. Using the GRADE methodology to define the key clinical questions, an expert panel then reviewed the results of the literature review, established the quality of the evidence and made recommendations for EMS care. A clinical care guideline is proposed for adoption by EMS systems. (3/14)

HIV

Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children
US Department of Health and Human Services

SUMMARY. This report updates the last version of the Guidelines for the Prevention and Treatment of Opportunistic Infections (OIs) in HIV-Exposed and HIV-Infected Children, published in 2009. These guidelines are intended for use by clinicians and other health-care workers providing medical care for HIV-exposed and HIV-infected children in the United States. The guidelines discuss opportunistic pathogens that occur in the United States and ones that might be acquired during international travel, such as malaria. Topic areas covered for each OI include a brief description of the epidemiology, clinical presentation, and diagnosis of the OI in children; prevention of exposure; prevention of first episode of disease; discontinuation of primary prophylaxis after immune reconstitution; treatment of disease; monitoring for adverse effects during treatment, including immune reconstitution inflammatory syndrome (IRIS); management of treatment failure; prevention of disease recurrence; and discontinuation of secondary prophylaxis after immune reconstitution. A separate document providing recommendations for prevention and treatment of OIs among HIV-infected adults and post-pubertal adolescents (*Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents*) was prepared by a panel of adult HIV and infectious disease specialists (see http://aidsinfo.nih.gov/guidelines).

These guidelines were developed by a panel of specialists in pediatric HIV infection and infectious diseases (the Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children) from the U.S. government and academic institutions. For each OI, one or more pediatric specialists with subject-matter expertise reviewed the literature for new information since the last guidelines were published and then proposed revised recommendations for review by the full Panel. After these reviews and discussions, the guidelines underwent further revision, with review and approval by the Panel, and final endorsement by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA), the Pediatric Infectious Disease Society (PIDS), and the American Academy of Pediatrics (AAP). So that readers can ascertain how best to apply the recommendations in their practice environments, the recommendations are rated by a letter that indicates the strength of the recommendation, a Roman numeral that indicates the quality of the evidence supporting the recommendation, and where applicable, a * notation that signifies a hybrid of higher-quality adult study evidence and consistent but lower-quality pediatric study evidence.

More detailed methodologic considerations are listed in Appendix 1 (Important Guidelines Considerations), including a description of the make-up and organizational structure of the Panel, definition of financial disclosure and management of conflict of interest, funding sources for the guidelines, methods of collecting and synthesizing evidence and formulating recommendations, public commentary, and plans for updating the guidelines. The names and financial disclosures for each of the Panel members are listed in Appendices 2 and 3, respectively.

An important mode of childhood acquisition of OIs and HIV infection is from infected mothers. HIV-infected women may be more likely to have coinfections with opportunistic pathogens (e.g., hepatitis C) and more likely than women who are not HIV-infected to transmit these infections to their infants. In addition, HIV-infected women or HIV-infected family members coinfected with certain opportunistic pathogens may be more likely to transmit these infections horizontally to their children, resulting in increased likelihood of primary acquisition of such infections in young children. Furthermore, transplacental transfer of antibodies that protect infants against serious infections may be lower in HIV-infected women than in women who are HIV-uninfected. Therefore, infections with opportunistic pathogens may affect not just HIV-infected infants but also HIV-exposed, uninfected infants. These guidelines for treating OIs in children, therefore, consider treatment of infections in all children—HIV-infected and HIV-uninfected—born to HIV-infected women.

In addition, HIV infection increasingly is seen in adolescents with perinatal infection who are now surviving into their teens and in youth with behaviorally acquired HIV infection. Guidelines for postpubertal adolescents can be found in the adult OI guidelines, but drug pharmacokinetics (PK) and response to treatment may differ in younger prepubertal or pubertal adolescents. Therefore, these guidelines also apply to treatment of HIV-infected youth who have not yet completed pubertal development.

Major changes in the guidelines from the previous version in 2009 include:

- Greater emphasis on the importance of antiretroviral therapy (ART) for prevention and treatment of OIs, especially those OIs for which no specific therapy exists;
- Increased information about diagnosis and management of IRIS;
- Information about managing ART in children with OIs, including potential drug-drug interactions;
- Updated immunization recommendations for HIV-exposed and HIV-infected children, including pneumococcal, human papillomavirus, meningococcal, and rotavirus vaccines;
- Addition of sections on influenza, giardiasis, and isosporiasis;
- Elimination of sections on aspergillosis, bartonellosis, and HHV-6 and HHV-7 infections; and
- Updated recommendations on discontinuation of OI prophylaxis after immune reconstitution in children.

The most important recommendations are highlighted in boxed major recommendations preceding each section, and a table of dosing recommendations appears at the end of each section. The guidelines conclude with summary tables that display dosing recommendations for all of the conditions, drug toxicities and drug interactions, and 2 figures describing immunization recommendations for children aged 0 to 6 years and 7 to 18 years.

The terminology for describing use of antiretroviral (ARV) drugs for treatment of HIV infection has been standardized to ensure consistency within the sections of these guidelines and with the *Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection.* Combination antiretroviral therapy (cART) indicates use of multiple (generally 3 or more) ARV drugs as part of an HIV treatment regimen that is designed to achieve virologic suppression; highly active antiretroviral therapy (HAART), synonymous with cART, is no longer used and has been replaced by cART; the term ART has been used when referring to use of ARV drugs for HIV treatment more generally, including (mostly historical) use of one- or two-agent ARV regimens that do not meet criteria for cART.

Because treatment of OIs is an evolving science, and availability of new agents or clinical data on existing agents may change therapeutic options and preferences, these recommendations will be periodically updated and will be available at http://AIDSinfo.nih.gov. (11/13, updated 11/18)

INFANTILE SPASMS

Evidence-based Guideline Update: Medical Treatment of Infantile Spasms

American Academy of Neurology and Child Neurology Society

ABSTRACT. ***Objective.*** To update the 2004 American Academy of Neurology/Child Neurology Society practice parameter on treatment of infantile spasms in children.

Methods. MEDLINE and EMBASE were searched from 2002 to 2011 and searches of reference lists of retrieved articles were performed. Sixty-eight articles were selected for detailed review; 26 were included in the analysis. Recommendations were based on a 4-tiered classification scheme combining pre-2002 evidence and more recent evidence.

Results. There is insufficient evidence to determine whether other forms of corticosteroids are as effective as adrenocorticotropic hormone (ACTH) for short-term treatment of infantile spasms. However, low-dose ACTH is probably as effective as high-dose ACTH. ACTH is more effective than vigabatrin (VGB) for short-term treatment of children with infantile spasms (excluding those with tuberous sclerosis complex). There is insufficient evidence to show that other agents and combination therapy are effective for short-term treatment of infantile spasms. Short lag time to treatment leads to better long-term developmental outcome. Successful short-term treatment of cryptogenic infantile spasms with ACTH or prednisolone leads to better long-term developmental outcome than treatment with VGB.

Recommendations. Low-dose ACTH should be considered for treatment of infantile spasms. ACTH or VGB may be useful for short-term treatment of infantile spasms, with ACTH considered preferentially over VGB. Hormonal therapy (ACTH or prednisolone) may be considered for use in preference to VGB in infants with cryptogenic infantile spasms, to possibly improve developmental outcome. A shorter lag time to treatment of infantile spasms with either hormonal therapy or VGB possibly improves long-term developmental outcomes. (6/12, reaffirmed 1/18)

INTRAVASCULAR CATHETER-RELATED INFECTIONS

Guidelines for the Prevention of Intravascular Catheter-Related Infections

Society of Critical Care Medicine, Infectious Diseases Society of America, Society for Healthcare Epidemiology of America, Surgical Infection Society, American College of Chest Physicians, American Thoracic Society, American Society of Critical Care Anesthesiologists, Association for Professionals in Infection Control and Epidemiology, Infusion Nurses Society, Oncology Nursing Society, Society of Cardiovascular and Interventional Radiology, American Academy of Pediatrics, and the Healthcare Infection Control Practices Advisory Committee of the Centers for Disease Control and Prevention

ABSTRACT. These guidelines have been developed for practitioners who insert catheters and for persons responsible for surveillance and control of infections in hospital, outpatient, and home health-care settings. This report was prepared by a working group comprising members from professional organizations representing the disciplines of critical care medicine, infectious diseases, health-care infection control, surgery, anesthesiology, interventional radiology, pulmonary medicine, pediatric medicine, and nursing. The working group was led by the Society of Critical Care Medicine (SCCM), in collaboration

with the Infectious Disease Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), Surgical Infection Society (SIS), American College of Chest Physicians (ACCP), American Thoracic Society (ATS), American Society of Critical Care Anesthesiologists (ASCCA), Association for Professionals in Infection Control and Epidemiology (APIC), Infusion Nurses Society (INS), Oncology Nursing Society (ONS), Society of Cardiovascular and Interventional Radiology (SCVIR), American Academy of Pediatrics (AAP), and the Healthcare Infection Control Practices Advisory Committee (HICPAC) of the Centers for Disease Control and Prevention (CDC) and is intended to replace the *Guideline for Prevention of Intravascular Device-Related Infections* published in 1996. These guidelines are intended to provide evidence-based recommendations for preventing catheter-related infections. Major areas of emphasis include (1) educating and training health-care providers who insert and maintain catheters; (2) using maximal sterile barrier precautions during central venous catheter insertion; (3) using a 2% chlorhexidine preparation for skin antisepsis; (4) avoiding routine replacement of central venous catheters as a strategy to prevent infection; and (5) using antiseptic/antibiotic impregnated short-term central venous catheters if the rate of infection is high despite adherence to other strategies (ie, education and training, maximal sterile barrier precautions, and 2% chlorhexidine for skin antisepsis). These guidelines also identify performance indicators that can be used locally by health-care institutions or organizations to monitor their success in implementing these evidence-based recommendations. (11/02)

MEDULLARY THYROID CARCINOMA

Revised American Thyroid Association Guidelines for the Management of Medullary Thyroid Carcinoma

American Thyroid Association Guidelines Task Force on Medullary Thyroid Carcinoma

ABSTRACT. ***Introduction.*** The American Thyroid Association appointed a Task Force of experts to revise the original Medullary Thyroid Carcinoma: Management Guidelines of the American Thyroid Association.

Methods. The Task Force identified relevant articles using a systematic PubMed search, supplemented with additional published materials, and then created evidence-based recommendations, which were set in categories using criteria adapted from the United States Preventive Services Task Force Agency for Healthcare Research and Quality. The original guidelines provided abundant source material and an excellent organizational structure that served as the basis for the current revised document.

Results. The revised guidelines are focused primarily on the diagnosis and treatment of patients with sporadic medullary thyroid carcinoma (MTC) and hereditary MTC.

Conclusions. The Task Force developed 67 evidence-based recommendations to assist clinicians in the care of patients with MTC. The Task Force considers the recommendations to represent current, rational, and optimal medical practice. (6/15)

MIGRAINE HEADACHE

Practice Guideline Update: Acute Treatment of Migraine in Children and Adolescents. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society

Maryam Oskoui, MD, MSc; Tamara Pringsheim, MD; Yolanda Holler-Managan, MD; Sonja Potrebic, MD, PhD; Lori Billinghurst, MD, MSc; David Gloss, MD; Andrew D. Hershey, MD, PhD; Nicole Licking, DO; Michael Sowell, MD; M. Cristina Victorio, MD; Elaine M. Gersz; Emily Leininger; Heather Zanitsch; Marcy Yonker, MD; and Kenneth Mack, MD, PhD

ABSTRACT. ***Objective.*** To provide evidence-based recommendations for the acute symptomatic treatment of children and adolescents with migraine.

Methods. We performed a systematic review of the literature and rated risk of bias of included studies according to the American Academy of Neurology classification of evidence criteria. A multidisciplinary panel developed practice recommendations, integrating findings from the systematic review and following an Institute of Medicine–compliant process to ensure transparency and patient engagement. Recommendations were supported by structured rationales, integrating evidence from the systematic review, related evidence, principles of care, and inferences from evidence.

Results. There is evidence to support the efficacy of the use of ibuprofen, acetaminophen (in children and adolescents), and triptans (mainly in adolescents) for the relief of migraine pain, although confidence in the evidence varies between agents. There is high confidence in the evidence that adolescents receiving oral sumatriptan/naproxen and zolmitriptan nasal spray are more likely to be headache-free at 2 hours than those receiving placebo. No acute treatments were effective for migraine-related nausea or vomiting; some triptans were effective for migraine-related phonophobia and photophobia.

Recommendations. Recommendations for the treatment of acute migraine in children and adolescents focus on the importance of early treatment, choosing the route of administration best suited to the characteristics of the individual migraine attack, and providing counseling on lifestyle factors that can exacerbate migraine, including trigger avoidance and medication overuse. (8/19)

Practice Guideline Update: Pharmacologic Treatment for Pediatric Migraine Prevention. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Headache Society

Maryam Oskoui, MD, MSc; Tamara Pringsheim, MD; Lori Billinghurst, MD; Sonja Potrebic, MD, PhD; Elaine M. Gersz; David Gloss, MD, MPH&TM; Yolanda Holler-Managan, MD; Emily Leininger; Nicole Licking, DO; Kenneth Mack, MD, PhD; Scott W. Powers, PhD, ABPP; Michael Sowell, MD; M. Cristina Victorio, MD; Marcy Yonker; Heather Zanitsch; and Andrew D. Hershey, MD, PhD

ABSTRACT. ***Objective.*** To provide updated evidence-based recommendations for migraine prevention using pharmacologic treatment with or without cognitive behavioral therapy in the pediatric population.

Methods. The authors systematically reviewed literature from January 2003 to August 2017 and developed practice recommendations using the American Academy of Neurology 2011 process, as amended.

Results. Fifteen Class I–III studies on migraine prevention in children and adolescents met inclusion criteria. There is insufficient evidence to determine if children and adolescents receiving divalproex, onabotulinumtoxinA, amitriptyline, nimodipine, or flunarizine are more or less likely than those receiving placebo to have a reduction in headache frequency. Children with migraine receiving propranolol are possibly more likely than those receiving placebo to have an at least 50% reduction in headache frequency. Children and adolescents receiving topiramate and cinnarizine are probably more likely than those receiving placebo to have a decrease in headache frequency. Children with migraine receiving amitriptyline plus cognitive behavioral therapy are more likely than those receiving amitriptyline plus headache education to have a reduction in headache frequency.

Recommendations. The majority of randomized controlled trials studying the efficacy of preventive medications for pediatric migraine fail to demonstrate superiority to placebo. Recommendations for the prevention of migraine in children include counseling on lifestyle and behavioral factors that influence headache frequency and assessment and management of comorbid disorders associated with headache persistence. Clinicians should engage in shared decision-making with patients and caregivers regarding the use of preventive treatments for migraine, including discussion of the limitations in the evidence to support pharmacologic treatments. (8/19)

NOSEBLEED (EPISTAXIS)

Clinical Practice Guideline: Nosebleed (Epistaxis)

David E. Tunkel, MD; Samantha Anne, MD, MS; Spencer C. Payne, MD; Stacey L. Ishman, MD, MPH; Richard M. Rosenfeld, MD, MPH, MBA; Peter J. Abramson, MD; Jacqueline D. Alikhaani; Margo McKenna Benoit, MD; Rachel S. Bercovitz, MD, MS; Michael D. Brown, MD, MSc; Boris Chernobilsky, MD; David A. Feldstein, MD; Jesse M. Hackell, MD; Eric H. Holbrook, MD; Sarah M. Holdsworth, MSN, APRN; Kenneth W. Lin, MD, MPH; Meredith Merz Lind, MD; David M. Poetker, MD, MA; Charles A. Riley, MD; John S. Schneider, MD, MA; Michael D. Seidman, MD; Venu Vadlamudi, MD; Tulio A. Valdez, MD; Lorraine C. Nnacheta, MPH, DrPH; Taskin M. Monjur

ABSTRACT. **Objective.** Nosebleed, also known as epistaxis, is a common problem that occurs at some point in at least 60% of people in the United States. While the majority of nosebleeds are limited in severity and duration, about 6% of people who experience nosebleeds will seek medical attention. For the purposes of this guideline, we define the target patient with a nosebleed as a patient with bleeding from the nostril, nasal cavity, or nasopharynx that is sufficient to warrant medical advice or care. This includes bleeding that is severe, persistent, and/or recurrent, as well as bleeding that impacts a patient's quality of life. Interventions for nosebleeds range from self-treatment and home remedies to more intensive procedural interventions in medical offices, emergency departments, hospitals, and operating rooms. Epistaxis has been estimated to account for 0.5% of all emergency department visits and up to one-third of all otolaryngology-related emergency department encounters. Inpatient hospitalization for aggressive treatment of severe nosebleeds has been reported in 0.2% of patients with nosebleeds.

Purpose. The primary purpose of this multidisciplinary guideline is to identify quality improvement opportunities in the management of nosebleeds and to create clear and actionable recommendations to implement these opportunities in clinical practice. Specific goals of this guideline are to promote best practices, reduce unjustified variations in care of patients with nosebleeds, improve health outcomes, and minimize the potential harms of nosebleeds or interventions to treat nosebleeds.

The target patient for the guideline is any individual aged ≥3 years with a nosebleed or history of nosebleed who needs medical treatment or seeks medical advice. The target audience of this guideline is clinicians who evaluate and treat patients with nosebleed. This includes primary care providers such as family medicine physicians, internists, pediatricians, physician assistants, and nurse practitioners. It also includes specialists such as emergency medicine providers, otolaryngologists, interventional radiologists/neuroradiologists and neurointerventionalists, hematologists, and cardiologists. The setting for this guideline includes any site of evaluation and treatment for a patient with nosebleed, including ambulatory medical sites, the emergency department, the inpatient hospital, and even remote outpatient encounters with phone calls and telemedicine. Outcomes to be considered for patients with nosebleed include control of acute bleeding, prevention of recurrent episodes of nasal bleeding, complications of treatment modalities, and accuracy of diagnostic measures.

This guideline addresses the diagnosis, treatment, and prevention of nosebleed. It focuses on nosebleeds that commonly present to clinicians via phone calls, office visits, and emergency room encounters. This guideline discusses first-line treatments such as nasal compression, application of vasoconstrictors, nasal packing, and nasal cautery. It also addresses more complex epistaxis management, which includes the use of endoscopic arterial ligation and interventional radiology procedures. Management options for 2 special groups of patients—patients with hereditary hemorrhagic telangiectasia syndrome and patients taking medications that inhibit coagulation and/or platelet function—are included in this guideline.

This guideline is intended to focus on evidence-based quality improvement opportunities judged most important by the guideline development group. It is not intended to be a comprehensive, general guide for managing patients with nosebleed. In this context, the purpose is to define useful actions for clinicians, generalists, and specialists from a variety of disciplines to improve quality of care. Conversely, the statements in this guideline are not intended to limit or restrict care provided by clinicians based on their experience and assessment of individual patients. (1/20)

PALLIATIVE CARE

Clinical Practice Guidelines for Quality Palliative Care, 4th Edition
National Consensus Project for Quality Palliative Care (2018)

POSITIONAL PLAGIOCEPHALY

Systematic Review and Evidence-based Guidelines for the Management of Patients With Positional Plagiocephaly
Congress of Neurologic Surgeons

ABSTRACT. *Background.* Positional plagiocephaly is a common problem seen by pediatricians, pediatric neurologists, and pediatric neurosurgeons. Currently, there are no evidence-based guidelines on the management of positional plagiocephaly. The topics addressed in subsequent chapters of this guideline include: diagnosis, repositioning, physical therapy, and orthotic devices.

Objective. To evaluate topics relevant to the diagnosis and management of patients with positional plagiocephaly. The rigorous systematic process in which this guideline was created is presented in this chapter.

Methods. This guideline was prepared by the Plagiocephaly Guideline Task Force, a multidisciplinary team comprised of physician volunteers (clinical experts), medical librarians, and clinical guidelines specialists. The task force conducted a series of systematic literature searches of the National Library of Medicine and the Cochrane Library, according to standard protocols described below, for each topic addressed in subsequent chapters of this guideline.

Results. The systematic literature searches returned 396 abstracts relative to the 4 main topics addressed in this guideline. The results were analyzed and are described in detail in each subsequent chapter included in this guideline.

Conclusion. Evidence-based guidelines for the management of infants with positional plagiocephaly will help practitioners manage this common disorder. (11/16)

RHINOPLASTY

Improving Nasal Form and Function after Rhinoplasty
American Academy of Otolaryngology—Head and Neck Surgery Foundation

ABSTRACT. Rhinoplasty, a surgical procedure that alters the shape or appearance of the nose while preserving or enhancing

the nasal airway, ranks among the most commonly performed cosmetic procedures in the United States, with >200,000 procedures reported in 2014. While it is difficult to calculate the exact economic burden incurred by rhinoplasty patients following surgery with or without complications, the average rhinoplasty procedure typically exceeds $4000. The costs incurred due to complications, infections, or revision surgery may include the cost of long-term antibiotics, hospitalization, or lost revenue from hours/days of missed work.

The resultant psychological impact of rhinoplasty can also be significant. Furthermore, the health care burden from psychological pressures of nasal deformities/aesthetic shortcomings, surgical infections, surgical pain, side effects from antibiotics, and nasal packing materials must also be considered for these patients. Prior to this guideline, limited literature existed on standard care considerations for pre- and postsurgical management and for standard surgical practice to ensure optimal outcomes for patients undergoing rhinoplasty. The impetus for this guideline is to utilize current evidence-based medicine practices and data to build unanimity regarding the peri- and postoperative strategies to maximize patient safety and to optimize surgical results for patients. (2/17)

SEIZURE

Treatment of the Child With a First Unprovoked Seizure

Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society

ABSTRACT. The Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society develop practice parameters as strategies for patient management based on analysis of evidence regarding risks and benefits. This parameter reviews published literature relevant to the decision to begin treatment after a child or adolescent experiences a first unprovoked seizure and presents evidence-based practice recommendations. Reasons why treatment may be considered are discussed. Evidence is reviewed concerning risk of recurrence as well as effect of treatment on prevention of recurrence and development of chronic epilepsy. Studies of side effects of anticonvulsants commonly used to treat seizures in children are also reviewed. Relevant articles are classified according to the Quality Standards Subcommittee classification scheme. Treatment after a first unprovoked seizure appears to decrease the risk of a second seizure, but there are few data from studies involving only children. There appears to be no benefit of treatment with regard to the prognosis for long-term seizure remission. Antiepileptic drugs (AED) carry risks of side effects that are particularly important in children. The decision as to whether or not to treat children and adolescents who have experienced a first unprovoked seizure must be based on a risk–benefit assessment that weighs the risk of having another seizure against the risk of chronic AED therapy. The decision should be individualized and take into account both medical issues and patient and family preference. (1/03, reaffirmed 7/06, 7/10, 7/13, 1/16, 10/18)

SEPTIC SHOCK AND SEPSIS-ASSOCIATED ORGAN DYSFUNCTION

Surviving Sepsis Campaign International Guidelines for the Management of Septic Shock and Sepsis-Associated Organ Dysfunction in Children

Scott L. Weiss, MD, MSCE, FCCM (Co-Vice Chair); Mark J. Peters, MD, PhD (Co-Vice Chair); Waleed Alhazzani, MD, MSc, FRCPC (Methodology Chair); Michael S. D. Agus, MD, FCCM, FAAP; Heidi R. Flori, MD, FAAP; David P. Inwald, MB, BChir, FRCPCH, FFICM, PhD; Simon Nadel, MBBS, MRCP, FRCP; Luregn J. Schlapbach, FCICM, FMH-ICU, FMH-Paeds, FMH-Neonatology; Robert C. Tasker, MB BS, MA, AM, MD, FRCPHC, FRCP; Andrew C. Argent, MB BCh, MMed, MD (Paediatrics); Joe Brierley, MD, MA; Joseph Carcillo, MD; Enitan D. Carrol, MB ChB, MD, FRCPCH, DTMH; Christopher L. Carroll, MD, MS, FCCM, FAAP; Ira M. Cheifetz, MD, FCCM; Karen Choong, MB, BCh, FRCP(C) (methodologist); Jeffrey J. Cies, PharmD, MPH, BCPS-AQ ID, BCPPS, FCCP, FCCM, FPPAG; Andrea T. Cruz, MD, MPH, FAAP; Daniele De Luca, MD, PhD; Akash Deep, MB BS, MD, FRCPCH; Saul N. Faust, MA, MB BS, FRCPCH, PhD, FHEA; Claudio Flauzino De Oliveira, MD, PhD; Mark W. Hall, MD, FCCM, FAAP; Paul Ishimine, MD, FACEP, FAAP; Etienne Javouhey, MD, PhD; Koen F. M. Joosten, MD, PhD; Poonam Joshi, PhD; Oliver Karam, MD, PhD; Martin C. J. Kneyber, MD, PhD, FCCM; Joris Lemson, MD, PhD; Graeme MacLaren, MD, MSc, FCCM; Nilesh M. Mehta, MD; Morten Hylander Møller, MD, PhD; Christopher J. L. Newth, MD, ChB, FRCPC, FRACP; Trung C. Nguyen, MD, FAAP; Akira Nishisaki, MD, MSCE, FAAP; Mark E. Nunnally, MD, FCCM (methodologist); Margaret M. Parker, MD, MCCM, FAAP; Raina M. Paul, MD, FAAP; Adrienne G. Randolph, MD, MS, FCCM, FAAP; Suchitra Ranjit, MD, FCCM; Lewis H. Romer, MD; Halden F. Scott, MD, MSCS, FAAP, FACEP; Lyvonne N. Tume, BS, MSN, PhD, RN; Judy T. Verger, RN, PhD, CPNP-AC, FCCM, FAAN; Eric A. Williams, MD, MS, MMM, FCCM, FAAP; Joshua Wolf, MBBS, PhD, FRACP; Hector R. Wong, MD; Jerry J. Zimmerman, MD, PhD, FCCM; Niranjan Kissoon, MB BS, MCCM, FRCP(C), FAAP, FACPE (Co-Chair); and Pierre Tissieres, MD, DSc (Co-Chair)

ABSTRACT. ***Objectives.*** To develop evidence-based recommendations for clinicians caring for children (including infants, school-aged children, and adolescents) with septic shock and other sepsis-associated organ dysfunction.

Design. A panel of 49 international experts, representing 12 international organizations, as well as three methodologists and three public members was convened. Panel members assembled at key international meetings (for those panel members attending the conference), and a stand-alone meeting was held for all panel members in November 2018. A formal conflict-of-interest policy was developed at the onset of the process and enforced throughout. Teleconferences and electronic-based discussion among the chairs, co-chairs, methodologists, and group heads, as well as within subgroups, served as an integral part of the guideline development process.

Methods. The panel consisted of six subgroups: recognition and management of infection, hemodynamics and resuscitation, ventilation, endocrine and metabolic therapies, adjunctive therapies, and research priorities. We conducted a systematic review for each Population, Intervention, Control, and Outcomes question to identify the best available evidence, statistically summarized the evidence, and then assessed the quality of evidence using the Grading of Recommendations Assessment, Development, and Evaluation approach. We used the evidence-to-decision framework to formulate recommendations as strong or weak, or as a best practice statement. In addition, "in our practice" statements were included when evidence was inconclusive to issue a recommendation, but the panel felt that some guidance based on practice patterns may be appropriate.

Results. The panel provided 77 statements on the management and resuscitation of children with septic shock and other sepsis-associated organ dysfunction. Overall, six were strong recommendations, 52 were weak recommendations, and nine were best-practice statements. For 13 questions, no recommendations could be made; but, for 10 of these, "in our practice" statements were provided. In addition, 49 research priorities were identified.

Conclusions. A large cohort of international experts was able to achieve consensus regarding many recommendations for the best care of children with sepsis, acknowledging that most aspects of care had relatively low quality of evidence resulting in the frequent issuance of weak recommendations. Despite this challenge, these recommendations regarding the management of children with septic shock and other sepsis-associated organ dysfunction provide a foundation for consistent care to improve outcomes and inform future research. (2/20)

STATUS EPILEPTICUS

Diagnostic Assessment of the Child With Status Epilepticus (An Evidence-based Review)

Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society

ABSTRACT. ***Objective.*** To review evidence on the assessment of the child with status epilepticus (SE).

Methods. Relevant literature were reviewed, abstracted, and classified. When data were missing, a minimum diagnostic yield was calculated. Recommendations were based on a four-tiered scheme of evidence classification.

Results. Laboratory studies (Na^{++} or other electrolytes, Ca^{++}, glucose) were abnormal in approximately 6% and are generally ordered as routine practice. When blood or spinal fluid cultures were done on these children, blood cultures were abnormal in at least 2.5% and a CNS infection was found in at least 12.8%. When antiepileptic drug (AED) levels were ordered in known epileptic children already taking AEDs, the levels were low in 32%. A total of 3.6% of children had evidence of ingestion. When studies for inborn errors of metabolism were done, an abnormality was found in 4.2%. Epileptiform abnormalities occurred in 43% of EEGs of children with SE and helped determine the nature and location of precipitating electroconvulsive events (8% generalized, 16% focal, and 19% both). Abnormalities on neuroimaging studies that may explain the etiology of SE were found in at least 8% of children.

Recommendations. Although common clinical practice is that blood cultures and lumbar puncture are obtained if there is a clinical suspicion of a systemic or CNS infection, there are insufficient data to support or refute recommendations as to whether blood cultures or lumbar puncture should be done on a routine basis in children in whom there is no clinical suspicion of a systemic or CNS infection (Level U). AED levels should be considered when a child with treated epilepsy develops SE (Level B). Toxicology studies and metabolic studies for inborn errors of metabolism may be considered in children with SE when there are clinical indicators for concern or when the initial evaluation reveals no etiology (Level C). An EEG may be considered in a child with SE as it may be helpful in determining whether there are focal or generalized epileptiform abnormalities that may guide further testing for the etiology of SE, when there is a suspicion of pseudostatus epilepticus (nonepileptic SE), or nonconvulsive SE, and may guide treatment (Level C). Neuroimaging may be considered after the child with SE has been stabilized if there are clinical indications or if the etiology is unknown (Level C). There is insufficient evidence to support or refute routine neuroimaging in a child presenting with SE (Level U). (11/06, Reaffirmed 7/10, 7/13, 7/16, 1/19)

TELEHEALTH

Operating Procedures for Pediatric Telehealth

American Telemedicine Association

INTRODUCTION. Children represent one of our most vulnerable populations, and, as such, require special considerations when participating in telehealth encounters. Some services provided to adult patients by telehealth may not be easily adapted to or appropriate for pediatric patients due to physical factors (patient size), legal factors (consent, confidentiality), the ability to communicate and provide a history, developmental stage, unique pediatric conditions, and age-specific differences in both normal and disease states (AHRQ, n.d.; Alverson, 2008). These operating procedures for pediatric telehealth aim to improve the overall telehealth experience for pediatric patients, providers, and patient families. Telehealth holds particular promise in facilitating the management and coordination of care for medically complex children and those with chronic conditions, such as asthma, chronic lung disease, autism, diabetes, and behavioral health conditions.

Through the use of telehealth, providers can provide appointment flexibility, increase access, promote continuity of care, and improve quality, either as a part of or as a complement to care delivered through the patient-centered medical home (PCMH). Whether telehealth services are delivered through the PCMH or as a complement to it, telehealth providers **should** routinely communicate with a patient's primary care provider and any relevant specialists regarding a telehealth encounter. Telehealth providers **shall** have a standard mechanism in place to share secure documentation of the encounter with the PCMH (AAP, 2015) in a timely manner.

These operating procedures do reference general telehealth operating principles that apply beyond pediatrics and that warrant particular emphasis, but they are not meant to serve as a comprehensive stand-alone guide to the development and operation of a telemedicine service. ATA has developed and published core standards for telehealth operations that provide overarching guidance for clinical, technical and administrative standards (ATA, 2014a). The Pediatric Operating Procedures complement existing professional organization guidance from the American Academy of Pediatrics, the American Psychological Association, the American Association of Family Physicians and the Society of Adolescent Health and Medicine. (4/17)

THYROID NODULES AND DIFFERENTIATED THYROID CANCER

Management Guidelines for Children With Thyroid Nodules and Differentiated Thyroid Cancer

American Thyroid Association Guidelines Task Force on Pediatric Thyroid Cancer

ABSTRACT. ***Background.*** Previous guidelines for the management of thyroid nodules and cancers were geared toward adults. Compared with thyroid neoplasms in adults, however, those in the pediatric population exhibit differences in pathophysiology, clinical presentation, and long-term outcomes. Furthermore, therapy that may be recommended for an adult may not be appropriate for a child who is at low risk for death but at higher risk for long-term harm from overly aggressive treatment. For these reasons, unique guidelines for children and adolescents with thyroid tumors are needed.

Methods. A task force commissioned by the American Thyroid Association (ATA) developed a series of clinically relevant questions pertaining to the management of children with thyroid nodules and differentiated thyroid cancer (DTC). Using an extensive literature search, primarily focused on studies that included subjects ≤18 years of age, the task force identified and reviewed relevant articles through April 2014. Recommendations were made based upon scientific evidence and expert opinion and were graded using a modified schema from the United States Preventive Services Task Force.

Results. These inaugural guidelines provide recommendations for the evaluation and management of thyroid nodules in children and adolescents, including the role and interpretation of

ultrasound, fine-needle aspiration cytology, and the management of benign nodules. Recommendations for the evaluation, treatment, and follow-up of children and adolescents with DTC are outlined and include preoperative staging, surgical management, postoperative staging, the role of radioactive iodine therapy, and goals for thyrotropin suppression. Management algorithms are proposed and separate recommendations for papillary and follicular thyroid cancers are provided.

Conclusions. In response to our charge as an independent task force appointed by the ATA, we developed recommendations based on scientific evidence and expert opinion for the management of thyroid nodules and DTC in children and adolescents. In our opinion, these represent the current optimal care for children and adolescents with these conditions. (7/15)

TOBACCO USE

Treating Tobacco Use and Dependence: 2008 Update
US Department of Health and Human Services

ABSTRACT. *Treating Tobacco Use and Dependence: 2008 Update,* a Public Health Service-sponsored Clinical Practice Guideline, is a product of the Tobacco Use and Dependence Guideline Panel ("the Panel"), consortium representatives, consultants, and staff. These 37 individuals were charged with the responsibility of identifying effective, experimentally validated tobacco dependence treatments and practices. The updated Guideline was sponsored by a consortium of eight Federal Government and nonprofit organizations: the Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); National Cancer Institute (NCI); National Heart, Lung, and Blood Institute (NHLBI); National Institute on Drug Abuse (NIDA); American Legacy Foundation; Robert Wood Johnson Foundation (RWJF); and University of Wisconsin School of Medicine and Public Health's Center for Tobacco Research and Intervention (UW-CTRI). This Guideline is an updated version of the 2000 *Treating Tobacco Use and Dependence: Clinical Practice Guideline* that was sponsored by the U.S. Public Health Service, U. S. Department of Health and Human Services.

An impetus for this Guideline update was the expanding literature on tobacco dependence and its treatment. The original 1996 Guideline was based on some 3,000 articles on tobacco treatment published between 1975 and 1994. The 2000 Guideline entailed the collection and screening of an additional 3,000 articles published between 1995 and 1999. The 2008 Guideline update screened an additional 2,700 articles; thus, the present Guideline update reflects the distillation of a literature base of more than 8,700 research articles. Of course, this body of research was further reviewed to identify a much smaller group of articles that served as the basis for focused Guideline data analyses and review.

This Guideline contains strategies and recommendations designed to assist clinicians; tobacco dependence treatment specialists; and health care administrators, insurers, and purchasers in delivering and supporting effective treatments for tobacco use and dependence. The recommendations were made as a result of a systematic review and meta-analysis of 11 specific topics identified by the Panel (proactive quitlines; combining counseling and medication relative to either counseling or medication alone; varenicline; various medication combinations; long-term medications; cessation interventions for individuals with low socioeconomic status/limited formal education; cessation interventions for adolescent smokers; cessation interventions for pregnant smokers; cessation interventions for individuals with psychiatric disorders, including substance use disorders; providing cessation interventions as a health benefit; and systems interventions, including provider training and the combination of training and systems interventions). The strength of evidence that served as the basis for each recommendation is indicated clearly in the Guideline update. A draft of the Guideline update was peer reviewed prior to publication, and the input of 81 external reviewers was considered by the Panel prior to preparing the final document. In addition, the public had an opportunity to comment through a *Federal Register* review process. The key recommendations of the updated Guideline, *Treating Tobacco Use and Dependence: 2008 Update,* based on the literature review and expert Panel opinion, are as follows:

Ten Key Guideline Recommendations

The overarching goal of these recommendations is that clinicians strongly recommend the use of effective tobacco dependence counseling and medication treatments to their patients who use tobacco, and that health systems, insurers, and purchasers assist clinicians in making such effective treatments available.

1. Tobacco dependence is a chronic disease that often requires repeated intervention and multiple attempts to quit. Effective treatments exist, however, that can significantly increase rates of long-term abstinence.
2. It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting.
3. Tobacco dependence treatments are effective across a broad range of populations. Clinicians should encourage every patient willing to make a quit attempt to use the counseling treatments and medications recommended in this Guideline.
4. Brief tobacco dependence treatment is effective. Clinicians should offer every patient who uses tobacco at least the brief treatments shown to be effective in this Guideline.
5. Individual, group, and telephone counseling are effective, and their effectiveness increases with treatment intensity. Two components of counseling are especially effective, and clinicians should use these when counseling patients making a quit attempt:
   - Practical counseling (problem solving/skills training)
   - Social support delivered as part of treatment
6. Numerous effective medications are available for tobacco dependence, and clinicians should encourage their use by all patients attempting to quit smoking—except when medically contraindicated or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents).
   - Seven first-line medications (5 nicotine and 2 non-nicotine) reliably increase long-term smoking abstinence rates:
     - Bupropion SR
     - Nicotine gum
     - Nicotine inhaler
     - Nicotine lozenge
     - Nicotine nasal spray
     - Nicotine patch
     - Varenicline
     - Clinicians also should consider the use of certain combinations of medications identified as effective in this Guideline.
7. Counseling and medication are effective when used by themselves for treating tobacco dependence. The combination of counseling and medication, however, is more effective than either alone. Thus, clinicians should encourage all individuals making a quit attempt to use both counseling and medication.

8. Telephone quitline counseling is effective with diverse populations and has broad reach. Therefore, both clinicians and health care delivery systems should ensure patient access to quitlines and promote quitline use.
9. If a tobacco user currently is unwilling to make a quit attempt, clinicians should use the motivational treatments shown in this Guideline to be effective in increasing future quit attempts.
10. Tobacco dependence treatments are both clinically effective and highly cost-effective relative to interventions for other clinical disorders. Providing coverage for these treatments increases quit rates. Insurers and purchasers should ensure that all insurance plans include the counseling and medication identified as effective in this Guideline as covered benefits.

The updated Guideline is divided into seven chapters that provide an overview, including methods (Chapter 1); information on the assessment of tobacco use (Chapter 2); clinical interventions, both for patients willing and unwilling to make a quit attempt at this time (Chapter 3); intensive interventions (Chapter 4); systems interventions for health care administrators, insurers, and purchasers (Chapter 5); the scientific evidence supporting the Guideline recommendations (Chapter 6); and information relevant to specific populations and other topics (Chapter 7).

A comparison of the findings of the updated Guideline with the 2000 Guideline reveals the considerable progress made in tobacco research over the brief period separating these two publications. Tobacco dependence increasingly is recognized as a chronic disease, one that typically requires ongoing assessment and repeated intervention. In addition, the updated Guideline offers the clinician many more effective treatment strategies than were identified in the original Guideline. There now are seven different first-line effective agents in the smoking cessation pharmacopoeia, allowing the clinician and patient many different medication options. In addition, recent evidence provides even stronger support for counseling (both when used alone and with other treatments) as an effective tobacco cessation strategy; counseling adds to the effectiveness of tobacco cessation medications, quitline counseling is an effective intervention with a broad reach, and counseling increases tobacco cessation among adolescent smokers.

Finally, there is increasing evidence that the success of any tobacco dependence treatment strategy cannot be divorced from the health care system in which it is embedded. The updated Guideline contains new evidence that health care policies significantly affect the likelihood that smokers will receive effective tobacco dependence treatment and successfully stop tobacco use. For instance, making tobacco dependence treatment a covered benefit of insurance plans increases the likelihood that a tobacco user will receive treatment and quit successfully. Data strongly indicate that effective tobacco interventions require coordinated interventions. Just as the clinician must intervene with his or her patient, so must the health care administrator, insurer, and purchaser foster and support tobacco intervention as an integral element of health care delivery. Health care administrators and insurers should ensure that clinicians have the training and support to deliver consistent, effective intervention to tobacco users. One important conclusion of this Guideline update is that the most effective way to move clinicians to intervene is to provide them with information regarding multiple effective treatment options and to ensure that they have ample institutional support to use these options. Joint actions by clinicians, administrators, insurers, and purchasers can encourage a culture of health care in which failure to intervene with a tobacco user is inconsistent with standards of care. (5/08, last reviewed 9/19)

TURNER SYNDROME

Clinical Practice Guidelines for the Care of Girls and Women With Turner Syndrome: Proceedings From the 2016 Cincinnati International Turner Syndrome Meeting

Claus H. Gravholt; Niels H. Andersen; Gerard S. Conway; Olaf M. Dekkers; Mitchell E. Geffner; Karen O. Klein; Angela E. Lin; Nelly Mauras; Charmian A. Quigley; Karen Rubin; David E. Sandberg; Theo C. J. Sas; Michael Silberbach; Viveca Söderström-Anttila; Kirstine Stochholm; Janielle A. van Alfen-van derVelden; Joachim Woelfle; and Philippe F. Backeljauw (on behalf of the International Turner Syndrome Consensus Group)

ABSTRACT. Turner syndrome affects 25–50 per 100,000 females and can involve multiple organs through all stages of life, necessitating multidisciplinary approach to care. Previous guidelines have highlighted this, but numerous important advances have been noted recently. These advances cover all specialty fields involved in the care of girls and women with TS. This paper is based on an international effort that started with exploratory meetings in 2014 in both Europe and the USA, and culminated with a Consensus Meeting held in Cincinnati, Ohio, USA in July 2016. Prior to this meeting, five groups each addressed important areas in TS care: 1) diagnostic and genetic issues, 2) growth and development during childhood and adolescence, 3) congenital and acquired cardiovascular disease, 4) transition and adult care, and 5) other comorbidities and neurocognitive issues. These groups produced proposals for the present guidelines. Additionally, four pertinent questions were submitted for formal GRADE (Grading of Recommendations, Assessment, Development and Evaluation) evaluation with a separate systematic review of the literature. These four questions related to the efficacy and most optimal treatment of short stature, infertility, hypertension, and hormonal replacement therapy. The guidelines project was initiated by the European Society of Endocrinology and the Pediatric Endocrine Society, in collaboration with the European Society for Paediatric Endocrinology, the Endocrine Society, the European Society of Human Reproduction and Embryology, the American Heart Association, the Society for Endocrinology, and the European Society of Cardiology. The guideline has been formally endorsed by the European Society of Endocrinology, the Pediatric Endocrine Society, the European Society for Paediatric Endocrinology, the European Society of Human Reproduction and Embryology and the Endocrine Society. Advocacy groups appointed representatives who participated in pre-meeting discussions and in the consensus meeting. (9/17)

SECTION 3

2020 Policies

From the American Academy of Pediatrics

- *Policy Statements*
  ORGANIZATIONAL PRINCIPLES TO GUIDE AND DEFINE THE CHILD HEALTH CARE SYSTEM AND TO IMPROVE THE HEALTH OF ALL CHILDREN

- *Clinical Reports*
  GUIDANCE FOR THE CLINICIAN IN RENDERING PEDIATRIC CARE

- *Technical Reports*
  BACKGROUND INFORMATION TO SUPPORT AMERICAN ACADEMY OF PEDIATRICS POLICY

Includes policy statements, clinical reports, and technical reports published between January 1, 2020, and December 31, 2020

INTRODUCTION

This section of ***Pediatric Clinical Practice Guidelines & Policies: A Compendium of Evidence-based Research for Pediatric Practice*** is composed of policy statements, clinical reports, and technical reports issued by the American Academy of Pediatrics (AAP) and is designed as a quick reference tool for AAP members, AAP staff, and other interested parties. Section 3 includes the full text of all AAP policies published in 2020. Section 4 is a compilation of all active AAP policies (through December 31, 2020) arranged alphabetically, with abstracts where applicable. A subject index is also available. These materials should help answer questions that arise about the AAP position on child health care issues. **However, remember that AAP policy statements, clinical reports, and technical reports do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.**

Policy statements have been written by AAP committees, councils, task forces, or sections and approved by the AAP Board of Directors. Most of these statements have appeared previously in ***Pediatrics*** or ***AAP News***.

This section does not contain all AAP policies. It does not include

- Press releases.
- Motions and resolutions that were approved by the Board of Directors. These can be found in the Board of Directors' minutes.
- Policies in manuals, pamphlets, booklets, or other AAP publications. These items can be ordered through the AAP. To order, visit http://shop.aap.org/books or call 866/843-2271.
- Testimony before Congress or government agencies.

All policy statements, clinical reports, and technical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time. Please check the American Academy of Pediatrics website at www.aap.org for up-to-date reaffirmations, revisions, and retirements.

2020 Recommendations for Preventive Pediatric Health Care

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

2020 Recommendations for Preventive Pediatric Health Care

COMMITTEE ON PRACTICE AND AMBULATORY MEDICINE, BRIGHT FUTURES PERIODICITY SCHEDULE WORKGROUP

The 2020 Recommendations for Preventive Pediatric Health Care (Periodicity Schedule) have been approved by the American Academy of Pediatrics (AAP) and represents a consensus of the AAP and the Bright Futures Periodicity Schedule Workgroup. Each child and family is unique; therefore, these recommendations are designed for the care of children who are receiving competent parenting, have no manifestations of any important health problems, and are growing and developing in a satisfactory fashion. Developmental, psychosocial, and chronic disease issues for children and adolescents may require frequent counseling and treatment visits separate from preventive care visits. Additional visits also may become necessary if circumstances suggest variations from the normal.

The AAP continues to emphasize the great importance of continuity of care in comprehensive health supervision and the need to avoid fragmentation of care.[1]

The Periodicity Schedule will not be published in *Pediatrics*. Readers are referred to the AAP website (www.aap.org/periodicityschedule) for the most recent version of the Periodicity Schedule and the full set of footnotes. This process will ensure that health care professionals have the most current recommendations. The Periodicity Schedule will be reviewed and revised annually to reflect current recommendations.

The following is the change made to the Periodicity Schedule since it was last published in March 2019.

MATERNAL DEPRESSION

Footnote 16 has been updated to read, "Screening should occur per 'Incorporating Recognition and Management of Perinatal Depression Into Pediatric Practice' (https://pediatrics.aappublications.org/content/143/1/e20183259)."

DOI: https://doi.org/10.1542/peds.2020-0013

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

To cite: COMMITTEE ON PRACTICE AND AMBULATORY MEDICINE, AAP BRIGHT FUTURES PERIODICITY SCHEDULE WORKGROUP. 2020 Recommendations for Preventive Pediatric Health Care. *Pediatrics*. 2020;145(3):e20200013

ABBREVIATION

AAP: American Academy of Pediatrics

REFERENCES

1. Hagan JF Jr., Shaw JS, Duncan PM, eds. *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*, 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017

Abusive Head Trauma in Infants and Children

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Abusive Head Trauma in Infants and Children

Sandeep K. Narang, MD, JD, FAAP,[a] Amanda Fingarson, DO, FAAP,[a] James Lukefahr, MD, FAAP,[b] COUNCIL ON CHILD ABUSE AND NEGLECT

Abusive head trauma (AHT) remains a significant cause of morbidity and mortality in the pediatric population, especially in young infants. In the past decade, advancements in research have refined medical understanding of the epidemiological, clinical, biomechanical, and pathologic factors comprising the diagnosis, thereby enhancing clinical detection of a challenging diagnostic entity. Failure to recognize AHT and respond appropriately at any step in the process, from medical diagnosis to child protection and legal decision-making, can place children at risk. The American Academy of Pediatrics revises the 2009 policy statement on AHT to incorporate the growing body of knowledge on the topic. Although this statement incorporates some of that growing body of knowledge, it is not a comprehensive exposition of the science. This statement aims to provide pediatric practitioners with general guidance on a complex subject. The Academy recommends that pediatric practitioners remain vigilant for the signs and symptoms of AHT, conduct thorough medical evaluations, consult with pediatric medical subspecialists when necessary, and embrace the challenges and need for strong advocacy on the subject.

HISTORY

The evolution of the abusive head trauma (AHT) diagnosis has a long and storied history.[1–3] Earlier nomenclature included whiplash shaken infant syndrome, shaken impact syndrome, inflicted childhood neurotrauma, and shaken baby syndrome. The current term, AHT, was adopted by the American Academy of Pediatrics (AAP) in 2009 in recognition of the fact that inflicted head injury of children can involve a variety of biomechanical forces, including shaking. That change in terminology (from shaken baby syndrome), however, was misinterpreted by some in the legal and medical communities as an indication of some doubt in or invalidation of the diagnosis and the mechanism of shaking as a cause of injury. The AAP continues to affirm the dangers and harms of shaking infants, continues to embrace the "shaken baby syndrome" diagnosis as a valid subset of the AHT diagnosis, and encourages pediatric practitioners to educate

abstract

[a]Division of Child Abuse Pediatrics, Feinberg School of Medicine, Northwestern University and Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Illinois; and [b]Department of Pediatrics, The University of Texas Health Science Center at San Antonio, San Antonio, Texas

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Drs Narang, Fingarson, and Lukefahr were equally responsible for conceptualizing, writing, and revising the manuscript and considering input from all reviewers and the Board of Directors; and all authors approved the final manuscript as submitted.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-0203

Address correspondence to Sandeep K. Narang, MD, JD. E-mail: sanarang@luriechildrens.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Narang SK, Fingarson A, Lukefahr J, AAP COUNCIL ON CHILD ABUSE AND NEGLECT. Abusive Head Trauma in Infants and Children. *Pediatrics*. 2020;145(4):e20200203

community stakeholders when necessary.

PRESENTATION AND EVALUATION

AHT has an estimated incidence of 32 to 38 cases per 100 000 children per year in the first year of life and is fatal in nearly one-quarter of cases.[4,5] AHT presents with a wide spectrum of signs and symptoms. The clinical manifestations of AHT can be subtle (such as vomiting and fussiness) and are often missed. Sheets et al[6] found that more than one-quarter of children with severe physical abuse had previous sentinel injuries missed by physicians, and over 80% of those sentinel injuries were bruises. Bruising in infants should alert the physician to the possibility of abuse. Particular attention should be given to "TEN-4" bruising (bruising of the torso, ears, and neck in children younger than 4 years or any bruising in an infant younger than 4 months).[7] Oral injuries in infants, such as frenulum tears, may also accompany or precede AHT and should prompt consideration of abuse.[8] Thus, it is crucial for the pediatric practitioner to maintain high vigilance for subtle findings that can indicate AHT and perform a careful evaluation as dictated by the clinical presentation.

AHT is on the differential of common presenting complaints of infants and young children, such as fussiness, vomiting, or altered mental status. Medical diseases that can mimic the findings commonly seen in AHT are increasingly recognized, and screening is performed when indicated. A comprehensive medical evaluation, including a thorough skin examination, skeletal survey, head imaging, and a timely ophthalmology consultation, remains the cornerstone of AHT assessments.[9] As with all medical diagnoses, caregiver histories are important, and careful documentation of the reported history is needed.

Children with suspected intracranial injury should have a cranial computed tomography and/or MRI scan.[9,10] MRI of the spine should also be considered to assess for ligamentous injuries or spinal subdural hemorrhage.[10,11] Cranial ultrasonography is diagnostically insensitive for detecting AHT and should not be considered a sufficient diagnostic neuroimaging modality in cases of suspected AHT.[10] Although many cases of AHT do not demonstrate osseous injury, a complete skeletal survey should be performed in children younger than 2 years with concerns for AHT because occult fractures can occur in up to 42% of cases.[4] It is important that skeletal surveys conform to established guidelines of multiple views of the axial and appendicular skeleton.[10] A skeletal survey should be performed by technicians and read by radiologists who are experienced in these specialized imaging studies; otherwise, findings can be missed or misread, which can place both the pediatric practitioner at medicolegal risk and the patient at risk for further physical harm. Limited imaging, such as "babygrams," diminishes the diagnostic sensitivity of skeletal findings.[10]

Pediatric practitioners often find it helpful to consult a subspecialist in the field of child abuse pediatrics to ensure that the medical evaluation has been complete and that the diagnosis is accurate. Subspecialists in radiology, ophthalmology, neurosurgery, neurology, general pediatric surgery, and other fields should also be consulted when necessary to ensure a complete and accurate evaluation.

DIAGNOSIS AND OUTCOMES

Advancements in technology, research, and clinical experience have improved our current understanding of the etiologies, clinical features, and outcomes of AHT. Several recent systematic reviews have assisted in identifying clinical features more suggestive of abusive than accidental injury.[11–13] Features such as apnea, retinal hemorrhages, and "TEN-4" bruising are much more common in abusive than accidental injury.[7,12] Additionally, advancements in our clinical understanding of retinal hemorrhages have revealed that certain patterns of retinal hemorrhages (specifically too numerous to count in one or both eyes, present in all layers of the retina, and extending into the retinal periphery) are far more common in AHT than in accidental head injury.[13] Finally, traumatic retinoschisis (blood accumulating in the macula beneath the internal limiting membrane or deeper retinal layers, with or without surrounding circumlinear paramacular retinal folds) is highly suggestive of abusive trauma.[14]

Although there is not a particular pattern of cranial injury unique to AHT, certain findings, such as a subdural hemorrhage in certain locations (multiple, along the convexities, or interhemispheric), cerebral ischemia, cerebral edema, and skull fractures (co-occurring with intracranial injury), are more common in AHT than in accidental injury.[11] Additionally, recent studies have revealed spinal subdural hemorrhage to be more common in children with abusive (versus accidental) head trauma.[15]

Short falls (often defined as less than 1.5 m, or 5 ft)[16] continue to be a common historical explanation for injuries often seen in AHT. Although a few isolated case reports have identified the potential mortality of some short-fall events, numerous lines of clinical research have clarified the extreme rarity of short falls as a cause of severe neurologic injury or death in young infants. In a comprehensive review of short-fall literature, the estimated mortality rate of short falls affecting infants and

young children is <0.48 deaths per 1 million young children per year.[16] Because short falls may be proffered in courts as a likely medical explanation for the findings commonly seen in AHT,[17] pediatric practitioners should be prepared to educate multidisciplinary colleagues on the relative improbability of serious injuries or death as a result of short falls.

Clinical prediction tools have been developed to determine the probability of AHT given specific combinations of physical examination and clinical, laboratory, and radiographic findings.[18,19] Additionally, early work using serum biomarkers to identify acute intracranial hemorrhage has shown promise in identifying infants with nonspecific clinical symptoms who warrant neuroimaging.[20] Although these diagnostic advancements show significant promise, their application to current-day pediatric practice is premature.

It is important for pediatric practitioners to recognize the significant morbidity and mortality that accompany AHT. Secondary brain injury from hypoxia, ischemia, and metabolic or inflammatory cascades contribute to poor outcomes.[21,22] Almost 70% of survivors of AHT have some degree of lasting neurologic impairment, including static encephalopathy, intellectual disability, cerebral palsy, cortical blindness, seizure disorders, behavior problems, and learning disabilities.[23,24] Endocrine dysfunction is common in survivors of AHT and may manifest years after injury.[25] Survivors of AHT should be referred at hospital discharge to medical homes where pediatricians can provide ongoing follow-up and prompt referral to pediatric medical subspecialists when indicated.[25]

BIOMECHANICS

The biomechanics of AHT is a complex topic. For obvious ethical reasons, scientific studies of the topic depend on the development and use of biofidelic models, either physical or computer generated. Throughout decades of clinical and laboratory research on infant head trauma, a number of biomechanical models have been used to assess the impact of various force parameters on the infant head and spine. Some early biomechanical models raised concerns about the ability of shaking events alone to generate sufficient forces to induce a variety of infant brain injuries, inferring that impact was a necessary prerequisite to induce infant head injury.[26] However, subsequent studies have highlighted the biofidelic limitations of that earlier work and have validated shaking alone as a mechanism for inducing infant brain injury.[27,28]

Additionally, in clinical studies, researchers continue to emphasize the importance of shaking as an injurious mechanism in many cases of AHT. In a study examining 112 cases of perpetrator admissions to AHT in court, shaking was a commonly reported mechanism of injury, with the shaking being described as violent in 100% of cases and being separate, repetitive incidents in 55% of the cases (with a mean repetitive incidence of 10 times).[29]

Some authors have postulated that evidence of significant cervical spine injury was a necessary finding before infant brain injury could be attributed to exclusive shaking events.[30] Although improvements in radiologic imaging have led to increased detection rates of ligamentous and other cervical spine injury in AHT cases, the biomechanical literature does not support the contention that bony, soft-tissue, or spinal cord injury must always be present in cases of AHT.[30]

All biomechanical models, whether physical or computer generated, have limitations and fall short of a precise representation of the complex pathophysiology of the human infant.[31] Clinicians and researchers acknowledge that although precise mechanisms for all abusive injuries remain incompletely understood, sound evidence-based literature supports the conclusion that both inflicted rotational and contact forces to the head can cause brain injury, intracranial hemorrhage, spinal hemorrhage and/or injury, and retinal hemorrhage.[31] Biomechanical research forms an important adjunct to the growing body of knowledge on pediatric traumatic brain injury. However, pediatric practitioners may need to educate multidisciplinary partners on the benefits and limitations of biomechanical literature in AHT.

PREVENTION

Prevention strategies to curtail the incidence of AHT have been developed and researched, and some states have mandated “shaken baby syndrome” education for parents of all newborn infants. Some hospital-based programs have shown success in some settings. Dias et al[32] demonstrated a decrease in AHT in a region of New York using written and video content about the dangers of shaking in addition to asking parents to voluntarily sign a commitment statement acknowledging and affirming receipt and understanding of the information. Their findings were replicated in another part of New York, but larger implementation across the state of Pennsylvania failed to demonstrate a reduction in AHT.[33,34] The Period of PURPLE Crying is a multifaceted program that aims to educate parents about infant sleeping, crying, and soothing behaviors. It involves an in-hospital postpartum implementation phase in which, in addition to the written and DVD education that parents receive, there is later education from public

health nurses and annual community education. This program revealed a decrease in AHT incidence after implementation in British Columbia, but implementation in the state of North Carolina did not demonstrate a decrease in the incidence of AHT.[35,36]

Although it has been difficult to consistently demonstrate a decrease in AHT rates with educational interventions, some prevention programs have found other worthwhile results, including parental reports of improved understanding of infant crying, parental reports of improved emotional self-regulation, and an increase in parental knowledge of AHT.[37] Similarly, although the Nurse-Family Partnership, an in-home visitation program, has not demonstrated an effect on AHT rates specifically, the program has demonstrated a long-term decrease in child maltreatment and may be a useful approach in addressing AHT.[38] Providing economic support for families may be another prevention approach. Studies evaluating the impact of paid family leave and the earned income tax credit in California have demonstrated a reduction in AHT rates, although further research about generalizability is needed.[39,40] The AAP supports prevention efforts aimed at reducing the frequency of AHT and has called for continued research in this area.

LEGAL IMPACT

Few pediatric diagnoses have engendered as much debate in medicolegal circles as AHT. Because the diagnosis may result in children being removed from their homes and adults being imprisoned for their actions, the existence of a debate is understandable. However, the debate is a philosophical one, not a scientific one.

The debate arises from the legal requirement of physicians to subsequently express in court their degree of certainty of the AHT diagnosis (ie, to a "reasonable medical certainty"). Some authors have clarified that "reasonable medical certainty" is a pro forma legal expression required of physicians to assure courts that the opinions expressed are reasonable and nonspeculative.[41] Pediatric practitioners should understand that legal burdens of proof (ie, beyond a reasonable doubt) are not required for the diagnosis. Diagnosing AHT requires the same meticulousness, thoughtfulness, and comprehensiveness as any other medical diagnosis, no more and no less.

Because civil and criminal justice systems are often involved in cases of AHT, debates related to mechanism and causation of injury often are transferred to the courtroom. On occasion, a pediatric practitioner may be called on to testify in AHT hearings. The court may allow extraneous or pseudoscientific theories to be considered as explanations for findings of AHT, and a pediatrician who is called to testify should be sufficiently versed in these extraneous theories and in the scientific literature girding the AHT diagnosis so that he or she can present responsible, ethical testimony to the court.[17] In preparing for testimony, reviewing the literature with a child abuse pediatrician can be helpful.

The term "shaken baby syndrome" has become synonymous in public discourse with AHT in all its forms.[42] The term is sometimes used inaccurately to describe infants with impact injury alone or with multiple mechanisms of head and brain injury and is focused on a specific mechanism of injury rather than the abusive event that was perpetrated against a helpless victim. Legal challenges to the term "shaken baby syndrome" can distract from the more important questions of accountability of the perpetrator and/or the safety of the victim. The pediatric practitioner should be prepared to "use the term 'abusive head trauma' rather than a term that implies a single injury mechanism, such as shaken baby syndrome, in their diagnosis and medical communications."[43]

THE ROLE OF THE PEDIATRICIAN

The diagnosis of child abuse has enormous social, psychological, and legal implications for families. The role of the pediatric practitioner is not to apportion blame or investigate potential criminal activity but to identify the medical problem, evaluate and treat the child's injuries, and offer honest medical information to parents, families, investigators, and attorneys and/or judges. When child protective services or law enforcement are involved in an investigation, the pediatric practitioner is often called on to interpret and communicate medical information for nonmedical professionals in an understandable manner that accurately reflects the medical data.

Pediatricians are mandated reporters, which means they are required to report suspected abuse and neglect to state child protective services, regardless of whether a definitive diagnosis of maltreatment has been made. As mandated reporters of suspected child abuse and neglect, pediatric practitioners carry the burden of recognizing and responding to medical manifestations of AHT. The diagnosis is sometimes obvious but can be missed by practitioners, particularly when infants present with subtle signs and symptoms.[4] Additionally, pediatric practitioners do not always report injuries that are highly suspicious for abuse to child welfare agencies, putting children at

further risk for injury.[44,45] To protect infants who are abused and prevent future severe neurologic injury, pediatric practitioners must remain vigilant for the possibility of AHT in infants who present with both subtle and overt neurologic symptoms and take seriously the ethical and legal mandates to report suspected child abuse to child protective agencies for investigation.

As with any other diagnosis, pediatric practitioners have a responsibility to formulate a thorough differential diagnosis when presented with a patient with findings suggestive of AHT and to consider the possibility of abuse early in that process, with the understanding that a final medical diagnosis of AHT is made only after consideration of all the available clinical data.

On some occasions, the diagnosis is apparent early in the course of the evaluation because some infants and children have injuries to multiple organ systems that could only be the result of inflicted trauma. On other occasions, the diagnosis is less certain. In these less certain circumstances, the pediatric practitioner should carefully balance, both in verbal expression and written documentation, the need for child protection with ongoing medical evaluations. Pediatric practitioners should be cautious to not overstate the significance of particular medical findings, yet they should still effectively communicate the need for child safety when indicated. Because verbal and written communications with collaborative investigative agencies can be challenging, early consultation with a child abuse pediatrician may be prudent.

Providing a medical home for survivors of AHT is an important role for pediatricians because both short- and long-term complications can occur. Frequent monitoring and prompt referral to subspecialists when needed are key to achieving the best possible outcomes.

Finally, pediatric practitioners can work to prevent AHT by supporting prevention efforts in their clinical practices. Pediatric practitioners may help prevent AHT by carefully assessing for psychosocial risk factors often associated with abuse,[46] by providing anticipatory guidance to new parents about the dangers of shaking and impact, by providing methods for dealing with the frustration of a crying infant, and by providing access to prevention resources and supports. They can also stress the importance of leaving a young infant or toddler in the care of adults whom the parents trust will not harm their child and has been educated on the topic of AHT. Lastly, pediatric practitioners can work to advance evidence-based prevention efforts through research.

RECOMMENDATIONS

The AAP recommends the following:

1. Pediatric practitioners should remain vigilant for the signs, symptoms, and head injury patterns associated with AHT.
2. Pediatric practitioners should perform a thorough and objective medical evaluation of infants and children who present to medical care with signs and symptoms of potential AHT. Consultants in radiology, ophthalmology, neurosurgery, general pediatric surgery, and other subspecialties are important partners in the medical evaluation and can assist in interpreting data and reaching a diagnosis.
3. Pediatric practitioners should consider consulting a subspecialist in the field of child abuse pediatrics to ensure that the medical evaluation of the patient has been complete and that the diagnosis is accurate.
4. Pediatric practitioners should continue to use the term "abusive head trauma" rather than a term that implies a single injury mechanism, such as shaken baby syndrome, in their diagnosis and medical communications.
5. Pediatric practitioners should report cases to child protective services when there is reasonable suspicion or reasonable cause to believe AHT has occurred and be prepared to educate investigative agencies on the medical information that forms the basis of the suspicion.
6. Pediatric practices should provide medical homes for survivors of AHT or refer them to medical homes to help achieve optimal rehabilitation and long-term monitoring for complications.
7. Pediatric practitioners who are called on to interact with legal and child protective agencies should be versed in the science underpinning AHT and be prepared to educate these stakeholders on both supported and unsupported theories of causation commonly proffered in court.
8. Pediatric practitioners should educate parents and caregivers about safe approaches to soothing an infant and coping with crying infants and about the dangers of shaking an infant, striking an infant, or impacting an infant's head against a surface.

LEAD AUTHORS

Sandeep K. Narang, MD, JD, FAAP
Amanda Fingarson, DO, FAAP
James Lukefahr, MD, FAAP

COUNCIL ON CHILD ABUSE AND NEGLECT EXECUTIVE COMMITTEE, 2017–2019

Andrew P. Sirotnak, MD, FAAP, Chairperson
Emalee G. Flaherty, MD, FAAP, Immediate Past Chairperson

ABBREVIATIONS

AAP: American Academy of Pediatrics
AHT: abusive head trauma

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Drs Narang, Fingarson, and Lukefahr have served as paid expert witnesses/consultants in cases of abusive head trauma in infants and children.

REFERENCES

1. Al-Holou WN, O'Hara EA, Cohen-Gadol AA, Maher CO. Nonaccidental head injury in children. Historical vignette. *J Neurosurg Pediatr*. 2009;3(6):474–483
2. Caffey J. Multiple fractures in the long bones of infants suffering from chronic subdural hematoma. *Am J Roentgenol Radium Ther*. 1946;56(2):163–173
3. Guthkelch AN. Infantile subdural haematoma and its relationship to whiplash injuries. *Br Med J*. 1971; 2(5759):430–431
4. Jenny C, Hymel KP, Ritzen A, Reinert SE, Hay TC. Analysis of missed cases of abusive head trauma [published correction appears in *JAMA*. 1999; 282(1):29]. *JAMA*. 1999;281(7):621–626
5. Shanahan ME, Zolotor AJ, Parrish JW, Barr RG, Runyan DK. National, regional, and state abusive head trauma: application of the CDC algorithm. *Pediatrics*. 2013;132(6). Available at: www.pediatrics.org/cgi/content/full/132/6/e1546
6. Sheets LK, Leach ME, Koszewski IJ, Lessmeier AM, Nugent M, Simpson P. Sentinel injuries in infants evaluated for child physical abuse. *Pediatrics*. 2013;131(4):701–707
7. Pierce MC, Kaczor K, Aldridge S, O'Flynn J, Lorenz DJ. Bruising characteristics discriminating physical child abuse from accidental trauma [published correction appears in *Pediatrics*. 2010; 125(4):861]. *Pediatrics*. 2010;125(1): 67–74
8. Dorfman MV, Metz JB, Feldman KW, Farris R, Lindberg DM; ExSTRA Investigators. Oral injuries and occult harm in children evaluated for abuse. *Arch Dis Child*. 2018; 103(8):747–752
9. Christian CW; Committee on Child Abuse and Neglect, American Academy of Pediatrics. The evaluation of suspected child physical abuse [published correction appears in *Pediatrics*. 2015; 136(3):583]. *Pediatrics*. 2015;135(5). Available at: www.pediatrics.org/cgi/content/full/135/5/e1337
10. Section on Radiology; American Academy of Pediatrics. Diagnostic imaging of child abuse. *Pediatrics*. 2009;123(5):1430–1435
11. Piteau SJ, Ward MG, Barrowman NJ, Plint AC. Clinical and radiographic characteristics associated with abusive and nonabusive head trauma: a systematic review. *Pediatrics*. 2012; 130(2):315–323
12. Maguire S, Pickerd N, Farewell D, Mann M, Tempest V, Kemp AM. Which clinical features distinguish inflicted from non-inflicted brain injury? A systematic review. *Arch Dis Child*. 2009;94(11): 860–867
13. Maguire SA, Watts PO, Shaw AD, et al. Retinal haemorrhages and related findings in abusive and non-abusive head trauma: a systematic review. *Eye (Lond)*. 2013;27(1):28–36
14. American Academy of Ophthalmology Quality of Care Secretariat; Hoskins Center for Quality Eye Care. Abusive Head Trauma/Shaken Baby Syndrome. San Francisco, CA: American Academy of Ophthalmology; 2015. Available at: https://www.aao.org/clinical-statement/abusive-head-traumashaken-baby-syndrome. Accessed September 24, 2019
15. Choudhary AK, Bradford RK, Dias MS, Moore GJ, Boal DK. Spinal subdural hemorrhage in abusive head trauma: a retrospective study. *Radiology*. 2012; 262(1):216–223
16. Chadwick DL, Bertocci G, Castillo E, et al. Annual risk of death resulting from short falls among young children: less than 1 in 1 million. *Pediatrics*. 2008;121(6):1213–1224
17. Leventhal JM, Edwards GA. Flawed theories to explain child physical abuse: what are the medical-legal consequences? *JAMA*. 2017;318(14): 1317–1318
18. Hymel KP, Willson DF, Boos SC, et al; Pediatric Brain Injury Research Network (PediBIRN) Investigators. Derivation of a clinical prediction rule for pediatric abusive head trauma. *Pediatr Crit Care Med*. 2013;14(2): 210–220
19. Maguire SA, Kemp AM, Lumb RC, Farewell DM. Estimating the probability

of abusive head trauma: a pooled analysis. *Pediatrics*. 2011;128(3). Available at: www.pediatrics.org/cgi/content/full/128/3/e550

20. Berger RP, Pak BJ, Kolesnikova MD, et al. Derivation and validation of a serum biomarker panel to identify infants with acute intracranial hemorrhage. *JAMA Pediatr*. 2017;171(6):e170429
21. Ichord RN, Naim M, Pollock AN, Nance ML, Margulies SS, Christian CW. Hypoxic-ischemic injury complicates inflicted and accidental traumatic brain injury in young children: the role of diffusion-weighted imaging. *J Neurotrauma*. 2007;24(1):106–118
22. Bayir H, Kochanek PM, Kagan VE. Oxidative stress in immature brain after traumatic brain injury. *Dev Neurosci*. 2006;28(4–5):420–431
23. Barlow KM, Thomson E, Johnson D, Minns RA. Late neurologic and cognitive sequelae of inflicted traumatic brain injury in infancy. *Pediatrics*. 2005; 116(2). Available at: www.pediatrics.org/cgi/content/full/116/2/e174
24. Fanconi M, Lips U. Shaken baby syndrome in Switzerland: results of a prospective follow-up study, 2002-2007. *Eur J Pediatr*. 2010;169(8): 1023–1028
25. Flaherty E, Legano L, Idzerda S; Council on Child Abuse and Neglect. Ongoing pediatric health care for the child who has been maltreated. *Pediatrics*. 2019; 143(4):e20190284
26. Duhaime AC, Gennarelli TA, Thibault LE, Bruce DA, Margulies SS, Wiser R. The shaken baby syndrome. A clinical, pathological, and biomechanical study. *J Neurosurg*. 1987;66(3):409–415
27. Cory CZ, Jones BM. Can shaking alone cause fatal brain injury? A biomechanical assessment of the Duhaime shaken baby syndrome model. *Med Sci Law*. 2003;43(4):317–333
28. Finnie JW, Blumbergs PC, Manavis J, et al. Neuropathological changes in a lamb model of non-accidental head injury (the shaken baby syndrome). *J Clin Neurosci*. 2012;19(8):1159–1164
29. Adamsbaum C, Grabar S, Mejean N, Rey-Salmon C. Abusive head trauma: judicial admissions highlight violent and repetitive shaking. *Pediatrics*. 2010; 126(3):546–555
30. Margulies S, Prange M, Myers B, et al. Shaken baby syndrome: a flawed biomechanical analysis [Comment Letter]. *Forensic Sci Int*. 2006;164(2–3): 278–279
31. Pierce MC, Bertocci G. Injury biomechanics and child abuse. *Annu Rev Biomed Eng*. 2008;10:85–106
32. Dias MS, Smith K, DeGuehery K, Mazur P, Li V, Shaffer ML. Preventing abusive head trauma among infants and young children: a hospital-based, parent education program. *Pediatrics*. 2005;115(4). Available at: www.pediatrics.org/cgi/content/full/115/4/e470
33. Altman RL, Canter J, Patrick PA, Daley N, Butt NK, Brand DA. Parent education by maternity nurses and prevention of abusive head trauma. *Pediatrics*. 2011; 128(5). Available at: www.pediatrics.org/cgi/content/full/128/5/e1164
34. Dias MS, Rottmund CM, Cappos KM, et al. Association of a postnatal parent education program for abusive head trauma with subsequent pediatric abusive head trauma hospitalization rates. *JAMA Pediatr*. 2017;171(3): 223–229
35. Barr RG, Barr M, Rajabali F, et al. Eight-year outcome of implementation of abusive head trauma prevention. *Child Abuse Negl*. 2018;84:106–114
36. Zolotor AJ, Runyan DK, Shanahan M, et al. Effectiveness of a statewide abusive head trauma prevention program in North Carolina. *JAMA Pediatr*. 2015;169(12):1126–1131
37. Lopes NRL, Williams LCA. Pediatric abusive head trauma prevention initiatives: a literature review. *Trauma Violence Abuse*. 2018;19(5):555–566
38. Eckenrode J, Campa MI, Morris PA, et al. The prevention of child maltreatment through the nurse family partnership program: mediating effects in a long-term follow-up study. *Child Maltreat*. 2017;22(2):92–99
39. Klevens J, Luo F, Xu L, Peterson C, Latzman NE. Paid family leave's effect on hospital admissions for pediatric abusive head trauma. *Inj Prev*. 2016; 22(6):442–445
40. Klevens J, Schmidt B, Luo F, Xu L, Ports KA, Lee RD. Effect of the earned income tax credit on hospital admissions for pediatric abusive head trauma, 1995-2013. *Public Health Rep*. 2017;132(4): 505–511
41. Narang SK. The unreasonableness of 'reasonable medical certainty'. *Child Abuse Negl*. 2015;50:232–233
42. Lazoritz S, Baldwin S, Kini N. The whiplash shaken infant syndrome: has Caffey's syndrome changed or have we changed his syndrome? *Child Abuse Negl*. 1997;21(10):1009–1014
43. Christian CW, Block R; Committee on Child Abuse and Neglect; American Academy of Pediatrics. Abusive head trauma in infants and children. *Pediatrics*. 2009;123(5):1409–1411
44. Jones R, Flaherty EG, Binns HJ, et al; Child Abuse Reporting Experience Study Research Group. Clinicians' description of factors influencing their reporting of suspected child abuse: report of the Child Abuse Reporting Experience Study Research Group. *Pediatrics*. 2008; 122(2):259–266
45. Flaherty EG, Sege RD, Griffith J, et al; PROS network; NMAPedsNet. From suspicion of physical child abuse to reporting: primary care clinician decision-making. *Pediatrics*. 2008; 122(3):611–619
46. Pierce MC, Kaczor K, Acker D, et al. History, injury, and psychosocial risk factor commonalities among cases of fatal and near-fatal physical child abuse. *Child Abuse Negl*. 2017;69: 263–277

Advocacy and Collaborative Health Care for Justice-Involved Youth

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Advocacy and Collaborative Health Care for Justice-Involved Youth

Mikah C. Owen, MD, MPH, FAAP,[a] Stephenie B. Wallace, MD, MSPH, FAAP,[b] COMMITTEE ON ADOLESCENCE

Children and adolescents who become involved with the justice system often do so with complex medical, mental health, developmental, social, and legal needs. Most have been exposed to childhood trauma or adversity, which both contribute to their involvement with the justice system and negatively impact their health and well-being. Whether youth are held in confinement or in their home communities, pediatricians play a critical role in promoting the health and well-being of justice-involved youth. Having a working knowledge of the juvenile justice system and common issues facing justice-involved youth may help pediatricians enhance their clinical care and advocacy efforts. This policy statement is a revision of the 2011 policy "Health Care for Youth in the Juvenile Justice System." It provides an overview of the juvenile justice system, describes racial bias and overrepresentation of youth of color in the justice system, reviews the health and mental health status of justice-involved youth, and identifies advocacy opportunities for juvenile justice reform.

INTRODUCTION

In 2017, approximately 809 700 persons under the age of 18 were arrested in the United States,[1] a number that has steadily declined from the peak of nearly 2.7 million in 1996.[2] Decreases in juvenile arrests coincide with concomitant decreases in the number of confined youth. In 2017, approximately 202 900 delinquency cases involved detention,[3] a 50% decrease from the peak of 405 700 in 2005.[3] Whether detained pending the resolution of their legal case or committed to a correctional facility by a judge, most youth quickly return to their home communities. In 2017, the median time in placement was 68 days (23 days for detained youth versus 114 days for committed youth).[4] Thus, pediatricians, whether practicing in juvenile correctional facilities or in communities, may have the opportunity to care for youth involved in the justice system.

Despite improving trends in juvenile arrests and confinement, justice-involved youth continue to experience significant barriers to reaching their full potential. Barriers such as racial and ethnic bias, exposure to

abstract

[a]*Department of Pediatrics, School of Medicine, University of California, Davis, Sacramento, California; and* [b]*Division of Adolescent Medicine, Department of Pediatrics, School of Medicine, The University of Alabama at Birmingham, Birmingham, Alabama*

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Drs Owen and Wallace wrote the initial draft, contributed subsequent revisions, and approved the final manuscript as submitted.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-1755

Address correspondence to Mikah C. Owen, MD, MPH, FAAP. E-mail: mcowen@ucdavis.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

To cite: Owen MC, Wallace SB, AAP COMMITTEE ON ADOLESCENCE. Advocacy and Collaborative Health Care for Justice-Involved Youth. *Pediatrics*. 2020;146(1):e20201755

adverse childhood experiences (ACEs), and unmet physical and mental health needs continue to interfere with the optimal health and development of youth involved with the justice system. Ideally, contact with the juvenile justice system would serve as an opportunity to improve the health and developmental trajectory of youth by identifying precipitants to involvement with the justice system and implementing services to address the young person's needs. Unfortunately, for many youth, involvement with the justice system serves as nothing more than another traumatic experience. Pediatricians, as trusted child advocates, are uniquely positioned to identify and respond to the needs of justice-involved youth and their families. Whether through the provision of clinical care, participation in advocacy activities aimed at reforming the juvenile justice system, or by addressing the root causes of juvenile delinquency, pediatricians have a critical role in improving outcomes for youth involved with the justice system.

OVERVIEW OF THE JUVENILE JUSTICE SYSTEM

In the United States, most children and adolescents suspected of committing a crime are typically placed under the jurisdiction of the juvenile justice system, which is separate from the criminal (adult) justice system. Although each state, and the District of Columbia, have a unique juvenile justice system with different structures and processes, the way a delinquency case progresses through the juvenile justice system is similar among most jurisdictions.[5,6] Law enforcement and non–law enforcement sources (parents, victims, schools) may refer youth under the age of 18 to the juvenile justice system. At the time of arrest, law enforcement agencies may refer the youth for further processing within the juvenile justice system or divert the case to an alternative program outside the system, known as diversion. At or around the time of arrest, adolescents may be held in facilities pending the resolution of their case (detention). If the legal agency refers a case to juvenile court, an intake officer reviews the case and decides whether to dismiss the case, handle the case informally, or proceed to formal processing in juvenile court (petition). Formal cases in juvenile court proceed to an adjudicatory hearing (trial) in which a judge may find a young person not guilty or adjudicated delinquent (guilty). In the case of adjudication, the case progresses to a disposition hearing (sentencing) in which a juvenile court judge orders the disposition (sanctions). Juvenile court judges have a wide range of disposition options, starting with less severe options such as community service and counseling, progressing to more severe options such as intensive probation or residential placement. Residential placement is the out-of-home placement of adjudicated delinquent youth and may include group homes, residential treatment facilities, and long-term secure facilities.

Not all minors accused of breaking the law progress through the juvenile justice system. The maximum age of juvenile court jurisdiction varies between states: 45 states have a maximum age of 17 and 5 states have a maximum age of 16.[7] Additionally, all states have transfer laws that remove youth from the jurisdiction of juvenile court and place them in the jurisdiction of criminal (adult) court in certain circumstances. Transfer laws and processes vary by state and are discussed in the section of this statement on juvenile transfer laws.

States and local jurisdictions mostly administer juvenile justice systems; however, the federal government has established guidelines for minimum protections of youth involved with the justice system. The Juvenile Justice Delinquency and Prevention Act (JJDPA), first enacted in 1974[8] and reauthorized by the Juvenile Justice Reform Act of 2018,[9] maintains 4 core protections for youth involved with the justice system:

- deinstitutionalization of status offenders: juveniles who have committed an offense that would not be a crime if committed by an adult (eg, curfew violation or running away) and juveniles who are not charged with any crimes may not be placed in secure detention facilities;
- removal from adult jail: with a few exceptions, juveniles should not be held in adult jails or lockups (this provision was strengthened in 2018, and states have 3 years to comply);
- sight and sound separation: juveniles held in adult facilities should be separated from incarcerated adults by both sight and sound; and
- racial and ethnic disparities: states must implement policy, practice, and system improvement strategies to identify and reduce racial and ethnic disparities among youth who come into contact with the juvenile justice system.

States that do not comply with these core protections are not eligible to receive federal grant funding provided through the JJDPA.

YOUTH INVOLVED WITH THE JUSTICE SYSTEM

Racial and Ethnic Disparities

Despite decreases in youth arrest and confinement rates, there remain significant racial and ethnic disparities throughout the juvenile justice system. As seen in Table 1, racial and ethnic disparities exist at virtually every decision point in the juvenile justice system.

TABLE 1 Racial and/or Ethnic Disparities in the Juvenile Justice System (All Data From 2018, Unless Otherwise Specified)

	White	African American	Hispanic	AIAN	AHPI
US population <18 y,[10] %	50	14	26	1	5
Juvenile arrest relative rate (RR)[11,a]	—	2.6	Not reported[b]	1.3	0.3
Cases referred to juvenile court RR[12]	—	2.9	0.9	1.2	0.2
Cases diverted RR[12]	—	0.6	0.8	0.8	1.0
Cases detained RR[12]	—	1.4	1.5	1.3	1.2
Cases adjudicated delinquent RR[12]	—	0.9	1.1	1.1	1.0
Adjudicated cases resulting in secure confinement RR[12]	—	1.4	1.4	1.2	0.9
Cases judicially waived to criminal court[12]	—	1.6	1.0	0.9	0.9
Juvenile residential placement RR[13]	—	4.6	1.4	2.8	0.2
Decrease juveniles in residential placement 2006–2015,[14] %	54	46	45	51	65
Decline in juvenile court delinquency cases 2005–2015,[15] %	53	44	38	40	57

AIAN, American Indian or Alaskan native; AHPI, Asian American, Hawaiian, or Pacific Islander; —, not applicable.

[a] Relative rates relative to white youth.

[b] Not all agencies provide ethnicity data; thus, arrest rates for Hispanic juveniles are not reported.

Empirical explanations for racial and ethnic disparities within the justice system are commonly grouped into 2 broad conceptual frameworks: differential treatment and differential offending.[16–18] The differential treatment hypothesis[16–18] attributes racial and ethnic disparities to "inequities—intended or unintended—in justice system practices."[18] Multiple studies have demonstrated racial bias against youth of color at all decision points in the juvenile justice system (arrest, referral to court, diversion, detention, petition, adjudication, probation, secure confinement, and transfer to criminal court).[16,19] Authors of a 2018 review article[19] examined official processing of youth of color at various juvenile justice decision points from January 2001 to December 2014. The authors of that review found that 79% of studies showed that status as a person of color had some disadvantaging effect for youth processed in the juvenile justice system. The negative impact of race was especially prominent at earlier decision points in the juvenile justice system (eg, arrest, referral to court, and preadjudication detention). Conversely, the differential offending hypothesis attributes racial and ethnic disparities within the juvenile justice system to "differences in the incidence, seriousness, and persistence of engagement in delinquent and criminal behavior."[18] The differential offending hypothesis does not ascribe differences in delinquent behavior to biological or genetic differences between races or ethnicities. Instead, the hypothesis posits youth of color are more likely to experience a variety of risk factors for delinquency (poverty, low-performing schools, harsh discipline practices in schools, increased police presence in communities, exposure to violence, incarcerated parents, toxic stress, etc) and thus more likely to commit certain types of crimes.[17] Much of the research supporting this hypothesis relies on the use of official records such as arrest rates, confinement rates, and/or conviction rates. Citing empirical data from official records, which are influenced by inequities in justice system practices (eg, overpolicing of historically disenfranchised neighborhoods, racial profiling, disparate sentencing of youth of color, differential treatment in the plea-bargaining process, implicit and/or explicit bias against youth of color), may overestimate the differences in delinquent and/or criminal behaviors between racial and ethnic groups and perpetuate bias within the literature. Furthermore, more research is needed to identify how social factors more commonly experienced by youth of color mediate racial and/or ethnic disparities in the juvenile justice system.

Although helpful as conceptual frameworks, the differential treatment and differential offending hypotheses represent an oversimplification of the causes of racial and ethnic disparities within the juvenile justice system. Racial and ethnic disparities within the juvenile justice system exist within the broader context of disparities in child health and well-being. Collectively, the sources of these disparities are rooted in inequities in the social and environmental determinants of health (eg, poverty, racism) and the failure of public policies to adequately address them. Key policy statements from the American Academy of Pediatrics (AAP), "The Impact of Racism on Child and Adolescent Health,"[20] "Poverty and Child Health in the United States"[21] and "Health Equity and Children's Rights"[22] provide insight on how these inequities impact the health and development of children and adolescents and how pediatricians can respond to mitigate their impact.

Children and Adolescents Exposed to ACEs

Research has established the significant impact of childhood trauma, adversity, or ACEs on the health and well-being of children and adolescents.[23] Multiple studies have documented high prevalence rates of childhood trauma among justice-involved youth, with many studies finding that over 90% of youth in the justice system have experienced at least one form of childhood trauma.[24–26] The National Child Traumatic Stress Network found justice-involved youth experience an

average of 5 different forms of childhood trauma.[27] Sixty-two percent of youth in the National Center for Child Traumatic Stress study experienced trauma within the first 5 years of life; Table 2 identifies the different types of trauma justice-involved youth experienced in this study.

Aware of the high prevalence of trauma and cognizant that incarceration itself represents a traumatic experience, advocates have called for the implementation of trauma-informed policies, procedures, and standards across the spectrum of juvenile justice settings. In 2015, the National Child Traumatic Stress Network published the *Essential Elements of a Trauma-Informed Juvenile Justice System*,[28] a guide that educates programs working with justice-involved youth to recognize and respond to the needs of youth who have experienced trauma. A 2012 report by the US Department of Justice provides recommendations on how to incorporate trauma-informed care practices throughout the spectrum of the juvenile justice system.[29] Recommendations include the following:

- make trauma-informed screening, assessment, and care the standard in juvenile justice services;
- abandon juvenile justice correctional practices that traumatize children;
- provide juvenile justice services appropriate to children's ethnocultural background;
- provide care and services to address the special circumstances and needs of girls in the juvenile justice system;
- provide care and services to address the special circumstances and needs of lesbian, gay, bisexual, transgender, and queer and/or questioning (LGBTQ) youth in the juvenile justice system;
- develop and implement policies in every school system that aim to keep children in school rather than policies that lead to suspension and expulsion;
- guarantee that all violence-exposed children accused of a crime have legal representation;
- help, do not punish, child victims of sex trafficking; and
- whenever possible, prosecute young offenders in the juvenile justice system.

For justice-involved youth receiving care in the community, the AAP Resilience Project (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/resilience/Pages/Resilience-Project.aspx) is a great resource to educate pediatricians to incorporate trauma-informed care into their practice.

TABLE 2 Prevalence of Trauma Types Among Justice-Involved Youth[27]

Trauma Type	Percentage of Youth	
	Male	Female
Traumatic loss or bereavement	59	65
Domestic violence	51	56
Impaired caregiver	48	57
Emotional abuse	46	54
Community violence	41	30
Neglect	31	30
Physical maltreatment and/or abuse	39	41
Physical assault	27	24
School violence	23	23
Serious injury or unintentional injury	20	19
Sexual maltreatment and/or abuse	16	32
Sexual assault and/or rape	9	39

Female Youth

Because of larger relative declines in the arrest rates of male youth, the proportion of justice-involved girls and young women has increased.[30] Recent data reveal that female youth accounted for 29% of youth arrests[31] and 15% of youth residential placement.[32]

Available literature suggests that in comparison with male youth, justice-involved female youth experience higher rates of trauma exposure, sexual and physical abuse victimization, and mental illness[25] and are more likely to have been involved with the child welfare system.[33]

In 2015, the Office of Juvenile Justice and Delinquency Prevention issued policy guidance aimed at improving system and programmatic responses for justice-involved female youth.[34] Key recommendations from the report include the following:

- prohibition of placement of minor sex trafficking victims in the juvenile justice system;
- development of alternatives to detention and incarceration for female youth; and
- competency of all programs and services to serve girls and young women in, or at risk of entering, the juvenile justice system.

LGBTQ Youth

Studies report LGBTQ youth compose 13% to 15% of youth in the juvenile justice system,[35–37] but this may be an underestimate because many jurisdictions do not collect information on sexual orientation or gender identity, and youth may not disclose this information because of fear of mistreatment.[35] Most research on LGBTQ youth in the juvenile justice system is focused on sexual orientation and does not include data on transgender or gender-diverse

youth. Like youth from historically disenfranchised racial and/or ethnic groups, LGBTQ youth experience more risk factors for involvement with the juvenile justice system and differential treatment within the system. LGBTQ youth experience higher rates of physical and sexual violence, familial rejection, bullying, mental health problems, and other risk factors that increase the likelihood of system involvement.[36,37] Literature suggests LGBTQ youth face bias and maltreatment across the spectrum of juvenile justice settings. One study found that LGBTQ and gender-diverse youth were more likely to be detained for truancy, warrants, probation violations, running away, and child sex trafficking.[38] Another study found LGBTQ youth reported youth-on-youth sexual victimization at a rate of nearly 7 times that of heterosexual youth (10.3% vs 1.5%).[39] Multiple reports have found LGBTQ youth in detention facilities experience increased rates of emotional abuse, physical abuse, and time in isolation.[36,37,40] The Prison Rape Elimination Act of the Juvenile Facility Standards of 2003[41] includes provisions to keep LGBTQ youth safe in detention facilities and include, but are not limited to, the following:

- staff must receive training on how to communicate effectively with LGBTQ and gender-nonconforming youth;
- facilities are required to ascertain whether youth are (or are perceived to be) lesbian, bisexual, gay, and/or transgender or gender nonconforming;
- the use of isolation and/or solitary confinement is limited; and
- case-by-case housing decisions are required for transgender and intersex adolescents.

Although the Prison Rape Elimination Act standards provide basic protections for detained LGBTQ youth, they do not set comprehensive standards that promote the overall well-being of confined LGBTQ youth. The Annie E. Casey Foundation[37] and The Equity Project provide best practices and guidance for the development and implementation of more comprehensive standards.[42]

Medical Care for Transgender Youth

Medical care for transgender youth in confinement, including access to hormone therapy, is variable. In a 2015 article, authors analyzed state statutes and department of corrections policies regarding medical services and treatment of transgender inmates and found that 13 states allow for the initiation of hormone treatment and 21 states allow for the continuation of hormone treatment; the authors were unable to identify relevant policies or statues in 10 states.[43] The 2015 National Commission on Correctional Health Care (NCCHC) position statement "Transgender, Transsexual, and Gender Nonconforming Health Care in Correctional Settings"[44] makes recommendations for the health management of transgender patients held in confinement. Recommendations include the following:

- health staff should manage transgender patients in a manner that respects their biomedical and psychosocial needs;
- the management of medical or surgical transgender care should follow accepted standards developed by professionals with expertise in transgender health;
- there should be no blanket administrative or other policies that restrict specific medical treatments; and
- transgender patients who received hormone therapy with or without a prescription before incarceration should have therapy continued without interruption.

Youth Involved With the Child Welfare System

Youth with current or past involvement with the child welfare system, often referred to as crossover or dual-status youth, are overrepresented in the juvenile justice system. Although national data are lacking and estimates vary by jurisdiction, studies reveal the prevalence of dual-status youth in the juvenile justice system commonly exceeds 50%.[45,46] When compared with youth who are not involved in both systems, dual-status youth are younger at the time of first arrest, detained more often, and have more significant mental health and educational needs.[33] The JJDPA requires states to establish polices and systems to incorporate child welfare records into juvenile justice records to establish and implement treatment plans of justice-involved youth.

MEDICAL AND MENTAL HEALTH CARE FOR CONFINED YOUTH

Confined youth have a constitutional right to adequate medical and mental health care[47,48]; however, because of the lack of clearly defined federal standards and differences in state laws regarding the provision of health care for confined youth, on-site medical and mental health care services vary widely between jurisdictions and correctional facilities.[49] States, counties, or private contractors may provide health care services for confined youth.[50] Federal law prohibits the use of Medicaid funds for inmates of a public institution,[50] and local governments (states, counties, cities) are responsible for funding health care services for confined youth.

In addition to state laws governing the provision of health care for confined youth, detention facilities may seek voluntary accreditation from the NCCHC. The NCCHC published "Standards for Health

Services in Juvenile Detention and Confinement Facilities" and provides accreditation for health services in juvenile detention facilities.[51] The AAP, American Academy of Child and Adolescent Psychiatry (AACAP), American College of Obstetricians and Gynecologists (ACOG), and the American Public Health Association support the NCCHC standards, which address 9 general areas: health care services and support, patient care and treatment, special needs and services, governance and administration, safety, personnel and training, health records, health promotion, and medical legal issues.[51] The NCCHC recommends physical, mental, and oral health screenings after admission, a comprehensive health assessment within 7 days of admission, and appropriate follow-up care. Although NCCHC accreditation is voluntary, it is important for providers in confinement facilities to be aware of these standards and juvenile correctional facilities to adopt and comply with the standards.

The 2011 AAP policy statement "Health Care for Youth in the Juvenile Justice System"[52] provided a detailed overview of the physical and mental health needs of confined youth and the provision of health care services for youth in correctional facilities. Since the 2011 policy statement, there have been few additional nationally representative studies on the health status of justice-involved youth published. The Survey of Youth in Residential Placement (SYRP) of 2010[53] remains the most comprehensive nationally representative examination of the health needs of confined youth. The SYRP found 69% of confined youth reported an unmet health care need, including injury, problems with vision or hearing, dental needs, or "other illness." The SYRP did not inquire about specific illnesses or injuries. Common health concerns for these youth include traumatic injuries, oral health needs, sexually transmitted infections (STIs), and reproductive health needs.[53,54]

Few studies have been used to examine chronic illness in incarcerated youth, and incarcerated youth may have difficulty accessing care before confinement.[52] Quality coordinated care within the justice and medical systems can identify and manage chronic illnesses during confinement. The NCCHC recommends that systems identify and enroll youth with chronic illnesses in a chronic disease management plan.[51]

Reproductive and/or Sexual Health

The 1991 NCCHC study[55] remains the only nationally representative sample evaluating the history of sexual activity and contraceptive use among confined youth. Confined youth reported higher rates of sexual activity, increased likelihood of 4 or more lifetime sexual partners, and lower rates of contraception or condom use during their most recent sexual intercourse. Multiple smaller studies have revealed similar results,[56–59] and these behaviors place justice-involved youth at risk for unintended pregnancy as well as STIs and HIV infections. It is important for adolescents to receive counseling on safe sex practices, which include barrier methods, hormonal contraception, long-acting reversible contraception, and emergency contraception, and receive timely and appropriate reproductive health care during confinement. Reproductive health care includes assessment of youth's self-reported sexual behaviors and practices, STI and HIV testing and treatment, trauma counseling, necessary emergency contraception, and counseling on all other forms of contraception as recommended by the AAP.[60] The NCCHC recommends evaluating all youth assigned female sex at birth for pregnancy risk after admission. Early pregnancy identification allows youth to consider options regarding their pregnancy and parenthood.

The 2010 SYRP revealed 13% of confined male and 5% of female youth were expecting children.[53] ACOG recommends incarcerated pregnant adolescents receive the same pregnancy care (pregnancy counseling, prenatal and perinatal care, and abortion services) as nonincarcerated adolescents.[61] A unique challenge for pregnant incarcerated women and adolescents is the use of mechanical restraints, commonly known as shackling. ACOG[62] notes that shackling interferes with the ability of the health care clinician to assess and evaluate the health of the woman and fetus and may put the health of both at risk (increased risk of falls, increased risk of venous thrombosis due to limited mobility, interference with normal labor and delivery, and interference with mother-child bonding).[61] ACOG, the American Medical Association, and many other professional organizations have called for prohibiting, or severely restricting, the use of shackles to restrain pregnant women.[62] The Juvenile Justice Reform Act of 2018 prohibits the use of restraints on pregnant women and adolescents during labor, delivery, and postpartum recovery unless there is an immediate threat of harm to self or others (states have 2 years to phase out the use of restraints).[9]

Infections

It is important for health care clinicians to give special attention to screening, immunization, and treatment of specific infections among justice-involved youth.

Tuberculosis

The NCCHC recommends screening all youth for tuberculosis after entry into the justice system unless the local health department determines the community's prevalence does not warrant screening.[51] The 2018 AAP

Red Book: 2018 Report of the Committee on Infectious Diseases outlines methods for assessing risk and screening youth for exposure.[63] The Centers for Disease Control and Prevention also provides recommendations for prevention and control of tuberculosis in detention facilities.[64]

STIs and/or HIV

Data from the Center for Disease Control and Prevention's *Sexually Transmitted Disease Surveillance 2011*[65] found confined youth have elevated rates of STIs (Table 3).

Although HIV prevalence data for confined youth are not available, the same risk factors for STIs place them at risk for HIV infection. In 2017, youth aged 13 to 24 made up 21% of all new HIV diagnoses in the United States.[66]

Routine screening, education (including safe sex practices; abstinence; and barrier, hormonal, long-acting reversible contraception; and emergency contraception), and treatment of STIs and/or HIV among confined youth may decrease the overall disease burden and improve sexual and relationship health. The NCCHC recommends STI testing (chlamydia, gonorrhea, HIV, and syphilis, of which there is significant prevalence) be offered to all youth within 48 hours of arrival.[51]

Immunizations

There is a lack of nationally representative data regarding the immunization status of confined youth, but facility-level data suggest they have significantly lower immunization coverage rates. In a study of one juvenile detention facility in California, authors found only 3% of adolescents had received all recommended immunizations before their first detention.[67] Barriers to full immunization coverage among justice-involved youth may include poor access to health care and lack of a medical home before confinement.[67]

Although immunization requirements for confined youth vary between jurisdictions, confinement may be an opportunity for justice-involved youth to receive immunizations. Studies have revealed that detention and/or secure placement of youth may be associated with higher immunization coverage rates.[67,68] Implementing routine immunization policies in juvenile detention facilities may increase immunization coverage for confined youth. Use of state immunization registries can help determine necessary immunizations.

Mental Health Disorders

Although estimates vary, the prevalence of mental health disorders among justice-involved youth commonly ranges from 50% to 80%.[69–73] Common mental health disorders include depressive disorders, anxiety disorders, disruptive behavior, attention-deficit/hyperactivity disorder, posttraumatic stress disorder, and substance use disorders.[69]

The variable data on the prevalence of mental health disorders among juvenile justice-involved youth are indicative of the limitations of the studies in the literature (use of nonstandardized measures, different diagnostic tools, measurement at different levels of the juvenile justice system, and data specific to individual facility or state). Furthermore, the high prevalence of mental health disorders is interconnected with the high prevalence of trauma and ACEs found in this population.[74,75] Most justice-involved youth experience trauma and polyvictimization from a young age. These experiences, and resulting toxic stress response, may result in maladaptive behaviors such as increased stress reactivity, impulsivity, hyperarousal, and decreased ability to self-regulate.[76] Youth who have experienced multiple traumatic events are at increased risk of delinquency, contact with law enforcement, involvement with the juvenile justice system, school suspension and dropout, volatile relationships, and substance use.[77] Polyvictimized youth are also more likely to receive diagnoses of externalizing disorders such as conduct disorders, oppositional defiant disorder, and antisocial behaviors.[72,78] There is increasing recognition that for many youth, these diagnoses may be rooted in complex trauma and polyvictimization.[79,80]

Substance Use

As illustrated in Table 4, the prevalence of substance use in confined youth exceeds that of the general adolescent population. However, it is important to consider that for many justice-involved youth, substance use may be the instigating factor of their arrest or confinement.

Recognizing the high prevalence of mental health disorders and substance use among justice-involved youth and the lack of appropriate care in many juvenile facilities, many jurisdictions have implemented programs (ie, mental health courts, substance abuse courts) aimed at providing community-based alternatives to detention for those with mental health and/or substance use disorders.[33] Several diversion programs are effective at decreasing recidivism and/or improving

TABLE 3 STI Rates Among Adolescents Aged 12–18 Years in Juvenile Correction Facilities, 2011 (Last Year Data From Juvenile Correctional Facilities Were Included)

Disease	Overall Positivity, %	
	Female	Male
Chlamydia	15.7	7.4
Gonorrhea	4.4	1.2

TABLE 4 Prevalence of Substance Use Among Confined Youth and the General Adolescent Population

Substance	Lifetime Prevalence Among Confined Youth,[53,a] %	Lifetime Prevalence at Grade 12, General Population, 2018,[81,b] %
Alcohol	74	59
Marijuana or hashish	84	44
Cocaine/crack	30	4/1.5
Ecstasy	26	4
Methamphetamine	22	0.7
Acid/LSD	19	5
Heroin	7	0.8
Any illegal drug (excluding marijuana)	50	19

LSD, lysergic acid diethylamide.

[a] Self-reported data from the SYRP, a nationally representative sample of 7073 youth in custody in 2003.

[b] Self-reported data from the Monitoring the Future National Survey on Drug Use.

behavioral health outcomes in justice-involved youth[82]; however, there is significant variability in the design and implementation of these programs, leading to limitations in studying their collective impact.[82] Further studies to identify eligible youth and effective diversion services and programs may improve outcomes in justice-involved youth.

Screening and Assessment for Mental Health and Substance Use Disorders

NCCHC standards recommend screening all confined youth for current or past mental illness and legal and illegal drug use at the time of arrival to the facility.[51] A 2014 survey[83] of juvenile facilities across the United States found 88% of facilities screened all or some youth for substance use and 99% of facilities reported screening all or some youth for mental health needs. Generally, mental health screening involves nonclinical staff using a standardized screening tool.

On-site Psychiatric Care and Psychotropic Medications

The decision to initiate or change medical treatment of psychiatric disorders in confined youth is challenging. The AACAP published recommendations for mental health assessment and treatment of youth in the correctional system.[84] The AACAP recommends psychotropic medications only be used as part of an individually developed comprehensive treatment plan. To ensure treatment can proceed in a safe and supervised fashion, AACAP guidance recommends determining the youth's legal disposition and placement before initiating or changing medication regimens.[85]

National data are lacking on the use of psychotropic medications for justice-involved youth; however, state- and facility-level data suggest these youth receive psychotropic medications at a higher rate than the general adolescent population. In an analysis of juvenile facilities in 55 California counties, authors found the average proportion of youth receiving psychoactive medication was 17%.[86] In a study of 668 youth in 3 detention facilities in 1 state, authors found that 10% had psychotropic medication dispensed within 1 month of intake.[87] In comparison, from 2005 to 2010, 6% of adolescents reported use of psychotropic medication within the past month.[88]

Suicide and Suicidality

Studies consistently demonstrate justice-involved youth are at increased risk for suicidal thoughts and behaviors. In a longitudinal study of 1829 youth detained at 1 facility over a 3-year period, authors found 36% had ever felt like life was hopeless, 10% had thought about killing themselves in the past 6 months, and 11% had attempted suicide in the past.[89] In a 2015 literature review, authors found that 19% to 32% of justice-involved youth had suicidal ideations in the past year and 12% to 16% had attempted suicide in the past year.[90]

The 2014 Juvenile Residential Facility Census (JRFC) found that suicide was the most common cause of death for youth in residential placement.[83] From 2000 to 2014, there was an average of 7 suicides per year in juvenile detention facilities across the United States.

The JRFC report found that 93% of reporting facilities screened some or all youth for suicide risk. Available studies indicate facilities with annual suicide prevention training and suicide risk screening shortly after admission reported lower suicide rates.[91,92] Only one-fifth of facilities had the 7 key components deemed necessary for suicide prevention.[91,93] These components include written protocols, intake screening, suicide prevention training, safe housing, observation, mortality review, and cardiopulmonary resuscitation and certification.

Informed Consent and the Right to Refuse Care

According to NCCHC standards, "all examinations, treatments, and procedures are governed by informed consent practices for juvenile care that are applicable in the jurisdiction. A juvenile may refuse specific health evaluations and treatments in accordance with the laws in the jurisdiction."[51] NCCHC standards also state that youth may not be punished for refusing medical or mental health treatment.[51]

Continuity of Care

It is ideal for justice-involved youth to receive comprehensive and coordinated physical and mental health care during confinement and in their communities. Barriers to such

care include lack of preventive care in the community, lack of an established medical home, and disruptions in Medicaid or Children's Health Insurance Program coverage. Federal law prohibits the use of Medicaid funds for inmates of a public institution.[94] As a result, many jurisdictions terminate Medicaid eligibility at the time of entry into secure detention facilities.[94] In 2018, Congress passed legislation prohibiting states from terminating Medicaid eligibility for incarcerated juveniles.[95] States may suspend Medicaid coverage during incarceration, but before release, they must conduct a redetermination of eligibility and restore coverage, if eligible. States remain prohibited from using Medicaid to cover incarcerated juveniles.

Identifying and connecting youth with a medical home before release may have long-term benefits to their overall health and well-being. Winkelman et al[96] showed that youth with any justice involvement (detained, paroled, probation, or arrest) were more likely to have an emergency department (ED) visit in the last year compared with youth not involved with the justice system. Similarly, justice-involved youth are more likely to be hospitalized than their peers, and their use of the ED and inpatient services, as measured in person-years, is significantly higher than that of youth not involved with the justice system.[96] Use of the ED and increased hospitalization days by justice-involved youth may contribute to increased health care costs and represents an opportunity to improve the continuity of care for these youth once they return to their communities. It is ideal for these youth to be connected to medical homes and pediatricians who are prepared to address their needs.

Continuity of care starts at the time of admission to the facility. If the youth already has a primary care provider (PCP), it is crucial for the medical staff to contact the PCP to verify previous diagnoses and treatment(s).[97] For cases in which the youth does not have a PCP, medical staff can provide resources to establish primary care. Providing summaries of medical care for the PCP, appropriate subspecialists, or mental health specialists at the time of release to the community is also important. Additionally, detention facilities and jurisdictions can establish policies and procedures that ensure eligible uninsured youth are enrolled in Medicaid or the Children's Health Insurance Program before release from detention and have access to health care coverage as they reenter their home communities.[98,99]

DEVELOPMENTALLY APPROPRIATE CONFINEMENT FACILITIES

Conditions of Confinement

Youth may be confined in a variety of confinement facilities (short-term detention facilities, long-term secure facilities, camps, residential treatment facilities, etc); however, most are confined in locked facilities, many of which resemble adult jails and prisons in form and function (restricted by gates, fences and locked doors, regular use of restraints such as handcuffs and shackles, locking youth in their room for sleep and/or punishment, use of punitive discipline strategies, etc). For youth with a history of trauma, confinement in such facilities may exacerbate symptomatology related to trauma.[100] The trauma of confinement extends beyond the physical environment. Since 2000, systemic abuses of confined youth have been documented in 29 states.[101] Thirty-eight percent of confined youth fear being physically attacked, 50% report detention staff applies punishments without cause, and 33% report the use of unnecessary force.[101] In 2017, the National Council of Juvenile and Family Court Judges passed a resolution urging states to establish independent monitoring systems (independent bodies responsible for receiving and investigating complaints) for confined youth, with a special focus on the use of isolation, use of mechanical restraints, use of force, access to programming, levels of violence, and access to families.[102] Several jurisdictions have implemented independent monitoring systems for confined youth.[103] The Annie E. Casey Foundation's Juvenile Detention Alternatives Initiative provides guidance and technical assistance for jurisdictions interested in monitoring and improving conditions of confinement.[104]

Isolation and Solitary Confinement

Solitary confinement is "the involuntary placement of a youth alone in a cell, room, or other area for any reason other than as a temporary response to behavior that threatens immediate harm to the youth or others."[105] While in isolation, youth may be denied access to educational material, detention facility programming, recreational activities, and contact with family.[106]

Nationally representative data suggest the use of isolation and solitary confinement is common in juvenile detention facilities. The JRFC found 47% of juvenile detention centers reported locking youth in a room for 4 or more hours within the previous month.[83] The SYRP found 35% of youth reported being held in isolation or solitary confinement.[53] Of those held in isolation, 55% reported being held for more than 24 hours.[53] These reports may understate the use of juvenile isolation and solitary confinement because they do not include youth in adult facilities.

The negative effects of solitary confinement on adults are well documented and may include anxiety, depression, impaired memory, hallucinations, suicidal thoughts, anger, psychosis, paranoia, heart

palpitations, headaches, abdominal pain, and insomnia.[107] The 2009 "Juvenile Suicide in Confinement: A National Survey" highlights this vulnerability.[108] In this report, the authors examined 110 juvenile suicides occurring between 1995 and 1999 and found 62% of suicide victims had a history of room confinement, and 51% were on room confinement status at the time of their death.

In 2016, the US Department of Justice issued guiding principles on the use of isolation and solitary confinement and recommended against the use of isolation and solitary confinement in juveniles, stating, "In very rare situations, a juvenile may be separated from others as a temporary response to behavior that poses a serious and immediate risk of physical harm to any person. Even in such cases, the placement should be brief, designed as a 'cool down' period, and done only in consultation with a mental health professional."[109] In 2018, Congress passed legislation prohibiting the use of room confinement (except as a temporary response for juveniles who pose a serious and immediate risk to themselves or others) for youth in federal facilities.[110] There are few juveniles in federal detention centers, and nonfederal detention centers are not obligated to adhere to these principles.

Many states have passed legislation aimed at restricting or eliminating juvenile isolation. A 2016 analysis by the Lowenstein Center for the Public Interest found that 29 states or jurisdictions prohibit the use of punitive solitary confinement in juvenile detention facilities, 15 states impose time limits on the use of punitive solitary confinement, and 7 states place no limits to the use of solitary confinement.[111] In 2016, the AAP endorsed the United Nations position and the AACAP policy statement on solitary confinement of juvenile offenders and opposed the use of solitary confinement for juveniles in correctional facilities.

Many organizations have developed tools to reduce the use of isolation in juvenile confinement. The Council of Juvenile Correctional Administrators published a tool kit[112] outlining steps to reduce the use of isolation and recommendations to use alternative behavior management options and responses. These options may include cognitive behavioral therapy, dialectical behavior therapy, collaborative problem solving and trauma-informed care, and de-escalation training for juvenile correctional employees, workers, and/or officers.

Educational Needs

Youth involved with the justice system often present with significant educational challenges. The SYRP[53] found that 24% of youth reported they were not enrolled in school at the time they entered custody, 61% had been expelled or suspended, and 48% reported being below the level expected for their age. Learning disabilities are more common among youth in custody, with reported rates as high as 30%.[53]

Despite increased educational need, available data suggest confined youth receive inadequate educational support. A 2016 report from the US Department of Education Office for Civil Rights[113] found the number of hours and days of educational programming varies widely between facilities, teachers working in confinement facilities are more likely to be absent, and confinement facilities are less likely to offer essential math and science courses. The US Department of Education and Department of Justice developed guiding principles for the provision of high-quality education in juvenile justice secure settings.[114]

In multiple studies, authors have documented that youth with intellectual and developmental disabilities are overrepresented in the juvenile justice system. Although there is variance between sites, the estimated national average prevalence of intellectual and developmental disabilities in confined youth is 33%.[115] Confined youth with intellectual and developmental disabilities have the same rights under the Individuals with Disabilities Education Act as nonconfined youth and are entitled to individualized education programs and special education services.[115] The National Center on Criminal Justice and Disability provides recommendations for preventing involvement of adolescents with intellectual and developmental disabilities in the justice system and improving the delivery of special education services for confined youth.[116]

JUVENILE JUSTICE REFORM AND OPPORTUNITIES FOR ADVOCACY

Community-Based Interventions and Alternatives to Youth Confinement

Over the last 2 decades, advances in social, developmental, and neurologic sciences have transformed our understanding of health and well-being across the life course. It is recognized that trauma, adversity, and ACEs are associated with a maladaptive stress response, changes in brain architecture, and poor physical, mental, and behavioral health outcomes.[23,26] Advances in neuroscience and neuroimaging have demonstrated numerous structural and functional changes in the brain occur during the period of adolescence.[117] These changes may be associated with impulsive, risk-taking, and reward-seeking behaviors that may make adolescents more likely to interact with the justice system.

This evolving knowledge has contributed to the development and

implementation of community-based alternatives to incarceration that are more appropriate for the unique developmental needs of justice-involved youth. Numerous reports have highlighted shortcomings associated with the incarceration of juveniles in the United States. The Annie E. Casey Foundation's *No Place For Kids: The Case for Reducing Juvenile Incarceration* argues that juvenile incarceration is dangerous (documented cases of physical and sexual abuse), ineffective (does not decrease involvement in delinquent behaviors), unnecessary (only 26% of youth confined in residential facilities committed a violent offense), obsolete (community-based alternatives have been demonstrated to reduce recidivism), wasteful (in 2008, an estimated $5 billion was spent on juvenile incarceration), and inadequate (deficient in mental health treatment, substance use treatment, educational programming, and transitional support and often retraumatizes youth).[118]

Many jurisdictions responded to these concerns by implementing reforms (diversion programs, mentor programs, implementation of the Juvenile Detention Alternatives Initiative, etc)[118,119] aimed at reducing the rate of juvenile incarceration and improving outcomes for justice-involved youth. The Juvenile Detention Alternatives Initiative is one available resource and tool that provides training and technical assistance to jurisdictions interested in reforming their juvenile justice systems. Examples of community-based alternatives to detention and secure confinement include day and evening reporting centers (providing youth with supervision and programming during the day and/or evening), electronic monitoring, home- or community-based detention, and intensive family treatment models such as multisystemic therapy, functional family therapy, and multidimensional foster care.[118,119]

The Office of Juvenile Justice and Delinquency Prevention[120] advocates for a comprehensive strategy of supporting the adolescent's family and engaging core institutions, such as schools, businesses, and religious organizations, to help develop mature and responsible youth. The strategy of delinquency prevention is the most effective approach while recognizing the need for graduated sanctions to protect the community. The best prevention involves targeting risk factors for delinquency, such as ACEs, childhood trauma, drugs and firearms in the community, family conflict, abuse and neglect, poor commitment to school, and negative peer influences, while focusing on protective factors such as a resilient individual temperament; close relationships with family, teachers, other adults, and peers; and promoting school success and avoidance of drugs and crime.[17,29,118–120]

Overall, there is growing evidence that for many youth, community-based alternatives to incarceration are more effective options than confinement.[118,119] This evidence and overall reductions in youth crime have contributed to significant decreases in the rate of juvenile confinement in the United States.

Juvenile Transfer Laws

Juvenile transfer laws govern the relocation of juvenile cases to adult court. Current juvenile transfer laws were created largely as a result of state legislative actions during the 1980s and 1990s, triggered by a rise in youth crime and intense media focus on juvenile crime during that period.[121] States responded by enacting legislation that automatically placed juveniles in the jurisdiction of the adult court for certain offenses or gave prosecutors discretion to place juveniles in adult court. Although juvenile crime rates have steadily decreased since the mid-1990s, many of the juvenile transfer laws of this era remain in effect.[121]

Although legislators enacted these laws as a deterrent to juvenile crime, evidence suggests that juvenile transfer laws have little or no effect on general juvenile crime rates.[122] Additionally, compared with youth in the juvenile court system, recidivism rates were higher for juveniles with cases in adult criminal court. Recidivism rates were higher particularly for violent offenders.[122] Proposed explanations for increased recidivism rates among youth tried in criminal court include the stigma of having a felony criminal record, less focus on rehabilitation in the adult criminal justice system, and sense of resentment among youth tried and punished as adults.[122]

Currently, all states have transfer laws that allow juvenile offenders to be prosecuted in adult court. The 4 types of transfer laws[7] are as follows:

- statutory exclusion: specific crimes are automatically transferred to adult court;
- judicially controlled transfer: all juvenile cases begin in juvenile court and must be transferred to adult court by the juvenile court;
- prosecutorial discretion: also known as "direct file," prosecutors may choose to file in adult or juvenile court; and
- once an adult, always an adult: once a juvenile has been prosecuted in adult court, all future cases go to adult court.

Juveniles prosecuted in adult court may be confined in adult detention facilities. Juveniles in adult prisons report learning more criminal behavior from adult inmates, fear of victimization, and being least likely to say they would not reoffend. Juveniles in adult facilities, compared with those in juvenile facilities, have an eightfold increase in suicide, fivefold increase in being sexually assaulted,

and twofold increase in likelihood of being attacked with a weapon by other inmates or beaten by staff.[123]

Reform efforts have focused on changing the ways in which juveniles may be transferred to adult court. Advocates argue that statutory exclusion and prosecutorial discretion may limit the juvenile court's ability to provide the most appropriate sanctions for youth. There is also concern that prosecutors may use the threat of adult sanctions to coerce youth to accept plea bargains to avoid longer sentences. Several states have successfully enacted legislation limiting the transfer of juveniles to adult court.[123] For example, in 2012, Colorado enacted legislation limiting juvenile transfer to adult court, allowing for judicial review for all juvenile cases and adding juvenile sentencing provisions to convictions in adult court. In the 5 years after this legislation, Colorado saw a 78% reduction in direct file cases and a 99% reduction in adult jailing of juveniles.[124]

Life Without Parole and Death Penalty

Over the last 15 years, the US Supreme Court issued several decisions limiting extreme sentences for juvenile offenders declaring unconstitutional capital punishment of individuals who committed crimes as a juvenile (under age 18)[125] and abolishing mandatory life without parole sentences for crimes committed as a juvenile; however, it is still permissible to impose life without parole sentences for juveniles after judicial consideration of individual case circumstances.[126] The United States is the only country in the world that sentences juveniles to life without the possibility of parole.[127] Extensive advocacy efforts, including litigation, media campaigns, and legislative advocacy are underway with goals of abolishing juvenile sentences of life without parole in the United States.[128]

Minimum Age of Juvenile Court Jurisdiction

The minimum age of juvenile court jurisdiction is the youngest age at which a child may be referred to a juvenile court for a delinquent act. At the time this policy was written, only 21 states had a minimum age standard, varying from 6 to 11 years of age.[129] In 2017, approximately 29 779 children younger than 12 years were referred to juvenile court, and 3375 were held in detention.[130] Article 40 of the United Nations Convention on the Rights of the Child decrees governments establish "a minimum age below which children shall be presumed not to have the capacity to infringe the penal law"[131] and specified that this age be no younger than 12 years.[132] Many advocates have called for the establishment of state and/or federal laws that set the minimum age of criminal responsibility at no younger than 12 years.[133]

Fines and Fees in the Juvenile Justice System

Juvenile courts throughout the country regularly impose costs that may include court costs, fees for a public defender, probation supervision fees, child support to the state, cost of Global Positioning System monitoring, cost for participation in diversion programs, health care costs, and fines.[134] Low socioeconomic status is a well-established risk factor for involvement with the juvenile justice system, and imposition of such costs may place an undue burden on justice-involved youth and their families.[17] Furthermore, inability or failure to pay these costs may lead to significant consequences for justice-involved youth, including civil judgment, extension of probation, violation of probation, incarceration, suspension of driver's license, ineligibility for expungement, and imposition of additional fees.[135]

Access to Legal Representation

Children and adolescents accused of crimes have a constitutional right to legal counsel regardless of their ability to pay.[136] However, youth may encounter many barriers to obtaining adequate legal representation. An analysis by the National Juvenile Defender Center[137] found the following:

- only 11 states have a presumption that youth are automatically eligible for an attorney irrespective of financial status;
- no states guarantee lawyers for youth during interrogation; and
- 43 states allow youth to waive their right to a lawyer without first consulting a lawyer.

Youth without adequate access to legal representation throughout their involvement in the justice system may not fully understand their rights and may be influenced to make decisions that are not in their best interest. Recommendations made by the National Juvenile Defender Center[137] include making all youth eligible for a publicly funded juvenile defender, appointing youth a lawyer before interrogation and well in advance of the first court hearing, and prohibiting waiver of counsel until youth have the chance to consult with a lawyer.

Empowerment of Justice-Involved Youth

Decades of research have been conducted on risk factors for juvenile delinquency, protective factors, and outcomes for justice-involved youth; however, until recently, the voices of justice-involved youth have been largely absent from juvenile justice research and policy.[138] Justice-involved youth are the experts of their lived experience and have unique insight into the strengths and weaknesses of the juvenile justice system. Justice-involved youth have

demonstrated that when given the opportunity, they can provide both insight into the root causes of juvenile delinquency and offer recommendations for improvement of the juvenile justice system.[138,139]

RECOMMENDATIONS

The following recommendations are provided for caring and advocating for justice-involved youth and their families.

Delivery of Care

- Confined youth should receive the same level and standards of medical, oral, mental health, and substance use care as nonconfined youth accessing care in their communities. Pediatricians should ensure that confidential health care is practiced in accordance with state and local laws, even in correction health clinics.
- All juvenile correctional facilities should adopt and comply with the NCCHC's "Standards for Health Services in Juvenile Detention and Confinement Facilities."
- Facilities should provide youth who are confined for more than 1 week comprehensive preventive services, including a comprehensive history and physical examination; mental health and substance use screening; dental screening; vision screening; pregnancy screening with options counseling; the full range of contraception, including emergency contraception; vaccines; STI and/or HIV testing; adequate pregnancy care; and management of chronic health conditions. Care should be affirming and appropriate for all youth, including those who identify as LGBTQ.
- Consistent with NCCHC recommendations, transgender youth who received hormone therapy before incarceration should have therapy continued without interruption, absent urgent medical reasons to cease treatment.
- All juvenile facilities should implement a comprehensive suicide prevention program that includes ongoing suicide risk assessment.
- Whenever possible, the pediatrician from the medical home should be notified when an adolescent is admitted and discharged from a detention facility. In cases in which confined youth do not have a pediatrician, efforts should be made to establish care in a medical home.
- Strict limits should be placed on the use of restraints for pregnant and hospitalized adolescents.
- Incarcerated youth should maintain eligibility for their existing health insurance benefits. If insurance eligibility is terminated or suspended during confinement, it should be reinstated before release. Eligible uninsured youth should be enrolled in Medicaid while incarcerated.
- Legislation repealing the Medicaid inmate exclusion policy should be supported, thus allowing Medicaid coverage for incarcerated children and adolescents.

Developmentally Appropriate Confinement Facilities

- Children and adolescents should be detained or incarcerated only in facilities with developmentally appropriate programs with staff who are trained to deal with their unique mental health, social, educational, recreational, and supervisory needs and should not be detained in adult facilities.
- Detention facilities and juvenile justice systems should implement a trauma-informed approach that responds to the needs of justice-involved youth and their families.
- Consistent with recommendations of the US Department of Education and Department of Justice, education in confinement facilities should be provided in "a safe, healthy facility-wide climate that prioritizes education, provides the conditions for learning, and encourages the necessary behavioral and social support services that address the individual needs of all youths, including those with disabilities and English learners."[114]
- Use of isolation and solitary confinement for children and adolescents should be prohibited.
- Because of documented cases of systemic and recurring maltreatment of confined youth, jurisdictions should establish independent oversight entities for youth confinement facilities.
- Confinement facilities should recognize and respond to the unique needs of justice-involved female youth, LGBTQ youth, and youth with chronic medical, mental health, and developmental needs.

Advocacy and Juvenile Justice Reform

Many opportunities exist for pediatricians to advocate for juvenile justice reform. Pediatricians can work with the AAP chapter in their state, justice-involved youth and their families, the juvenile justice sections of their state judiciary and bar, state and local governmental officials, detention facilities, and community organizations serving justice-involved youth. Although key issues may vary between jurisdictions, priority targets for juvenile justice reform may include the following recommendations:

- Incarceration of adolescents is a last resort and only for offenders who have committed serious crimes and cannot be safely placed in a community-based program.
- Support research and advocacy efforts aimed at eliminating racial and ethnic disparities within the justice system. Research and

advocacy efforts should include an examination of racial and/or ethnic bias throughout the justice system and focus on delinquency prevention by mitigating the impact of interpersonal and structural racism.

- Support legislation that establishes a minimum age of (at least) 12 years for criminal responsibility under which a person may not be charged with a crime.
- Support legislation abolishing sentencing of adolescents to life without the possibility of parole.
- Support legislation reducing and/or eliminating the imposition of fees and fines for justice-involved youth and their families.
- Support legislation ensuring all justice-involved youth receive adequate and timely legal representation.
- Advocate for adolescents to be prosecuted in the juvenile justice system. Transfer to the adult court should occur only after judicial review. A youth's mental health status and exposure to trauma, adversity, and ACEs should be considered as mitigating factors.
- Advocate for research to identify risk factors for involvement with the justice system, protective factors, outcomes for incarcerated youth, and effectiveness of community-based alternatives to incarceration and use resulting data to make evidence-based juvenile justice policy reforms.
- Engage justice-involved youth and families as advocates for juvenile delinquency prevention and juvenile justice reform.

LEAD AUTHORS

Mikah C. Owen, MD, MPH, FAAP
Stephenie B. Wallace, MD, MSPH, FAAP

COMMITTEE ON ADOLESCENCE, 2019–2020

Elizabeth M. Alderman, MD, FAAP, FSAHM, Chairperson
Richard Chung, MD, FAAP
Laura K. Grubb, MD, MPH, FAAP
Janet Lee, MD, FAAP
Makia E. Powers, MD, MPH, FAAP
Maria H. Rahmandar, MD, FAAP
Krishna K. Upadhya, MD, FAAP
Stephenie B. Wallace, MD, MSPH, FAAP

FORMER COMMITTEE MEMBER

Cora C. Breuner, MD, MPH, FAAP, Immediate Past Chairperson

LIAISONS

Liwei L. Hua, MD, PhD – *American Academy of Child and Adolescent Psychiatry*
Ellie Vyver, MD – *Canadian Paediatric Society*
Geri Hewitt, MD – *American College of Obstetricians and Gynecologists*
Seema Menon, MD – *North American Society of Pediatric and Adolescent Gynecology*
Lauren B. Zapata, PhD, MSPH – *Centers for Disease Control and Prevention*

STAFF

Karen Smith
James Baumberger, MPP

ABBREVIATIONS

AACAP: American Academy of Child and Adolescent Psychiatry
AAP: American Academy of Pediatrics
ACE: adverse childhood experience
ACOG: American College of Obstetricians and Gynecologists
ED: emergency department
JJDPA: Juvenile Justice Delinquency and Prevention Act
JRFC: Juvenile Residential Facility Census
LGBTQ: lesbian, gay, bisexual, transgender, and queer and/or questioning
NCCHC: National Commission on Correctional Health Care
PCP: primary care provider
STI: sexually transmitted infection
SYRP: Survey of Youth in Residential Placement

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Law enforcement & juvenile crime. Juvenile arrests: estimated number of juvenile arrests, 2017. Available at: https://www.ojjdp.gov/ojstatbb/crime/qa05101.asp?qaDate=2017. Accessed December 18, 2019
2. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Law enforcement & juvenile crime. Trends in the number of arrests by age group for all offenses. Available at: https://www.ojjdp.gov/ojstatbb/crime/ucr_trend.asp?table_in=1. Accessed December 18, 2019
3. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Detained delinquency cases, 1985–2017. Available at: https://www.ojjdp.gov/ojstatbb/court/qa06301.asp?qaDate=2018&text=yes. Accessed May 20, 2020
4. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Juveniles in corrections. Time in placement: median days in placement since admission, by placement status, 1997-2017. Available at: https://www.ojjdp.gov/ojstatbb/corrections/qa08405.asp?qaDate=2017. Accessed December 18, 2019

5. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Juvenile justice system structure & process. Case flow diagram. Available at: https://www.ojjdp.gov/ojstatbb/structure_process/case.html. Accessed December 18, 2019
6. National Center for Juvenile Justice; Office of Juvenile Justice and Delinquency Prevention. Juvenile offenders and victims: 2014 national report. 2014. Available at: https://www.ojjdp.gov/ojstatbb/nr2014/downloads/NR2014.pdf. Accessed December 18, 2019
7. National Conference of State Legislatures. Juvenile age of jurisdiction and transfer to adult court laws. Available at: www.ncsl.org/research/civil-and-criminal-justice/juvenile-age-of-jurisdiction-and-transfer-to-adult-court-laws.aspx. Accessed December 18, 2019
8. National Research Council; Division of Behavioral and Social Sciences and Education; Committee on Law and Justice; Committee on a Prioritized Plan to Implement a Developmental Approach in Juvenile Justice Reform. *Implementing Juvenile Justice Reform: The Federal Role*. Washington, DC: National Academies Press; 2014
9. Juvenile Justice Reform Act of 2018, HR 6964, 115th Cong (2017–2018). Publ L No. 115-385. Available at: https://www.congress.gov/115/bills/hr6964/BILLS-115hr6964enr.pdf. Accessed December 18, 2019
10. Federal Interagency Forum on Child and Family Statistics. POP3 race and Hispanic origin composition: percentage of U.S. children ages 0–17 by race and Hispanic origin, 1980–2018 and projected 2019–2050. Available at: https://www.childstats.gov/americaschildren/tables/pop3.asp. Accessed December 18, 2019
11. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Racial and ethnic fairness: juvenile arrest rates by race, 1980–2018. Available at: https://www.ojjdp.gov/ojstatbb/special_topics/qa11502.asp?qaDate=2018&text=yes . Accessed May 20, 2020
12. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Racial and ethnic fairness: case processing characteristics of delinquency offenses by race, 2018. Available at: https://www.ojjdp.gov/ojstatbb/special_topics/qa11601.asp?qaDate=2018
13. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Racial and ethnic fairness: juvenile residential placement rates by race/ethnicity, 1997–2017. Available at: https://www.ojjdp.gov/ojstatbb/special_topics/qa11801.asp?qaDate=2017&text=yes . Accessed May 20, 2020
14. Hockenberry S. *Juveniles in Residential Placement, 2015*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, US Department of Justice; 2018
15. Hockenberry S, Puzzanchera C. *Juvenile Court Statistics 2015*. Pittsburgh, PA: National Center for Juvenile Justice; 2018
16. Developmental Services Group, Inc. *Disproportionate Minority Contact*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, US Department of Justice; 2014. Available at: https://www.ojjdp.gov/mpg/litreviews/Disproportionate_Minority_Contact.pdf. Accessed December 18, 2019
17. Committee on Assessing Juvenile Justice Reform; Committee on Law and Justice; Division of Behavioral and Social Sciences and Education; National Research Council. In: Bonnie R, Johnson R, Chemers B, Schuck J, eds. *Reforming Juvenile Justice: A Developmental Approach*. Washington, DC: National Academies Press; 2013
18. Kakade M, Duarte C, Liu X, et al. Adolescent substance use and other illegal behaviors and racial disparities in criminal justice system involvement: findings from a US national survey. *Am J Public Health*. 2012;102(7):1307–1310
19. Spinney E, Cohen M, Feyerherm W, Stephenson R, Yeide M, Shreve T. Disproportionate minority contact in the U.S. juvenile justice system: a review of the DMC literature, 2001–2014, Part 1. *J Crime Justice*. 2018;41(5):596–626
20. Trent M, Dooley D, Dougé J; Section on Adolescent Health; Council on Community Pediatrics; Committee on Adolescence. The impact of racism on child and adolescent health. *Pediatrics*. 2019;144(2):e20191765
21. Council on Community Pediatrics. Poverty and child health in the United States. *Pediatrics*. 2016;137(4):e20160339
22. Council on Community Pediatrics and Committee on Native American Child Health. Policy statement--health equity and children's rights. *Pediatrics*. 2010;125(4):838–849
23. Garner AS, Shonkoff JP; Committee on Psychosocial Aspects of Child and Family Health; Committee on Early Childhood, Adoption, and Dependent Care; Section on Developmental and Behavioral Pediatrics. Early childhood adversity, toxic stress, and the role of the pediatrician: translating development science into lifelong health. *Pediatrics*. 2012;129(1). Available at: www.pediatrics.org/cgi/content/full/129/1/e224
24. Baglivio M, Epps N, Swartz K, Huq M, Sheer A, Hardt N. The prevalence of adverse childhood experiences (ACE) in the lives of juvenile offenders. *J Juv Justice*. 2014;3(2):1–23
25. Kerig PK, Ford JD. *Trauma Among Girls in the Juvenile Justice System*. Los Angeles, CA: National Child Traumatic Stress Network; 2014. Available at www.nctsn.org/sites/default/files/assets/pdfs/trauma_among_girls_in_the_jj_system_2014.pdf. Accessed December 18, 2019
26. Bucci M, Marques S, Oh D, Harris N. Toxic stress in children and adolescents. *Adv Pediatr*. 2016;63(1):403–428
27. Dierkhising C, Ko S, Woods-Jaeger B, Briggs E, Lee R, Pynoos R. Trauma histories among justice-involved youth: findings from the National Child Traumatic Stress Network. *Eur J Psychotraumatol*. 2013;4
28. National Child Traumatic Stress Network. *Essential Elements of a Trauma-Informed Juvenile Justice System*. Los Angeles, CA: National Child

Traumatic Stress Network; 2015. Available at: https://www.nctsn.org/sites/default/files/resources//essential_elements_trauma_informed_juvenile_justice_system.pdf. Accessed December 18, 2019

29. US Department of Justice. *Report of the Attorney General's National Task Force on Children Exposed to Violence.* Washington, DC: US Department of Justice; 2012. Available at: https://www.justice.gov/defendingchildhood/cev-rpt-full.pdf. Accessed December 18, 2019
30. Puzzanchera C, Ehreman S; National Center for Juvenile Justice. *Spotlight on Girls in the Juvenile Justice System Snapshot.* Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2018. Available at: https://www.ojjdp.gov/ojstatbb/snapshots/DataSnapshot_GIRLS2015.pdf. Accessed December 18, 2019
31. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Law enforcement & juvenile crime. Juvenile arrests: demographic characteristics of juvenile arrests, 2017. Available at: https://www.ojjdp.gov/ojstatbb/crime/qa05104.asp?qaDate=2017&text=yes. Accessed January 3, 2020
32. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. Juveniles in corrections. Demographics: female proportion of juveniles in residential placement, 2017. Available at: https://www.ojjdp.gov/ojstatbb/corrections/qa08202.asp?qaDate=2017&text=yes. Accessed January 3, 2020
33. The Children's Partnership; Robert F. Kennedy National Resource Center for Juvenile Justice. *Building a Brighter Future for Youth With Dual Status: A Policy Roadmap Forward.* Boston, MA: The Children's Partnership/Robert F. Kennedy National Resource Center for Juvenile Justice; 2018. Available at: https://rfknrcjj.org/wp-content/uploads/2018/11/Building-a-Brighter-Future-For-Youth-with-Dual-Status-A-Policy-Roadmap.pdf. Accessed December 18, 2019
34. US Department of Justice; Office of Justice Programs; Office of Juvenile Justice and Delinquency Prevention. *Policy Guidance: Girls and the Juvenile Justice System.* Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2015
35. Development Services Group, Inc. *LGBTQ Youths in the Juvenile Justice System.* Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2014. Available at: https://www.ojjdp.gov/mpg/litreviews/LGBTQYouthsintheJuvenileJusticeSystem.pdf. Accessed December 18, 2019
36. Majd K, Marksamer J, Reyes C. *Hidden Injustice: Lesbian, Gay, Bisexual and Transgender Youth in Juvenile Courts.* San Francisco, CA: Legal Services for Children/National Juvenile Defender Center/National Center for Lesbian Rights; 2009. Available at: www.nclrights.org/wp-content/uploads/2014/06/hidden_injustice.pdf. Accessed December 18, 2019
37. Wilber S. *A Guide to Juvenile Detention Reform: Lesbian, Gay, Bisexual and Transgender Youth in the Juvenile Justice System.* Baltimore, MD: Annie E. Casey Foundation; 2015. Available at https://www.aecf.org/m/resourcedoc/AECF-lesbiangaybisexualandtransgenderyouthinjj-2015.pdf. Accessed December 18, 2019
38. Irvine A. 'We've had three of them': addressing the invisibility of lesbian, gay, bisexual and gender non-conforming youths in the juvenile justice system. *Columbia J Gend Law.* 2010;19(3):675–701
39. Beck A, Cantor D. *Sexual Victimization in Juvenile Facilities Reported by Youth, 2012: National Survey of Youth in Custody, 2012.* Washington, DC: Bureau of Justice Statistics, US Department of Justice; 2013
40. Movement Advancement Project; Center for American Progress; Youth First. Unjust: LGBTQ Youth Incarcerated in The Juvenile Justice System. Washington, DC: Center for American Progress; 2017. Available at: https://www.lgbtmap.org/file/lgbtq-incarcerated-youth.pdf. Accessed May 20, 2020
41. US Department of Justice. Prison Rape Elimination Act. 28 CFR §115 (2012). Available at: https://www.prearesourcecenter.org/sites/default/files/content/preafinalstandardstype-juveniles.pdf. Accessed December 18, 2019
42. Bergen S, Chiu L, Curry T, Gilbert C, Reyes C, Wilber S; The Equity Project. *Toward Equity: A Training Curriculum For Understanding Sexual Orientation, Gender Identity, and Gender Expression, and Developing Competency to serve Lesbian, Gay, Bisexual, and Transgender Youth in the Juvenile Justice System.* Washington, DC: The Equity Project; 2015. Available at: www.equityproject.org/wp-content/uploads/2015/01/Equity_Curriculum_Complete.pdf. Accessed December 18, 2019
43. Routh D, Abess G, Makin D, Stohr M, Hemmens C, Yoo J. Transgender inmates in prisons. *Int J Offender Ther Comp Criminol.* 2017;61(6):645–666
44. National Commission on Correctional Health Care. *Transgender, Transsexual, and Gender Nonconforming Health Care in Correctional Settings.* Chicago, IL: National Commission on Correctional Health Care; 2015. Available at: https://www.ncchc.org/transgender-transsexual-and-gender-nonconforming-health-care. Accessed December 18, 2019
45. Hyland N. *JJGPS StateScan: Dual Status Youth: Data Integration to Support System Integration.* Pittsburgh, PA: National Center for Juvenile Justice; 2016. Available at: www.ncjj.org/pdf/JJGPS%20StateScan/JJGPS_U.S._Dual_Status_Youth_Data_Integration_2016_10.pdf. Accessed December 18, 2019
46. Thomas D; When Systems Collaborate. *How Three Jurisdictions Improved Their Handling of Dual-Status Cases.* Pittsburgh, PA: National Center for Juvenile Justice; 2015
47. Umpierre M. Rights and responsibilities of youth, families, and staff. In: National Institutes of Corrections, ed. *Desktop Guide to Quality Practice for Working With Youth in Confinement.* Washington, DC: National Partnership for Juvenile Services/Office of Juvenile Justice and Delinquency Prevention; 2014. Available at https://info.nicic.gov/dtg/node/11. Accessed December 18, 2019
48. Rold W. Thirty years after *Estell v. Gamble*: a legal retrospective. *J Correct Health Care.* 2008;14(1):11–20

49. Perry R, Morris R. Health care for youth involved with the correctional system. *Prim Care*. 2014;41(3):691–705

50. Acoca L, Stephens J, Van Vleet A. *Health Coverage and Care for Youth in the Juvenile Justice System: The Role of Medicaid and CHIP*. Menlo Park, CA: Kaiser Family Foundation; 2014

51. National Commission on Correctional Health Care. *Standards for Health Services in Juvenile Detention and Confinement Facilities*. Chicago, IL: National Commission on Correctional Health Care; 2015

52. Committee on Adolescence. Health care for youth in the juvenile justice system [published correction appears in *Pediatrics*. 2012;129(3):595]. *Pediatrics*. 2011;128(6):1219–1235

53. Sedlak A, McPherson K. *Survey of Youth in Residential Placement: Youth's Needs and Services*. Rockville, MD: Westat; 2010

54. Barnert E, Perry R, Morris R. Juvenile incarceration and health. *Acad Pediatr*. 2016;16(2):99–109

55. Morris R, Harrison E, Knox G, Tromanhauser E, Marquis D, Watts L. Health risk behavioral survey from 39 juvenile correctional facilities in the United States. *J Adolesc Health*. 1995; 17(6):334–344

56. Donaldson A, Burns J, Bradshaw C, Ellen J, Maehr J. Screening juvenile justice-involved females for sexually transmitted infection: a pilot intervention for urban females in community supervision. *J Correct Health Care*. 2013;19(4):258–268

57. Gray S, Holmes K, Bradford D. Factors associated with pregnancy among incarcerated African American adolescent girls. *J Urban Health*. 2016; 93(4):709–718

58. Grubb L, Beyda R, Eissa M, Benjamins L. A contraception quality improvement initiative with detained young women: counseling, initiation, and utilization. *J Pediatr Adolesc Gynecol*. 2018;31(4): 405–410

59. Danielson C, Walsh K, McCauley J, et al. HIV-related sexual risk behavior among African American adolescent girls. *J Womens Health (Larchmt)*. 2014;23(5): 413–419

60. Committee on Adolescence. Contraception for adolescents. *Pediatrics*. 2014;134(4). Available at: www.pediatrics.org/cgi/content/full/134/4/e1244

61. Committee on Health Care for Underserved Women of American College Obstetricians and Gynecologists. ACOG Committee Opinion No. 511: Health care for pregnant and postpartum incarcerated women and adolescent females. Obstet Gynecol. 2011;118(5):1198-1202. doi:10.1097/AOG.0b013e31823b17e3 (Reaffirmed in 2016)

62. American Medical Association. *An "Act to Prohibit the Shackling of Pregnant Prisoners." Model State Legislation*. Chicago, IL: American Medical Association; 2015. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/specialty%20group/arc/shackling-pregnant-prisoners-issue-brief.pdf. Accessed December 18, 2019

63. American Academy of Pediatrics. Tuberculosis. In: Kimberlin D, Brady M, Jackson M, Long S, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*, 31st ed. Itasca, IL: American Academy of Pediatrics; 2018:829–853

64. Centers for Disease Control and Prevention (CDC); National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Prevention and control of tuberculosis in correctional and detention facilities: recommendations from CDC. Endorsed by the Advisory Council for the Elimination of Tuberculosis, the National Commission on Correctional Health Care, and the American Correctional Association. *MMWR Recomm Rep*. 2006;55(RR):1–44

65. Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2011*. Atlanta, GA: US Department of Health and Human Services; 2012

66. Centers for Disease Control and Prevention. HIV and youth. Available at: https://www.cdc.gov/hiv/group/age/youth/index.html. Accessed December 18, 2019

67. Gaskin G, Glanz J, Binswanger I, Anoshiravani A. Immunization coverage among juvenile justice detainees. *J Correct Health Care*. 2015;21(3): 265–275

68. Balogun T, Troisi C, Swartz M, Lloyd L, Beyda R. Does juvenile detention impact health? *J Correct Health Care*. 2018; 24(2):137–144

69. Underwood L, Washington A. Mental illness and juvenile offenders. *Int J Environ Res Public Health*. 2016;13(2): 228

70. Shufelt J, Cocozza J. *Youth With Mental Health Disorders in the Juvenile Justice System: Results from a Multi-State Prevalence Study. Research and Program Brief*. New York, NY: National Center for Mental Health and Juvenile Justice; 2006

71. Harzke A, Baillargeon J, Baillargeon G, et al. Prevalence of psychiatric disorders in the Texas juvenile correctional system. *J Correct Health Care*. 2012;18(2):143–157

72. Development Services Group, Inc. *Intersection Between Mental Health and the Juvenile Justice System*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2017. Available at: https://www.ojjdp.gov/mpg/litreviews/Intersection-Mental-Health-Juvenile-Justice.pdf. Accessed December 18, 2019

73. Abram KM, Teplin LA, King DC, et al. *PTSD, Trauma, and Comorbid Psychiatric Disorders in Detained Youth*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2013. Available at: https://www.ojjdp.gov/pubs/239603.pdf. Accessed December 18, 2019

74. Barnert E, Abrams L, Bath E. Solving the high unmet behavioral health treatment needs of adolescents involved in the justice system. *J Adolesc Health*. 2019; 64(6):687–688

75. White L, Aalsma M, Salyers M, et al. Behavioral health service utilization among detained adolescents: a meta-analysis of prevalence and potential moderators. *J Adolesc Health*. 2019; 64(6):700–708

76. Grasso D, Ford J, Briggs-Gowan M. Early life trauma exposure and stress sensitivity in young children. *J Pediatr Psychol*. 2013;38(1):94–103

77. Ford J, Elhai J, Connor D, Frueh B. Poly-victimization and risk of posttraumatic,

depressive, and substance use disorders and involvement in delinquency in a national sample of adolescents. *J Adolesc Health*. 2010; 46(6):545–552

78. National Center for Mental Health and Juvenile Justice. Trauma among youth in the juvenile justice system. 2016. Available at: https://www.ncmhjj.com/wp-content/uploads/2016/09/Trauma-Among-Youth-in-the-Juvenile-Justice-System-for-WEBSITE.pdf. Accessed December 18, 2019
79. Cannon Y, Hsi A. Disrupting the path from childhood trauma to juvenile justice: an upstream health and justice approach. *Fordham Urban Law J*. 2016; 43(3):425–493
80. D'Andrea W, Ford J, Stolbach B, Spinazzola J, van der Kolk B. Understanding interpersonal trauma in children: why we need a developmentally appropriate trauma diagnosis. *Am J Orthopsychiatry*. 2012; 82(2):187–200
81. Johnston L, Miech R, O'Malley P, Bachman J, Schulenberg J, Patrick M. *Monitoring the Future National Survey Results on Drug Use 1975–2018: Overview, Key Findings on Adolescent Drug Use*. Ann Arbor, MI: Institute for Social Research, University of Michigan; 2019
82. Development Services Group, Inc. *Diversion From Formal Juvenile Court Processing*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2017. Available at: https://www.ojjdp.gov/mpg/litreviews/Diversion_Programs.pdf. Accessed December 18, 2019
83. Hockenberry S, Wachter A, Sladky A. *Juvenile Residential Facility Census, 2014: Selected Findings*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2016. Available at: https://ojjdp.ojp.gov/sites/g/files/xyckuh176/files/pubs/250123.pdf. Accessed December 18, 2019
84. American Academy of Child and Adolescent Psychiatry. AACAP position statement on oversight of psychotropic medication use for children in state custody: a best principles guideline. Available at: https://www.aacap.org/App_Themes/AACAP/docs/clinical_practice_center/systems_of_care/FosterCare_BestPrinciples_FINAL.pdf. Accessed December 18, 2019
85. Penn J, Thomas C. Practice parameter for the assessment and treatment of youth in juvenile detention and correctional facilities. *J Am Acad Child Adolesc Psychiatry*. 2005;44(10): 1085–1098
86. Cohen E, Pfeifer J, Wallace N. Use of psychiatric medications in juvenile detention facilities and the impact of state placement policy. *J Child Fam Stud*. 2014;23:738–744
87. Lyons C, Wasserman G, Olfson M, McReynolds L, Musabegovic H, Keating J. Psychotropic medication patterns among youth in juvenile justice. *Adm Policy Ment Health*. 2013;40(2):58–68
88. Jonas B, Gu Q, Albertorio-Diaz J. Psychotropic medication use among adolescents: United States, 2005-2010. *NCHS Data Brief*. 2013;(135):1–8
89. Abram KM, Choe JY, Washburn JJ, et al. Suicidal thoughts and behaviors among detained youth. 2014. Available at: https://ojjdp.ojp.gov/sites/g/files/xyckuh176/files/pubs/243891.pdf. Accessed December 18, 2019
90. Stokes M, McCoy K, Abram K, Byck G, Teplin L. Suicidal ideation and behavior in youth in the juvenile justice system: a review of the literature. *J Correct Health Care*. 2015;21(3):222–242
91. US Department of Justice; Office of Juvenile Justice and Delinquency Prevention. *Juvenile Suicide in Confinement: A National Survey*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2009. Available at: www.ncjrs.gov/pdffiles1/ojjdp/213691.pdf. Accessed December 18, 2019
92. Gallagher C, Dobrin A. Facility-level characteristics associated with serious suicide attempts and deaths from suicide in juvenile justice residential facilities. *Suicide Life Threat Behav*. 2006;36(3):363–375
93. Hayes LM. Characteristics of juvenile suicide in confinement. 2009. Available at: www.ncjrs.gov/pdffiles1/ojjdp/214434.pdf. Accessed December 18, 2019
94. Acoca L, Stephens J, Van Vleet A. *Health Coverage and Care for Youth in the Juvenile Justice System: The Role of Medicaid and CHIP*. Menlo Park, CA: Kaiser Family Foundation; 2014. Available at: https://www.kff.org/medicaid/issue-brief/health-coverage-and-care-for-youth-in-the-juvenile-justice-system-the-role-of-medicaid-and-chip/. Accessed December 18, 2019
95. SUPPORT for Patients and Communities Act, HR 6, 115th Cong (2017–2018). Available at: https://www.congress.gov/bill/115th-congress/house-bill/6. Accessed December 18, 2019
96. Winkelman T, Genao I, Wildeman C, Wang E. Emergency department and hospital use among adolescents with justice system involvement. *Pediatrics*. 2017;140(5):e20171144
97. Beyda R, Balogun T, Trojan N, Eissa M. Medical homes for detained youth. *J Adolesc Health*. 2015;56(2):S16–S17
98. Aalsma M, Anderson V, Schwartz K, et al. Preventive care use among justice-involved and non-justice-involved youth. *Pediatrics*. 2017;140(5): e20171107
99. Zemel S, Mooney K, Justice D, Baudouin K; National Academy for State Health Policy. *Facilitating Access to Health Care Coverage for Juvenile Justice-Involved Youth. Models for Change. Systems Reform in Juvenile Justice*. Washington, DC: National Academy for State Health Policy; 2013. Available at: https://nashp.org/wp-content/uploads/sites/default/files/Facilitating_Access_to_Health_Care_Coverage.pdf. Accessed December 18, 2019
100. Burrell S. *Trauma and the Environment of Care in Juvenile Institutions*. Los Angeles, CA: National Center for Child Traumatic Stress; 2013. Available at https://www.nctsn.org/sites/default/files/resources//trauma_and_environment_of_care_in_juvenile_institutions.pdf. Accessed December 18, 2019
101. Mendel RA. *Maltreatment of Youth in U.S. Juvenile Corrections Facilities: An Update*. Baltimore, MD: The Annie E. Casey Foundation; 2015. Available at https://www.aecf.org/m/resourcedoc/aecf-maltreatmentyouthuscorrections-2015.pdf. Accessed December 18, 2019
102. National Council of Juvenile and Family Court Judges. Resolution regarding the need for independent oversight of youth confinement facilities. 2017. Available at: https://www.ncjfcj.org/wp-

content/uploads/2019/08/regarding-the-need-for-independent-oversight-of-youth-confinement-facilities.pdf. Accessed May 20, 2020

103. Center for Children's Law and Policy. Independent monitoring systems for juvenile facilities. 2012. Available at: www.cclp.org/wp-content/uploads/2016/06/IM.pdf. Accessed December 18, 2019

104. The Annie E. Casey Foundation. Juvenile Detention Alternatives Initiative (JDAI). Available at: https://www.aecf.org/work/juvenile-justice/jdai/. Accessed December 18, 2019

105. Stop Solitary for Kids. Position statement with supporters. Available at: https://www.stopsolitaryforkids.org/wp-content/uploads/2017/03/Position-Statement-with-Supporters-7-6-18.pdf. Accessed December 18, 2019

106. American Civil Liberties Union. *Alone & Afraid: Children Held in Solitary Confinement and Isolation in Juvenile Detention and Correctional Facilities*. New York, NY: American Civil Liberties Union; 2014. Available at: https://www.aclu.org/report/alone-afraid. Accessed December 18, 2019

107. Smith P. The effects of solitary confinement on prison inmates: a brief history and review of the literature. *Crime Justice*. 2006;34(1):441–568

108. Hayes LM. *Juvenile Suicide in Confinement: A National Survey*. Washington, DC: Office of Juvenile Delinquency and Prevention; 2009. Available at: https://www.ncjrs.gov/pdffiles1/ojjdp/213691.pdf. Accessed December 18, 2019

109. US Department of Justice. U.S. Department Justice report and recommendations concerning the use of restrictive housing. 2016. Available at: https://www.justice.gov/archives/dag/file/815551/download. Accessed December 18, 2019

110. First Step Act, S 3649, 115th Cong, 2nd Sess (2017–2018) Available at: https://www.congress.gov/bill/115th-congress/senate-bill/3649/text?q=%7B%22search%22%3A%5B%22S.+3649%22%5D%7D&r=1#toc-iddf565a43-5d49-48a4-9f05-011eb4e57668. Accessed December 18, 2019

111. Kraner NJ, Barrowclough ND, Weiss C, Fisch J; Lowenstein Center for the Public Interest. 51 – jurisdiction survey of juvenile solitary confinement rules in juvenile justice systems. 2016. Available at: https://www.lowenstein.com/media/2825/51-jurisdiction-survey-of-juvenile-solitary-confinement-rules-72616.pdf. Accessed December 18, 2019

112. Council of Juvenile Correctional Administrators. Council of Juvenile Correctional Administrators Toolkit: reducing the use of isolation. 2015. Available at: http://dcfs.nv.gov/uploaded Files/dcfsnvgov/content/Programs/JJS/CJCA%20Toolkit%20Reducing%20the%20use%20of%20Isolation.pdf. Accessed December 18, 2019

113. US Department of Education and Office of Civil Rights. Protecting the civil rights of students in the juvenile justice system. 2016. Available at: https://www2.ed.gov/about/offices/list/ocr/docs/2013-14-juvenile-justice.pdf. Accessed December 18, 2019

114. US Department of Education; US Department of Justice. Guiding principles for providing high-quality education in juvenile justice secure care settings. 2014. Available at: https://www2.ed.gov/policy/gen/guid/correctional-education/guiding-principles.pdf. Accessed December 18, 2019

115. Developmental Services Group, Inc. *Youths With Intellectual and Developmental Disabilities in the Juvenile Justice System*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2017. Available at: https://www.ojjdp.gov/mpg/litreviews/Intellectual-Developmental-Disabilities.pdf. Accessed December 18, 2019

116. The Arc National Center on Criminal Justice and Disability. *Violence, Abuse and Bullying Affecting People With Intellectual/Developmental Disabilities: A Call to Action for the Criminal Justice Community*. Washington, DC: The Arc National Center on Criminal Justice and Disability; 2015. Available at: https://thearc.org/wp-content/uploads/forchapters/NCCJD%20White%20Paper%20%231%20Violence%20Abuse%20Bullying_5.pdf. Accessed December 18, 2019

117. Balvin N, Banati P, eds. The adolescent brain: a second window of opportunity - a compendium. 2017. Available at: https://www.unicef-irc.org/publications/933-the-adolescent-brain-a-second-window-of-opportunity-a-compendium.html. Accessed December 18, 2019

118. Mendel RA. *No Place for Kids: The Case for Reducing Juvenile Incarceration*. Baltimore, MD: The Annie E. Casey Foundation; 2011. Available at https://www.aecf.org/resources/no-place-for-kids-full-report/. Accessed December 18, 2019

119. McCarthy P, Schiraldi V, Shark M. *The Future of Youth Justice: A Community-Based Alternative to the Youth Prison Model*. Washington, DC: US Department of Justice, National Institute of Justice; 2016. Available at: https://www.ncjrs.gov/pdffiles1/nij/250142.pdf. Accessed December 18, 2019

120. US Department of Justice; Office of Juvenile Justice and Delinquency Prevention. *OJJPD Research: Making a Difference for Juveniles*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 1999. Available at: www.ncjrs.gov/pdffiles1/177602.pdf. Accessed December 18, 2019

121. Griffin P, Addie S, Adams B, Firestine K. *Trying Juveniles as Adults: An Analysis of State Transfer Laws and Reporting*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2011. Available at: https://www.ncjrs.gov/pdffiles1/ojjdp/232434.pdf. Accessed December 18, 2019

122. Redding R. *Juvenile Transfer Laws: An Effective Deterrent To Delinquency?*. Washington, DC: Office of Juvenile Justice and Delinquency Prevention; 2010. Available at: https://www.ncjrs.gov/pdffiles1/ojjdp/220595.pdf. Accessed December 18, 2019

123. Thomas J. *Raising the Bar: State Trends in Keeping Youth Out of Adult Courts (2015-2017)*, 4th ed. Washington, DC: Campaign for Youth Justice; 2017

124. Colorado Juvenile Defender Center. Direct file & transfer to adult court. Available at: http://cjdc.org/wp/juvenile-justice-policy/direct-file/. Accessed December 18, 2019

125. *Roper v Simmons*, 543 US 551 (2005), 112 SW 3d 397, affirmed

126. *Miller v Alabama*, 567 US xxx (2012). Available at: https://www.

supremecourt.gov/opinions/11pdf/10-9646g2i8.pdf. Accessed December 18, 2019

127. Kloepfer A. Denial of hope: sentencing children to life in prison without the possibility of parole. *J Civil Rights Econ Dev.* 2012;26(2):387–413

128. Columbia Law School Human Rights Institute. Challenging juvenile life without parole: how has human rights made a difference. 2014. Available at: https://web.law.columbia.edu/sites/default/files/microsites/human-rights-institute/files/jlwop_case_study_hri_0.pdf. Accessed May 20, 2020

129. National Juvenile Defender Center. Minimum age for delinquency adjudication—multi-jurisdiction survey. 2016. Available at: https://njdc.info/practice-policy-resources/state-profiles/multi-jurisdiction-data/minimum-age-for-delinquency-adjudication-multi-jurisdiction-survey/. Accessed December 18, 2019

130. Sickmund M, Sladky A, Kang W. Easy access to juvenile court statistics: 1985-2018: year of disposition by age at referral Available: https://www.ojjdp.gov/ojstatbb/ezajcs/asp/display.asp. Accessed December 18, 2019

131. United Nations Human Rights Office of the High Commissioner. Convention on the Rights of the Child. Available at: www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx. Accessed December 18, 2019

132. United Nations Committee on the Rights of the Child. United Nations Convention on the Rights of the Child. Available at: www2.ohchr.org/English/bodies/crc/docs/CRC.C.GC.10.pdf. Accessed December 18, 2019

133. Barnert E, Abrams L, Maxson C, et al. Setting a minimum age for juvenile justice jurisdiction in California. *Int J Prison Health*. 2017;13(1):49–56

134. Feierman J, Goldstein N, Haney-Caron E, Columbo JF. Debtors' prison for kids? The high cost of fines and fees in the juvenile justice system. 2016. Available at: https://debtorsprison.jlc.org/documents/JLC-Debtors-Prison.pdf. Accessed December 18, 2019

135. National Juvenile Defender Center. The cost of juvenile probation: a critical look into juvenile supervision fees. Available at: http://njdc.info/wp-content/uploads/2017/08/NJDC_The-Cost-of-Juvenile-Probation.pdf. Accessed December 18, 2019

136. United States Courts. Facts and case summary – in re Gault. Available at: https://www.uscourts.gov/educational-resources/educational-activities/facts-and-case-summary-re-gault. Accessed December 18, 2019

137. National Juvenile Defender Center. Access denied: a national snapshot of states' failure to protect children's right to counsel. 2017. Available at: https://njdc.info/wp-content/uploads/2017/05/Snapshot-Final_single-4.pdf. Accessed December 18, 2019

138. Barnert E, Perry R, Azzi V, et al. Incarcerated youth's perspectives on protective factors and risk factors for juvenile offending: a qualitative analysis. *Am J Public Health*. 2015; 105(7):1365–1371

139. The Pittsburgh Foundation. A qualitative study of youth and the juvenile justice system. A 100 Percent Pittsburgh Pilot Project. Available at: https://pittsburghfoundation.org/sites/default/files/100%20Percent%20Pittsburgh%20–%20Youth%20and%20Juvenile%20Justice%20Report.pdf. Accessed December 18, 2019

Barrier Protection Use by Adolescents During Sexual Activity

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Barrier Protection Use by Adolescents During Sexual Activity

Laura K. Grubb, MD, MPH, FAAP, COMMITTEE ON ADOLESCENCE

abstract

Rates of sexual activity, pregnancies, and births among adolescents have continued to decline during the past decade to historic lows. Despite these positive trends, many adolescents remain at risk for unintended pregnancy and sexually transmitted infections (STIs). When used consistently and correctly, latex and synthetic barrier methods reduce the risk of many STIs, including HIV, and pregnancy. This update of the 2013 policy statement is intended to assist pediatricians in understanding and supporting the use of barrier methods by their patients to prevent unintended pregnancies and STIs and address obstacles to their use.

Departments of Pediatrics and Public Health and Community Medicine, Floating Hospital for Children at Tufts Medical Center, Boston, Massachusetts

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Dr Grubb, along with the Committee on Adolescence, researched, conceived of, designed, analyzed and interpreted data for, drafted, and revised this policy statement and approved the final manuscript as submitted.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

The Society for Adolescent Health and Medicine has endorsed this policy statement.

DOI: https://doi.org/10.1542/peds.2020-007237

Address correspondence to Laura K Grub, MD, MPH, FAAP.
E-mail: lgrubb@tuftsmedicalcenter.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Grubb LK, AAP COMMITTEE ON ADOLESCENCE. Barrier Protection Use by Adolescents During Sexual Activity. *Pediatrics*. 2020;146(2):e2020007237

INTRODUCTION

This policy statement updates the 2013 American Academy of Pediatrics (AAP) statement on condom use.[1] Sexually transmitted infections (STIs), including new HIV infections, and unintended pregnancies among adolescents remain significant public health problems. Although abstinence from sexual activity is the most effective way to reduce pregnancy and STIs, it is important for young people to be prepared for the time when they will become sexually active. The prevention of STIs in adolescents involves abstinence or safer sexual practices by those who are not abstinent. The accompanying technical report[2] provides new information concerning adolescent pregnancy, STIs and HIV, and minority youth to emphasize the need for comprehensive barrier method counseling and education for all youth, regardless of stated sexual orientation, behaviors, gender, or intellectual and/or physical differences. For this statement, the age range for adolescent visits, as defined in the AAP's *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition*, is 11 to 21 years of age.[3] Detailed information forming the basis of the recommendations in this policy statement is found in the technical report.[2]

BARRIER METHODS

Preventing HIV, STIs, or pregnancy involves more than traditional condoms, and sexual practices of adolescents consist of more than penile-

vaginal penetration. Therefore, this policy statement has been expanded to include all barrier methods and multiple types of sexual activity.[4] Adolescents and young adults may use a variety of barrier methods to reduce the transmission of STIs or prevent pregnancy by reducing or preventing the transmission of bodily fluids, skin-to-skin contact, or skin-to-mucous membrane contact. The external condom, commonly known as the male condom, is a latex, synthetic, or natural material shield designed to fit over the male penis and is available over the counter. The internal condom (formerly the female condom) is a loose-fitting polyurethane (nitrile) sheath with 2 flexible polyurethane rings and is the only US Food and Drug Administration–approved nonpenile barrier method for STI prevention currently available in the United States. Users may place it inside the anus, vagina, or mouth. The internal condom is only available in the United States with a prescription. Another over the counter barrier method is a dental dam, or a latex, synthetic (nitrile or polyurethane) sheet (usually square shaped) that users may place over the penis, vulva, vagina, mouth, anus, or any part of the body. Although not evidence based or advised, adolescents may also improvise using plastic wrap or plastic bags to act as barriers.

THE ROLE OF PEDIATRICIANS IN PROMOTING SAFER SEX AND BARRIER METHOD USE

Pediatricians are encouraged to address adolescent sexual and reproductive health on a routine basis, including with youth who have developmental or physical disabilities,[5,6] by taking a sexual history, discussing healthy sexuality, performing an appropriate examination, providing patient-centered and age-appropriate anticipatory guidance, and delivering appropriate screenings and vaccinations.[7] The HEADSS (home, education and employment, activities, drugs, sexuality, and suicide and depression) interview provides an excellent structure for discussing a variety of issues that may affect sexual health and barrier use.[8] Key AAP publications provide a framework to assist pediatricians in incorporating various aspects of sexual and reproductive health care into their practices and provide guidance on overcoming obstacles to delivering this care routinely while maximizing opportunities for confidential health services delivery in their offices.[9,10] The AAP Adolescent Sexual Health Web site also provides significant resources (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/adolescent-sexual-health/Pages/Assessing-the-Adolescent-Patient.aspx).

Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition, outlines how pediatricians and other providers can support parents and adolescents in promoting healthy sexual development and sexuality, including discussion of the use of barrier methods to protect against STIs, including HIV.[9] Multiple studies reviewed in the technical report[2] suggest increased efforts are needed by pediatricians, educators, and those in public health to encourage parents to talk about these issues. The implication for pediatricians is that providing parents with accurate information about adolescent sexual behavior, risks, and use and effectiveness of barrier methods can improve communication with their adolescents.

Pediatricians and other physicians may provide barrier education and free barrier methods within their offices and support efforts to increase availability within their communities. The World Health Organization offers instructions on proper external barrier method use (Table 1).[11] Table 2 provides a list of resources for pediatricians. In addition, the District of Columbia and the state of New York have condom distribution programs that may serve as models for health care providers and organizations.[12,13] Many states have Web sites that offer free mail delivery of barrier methods (Table 2).[14] Most

TABLE 1 World Health Organization Instructions for Proper Barrier Method Use

Use a new barrier method for each act of sexual intercourse.
Open the package carefully so the barrier does not tear.
Before any genital contact, place the condom on the tip of the erect penis with the rolled side out. Do not unroll the condom before putting it on. If not circumcised, pull the foreskin back. Squeeze the tip of the condom and put it on the end of the hard penis. Unroll the condom all the way to the base of the erect penis.
Always put the barrier on before entering partner or before genital, oral, or anal contact with partner.
Immediately after ejaculation, hold the rim of the condom and withdraw the penis while it is still erect (before it gets soft). Slide the condom off without spilling the liquid (semen) inside. Throw away or bury the used barrier or condom safely.
Do not use grease, oils, lotions, or petroleum jelly (Vaseline) to make barrier methods slippery. Only use a lubricant that does not have oil in it.[a]
Only use a barrier method once.
Store barrier methods in a cool, dry place.
Do not use barrier methods that are expired.

Adapted from World Health Organization Regional Office for the Western Pacific. *Promoting Barrier Methods in Clinics for Sexually Transmitted Infections: A Practical Guide for Programme Planners and Managers*. Manila, Philippines: World Health Organization Regional Office for the Western Pacific; 2001:15.

[a] This recommendation applies only to latex barriers.

TABLE 2 Resources for the Pediatrician

	Resources
AAP Bright Futures	https://brightfutures.aap.org/materials-and-tools/guidelines-and-pocket-guide/Pages/default.aspx
Advocates for Youth	http://www.advocatesforyouth.org/
Bedsider	https://www.bedsider.org/
Centers for Disease Control and Prevention	https://www.cdc.gov/condomeffectiveness/index.html
Condom Finder: find free condoms	http://www.condomfinder.org/
Knowledge for Health Toolkit: Health Communication to Promote Condom Use"	https://www.k4health.org/toolkits/condoms/health-communication-promote-condom-use
Rural Health Information Hub	https://www.ruralhealthinfo.org/toolkits/hiv-aids/2/prevent/condom-distribution
Sexuality Information and Education Council of the United States	https://siecus.org/

local or state public health departments offer low-cost or free barrier programs that pediatricians may contact for assistance. Additionally, to enhance safer sex and proper barrier usage, it is important for adolescents to receive comprehensive, evidence-based, medically accurate sexual education that includes barrier method instruction.

The AAP has published a policy statement on refusal to provide information or treatment based on claims conscience.[15] According to the policy, pediatricians and physicians have a duty to inform their patients about relevant, legally available treatment options to which they object and have a moral obligation to refer patients to other physicians who will provide and educate about those services.

CONCLUSIONS

When adolescents and young adults use barrier methods consistently and correctly, these methods are an excellent means to reduce the risk of many STIs, including HIV, and prevent pregnancy. Pediatricians are uniquely suited to provide screening and anticipatory guidance around sexual behaviors, prevention of adverse consequences, harm reduction, and availability and appropriate use of barrier methods. Pediatricians should advocate for increased education, availability, and reduced obstacles to barrier methods for adolescents in their practices and communities.

RECOMMENDATIONS

1. Discuss abstaining from sexual intercourse as the most effective way to prevent genital STIs, as well as HIV infection, and unintended pregnancy.
2. Support and encourage the consistent and correct use of barrier methods as well as other reliable contraception as part of anticipatory guidance during visits with adolescents who are sexually active or contemplating sexual activity, including emphasis on the responsibility of all genders in preventing unintended pregnancies and STIs.
3. Use the recommendations in *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition* promoting communication between parents and adolescents about healthy sexual development and sexuality and supporting education programs that help parents develop communications skills with their adolescents regarding the prevention of STIs and proper use of barrier methods.
4. Remove restrictions and obstacles to barrier method availability to encourage and promote barrier method use among adolescents. Beyond retail distribution of barrier methods, the provision of free or low-cost barrier methods is a priority for adolescent-friendly health services. Pediatricians and other clinicians are encouraged to provide barrier methods within their offices and support availability within their communities.
5. Advocate for barrier method availability programs through a collaborative community process and the provision of comprehensive sequential sexuality education. This is ideally part of a kindergarten-to-12th-grade health education program with parental involvement, counseling, coaching, and positive peer support.
6. Support school barrier method educational programs, especially because these programs reach large adolescent populations and may potentially provide a comprehensive array of related educational and health care resources.
7. Actively communicate to parents and communities that making barrier methods available to adolescents does not increase the onset or frequency of adolescent sexual activity and that use of barrier methods can help decrease rates of unintended pregnancy and acquisition of STIs.
8. Monitor adolescents who use preexposure prophylaxis or nonbarrier contraception, are bisexual or lesbian, and/or are in established relationships closely

for risk compensation (the adjustment of behavior in response to perceived level of risk) leading to decreased use of barrier methods. Pediatricians can assess risk during acute or routine visits to determine the need for additional counseling regarding barrier methods or STI testing. Engage and support additional research to identify strategies to increase continued barrier method use for populations that may engage in risk compensation.

9. Advocate for engagement and support of additional research regarding barrier use (and safer sex practices) for higher-risk youth and those living in areas with lack of access to barrier methods.

LEAD AUTHOR

Laura K. Grubb, MD, MPH, FAAP

COMMITTEE ON ADOLESCENCE, 2019–2020

Elizabeth M. Alderman, MD, FSAHM, FAAP, Chairperson
Richard J. Chung, MD, FAAP
Laura K. Grubb, MD, MPH, FAAP
Janet Lee, MD, FAAP
Makia E. Powers, MD, MPH, FAAP
Maria H. Rahmandar, MD, FAAP
Krishna K. Upadhya, MD, FAAP
Stephenie B. Wallace, MD, FAAP

PAST COMMITTEE MEMBERS

Cora C. Breuner, MD, MPH, FAAP
Laurie L. Hornberger, MD, MPH, FAAP

LIAISONS

Anne-Marie Amies, MD – *American College of Obstetricians and Gynecologists*
Liwei L. Hua, MD, PhD – *American Academy of Child and Adolescent Psychiatry*
Seema Menon, MD – *North American Society for Pediatric and Adolescent Gynecology*
Ellie E. Vyver, MD, FRCPC, FAAP – *Canadian Paediatric Society*
CDR Lauren B. Zapata, PhD, MSPH – *Centers for Disease Control and Prevention*

STAFF

Karen S. Smith

ABBREVIATIONS

AAP: American Academy of Pediatrics
STI: sexually transmitted infection

FINANCIAL DISCLOSURE: The author has indicated she has no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The author has indicated she has no potential conflicts of interest to disclose.

REFERENCES

1. Committee on Adolescence. Condom use by adolescents. *Pediatrics*. 2013; 132(5):973–981
2. Grubb LK; Committee on Adolescence. Barrier protection use by adolescents during sexual activity. *Pediatrics*. 2020; 146(2):e2020007245
3. American Academy of Pediatrics. Adolescence visits: 11 through 21 years. Available at: https://brightfutures.aap.org/Bright%20Futures%20Documents/BF4_AdolescenceVisits.pdf. Accessed June 1, 2020
4. Centers for Disease Control and Prevention. Dental dam use. Available at: https://www.cdc.gov/condomeffectiveness/Dental-dam-use.html. Accessed September 6, 2019
5. Centers for Disease Control and Prevention. STDs in adolescents and young adults. Available at: https://www.cdc.gov/std/stats17/adolescents.htm. Accessed September 6, 2019
6. Krashin JW, Koumans EH, Bradshaw-Sydnor AC, et al. Trichomonas vaginalis prevalence, incidence, risk factors and antibiotic-resistance in an adolescent population. *Sex Transm Dis*. 2010;37(7): 440–444
7. Centers for Disease Control and Prevention. Trends in the prevalence of sexual behaviors and HIV testing. National YRBS: 1991–2017. Available at: https://www.cdc.gov/healthyyouth/data/yrbs/pdf/trends/2017_sexual_trend_yrbs.pdf. Accessed September 6, 2019
8. Klein DA, Goldenring JM, Adelman WP. Probing scars for how to ask the essential questions. *Contemp Pediatr*. 2014;31(1):16–28
9. Hagan JF Jr., Shaw JS, Duncan PM, eds. *Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents*, 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017
10. Marcell AV, Burstein GR; Committee on Adolescence. Sexual and reproductive health care services in the pediatric setting. *Pediatrics*. 2017;140(5): e20172858
11. World Health Organization Regional Office for the Western Pacific. *Promoting Barrier Methods in Clinics for Sexually Transmitted Infections: A Practical Guide for Programme Planners and Managers*. Manila, Philippines: World Health Organization Regional Office for the Western Pacific; 2001
12. DC Health. Condoms and condom information. Available at: https://dchealth.dc.gov/service/condoms-and-condom-information. Accessed September 6, 2019
13. NYC Health. Effective interventions. Available at: https://www1.nyc.gov/site/doh/health/health-topics/condom.page. Accessed September 6, 2019
14. Centers for Disease Control and Prevention. Barrier method distribution. 2018. Available at: https://www.cdc.gov/hiv/effective-interventions/prevent/condom-distribution-programs/index.html. Accessed September 6, 2019
15. Committee on Bioethics. Policy statement–physician refusal to provide information or treatment on the basis of claims of conscience. *Pediatrics*. 2009;124(6):1689–1693

Barrier Protection Use by Adolescents During Sexual Activity

- *Technical Report*

TECHNICAL REPORT

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Barrier Protection Use by Adolescents During Sexual Activity

Laura K. Grubb, MD, MPH, FAAP, COMMITTEE ON ADOLESCENCE

Rates of sexual activity, pregnancies, and births among adolescents have continued to decline during the past decade to historic lows. Despite these positive trends, many adolescents remain at risk for unintended pregnancy and sexually transmitted infections (STIs). This technical report discusses the new data and trends in adolescent sexual behavior and barrier protection use. Since 2017, STI rates have increased and use of barrier methods, specifically external condom use, has declined among adolescents and young adults. Interventions that increase availability of or accessibility to barrier methods are most efficacious when combined with additional individual, small-group, or community-level activities that include messages about safer sex. Continued research informs public health interventions for adolescents that increase the consistent and correct use of barrier methods and promote dual protection of barrier methods for STI prevention together with other effective methods of contraception.

TRENDS IN ADOLESCENT SEXUAL ACTIVITY AND CONSEQUENCES: THE AMERICAN ACADEMY OF PEDIATRICS BRIGHT FUTURES

Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition provides guidance for adolescent visits for ages 11 to 21 years, and in this report, we will provide information that includes this age range.[1] Despite recent data indicating sexual activity has declined among adolescents, the current rates of sexual activity and health consequences of sexually transmitted infections (STIs) and pregnancy indicate that these remain significant public health concerns. The Centers for Disease Control and Prevention (CDC), through its Youth Risk Behavior Surveillance System, reports sexual behaviors in a nationally representative sample of high school students surveyed biannually. In the most recently available Youth Risk Behavior Survey (YRBS) from 2017, 40% of high school students reported they had ever had sexual intercourse (defined as penile-vaginal penetration), 29% reported they were currently sexually active, and 10% had sexual intercourse with 4 or more partners in their lifetime.[2]

abstract

Departments of Pediatrics and Public Health and Community Medicine, Floating Hospital for Children at Tufts Medical Center, Boston, Massachusetts

Technical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, technical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Dr Grubb, along with the Committee on Adolescence, researched, conceived of, designed, analyzed and interpreted data for, drafted, and revised this technical report and approved the final manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All technical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-007245

Address correspondence to Laura K. Grubb. E-mail: lgrubb@tuftsmedicalcenter.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The author has indicated she has no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

To cite: Grubb LK, AAP COMMITTEE ON ADOLESCENCE. Barrier Protection Use by Adolescents During Sexual Activity. *Pediatrics.* 2020;146(2):e2020007245

In 2017, the year for which the most recent data are available, 456 000 adolescent and young women younger than 20 years became pregnant; 448 000 of those pregnancies were among 15- to 19-year-olds, and 7400 were among those 14 years of age and younger.[3] In 2017, the US pregnancy rate among 15- to 19-year-olds was at its lowest point in at least 80 years[3]; however, the birth rate for US teenagers remains higher than that for other industrialized nations, with marked disparities by race and/or ethnicity and geographic area.[4]

New cases of STIs increased 31% in the United States from 2013 to 2017, with half of the 2.3 million new STIs reported each year among young people 15 to 24 years of age.[3,5,6] The CDC does not publish specific data on STI rates by modes of transmission. The rate of reported cases of chlamydia, gonorrhea, and syphilis increased for both sexes in both the adolescent (15–19 years of age) and young adult (20–24 years of age) age groups between 2012 and 2016. For chlamydia and gonorrhea, rates are consistently highest among adolescent and young women 15 to 24 years of age; however, the rate of reported chlamydia in male patients increased, whereas the rate in female patients decreased from 2012 to 2016.[3] Reported cases of syphilis have been consistently higher among adolescent and young adult men compared with women, and between 2012 and 2016, rates of reported syphilis cases increased substantially in both adolescent and young adult men and women.[6] Because trichomoniasis (*Trichomonas vaginalis* infection) is not a reportable disease, it is difficult to determine the prevalence among adolescents. In the United States, there are approximately 7 million new cases of trichomoniasis each year, and prevalence rates range from 3% in a nationally representative sample of women to 14% in adolescents.[7,8]

An estimated 50 900 youth had HIV infection in 2016, representing 4% of all people with HIV infection. Of those, an estimated 56% were aware of their infection, and people 15 to 24 years of age were the least likely to be aware of their infection compared with any other age group.[9] Young people (13–24 years of age) accounted for an estimated 21% of all new HIV diagnoses in the United States in 2018, totaling 7891 people, of whom 87% were natal male youth and 13% were natal female youth.[10] The CDC attributed 80% of new HIV diagnoses among youth to male-to-male sexual contact and 20% to other means (vaginal-penile sexual contact, intravenous drug use, dual male-to-male sexual contact, intravenous drug use, and other). Among young women who received an HIV diagnosis, the CDC attributed 85% of those infections to vaginal-penile contact and 15% to other transmission methods.[10] There is a paucity of data for transgender adolescents, but the results from the National HIV Surveillance System 2009–2014 revealed that youth 13 to 19 years of age accounted for 8% of new HIV diagnoses among transgender people.[10–12] The study also revealed that 25% of transgender women were living with HIV infection and that the percentage of transgender people who received a new HIV diagnosis was more than 3 times the national average in 2015.[13] In 2018, 1252 youth received a diagnosis of AIDS.[14]

In discussing barrier methods and risks, it is important to include information about youth living with HIV acquired through perinatal transmission (PHIV). The CDC does not report specific adolescent data, but at the end of 2016, 1814 children were living with PHIV, and 10 101 adults and adolescents (13 years of age and older) were living with PHIV.[15] Youth with HIV infection generally receive combination antiretroviral therapy (a combination of 3 or more drugs that stops the virus from making copies of itself in the body), and concern exists for extensive drug-resistant strains if these youth are not taking combination antiretroviral therapy consistently.[16] In a prospective cohort study of the reproductive health of sexually active female adolescents with PHIV, the cumulative incidence of pregnancy at 19 years of age was 21%, and incidence of STIs was 26%.[17,18] Several studies have revealed that adolescents with PHIV have higher rates of sexual activity, multiple partners, and unprotected penetrative intercourse compared with noninfected peers; more adolescents frequently tested positive for multidrug-resistant HIV and rarely disclosed their HIV status to partners.[19,20]

Adolescents with intellectual and physical disabilities are an overlooked group when it comes to sexual behavior, but they have similar rates of sexual behaviors when compared with their peers without disabilities.[20] These youth receive limited sexual education from their parents and pediatricians because many assume they will not engage in sexual behaviors.[21] The American Academy of Pediatrics clinical report "Sexuality of Children and Adolescents With Developmental Disabilities" provides additional information.[22]

This information concerning adolescent pregnancy, STIs and/or HIV, and minority youth is provided to emphasize the need for comprehensive barrier method counseling and education for all youth, regardless of stated sexual orientation, behaviors, gender, or intellectual and/or physical differences.

BARRIER METHOD USE

Recent Trends in Adolescent Barrier Method Use

The external condom remains the most popular contraceptive method

among adolescents. Most reported barrier method use data are for the external condom because there is a paucity of current available data for other barrier methods. The 2017 YRBS data refer to external condoms and vaginal-penile sexual activity.[23] Although overall sexual activity decreased among high school students, barrier method use (referred to as condom use in the YRBS) also declined among sexually active adolescents. Among sexually active high school students, 54% reported condom use during their last sexual encounter, a decline from 62% in 2007.[2] Among 12th-grade students, 57% reported ever being sexually active, but they had the lowest use of condoms among all grades.[23] The prevalence of having used a condom during the last sexual intercourse was higher among male than female students, and use rates were as follows: white male students, 62%; Black male students, 58%; Hispanic male students, 62%; white female students, 47%; Black female students, 46%; and Hispanic female students, 47%. Use rates declined with increasing grade level.[23] Among currently sexually active students, 56% of self-identified heterosexual students; 40% of self-identified gay, lesbian, and bisexual students; and 44% of questioning students used a condom during the last sexual intercourse.[23] The prevalence of having used a condom during the last sexual intercourse was higher among heterosexual (56%) than sexual-minority (40%) students. Among female students, the prevalence of having used a condom during the last sexual intercourse was higher among heterosexual students (50%) than lesbian and bisexual students (37%), and among male students, the prevalence was higher among heterosexual students (62%) than gay and bisexual students (53%). The prevalence of having used a condom at last sexual intercourse also was higher among heterosexual male students (62%) than heterosexual female students (50%).[23] In one study, approximately one-third of transgender female youth reported not using barrier methods consistently during receptive anal intercourse with casual and commercial partners; less than half consistently used them with a main partner.[24]

The National HIV Behavioral Surveillance interviewed individuals in 23 cities, and among HIV-negative males who have sex with males (MSM) 18 to 24 years of age, 10% reported having condomless vaginal sex with female partners, 3.5% reported having condomless anal sex with female partners (3.5%), and 73% reported having condomless anal sex with male partners. Among HIV-positive MSM, 7% reported having condomless vaginal sex with female partners, 3% reported having condomless anal sex with female partners, and 74% reported having condomless anal sex with male partners.[25] Rates of actual barrier method use in surveys also may be lower than reported because of the uncertain or questionable validity of self-report of this and other sexual behaviors that are prone to bias. For example, in a clinic-based sample of Black female participants 15 to 21 years of age in Atlanta, Georgia, 186 young women reported 100% condom use via an audio computer-assisted self-interviewing technique.[26] In these young women, 34% had a positive biological marker for unprotected vaginal sex (a Y chromosome polymerase chain reaction assay) in the past 14 days. As a possible explanation of these findings, participants may have used condoms inconsistently or incorrectly, or youth might have provided socially desirable answers.

The rate of barrier method use is significantly less for oral intercourse. Using data collected from 3816 cisgender female participants and 3520 cisgender male participants in the 2011–2015 National Survey of Family Growth, the authors found, for adolescents and young adults 15 to 24 years of age, that 58% of male participants and female participants reported having at least 1 oral opposite-sex partner in the last 12 months. Condom use at the last oral sex was 8% for female participants and 9% for male participants. Black male participants (adjusted odds ratio [aOR] 3.46), Black female participants (aOR 2.65), and female participants of other races and/or ethnicities (aOR 2.40) were more likely to use a condom at the last oral sex. Women 20 to 24 years of age (aOR 0.31), women whose mothers had a college education or more (aOR 0.43), and men and women who reported no intercourse experience were less likely to use a condom at the last oral sex (aORs 0.46 and 0.20, respectively).[27]

Factors That Influence Barrier Method Use

Several factors, including individual, family, cultural, sociodemographic, attitude, education, relationship, and partner-related factors, influence barrier method use[28] (Table 1). In the most current national study of male adolescents,[29] factors associated with greater consistency of barrier method use included Black race or ethnicity, more positive attitudes toward barrier methods, and more discussion of health topics with parents. Adolescents who did not have formal sex education were half as likely to use a barrier method at first intercourse and even less likely to use barrier methods consistently. A lower rate of barrier method use at first sexual intercourse was associated with older age, an older or casual first sexual partner, and a partner using another method of contraception. These factors were also associated with a lower rate of barrier method use at last sex, except for having a casual sexual partner, which was associated with a higher rate of barrier method use.[29] In a large study of rural adolescents,[30] authors found

TABLE 1 Factors Influencing Barrier Use Among Adolescents

Personal Factors	Environmental Factors	Behavioral Factors
Age	Parental communication	Barrier method use history
Barriers	Perceived social support	Sexual history
Sex	Social norms	Substance use
Goals		
Knowledge		
Personal standards		
Self-efficacy		
Self-esteem		
Worry		

that sexually active students who used barrier methods had significantly higher levels of knowledge about sexual risk, self-esteem, personal standards for barrier method use, self-efficacy (an individual's belief in his or her capacity to execute behaviors necessary to produce specific performance attainments) for barrier method use, self-efficacy for partner communication, self-efficacy for refusal of unwanted intercourse, barrier method use goals, and perceived norms and lower levels of worry about pregnancy compared with students who did not use barrier methods. Adolescents using barrier methods reported significantly higher levels of perceived support from their family, and the perceived level of support received from friends or from significant others did not differ between those who used barrier methods and those who did not.[30]

Relationship factors play an important role in barrier method use among adolescents. In the Toronto Relationship Study,[31] authors found that negative relationship dynamics (conflict, control, mistrust, jealousy, perceived partner inferiority) and positive qualities (love, enmeshment, salience, self-disclosure) were associated with consistent barrier method use. Teenagers who scored highly on both positive and negative qualities had the least consistent barrier method use. Conversely, teenagers in relationships with low positive and negative qualities had the most consistent barrier method use. Relationship duration was negatively associated with consistent barrier method use.[31] Another study revealed higher rates of barrier method use in youth who perceived their partners as wanting to use barrier methods and in those able to communicate their desire to use barrier methods with their partners.[32] Lack of barrier method use by adolescents is also associated with perceptions that barrier methods reduce sexual pleasure and/or that partners disapprove of barrier method use. This perception was supported by one large study that revealed that perceptions about how barrier methods reduce sexual pleasure were more strongly associated with not using a barrier method.[33] Other factors associated with increased barrier method use include receiving comprehensive sex and HIV education programs,[34] attending schools where barrier methods are available,[35,36] and perceived risk of getting STIs.[34]

In several studies, authors have examined the role of parent-adolescent communication about sexual risk and the association with increased adolescent use of barrier methods.[37–39] Parental communication about sexual risk and barrier method use is associated with increases in adolescents' use of barrier methods, especially at first intercourse. Timing of the discussion is important; in one study, the highest rates of barrier method use at first and last sex, as well as for regular use, were found among adolescent girls who communicated with their mothers about barrier method use before onset of sexual activity, as compared with after initiation.[40] In the most recent longitudinal study of parents and their children regarding the timing of parent and child communication about sexual behaviors, more than 40% of the children had intercourse before there were discussions about STI symptoms, barrier method use, birth control, or partner barrier method refusal.[41,42]

In a randomized clinical trial of Hispanic and Black mother-adolescent (11–14 years of age) dyads, mothers waiting in a pediatric clinic received a parent-based intervention. The intervention group demonstrated significantly reduced rates of transitioning to sexual activity and frequency of sexual intercourse, with decreases in oral sex nearly reaching statistical significance ($P < .054$), compared with controls. Specifically, sexual activity increased from 6% to 22% for adolescents in the standard of care control condition, although it remained at 6% among adolescents in the intervention condition at the 9-month follow-up.[42] The media also may influence adolescent sexual behavior.[43,44] Exposure to sexual content in music, movies, magazines, television, and the Internet may play an important role in adolescent sexual activity. Despite the increasingly sexually explicit material in media and programming, there are rare messages promoting responsible sexual activity, such as contraception use (including condom use).[35] In primetime television, 77% of programs have sexual content, but only 14% reference risks or responsibility of sexual behavior.[44]

Substance use also affects sexual behavior and barrier use. In studies of young adult and adolescent sexual behavior after use of alcohol, marijuana, or other illicit substances (including nonmedical use of

prescription drugs), authors found associated increases in risky sexual behavior and lower rates of barrier protection use.[45–47]

Barrier availability may significantly affect use among adolescents. External condoms, dental dams, and barrier sheets are available over the counter in all states but may still be difficult for adolescents to access. Many stores stock condoms in physically inaccessible places that require a store attendant to assist the customer.[48] Barrier methods can be expensive, and private insurance does not pay for them, but some states' Medicaid plans do.[49] Barrier methods are less available in poorer neighborhoods,[50] rural areas, American Indian or Alaska Native communities,[51,52] and certain faith-based communities or colleges or universities.[53]

Sexual-minority youth may have different patterns of barrier use, but there are limited data on their habits. Sexual-minority youth may not use barriers during sexual activity for similar reasons as their heteronormative peers, but they often have unique explanations. In a study of women who have sex with women (40% of participants were 24 years of age or younger), the percentage of women who reported never using barrier protection was significantly higher among those in monogamous relationships than among those in nonmonogamous relationships (78.6% vs 27.4%, respectively; $P < .01$).[54] Women who reported always using barrier protection were significantly more likely to be in nonmonogamous than monogamous relationships (14.3% vs 3.5%, respectively; $P < .01$). Of note, 27.7% of nonmonogamous women reported using barrier protection with their secondary partners only. Overall, most of the study population (83%–88%) reported never using barrier protection when performing and receiving digital sex or when performing and receiving oral sex. Barrier use was slightly more prevalent in the context of genital stimulation with a sex toy, with 62.1% and 63.4% of respondents reporting that they never used barrier protection when performing and receiving this type of stimulation, respectively.[54]

In a qualitative study of lesbian and bisexual female participants 14 to 18 years of age, reasons participants did not use latex barriers (external condom or dental dam) during sex with female partners included pleasure, risk perception based on sex of sexual partner, lack of knowledge of sexual risk or of barrier use for female-to-female sexual activities, and use of STI testing as a prevention tool.[55] One 17-year-old girl shared, "they [other girls] probably don't think [about barriers] since condoms are seen as a way to prevent pregnancy, and when two girls have sex they can't get pregnant so we forget that there's still a chance of STDs." Additionally, participants cited greater trust with female partners, no concern for pregnancy, lack of awareness of importance, and lack of inclusive sexuality education.

Among MSM, there are a variety of reasons for barrier use behaviors. In a survey of adolescent MSM,[56] most received sexual education from parents and school, but they lacked information on specific or explicit information concerning male-to-male sexual activity (eg, types of male-to-male sex, how to safely and comfortably have anal sex). For MSM, relationship to partner correlates with condom use. For HIV-negative MSM 18 to 24 years of age, 52% reported condomless anal sex with a main male partner, compared with 44% with casual male partners. In the same survey, 55% of HIV-positive MSM reported condomless anal sex with a main partner, compared with 41% with a casual partner.[25] In a large Internet study of adolescent MSM, participants reported increased likelihood of condom use with casual partners and first-time partners and associated higher perceived pleasure with condom use.[57] Participants' condom use was less likely if their partners did not ejaculate, when they had sex in a location other than a residence, or with higher levels of preintercourse arousal or erection difficulty. In a study of Black MSM, authors found that participants used perceived masculinity of potential partners to assess HIV-related risk, in which masculine men were presumed low risk and effeminate men were presumed high risk, thus contributing to condom use behavior.[58]

Dual Protection

Nonbarrier contraceptive methods offer pregnancy protection but no protection against STIs. Dual-method use, the use of barriers in combination with other contraceptive methods to protect against STIs and unwanted pregnancy, is the ideal contraceptive practice for adolescents. The 2017 YRBS revealed that 9% of all male and female high school students reported dual contraceptive use (defined as external condom use with another contraceptive method) with the last intercourse.[23] The overall percentage of dual usage increased with age, up to 10% among 12th-graders, and was highest among white (12%), Black (6%), and Hispanic (4%) students. Studies have revealed beliefs that positively correlate with dual contraceptive use, including perceived benefits of protected sex, positive attitudes about birth control, and higher perceived risk of STI and pregnancy consequences.[59] Additionally, predictors of dual-method use are similar to predictors of adolescent barrier use (Table 1). Younger age at first coitus, older partner age, history of sexual abuse, lower self-esteem, and obesity are predictive of inconsistent use and nonuse of barrier methods. Longer relationship duration is also predictive of lower barrier-only or

dual-method use but not of overall contraceptive use, even after controlling for age.[60] Adolescents with main and regular partners tend to discontinue use of barriers quickly, especially if they are using other pregnancy prevention methods.

Because adolescents have increased their use of long-acting reversible contraceptive (LARC) methods, there are concerns about their effects on adolescent use of barrier protection. LARCs are considered the best form of contraception for adolescents wishing to avoid pregnancy, but they offer no protection against STIs. An analysis of YRBS cross-sectional data revealed that among 2288 sexually active female participants, 2% used LARCs; 6% used depot medroxyprogesterone acetate injection, the ethinyl estradiol and norelgestromin patch, or the etonogestrel and ethinyl estradiol vaginal ring; 22% used oral contraceptives; 41% used condoms; 12% used withdrawal or another method; 16% used no contraceptive method; and 2% were not sure.[61] LARC users were approximately 60% less likely to use barriers compared with oral contraceptive users. Authors did not find significant differences in condom use between LARC users and depot injection, patch, or ring users, but LARC users were more than twice as likely to have 2 or more recent sexual partners compared with oral contraceptive, depot injection, patch, or ring users.[61] In a secondary analysis of the Contraceptive Choice Project, authors found that LARC use was associated with increased acquisition of an STI within the first 12 months after placement compared with no use of LARCs.[62] These findings suggest that adolescents using other contraceptive methods besides barriers may be engaging in risk compensation, the adjustment of behavior in response to perceived level of risk.

Preexposure Prophylactic Therapy and Barrier Use

For individuals at increased risk for HIV acquisition (sexually active MSM, individuals with an HIV-positive partner, those engaging in anal intercourse, those engaging in frequent sex without a barrier, or those with a high number of sexual partners), the CDC recommends preexposure prophylaxis (PrEP) to reduce HIV acquisition and transmission.[63] The US Food and Drug Administration (FDA) has approved both emtricitabine and tenofovir disoproxil fumarate and emtricitabine and tenofovir alafenamide for PrEP in adults and adolescents who weigh at least 35 kg.[64] The CDC Web site provides HIV risk behavior assessment, PrEP clinical practice guidelines, patient and provider education, and tool kits.[65–68] PrEP can reduce the risk of HIV acquisition by 90% when people use it consistently. With the increase in PrEP use, researchers have documented significant declines in barrier use[69–71] and increases in STIs among MSM (cisgender males and transgender females), suggesting that PrEP users may be engaging in risk compensation.

EFFECTIVENESS OF BARRIER METHOD USE

Most studies of barrier method effectiveness involve external condoms. External condoms consist of 3 types of materials: most (>80%) are latex (natural rubber), a small percentage (less than 5%) are natural membrane (lamb cecum), and approximately 15% are synthetic (eg, polyurethane).[72] The CDC only recommends latex and synthetic condoms for prevention of STIs and HIV because natural-membrane condoms contain small pores that may allow for passage of viruses, including HIV, hepatitis B virus, and herpes simplex virus.[73] In a recent Cochrane review, authors concluded that nonlatex synthetic condoms were linked with higher rates of clinical breakage than their latex counterparts.[74] The synthetic (AT-10 resin, polyisoprene, polyethylene, or polyurethane) condoms still provide an acceptable alternative for individuals with allergies, sensitivities, or preferences that might prevent the consistent use of latex condoms. The polyurethane condom is not as effective as the latex external condom for pregnancy prevention.[75] Synthetic barrier methods are compatible with both oil- and water-based lubricants, and although not extensively studied, synthetic external condoms are believed to provide STI protection similar to external latex condoms; however, FDA labeling currently restricts their recommended use to latex-sensitive or latex-allergic people.[76] In the United States, the FDA regulates external condoms and barrier methods (dental dams) marketed to prevent STIs as medical devices, and stringent manufacturing standards exist to ensure testing of each barrier for holes or weak spots before sale.[77,78]

External condoms can be effective against unintended pregnancy when used consistently and correctly. External condom failure rates have declined significantly since 1995, from 18% to 13% with typical use, according to the National Survey of Family Growth (2006–2010).[79] Researchers estimate that the failure rate of the external condom for pregnancy is 2% in 12 months of perfect use (ie, 2 pregnancies per 100 woman-years).[79] The most important noncontraceptive benefit of external condom use is the additional protection against acquisition and transmission of STIs, including HIV. If the user places the external condom on the penis before genital, oral, anal, or skin contact and uses it throughout activity, this should prevent contact with semen, vaginal secretions,

saliva, blood, skin and mucosal lesions, and infectious secretions. External condoms greatly reduce the risk of STI transmission to or from the penile urethra, including gonorrhea, chlamydia, trichomoniasis, hepatitis B virus, and HIV.[80–88] Barrier methods also provide protection against STIs transmitted via skin-to-skin contact or contact with mucosal surfaces in those covered areas, including genital herpes simplex virus, human papillomavirus, syphilis, and chancroid; all published studies refer to the external condom.[89–91] The latex condom effectively blocked passage of the smallest sexually transmitted pathogen, hepatitis B virus, according to in vitro studies.[91] In most studies on external condom effectiveness, vaginal-penile sexual activity is evaluated. Adolescents can also use either a latex or synthetic barrier during anogenital and orogenital intercourse to reduce the risk of STIs.

Well-designed epidemiological studies and those of couples with discordant HIV infection status have revealed that external condoms are highly effective against transmission of HIV. Researchers conducted a meta-analysis of studies comparing seroconversion rates among couples who regularly used external condoms and those who used them inconsistently to determine their use and/or effectiveness in preventing HIV transmission. Results of the analysis revealed that external condoms were 90% to 95% effective in preventing HIV transmission when opposite- and same-sex partners used them consistently.[80]

Given the coital-dependent nature of barrier methods, the degrees of consistency and correctness of use influence effectiveness against both unintended pregnancy and STIs. Factors associated with decreased effectiveness include failure to use a barrier with every act of intercourse, incomplete use (late application and early removal), improper use, barrier breakage and slippage, not using a new barrier when switching from one form of sex to another, barrier method–associated erection problems (either during application or during intercourse), and problems with the fit or feel of barriers, including problems related to the size or shape of the barrier or discomfort or interference with sensation.[92,93]

The internal condom (formerly female condom) is a loose-fitting polyurethane (nitrile) sheath with 2 flexible polyurethane rings and is the only FDA-approved nonpenile barrier method for STI prevention currently available in the United States.[94] The FDA regulates the internal condom as a level III product, on par with medical devices such as pacemakers, thus making manufacturing and distribution more challenging in the United States. The FDA approved the original device (brand name FC1) in 1993 and the revised product (brand name FC2) in 2009. In September 2018, the FDA petitioned to reclassify the female condom as a level II device and renamed it the internal condom.[95] This proposed change would increase access to internal barrier methods in the United States and broaden use, especially when it comes to the lesbian, gay, bisexual, transgender, and questioning community, because an increasing number of people have begun to use this method for nonvaginal intercourse. The FC2 device is the only internal condom available in the United States. Recently, the FC2 manufacturer, Veru, decided to take the FC2 off of pharmacy shelves and make it available exclusively through prescription with the rationale that by doing so, they would ensure that women with health insurance can access them free of charge under the Patient Protection and Affordable Care Act's mandate for contraceptive coverage.[96] There are no published data on the effects of this change.

Data regarding contraceptive effectiveness of FC1 internal condoms suggest that estimated rates of pregnancy during the first 12 months of perfect use and typical use are 5% and 21% respectively; these pregnancy rates are slightly higher than those of the external condom. Although available data suggest that internal condoms may provide similar degrees of protection against pregnancy and STIs as do latex external male condoms alone, this conclusion has not been demonstrated, and thus comparative research is needed.[61] Overall internal condom use accounts for less than 1% of US barrier use overall.[97]

Adolescents may also use dental dams, latex sheets, or improvised barriers to protect against STIs and pregnancy. Published data on the effectiveness of these barrier methods are unavailable, but the CDC does provide proper-use information on its Web site.[98]

EFFORTS AIMED AT INCREASING BARRIER METHOD USE

In a review of the literature, authors found contradicting evidence on the effectiveness of community- and behavioral-level barrier method promotion programs, highlighting the need for further evaluation of program effectiveness.[63,64,99,100] One large-scale review revealed concern that these programs might hasten the initiation of sex, but this concern appears unfounded.[65] In the 52 studies measuring timing of initiation of sex, 42% found that sexual initiation was significantly delayed for at least 6 months after participation in such a program, and 55% found no effect. There are few programs promoting enhanced sexual pleasure as a motivating factor, which

has led to increased uptake of barrier methods and safer sex behaviors.[101–103]

In 2017, the Society for Adolescent Health and Medicine published a position statement, "Condom Availability in Schools: A Practical Approach to the Prevention of Sexually Transmitted Infection/HIV and Unintended Pregnancy," recommending increased barrier method availability at schools.[35] The evidence on the impact of availability of barrier methods in schools is inconsistent.[104–107] In the most recent study of programs in Massachusetts high schools, adolescents attending schools where barrier methods were available were more likely to receive barrier method use instruction and less likely to report lifetime or recent sexual intercourse, and adolescents who were sexually active were twice as likely to use barrier methods at the most recent sexual encounter.[108] Studies have revealed that school condom programs do not increase sexual activity, the number of sexual partners, or risk behaviors.[109,110]

Likewise, clinic-based interventions have been effective in increasing barrier method use and decreasing STIs.[111,112] The CDC publishes a summary: "Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention."[113]

In a recent meta-analysis of high-quality US and international studies of structural-level barrier method distribution interventions, authors found significant effects on increased barrier method use, increased barrier method acquisition, increased barrier method carrying, delayed sexual initiation of youth, and reduced incidence of STIs.[114] The interventions that increase availability of or accessibility to barrier methods are most efficacious when combined with additional individual, small-group, or community-level activities. The intervention effects were significant across target participant characteristics (youth, adults, commercial sex workers, STI clinic populations, or male participants). In a large systematic review of the literature, authors found that interventions using constructs of the information, motivation, and behavioral skills model were associated with significant increases in condom use or condom-use intentions.[115] Additionally, interventions that included modules to increase self-efficacy for condom use and that taught participants where to obtain condoms and how to negotiate condom use with partners or elicit positive associations (feelings) toward condoms were associated with increased condom use or intention to use condoms.

Social networks may promote barrier use as well. In a study of homeless youth, those who had a condom-using peers reported increased condom use and reduced risky behavior.[116] In a large review of network-based condom intervention strategies, authors of all studies reported substantial improvement in condom use for the intervention groups compared with the control groups.[117] Social media platforms also provide information and promote safer sexual practices, including barrier use.[118] Study authors reported small short-term gains in condom use or consumption but mixed long-term behavioral effectiveness.[117,119,120]

Availability of barrier methods in the pediatrician's office may reduce obstacles to use for adolescents, but a survey of primary care providers revealed that most do not distribute condoms in their practices.[121] Providers cited the following risks to distribution of condoms: potential for parent or caregiver disproval (66%), potential of upsetting or offending patients (28%), possibility of preventing adolescents from developing self-reliance (11%), and potential of promoting sexual activity (7%). Of those who did not distribute condoms, the most cited reasons included unsure and had not thought about it (45%), inconvenience (31%), and concern for parent or caregiver disproval (27%). Ninety percent of providers endorsed that they would or may be willing to consider office-based condom distribution if they had help with organizing and funding this service.

To enhance safer sex and proper barrier usage, it is important for adolescents to receive comprehensive, evidence-based, and medically accurate sexual education that includes barrier method instruction. A review of states' sexuality education programs revealed that 16 states require instruction on barrier methods or contraception with sexuality or HIV and/or STI education.[122] Additionally, adolescents need affordable access to barrier methods without discrimination or other barriers. Most barrier methods are sold over the counter in all 50 states and territories, but obstacles persist, including barriers displayed behind counters or in locked cabinets, store or pharmacy personnel refusing to sell to adolescents of certain ages, cost, and poor availability in some neighborhoods.

CONCLUSIONS

Recent trends in adolescent and young adult sexual behavior reveal that adolescents and young adults remain at risk for unintended pregnancies, STIs, and HIV. When adolescents and young adults use barrier methods consistently and correctly, these methods are excellent means to reduce the risk of many

STIs, including HIV, and prevent pregnancy.

LEAD AUTHOR

Laura K. Grubb, MD, MPH, FAAP

COMMITTEE ON ADOLESCENCE, 2019–2020

Elizabeth M. Alderman, MD, FSAHM, FAAP, Chairperson
Richard J. Chung, MD, FAAP
Laura K. Grubb, MD, MPH, FAAP
Janet Lee, MD, FAAP
Makia E. Powers, MD, MPH, FAAP
Maria H. Rahmandar, MD, FAAP
Krishna K. Upadhya, MD, FAAP
Stephenie B. Wallace, MD, FAAP

PAST COMMITTEE MEMBERS

Cora C. Breuner, MD, MPH, FAAP
Laurie L. Hornberger, MD, MPH, FAAP

LIAISONS

Anne-Marie Amies, MD – *American College of Obstetricians and Gynecologists*
Liwei L. Hua, MD, PhD – *American Academy of Child and Adolescent Psychiatry*
Seema Menon, MD – *North American Society for Pediatric and Adolescent Gynecology*
Ellie E. Vyver, MD, FRCPC, FAAP – *Canadian Paediatric Society*
CDR Lauren B. Zapata, PhD, MSPH – *Centers for Disease Control and Prevention*

STAFF

Karen S. Smith

ABBREVIATIONS

aOR: adjusted odds ratio
CDC: Centers for Disease Control and Prevention
FDA: US Food and Drug Administration
LARC: long-acting reversible contraceptive
MSM: males who have sex with males
PHIV: HIV acquired through perinatal transmission
PrEP: preexposure prophylaxis
STI: sexually transmitted infection
YRBS: Youth Risk Behavior Survey

POTENTIAL CONFLICT OF INTEREST: The author has indicated she has no potential conflicts of interest to disclose.

REFERENCES

1. American Academy of Pediatrics. Adolescence visits: 11 through 21 years. Available at: https://brightfutures.aap.org/Bright%20Futures%20Documents/BF4_AdolescenceVisits.pdf. Accessed October 13, 2019
2. Centers for Disease Control and Prevention. Trends in the prevalence of sexual behaviors and HIV testing. National YRBS: 1991–2017. Available at: https://www.cdc.gov/healthyyouth/data/yrbs/pdf/trends/2017_sexual_trend_yrbs.pdf. Accessed March 6, 2020
3. Centers for Disease Control and Prevention. New CDC analysis shows steep and sustained increases in STDs in recent years. Available at: https://www.cdc.gov/nchhstp/newsroom/2018/press-release-2018-std-prevention-conference.html. Accessed September 6, 2019
4. Kost K, Maddow-Zimet I, Arpaia A. *Pregnancies, Births and Abortions Among Adolescents and Young Women in the United States, 2013: National and State Trends by Age, Race and Ethnicity.* New York, NY: Guttmacher Institute; 2017, Available at https://www.guttmacher.org/report/us-adolescent-pregnancy-trends-2013. Accessed September 6, 2019
5. Leichliter JS, Copen C, Dittus PJ. Confidentiality issues and use of sexually transmitted disease services among sexually experienced persons aged 15–25 years - United States, 2013–2015. *MMWR Morb Mortal Wkly Rep.* 2017;66(9):237–241
6. Centers for Disease Control and Prevention. STDs in adolescents and young adults. Available at: https://www.cdc.gov/std/stats17/adolescents.htm. Accessed September 6, 2019
7. Krashin JW, Koumans EH, Bradshaw-Sydnor AC, et al. Trichomonas vaginalis prevalence, incidence, risk factors and antibiotic-resistance in an adolescent population. *Sex Transm Dis.* 2010;37(7):440–444
8. Kissinger P. Epidemiology and treatment of trichomoniasis. *Curr Infect Dis Rep.* 2015;17(6):484
9. Beer L, Mattson CL, Shouse RL, Prejean J. Receipt of clinical and prevention services, clinical outcomes, and sexual risk behaviors among HIV-infected young adults in care in the United States. *AIDS Care.* 2016;28(9):1166–1170
10. Centers for Disease Control and Prevention. HIV and youth. Available at: https://www.cdc.gov/hiv/group/age/youth/index.html. Accessed June 25, 2020
11. Becasen JS, Denard CL, Mullins MM, Higa DH, Sipe TA. Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006-2017. *Am J Public Health.* 2019;109(1):e1–e8
12. Centers for Disease Control and Prevention. HIV surveillance report, 2018 (preliminary); vol. 30. Available at: http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html. Accessed June 28, 2020
13. Clark H, Babu AS, Wiewel EW, Opoku J, Crepaz N. Diagnosed HIV infection in transgender adults and adolescents: results from the National HIV Surveillance System, 2009-2014. *AIDS Behav.* 2017;21(9):2774–2783
14. Centers for Disease Control and Prevention. Statistics center. Available at: https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-preliminary-vol-30.pdf. Accessed June 28, 2020

15. Centers for Disease Control and Prevention. HIV and pregnant women, infants, and children. Available at: https://www.cdc.gov/hiv/group/gender/pregnantwomen/index.html. Accessed September 5, 2019

16. Hazra R, Siberry GK, Mofenson LM. Growing up with HIV: children, adolescents, and young adults with perinatally acquired HIV infection. *Annu Rev Med*. 2010;61:169–185

17. Agwu AL, Jang SS, Korthuis PT, Araneta MRG, Gebo KA. Pregnancy incidence and outcomes in vertically and behaviorally HIV-infected youth. *JAMA*. 2011;305(5):468–470

18. Brogly SB, Watts DH, Ylitalo N, et al. Reproductive health of adolescent girls perinatally infected with HIV. *Am J Public Health*. 2007;97(6):1047–1052

19. Kaushik A, Pineda C, Kest H. Sexual behavior and knowledge among adolescents with perinatally acquired human immunodeficiency virus infection compared to HIV-uninfected adolescents at an urban tertiary center in New Jersey. *Int J Reprod Med*. 2016;2016:7098027

20. Tassiopoulos K, Moscicki AB, Mellins C, et al; Pediatric HIV/AIDS Cohort Study. Sexual risk behavior among youth with perinatal HIV infection in the United States: predictors and implications for intervention development. *Clin Infect Dis*. 2013;56(2):283–290

21. Holland-Hall C, Quint EH. Sexuality and disability in adolescents. *Pediatr Clin North Am*. 2017;64(2):435–449

22. Murphy NA, Elias ER. Sexuality of children and adolescents with developmental disabilities. *Pediatrics*. 2006;118(1):398–403

23. Kann L, McManus T, Harris WA, et al. Youth risk behavior surveillance - United States, 2017. *MMWR Surveill Summ*. 2018;67(8):1–114

24. Wilson EC, Garofalo R, Harris DR, Belzer M. Sexual risk taking among transgender male-to-female youths with different partner types. *Am J Public Health*. 2010;100(8):1500–1505

25. Centers for Disease Control and Prevention. HIV infection risk, prevention, and testing behaviors among men who have sex with men—National HIV Behavioral Surveillance, 23 US cities, 2017. Available at: https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-22.pdf. Accessed September 6, 2019

26. Rose E, Diclemente RJ, Wingood GM, et al. The validity of teens' and young adults' self-reported condom use. *Arch Pediatr Adolesc Med*. 2009;163(1):61–64

27. Holway GV, Hernandez SM. Oral sex and condom use in a US national sample of adolescents and young adults. *J Adolesc Health*. 2018;62(4):402–410

28. Marcell AV, Gibbs SE, Choiriyyah I, et al. National needs of family planning among US men aged 15 to 44 years. *Am J Public Health*. 2016;106(4):733–739

29. Manlove J, Ikramullah E, Terry-Humen E. Condom use and consistency among male adolescents in the United States. *J Adolesc Health*. 2008;43(4):325–333

30. Haley T, Puskar K, Terhorst L, Terry MA, Charron-Prochownik D. Condom use among sexually active rural high school adolescents personal, environmental, and behavioral predictors. *J Sch Nurs*. 2013;29(3):212–224

31. Manning WD, Flanigan CM, Giordano PC, Longmore MA. Relationship dynamics and consistency of condom use among adolescents. *Perspect Sex Reprod Health*. 2009;41(3):181–190

32. Widman L, Noar SM, Choukas-Bradley S, Francis DB. Adolescent sexual health communication and condom use: a meta-analysis. *Health Psychol*. 2014;33(10):1113–1124

33. Higgins JA, Wang Y. The role of young adults' pleasure attitudes in shaping condom use. *Am J Public Health*. 2015;105(7):1329–1332

34. Gaydos CA, Hsieh YH, Galbraith JS, Barnes M, Waterfield G, Stanton B. Focus-on-teens, sexual risk-reduction intervention for high-school adolescents: impact on knowledge, change of risk-behaviours, and prevalence of sexually transmitted diseases. *Int J STD AIDS*. 2008;19(10):704–710

35. Society for Adolescent Health and Medicine. Condom availability in schools: a practical approach to the prevention of sexually transmitted infection/HIV and unintended pregnancy. *J Adolesc Health*. 2017;60(6):754–757

36. Wang T, Lurie M, Govindasamy D, Mathews C. The effects of school-based condom availability programs (CAPs) on condom acquisition, use and sexual behavior: a systematic review. *AIDS Behav*. 2017;22(1):308–320

37. Guilamo-Ramos V, Lee JJ, Jaccard J. Parent-adolescent communication about contraception and condom use. *JAMA Pediatr*. 2016;170(1):14–16

38. Widman L, Choukas-Bradley S, Noar SM, Nesi J, Garrett K. Parent-adolescent sexual communication and adolescent safer sex behavior: a meta-analysis. *JAMA Pediatr*. 2016;170(1):52–61

39. Guilamo-Ramos V, Bouris A, Jaccard J, Gonzalez B, McCoy W, Aranda D. A parent-based intervention to reduce sexual risk behavior in early adolescence: building alliances between physicians, social workers, and parents. *J Adolesc Health*. 2011;48(2):159–163

40. Miller KS, Levin ML, Whitaker DJ, Xu X. Patterns of condom use among adolescents: the impact of mother-adolescent communication. *Am J Public Health*. 1998;88(10):1542–1544

41. Beckett MK, Elliott MN, Martino S, et al. Timing of parent and child communication about sexuality relative to children's sexual behaviors. *Pediatrics*. 2010;125(1):34–42

42. Sutton MY, Lasswell SM, Lanier Y, Miller KS. Impact of parent-child communication interventions on sex behaviors and cognitive outcomes for black/African-American and Hispanic/Latino youth: a systematic review, 1988–2012. *J Adolesc Health*. 2014;54(4):369–384

43. Council on Communications and Media. American Academy of Pediatrics. Policy statement–sexuality, contraception, and the media. *Pediatrics*. 2010;126(3):576–582

44. Kunkel D, Eyai K, Finnerty K, Biely E, Donnerstein E. *Sex on TV 4: A Kaiser Family Foundation Report*. Menlo Park, CA: Kaiser Family Foundation; 2005

45. Clayton HB, Lowry R, August E, Everett Jones S. Nonmedical use of prescription drugs and sexual risk

behaviors. *Pediatrics*. 2016;137(1): e20152480

46. Parks KA, Collins RL, Derrick JL. The influence of marijuana and alcohol use on condom use behavior: findings from a sample of young adult female bar drinkers. *Psychol Addict Behav*. 2012; 26(4):888–894
47. Schumacher A, Marzell M, Toepp AJ, Schweizer ML. Association between marijuana use and condom use: a meta-analysis of between-subject event-based studies. *J Stud Alcohol Drugs*. 2018;79(3):361–369
48. Rizkalla C, Bauman LJ, Avner JR. Structural impediments to condom access in a high HIV/STI-risk area. *J Environ Public Health*. 2010;2010: 630762
49. Henry J. Kaiser Family Foundation. Medicaid coverage of over-the-counter contraceptives. 2015. Available at: https://www.kff.org/womens-health-policy/state-indicator/medicaid-coverage-of-over-the-counter-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D. Accessed September 6, 2019
50. Shacham E, Nelson EJ, Schulte L, Bloomfield M, Murphy R. Condom deserts: geographical disparities in condom availability and their relationship with rates of sexually transmitted infections. *Sex Transm Infect*. 2016;92(3):194–199
51. Ahtone T. One woman's campaign for safe sex in Navajo Nation. *Al Jazeera America*. March 28, 2015. Available at: http://america.aljazeera.com/articles/2015/3/28/one-womans-campaign-for-safe-sex-in-navajo-nation.html. Accessed September 6, 2019
52. Behay J; Women at the Center. Reproductive rights in Native America. 2015. Available at: https://medium.com/women-at-the-center/reproductive-rights-in-native-america-609a319c65e8. Accessed September 6, 2019
53. Butler SM, Procopio M, Ragan K, Funke B, Black DR. Assessment of university condom distribution programs: results of a national study. *Electron J Hum Sex*. 2014;17. Available at: http://www.ejhs.org/volume17/distribution.html. Accessed September 6, 2019
54. Rowen TS, Breyer BN, Lin TC, Li CS, Robertson PA, Shindel AW. Use of barrier protection for sexual activity among women who have sex with women. *Int J Gynaecol Obstet*. 2013; 120(1):42–45
55. Doull M, Wolowic J, Saewyc E, Rosario M, Prescott T, Ybarra ML. Why girls choose not to use barriers to prevent sexually transmitted infection during female-to-female sex. *J Adolesc Health*. 2018;62(4):411–416
56. Nelson KM, Pantalone DW, Carey MP. Sexual health education for adolescent males who are interested in sex with males: an investigation of experiences, preferences, and needs. *J Adolesc Health*. 2019;64(1):36–42
57. Hensel DJ, Novak D, Reece M, Rosenberger J. Factors associated with young MSM's event level condom use during insertive and receptive anal sex [abstract]. *J Adolesc Health*. 2012;50(2 suppl):S28–S29
58. Fields E, Bogart L, Ellen J, Malebranche D, Schuster M, Smith K. "He ain't got no AIDS": HIV risk and perceptions of masculinity among adolescent and young adult black males who have sex with males [abstract]. *J Adolesc Health*. 2011;48(2 suppl):S1
59. Sieving RE, Bearinger LH, Resnick MD, Pettingell S, Skay C. Adolescent dual method use: relevant attitudes, normative beliefs and self-efficacy. *J Adolesc Health*. 2007;40(3):275.e15-275.e22
60. Williams RL, Fortenberry JD. Dual use of long-acting reversible contraceptives and condoms among adolescents. *J Adolesc Health*. 2013;52(4 suppl): S29–S34
61. McNicholas CP, Klugman JB, Zhao Q, Peipert JF. Condom use and incident sexually transmitted infection after initiation of long-acting reversible contraception. *Am J Obstet Gynecol*. 2017;217(6):672.e1-672.e6
62. Steiner RJ, Liddon N, Swartzendruber AL, Rasberry CN, Sales JM. Long-acting reversible contraception and condom use among female US high school students: implications for sexually transmitted infection prevention. *JAMA Pediatr*. 2016;170(5):428–434
63. Moreno R, Nababan HY, Ota E, et al. Structural and community-level interventions for increasing condom use to prevent the transmission of HIV and other sexually transmitted infections. *Cochrane Database Syst Rev*. 2014;(7):CD003363
64. Carvalho FT, Gonçalves TR, Faria ER, et al. Behavioral interventions to promote condom use among women living with HIV. *Cochrane Database Syst Rev*. 2011;(9):CD007844
65. Kirby DB, Laris BA, Rolleri LA. Sex and HIV education programs: their impact on sexual behaviors of young people throughout the world. *J Adolesc Health*. 2007;40(3):206–217
66. Centers for Disease Control and Prevention; US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 update: a clinical practice guideline. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Accessed September 6, 2019
67. US Food and Drug Administration. TRUVADA (emtricitabine and tenofovir disoproxil fumarate) tablets, for oral use. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021752s055lbl.pdf. Accessed September 6, 2019
68. Centers for Disease Control and Prevention. Pre-exposure prophylaxis (PrEP). Available at: https://www.cdc.gov/hiv/risk/prep/index.html. Accessed September 6, 2019
69. Holt M, Lea T, Mao L, et al. Community-level changes in condom use and uptake of HIV pre-exposure prophylaxis by gay and bisexual men in Melbourne and Sydney, Australia: results of repeated behavioural surveillance in 2013-17. *Lancet HIV*. 2018;5(8): e448–e456
70. Chen YH, Snowden JM, McFarland W, Raymond HF. Pre-exposure prophylaxis (PrEP) use, seroadaptation, and sexual behavior among men who have sex with men, San Francisco, 2004–2014. *AIDS Behav*. 2016;20(12):2791–2797
71. Traeger MW, Schroeder SE, Wright EJ, et al. Effects of pre-exposure prophylaxis for the prevention of human immunodeficiency virus infection on sexual risk behavior in

men who have sex with men: a systematic review and meta-analysis. *Clin Infect Dis*. 2018;67(5):676–686

72. Hatcher, Robert H. *Contraceptive Technology*, 21st ed. Atlanta, GA: Managing Contraception LLC; 2018
73. Centers for Disease Control and Prevention. Condoms and STDs: fact sheet for public health personnel. 2013. Available at: https://www.cdc.gov/condomeffectiveness/latex.html. Accessed June 28, 2020
74. Gallo MF, Grimes DA, Lopez LM, Schulz KF. Non-latex versus latex male condoms for contraception. *Cochrane Database Syst Rev*. 2006;(1):CD003550
75. Steiner MJ, Dominik R, Rountree RW, Nanda K, Dorflinger LJ. Contraceptive effectiveness of a polyurethane condom and a latex condom: a randomized controlled trial. *Obstet Gynecol*. 2003; 101(3):539–547
76. US Food and Drug Administration. Labeling for natural rubber latex condoms classification under 21 CFR 884.5300 - class II special controls guidance document for industry and FDA staff. 2008. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/class-ii-special-controls-guidance-document-labeling-natural-rubber-latex-condoms-classified-under. Accessed September 6, 2019
77. ASTM International. ASTM D3492: standard specification for rubber contraceptives (male condoms). 2016. Available at: https://standards.globalspec.com/std/10039073/astm-d3492. Accessed September 6, 2019
78. Carey RF, Lytle CD, Cyr WH. Implications of laboratory tests of condom integrity. *Sex Transm Dis*. 1999;26(4):216–220
79. Trussell J. Contraceptive failure in the United States. *Contraception*. 2011; 83(5):397–404
80. Weller S, Davis K. Condom effectiveness in reducing heterosexual HIV transmission. *Cochrane Database Syst Rev*. 2002;(1):CD003255
81. Steiner MJ, Warner L, Stone KM, Cates W Jr.. Condoms and Other Barrier Methods for Prevention of STD/HIV Infection and Pregnancy. In: Holmes KK, Sparling PF, Stamm WE, eds., et al *Sexually Transmitted Diseases*, 4th ed. New York, NY: MacGraw-Hill; 2008: 1821–1830
82. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep*. 2015;64(RR-03):1–137
83. Warner L, Stone KM, Macaluso M, Buehler JW, Austin HD. Condom use and risk of gonorrhea and chlamydia: a systematic review of design and measurement factors assessed in epidemiologic studies. *Sex Transm Dis*. 2006;33(1):36–51
84. Warner L, Newman DR, Austin HD, et al; Project RESPECT Study Group. Condom effectiveness for reducing transmission of gonorrhea and chlamydia: the importance of assessing partner infection status. *Am J Epidemiol*. 2004; 159(3):242–251
85. Niccolai LM, Rowhani-Rahbar A, Jenkins H, Green S, Dunne DW. Condom effectiveness for prevention of Chlamydia trachomatis infection. *Sex Transm Infect*. 2005;81(4):323–325
86. Shlay JC, McClung MW, Patnaik JL, Douglas JM Jr.. Comparison of sexually transmitted disease prevalence by reported level of condom use among patients attending an urban sexually transmitted disease clinic. *Sex Transm Dis*. 2004;31(3):154–160
87. Paz-Bailey G, Koumans EH, Sternberg M, et al. The effect of correct and consistent condom use on chlamydial and gonococcal infection among urban adolescents. *Arch Pediatr Adolesc Med*. 2005;159(6):536–542
88. Gallo MF, Steiner MJ, Warner L, et al. Self-reported condom use is associated with reduced risk of chlamydia, gonorrhea, and trichomoniasis. *Sex Transm Dis*. 2007;34(10):829–833
89. Martin ET, Krantz E, Gottlieb SL, et al. A pooled analysis of the effect of condoms in preventing HSV-2 acquisition. *Arch Intern Med*. 2009; 169(13):1233–1240
90. Winer RL, Hughes JP, Feng Q, et al. Condom use and the risk of genital human papillomavirus infection in young women. *N Engl J Med*. 2006; 354(25):2645–2654
91. Bernabe-Ortiz A, Carcamo CP, Scott JD, Hughes JP, Garcia PJ, Holmes KK. HBV infection in relation to consistent condom use: a population-based study in Peru. *PLoS One*. 2011;6(9):e24721
92. Sanders SA, Yarber WL, Kaufman EL, Crosby RA, Graham CA, Milhausen RR. Condom use errors and problems: a global view. *Sex Health*. 2012;9(1): 81–95
93. World Health Organization Regional Office for the Western Pacific. *Promoting Condoms in Clinics for Sexually Transmitted Infections: A Practical Guide for Programme Planners and Managers*. Manila, Philippines: World Health Organization Regional Office for the Western Pacific; 2001
94. Department of Health and Human Services; Food and Drug Administration. Multiple-use female condom. 21 CFR §884.5330 (2000). Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=884.5330. Accessed September 6, 2019
95. Kosova E. The power of protection: why the FDA's policy on female condoms matters. Available at: https://www.nwhn.org/power-protection-fdas-policy-female-condoms-matters/. Accessed September 6, 2019
96. Food and Drug Administration, HHS. Obstetrical and gynecological devices; reclassification of single-use female condom, to be renamed single-use internal condom. Final order. *Fed Regist*. 2018;83(188):48711–48713
97. Gallo MF, Kilbourne-Brook M, Coffey PS. A review of the effectiveness and acceptability of the female condom for dual protection. *Sex Health*. 2012;9(1): 18–26
98. Centers for Disease Control and Prevention. Dental dam use. Available at: https://www.cdc.gov/condomeffectiveness/Dental-dam-use.html. Accessed September 6, 2019
99. Lopez LM, Stockton LL, Chen M, Steiner MJ, Gallo MF. Behavioral interventions for improving dual-method contraceptive use. *Cochrane Database Syst Rev*. 2014;(3):CD010915
100. Lopez LM, Bernholc A, Chen M, Tolley EE. School-based interventions for improving contraceptive use in

adolescents. *Cochrane Database Syst Rev*. 2016;(6):CD012249

101. deFur KM. Don't forget the good stuff! Incorporating positive messages of sexual pleasure into sexuality education. *Am J Sex Educ*. 2012;7(2): 160–169
102. Hensel DJ, Stupiansky NW, Herbenick D, Dodge B, Reece M. Sexual pleasure during condom-protected vaginal sex among heterosexual men. *J Sex Med*. 2012;9(5):1272–1276
103. Kalichman SC, Johnson JR, Adair V, Rompa D, Multhauf K, Kelly JA. Sexual sensation seeking: scale development and predicting AIDS-risk behavior among homosexually active men. *J Pers Assess*. 1994;62(3):385–397
104. Kirby D, Brener ND, Brown NL, Peterfreund N, Hillard P, Harrist R. The impact of condom availability [correction of distribution] in Seattle schools on sexual behavior and condom use. *Am J Public Health*. 1999;89(2): 182–187
105. Guttmacher S, Lieberman L, Ward D, Freudenberg N, Radosh A, Des Jarlais D. Condom availability in New York City public high schools: relationships to condom use and sexual behavior. *Am J Public Health*. 1997;87(9):1427–1433
106. Schuster MA, Bell RM, Berry SH, Kanouse DE. Impact of a high school condom availability program on sexual attitudes and behaviors. *Fam Plann Perspect*. 1998;30(2):67–72, 88
107. Furstenberg FF Jr., Geitz LM, Teitler JO, Weiss CC. Does condom availability make a difference? An evaluation of Philadelphia's health resource centers. *Fam Plann Perspect*. 1997;29(3): 123–127
108. Blake SM, Ledsky R, Goodenow C, Sawyer R, Lohrmann D, Windsor R. Condom availability programs in Massachusetts high schools: relationships with condom use and sexual behavior. *Am J Public Health*. 2003;93(6):955–962
109. Algur E, Wang E, Friedman HS, Deperthes B. A systematic global review of condom availability programs in high schools. *J Adolesc Health*. 2019;64(3): 292–304
110. Andrzejewski J, Liddon N, Leonard S. Condom availability programs in schools: a review of the literature. *Am J Health Promot*. 2019;33(3):457–467
111. Crosby R, DiClemente RJ, Charnigo R, Snow G, Troutman A. A brief, clinic-based, safer sex intervention for heterosexual African American men newly diagnosed with an STD: a randomized controlled trial. *Am J Public Health*. 2009;99(suppl 1): S96–S103
112. DiClemente RJ, Wingood GM, Rose ES, et al. Efficacy of sexually transmitted disease/human immunodeficiency virus sexual risk-reduction intervention for African American adolescent females seeking sexual health services: a randomized controlled trial. *Arch Pediatr Adolesc Med*. 2009;163(12): 1112–1121
113. Centers for Disease Control and Prevention. *Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention*. Atlanta, GA: Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html. Accessed September 6, 2019
114. Malekinejad M, Parriott A, Blodgett JC, et al. Effectiveness of community-based condom distribution interventions to prevent HIV in the United States: a systematic review and meta-analysis. *PLoS One*. 2017;12(8):e0180718
115. Whiting W, Pharr JR, Buttner MP, Lough NL. Behavioral interventions to increase condom use among college students in the United States: a systematic review. *Health Educ Behav*. 2019;46(5):877–888
116. Rice E. The positive role of social networks and social networking technology in the condom-using behaviors of homeless young people. *Public Health Rep*. 2010;125(4):588–595
117. Wang K, Brown K, Shen SY, Tucker J. Social network-based interventions to promote condom use: a systematic review. *AIDS Behav*. 2011;15(7): 1298–1308
118. Johnson TD. Online-only: social media tools put condom use on the map. *Nations Health*. 2012;42(3):e14
119. Bull SS, Levine DK, Black SR, Schmiege SJ, Santelli J. Social media-delivered sexual health intervention: a cluster randomized controlled trial. *Am J Prev Med*. 2012;43(5):467–474
120. Purdy CH. Using the Internet and social media to promote condom use in Turkey. *Reprod Health Matters*. 2011; 19(37):157–165
121. Mehringer JE, Gibson EJ, Huang JX, Frankowski BL. Providers' practices and beliefs regarding distribution of condoms to adolescents in the primary care office setting [abstract]. *J Adolesc Health*. 2017;60(2 suppl 1):S102
122. Sexuality Information and Education Council of the United States. State profiles: fiscal year 2017. 2017. Available at: https://siecus.org/wp-content/uploads/2018/07/SIECUS-SP-FY17-State-Law-and-Policy-Chart.pdf. Accessed September 6, 2019

Chemical-Biological Terrorism and Its Impact on Children

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Chemical-Biological Terrorism and Its Impact on Children

Sarita Chung, MD, FAAP,[a] Carl R. Baum, MD, FACMT, FAAP,[b] Ann-Christine Nyquist, MD, MSPH, FAAP,[c] DISASTER PREPAREDNESS ADVISORY COUNCIL, COUNCIL ON ENVIRONMENTAL HEALTH, COMMITTEE ON INFECTIOUS DISEASES

abstract

Chemical and biological events (including infectious disease outbreaks) may affect children disproportionately, and the threat of a chemical or biological attack remains in the United States and worldwide. Although federal programs and funding support a broad range of federal initiatives for public health preparedness and response, funding at the state and local levels has been flat or is decreasing, potentially leaving communities vulnerable. Consequently, pediatricians need to prepare and be ready to care for children in their communities before, during, and after a chemical or biological event, including during long-term recovery. Some medical countermeasures for particular chemical and biological agents have not been adequately studied or approved for children. The American Academy of Pediatrics provides resources and education on disaster preparedness and response, including information on the pediatrician's role in disasters, pediatric medical countermeasures, and mental health after an event as well as individual and family preparedness. This policy statement addresses the steps that clinicians and policy makers can take to protect children and mitigate the effects of a chemical or biological attack.

[a]Division of Emergency Medicine, Boston Children's Hospital and Harvard Medical School, Harvard University, Boston, Massachusetts; [b]Section of Pediatric Emergency Medicine, Departments of Pediatrics and Emergency Medicine, School of Medicine, Yale University, New Haven, Connecticut; and [c]Section of Pediatric Infectious Diseases and Epidemiology, Department of Pediatrics, Children's Hospital Colorado and School of Medicine, University of Colorado, Aurora, Colorado

Dr Chung provided substantial contributions to the conception and design of the work, contributed to drafting and revising it critically for important intellectual content, gives final approval of the version to be published, and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; Drs Baum and Nyquist provided substantial contributions to the conception and design of the work and contributed to drafting and revising it critically for important intellectual content; and all authors approved the final manuscript as submitted.

To cite: Chung S, Baum CR, Nyquist A-C, AAP DISASTER PREPAREDNESS ADVISORY COUNCIL, COUNCIL ON ENVIRONMENTAL HEALTH, COMMITTEE ON INFECTIOUS DISEASES. Chemical-Biological Terrorism and Its Impact on Children. *Pediatrics*. 2020;145(2): e20193749

INTRODUCTION

Children remain victims of chemical or biological terrorism; recent examples include the 2017–2018 chemical attacks by the Assad regime against civilians in Syria. Emerging biological outbreaks, such as the global 2013–2016 Ebola outbreaks originating in West Africa and the 2016–2018 Zika virus outbreak, offered opportunities to test response systems that would be needed in the case of biological terrorism. Consequently, pediatric health care providers, in collaboration with public health officials and emergency management personnel, must be prepared to respond to the needs of children before, during, and after a chemical or biological event. Pediatric health care providers can help by offering guidance to the local, state, and federal governmental and nongovernmental organizations that are charged with caring for children,

and they can be a valuable resource for first-responder training as well as community and hospital preparedness, response, and recovery. Involvement of pediatric health care providers in preparedness planning and training activities increases the likelihood that the needs of children will be considered and addressed.

STATEMENT OF THE PROBLEM

Pediatricians play a pivotal role in providing care in the medical home and supporting the community before, during, and after a chemical or biological event. To this end, pediatricians and their staff can proactively seek education and be prepared to promote and share information on readiness approaches, offer anticipatory guidance to families, report appearances of unusual disease clusters, and help guide families after events. The intent of this policy statement is to provide pediatricians and other professionals with an overview of the following:

1. children's vulnerabilities with respect to chemical and biological events;
2. chemical and biological agents of concern; and
3. roles of the pediatrician in the medical home and in collaboration with prehospital and hospital organizations and governmental agencies in preparation for, detection of, and response to chemical and biological events.

NEW INFORMATION

This revised policy statement and a new, accompanying technical report replace the 2006 policy statement "Chemical-Biological Terrorism and Its Impact on Children."

REVIEW OF EVIDENCE

Children's Vulnerabilities

Exposure to chemical and biological weapons may occur through a variety of routes, including airborne, waterborne, or foodborne routes. Compared with adults, children have greater risks of both exposure and harm because of key developmental, anatomic, and physiologic vulnerabilities. These risks include the following differences between children and adults: children inhale considerably more air on a per-kilogram basis; they breathe air from a breathing zone that is closer to the ground, where heavier-than-air substances concentrate; they have a proportionately greater body-surface area, which is important when it comes to agents that contact the skin; and they ingest considerably more fluid (particularly milk, which may be contaminated with chemicals, especially radioisotopes, or biological agents) and food on a per-kilogram basis.

Children are among those most at risk for psychological trauma and behavioral difficulties after chemical and biological terrorism. Children may suffer from a range of short- and long-term effects on their psychological functioning, emotional adjustment, and developmental trajectory. Persistent adjustment reactions can be anticipated in some children long after a chemical or biological event, particularly among those who have escaped countries where such attacks may have occurred, or even in children without direct exposure to these events. There may be a need for specific disaster plans in schools for these students. The American Academy of Pediatrics (AAP) offers recommendations for pediatricians and others to work with families to develop plans within its Family Readiness Kit[1] and the policy "Emergency Information Forms and Emergency Preparedness for Children With Special Health Care Needs."[2]

Agents of Concern

For the purposes of this policy statement, agents of concern (chemicals and biological agents that can be used in a terrorist attack) can be subdivided as follows: chemicals include nerve agents, blistering agents (vesicants), irritants (corrosives), choking agents, asphyxiants (cyanogens and carbon monoxide), and disabling (incapacitating) agents; biological agents include Centers for Disease Control and Prevention Category A agents (anthrax, botulism, plague, smallpox, tularemia, and the viral hemorrhagic fevers), which are considered the greatest public health threat. More details regarding these agents are in the accompanying technical report, "Chemical-Biological Terrorism and Its Impact on Children."[3]

Roles of the Pediatrician and Other Health Care Professionals

Comprehensive resources regarding presentation and management of illnesses due to chemical and biological agents are now accessible in different formats, such as apps or Web sites optimized for mobile devices, and have been developed to allow for just-in-time use in a disaster. The AAP continues to develop resources, including the accompanying technical report, to help all health care professionals to understand the needs of children in a disaster and provide specific guidance for chemical and biological threats. Additional information is provided in the AAP resource "Pediatric Disaster Preparedness and Response Topical Collection" (www.aap.org/disasters/manual).[4]

Pediatricians and other primary care providers are uniquely positioned to advance disaster preparedness and response: in their ability to care directly for patients, they can provide wisdom "from the field," coordinating with disaster response and public health authorities to guide rational preparedness and response efforts at local (including child care programs and schools), state, and federal levels. Because they understand the different developmental stages of children, pediatric health care providers can provide input on

planning for pediatric evacuation, triage, surge, and family reunification after disasters. In addition, pediatric health care providers may be the first to recognize and diagnose psychological trauma and behavioral difficulties after an event.

In recent years, these authorities have shifted their efforts to an "all-hazards approach," which establishes a single integrated model of disaster response that can be equally effective for chemical and biological agents. In a disaster, health care providers must be ready to provide care outside of their usual scope of practice. In addition, health care providers may be the first to encounter or report an outbreak. Recent pediatric research has demonstrated that educational efforts increase health care professionals' knowledge and confidence, which may improve their participation during an actual event.[5,6]

Syndromic surveillance (detection of health indicators that precede diagnosis) potentially signals early stages of a chemical release or an infectious disease outbreak and may serve to minimize consequences. Reports of unusual presentations from pediatricians and other clinicians are critical, but additional methods may inform rapid epidemic detection.[7] These methods include data gathered from automated monitoring of hospital emergency department diagnoses or individual Internet searches to crowd sourcing of social media applications on mobile devices. The latter technique was used after the 2017 sarin attacks in Syria, when researchers reviewed videos uploaded by civilians who documented clinical symptoms and gaps in clinical care.[8]

Prehospital and Hospital Organizations

Care of pediatric patients is becoming more regionalized, and definitive pediatric hospital care is becoming less available in the community.[9] Although recommendations to improve pediatric readiness in hospital emergency departments are available,[10] pediatric interhospital transfers are increasing, and more definitive pediatric hospital care is becoming gradually dependent on referral centers.[7] In addition, given that in 2013 only 46.8% of US hospitals reported having a disaster plan that included pediatric considerations, the care of children during a local chemical or biological attack can be impeded or delayed, which may lead to poor outcomes.[11] Recent ventilator research, for example, shows that there are few types of devices that are capable of supporting the ventilation of children of all ages.[12]

Hospital preparedness for patients with highly contagious infectious diseases has improved since the 2013–2016 Ebola outbreaks in West Africa. Federal agencies have established a regional treatment network for Ebola and other special pathogens, increasing the capacity to care for such patients, particularly children.[13] Because of this experience, protocols for donning and doffing personal protective equipment have improved to better protect the safety of health care professionals.

Hospital readiness plans are most often developed to accommodate surge capacity, or increased numbers of pediatric patients. These may include, for example, the ability to create additional bed spaces through cohorting or rapid discharge of inpatients. Hospital policies need to recognize the developmental and psychological needs of children, especially those with special health care needs, and the importance of using age-appropriate equipment and supplies.[14,15] Hospitals will want to prepare in advance to be able to track children who arrive without identification or parents or guardians and have plans for immediate family reunification.[16] Exercises and drills are an important part of preparedness, and resources are available to address pediatric preparedness and promote pediatrician involvement.[4,17,18]

Personal Protective Equipment and Decontamination

After exposure to a chemical or biological weapon, children may become covered by toxic material that can be absorbed, ingested, or inhaled and produce systemic toxicity. Although chemical exposures may cause immediate symptoms, infectious exposures may have an incubation period. Regardless, if an exposure is known, victims will need to undergo immediate decontamination to remove the contaminant and prevent additional sequelae.[19] To prepare for decontamination events, involved health care professionals need to be trained to don personal protective equipment to prevent secondary exposures. The decontamination process for victims includes removal of clothing followed by dry decontamination (absorbent or adsorbent materials) or wet decontamination (cleansed with soap and water or showers). For pediatric victims, the shower water should be warmed to avoid hypothermia and used at lower pressure to prevent additional skin damage. In cold climates, heat lamps, blankets, and other mechanisms may be needed to prevent hypothermia. Additional principles of decontamination are covered in the accompanying technical report.[3]

Poison Control Centers

In the event of a terrorist attack, the national network of state and regional poison control centers (1-800-222-1222) may be the first point of contact for health care providers and members of the public. These poison centers, staffed by certified specialists in poison information and backed by medical toxicologists, can triage disaster calls to appropriate local, state, and federal agencies.

Governmental Agencies

After the September 11, 2001, terrorist attacks and subsequent anthrax releases, the federal government expanded its emergency preparedness efforts. These include the establishment of the Department of Homeland Security in 2002 and, within the Department of Health and Human Services (DHHS), the Office of the Assistant Secretary for Preparedness and Response, in 2006. Other Department of Homeland Security and DHHS agencies, including the Federal Emergency Management Agency, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health, have been reorganized to accommodate chemical and biological preparedness and response.

Although there have been some advances in pediatric medical countermeasures (MCMs), significant gaps remain.[20] The US Strategic National Stockpile, a part of DHHS, is the largest supply of potentially life-saving pharmaceuticals and medical supplies and is designed to support citizens in response to disasters that overwhelm state and local resources. As of 2013, only 40% of the medications in the Strategic National Stockpile have been approved for use in the pediatric population.[21] There continue to be ongoing efforts at the federal level to ensure pediatric treatments for all chemical and biological threats. For medications that are not approved for pediatric patients, the Food and Drug Administration can issue an emergency use authorization or investigational new drug application for their use. If the medication falls under the investigational new drug application, additional consent would be needed, which could be challenging to explain to frightened parents and could present challenges to MCM mass-distribution efforts during a public health emergency. In addition, the absence of dedicated pediatric autoinjectors for medications such as atropine hampers the ability of first responders to provide immediate care to younger children. Ongoing research and development is needed to ensure that all MCMs can be used safely in children, with attention being paid to appropriate dosing, formulations, and devices (eg, autoinjectors).[5]

SUMMARY AND RECOMMENDATIONS

The AAP provides supplemental details on many of the topics discussed in this policy in the accompanying technical report, "Chemical-Biological Terrorism and Its Impact on Children."[3] This technical report contains more specific details on the role of the pediatric provider, specific hospital and health care needs, decontamination processes, and mental health implications related to chemical and bioterrorism events. Because the threat of chemical and biological terrorism continues, and children are likely to be affected by such acts, the AAP offers recommendations for pediatricians and others.

Recommendations for Pediatricians

1. Pediatricians should be aware of agents of concern as well as the response systems (eg, poison control centers and local and state agencies) that evaluate and manage children and strive to minimize their physical and mental trauma.
2. Pediatricians should become, and remain, aware of principles of preparation and response to similar public health emergencies (eg, hazardous-materials incidents or emerging infectious diseases). Education on the all-hazards approach should occur as early in training as possible as well as in continuing education. Telemedicine and telementoring (for example, Extension for Community Healthcare Outcomes) with subject matter experts are potential solutions for just-in-time training).
3. Pediatricians need to be aware of pediatric decontamination strategies and appropriate use of personal protective equipment to protect health care staff.[22]
4. Pediatricians should participate, as need and opportunity arise, in local public health and community exercises, drills, and activities (such as with first responders, at hospitals, and in the medical home) in chemical and biological terrorism preparedness, response, and recovery.[5]
5. Pediatricians should work, when possible, with local early care and education (ie, Head Start, child care, early childhood, and/or preschool) programs and school systems to develop plans for rapid evacuation, relocation, family reunification, triage, and treatment protocols (including vaccination) if an act of chemical or biological terrorism occurs. Pediatricians also should work with local school systems, child care centers, or child-serving agencies as well as mental health providers to help support children after such an event with age-appropriate and developmentally appropriate interventions.
6. Pediatricians should recognize their role in syndromic surveillance and detection of health indicators and familiarize themselves with the related medical sequelae and potential behavioral and mental health effects because children who were exposed to chemical or biological agents during a terrorist attack may present to their pediatrician's office for follow-up and long-term care. Many more children beyond those who were exposed directly will experience significant distress, and pediatricians will need to recognize signs and symptoms of

distress and proactively encourage these children and their families to receive support for their emotional and behavioral needs.

Recommendations for the Health Care Sector

1. Response to chemical and biological attacks will start locally. First responders and local public health officials should be prepared and ready to care for acutely ill and injured children of all ages. Preparation efforts should have adequate resources to provide appropriate MCMs, facility-transfer protocols, and pediatric training for staff (especially appropriate use of personal and protective equipment and decontamination protocols).
2. In addition to medical care of victims of a chemical or biological attack, health care systems and hospitals will need to prepare for the unique needs of children and their families in all phases of readiness, response, and recovery.[7] This includes, but is not limited to, disease surveillance, decontamination of children, identification and tracking of unaccompanied children, family reunification, administration of MCMs to families, and mental health screening and services. Health system readiness for the needs of children and families during and after a disaster should be built on day-to-day pediatric emergency preparedness guidance.[10]
3. The needs of children and youth with special health care needs, including those of children with chronic health conditions, as well as a variety of physical and developmental disabilities must be incorporated into disaster planning.
4. Disaster exercises and drills involving the whole health care community should be conducted and include pediatric victims.

Recommendations for Government

1. Public health and emergency management agencies should work actively with pediatric health care providers to continue to provide assistance and resources to hospitals, pediatric offices, local AAP chapters, community health centers, and other health care facilities to ensure that workers in these facilities are prepared to respond to chemical or biological terrorist incidents that involve children.
2. The needs of children should always be included among the required deliverables and performance benchmarks in funding programs for emergency preparedness, response, and recovery. Furthermore, it is critical for this funding to include the ability to conduct research and collect data during disasters on the impact of the disaster on children (such as chemical or biological exposures) to develop or evaluate innovative solutions.
3. The federal government must ensure, through funding, research, and study trials, that all vaccines and MCMs can be used in children, which would include but not be limited to pediatric-friendly forms of administration, such as rapidly dissolvable formulations or appropriately dosed autoinjectors.
4. State and federal governments should support both funding and accreditation of continuing education on the topic of chemical and biological terrorism and ensure that mechanisms to address the needs of children are included. Maintenance of Certification credits are an important vehicle for the ongoing education of health care providers. Collaboration with the AAP on education is important because the AAP can assist with implementing Maintenance of Certification, quality-improvement projects, Extension for Community Healthcare Outcomes clinics and telementoring projects, and additional educational efforts.

AUTHORS

Sarita Chung, MD, FAAP
Carl R. Baum, MD, FACMT, FAAP
Ann-Christine Nyquist, MD, MSPH, FAAP

ABBREVIATIONS

AAP: American Academy of Pediatrics
DHHS: Department of Health and Human Services
MCM: medical countermeasure

DOI: https://doi.org/10.1542/peds.2019-3749

Address correspondence to Sarita Chung, MD, FAAP. E-mail: sarita.chung@childrens.harvard.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: Dr Chung is the codirector for the Diaster Domain of the Emergency Medical Services for Children Innovation and Improvement Center. Dr Baum is the medical director for a grant from the Agency for Toxic Substances and Disease Registry and American College of Medical Toxicology; advisory board member for the National Biodefense Science Board, American Board of Pediatrics Medical Toxicology Subboard, Elsevier, and Wolters Kluwer; a shareholder at Biogen Inc; an author at UpToDate; and an expert witness for medical testimony on lead with attorney Michael Foley.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. American Academy of Pediatrics. Family readiness kit. Available at: https://www.aap.org/en-us/Documents/disasters_family_readiness_kit.pdf. Accessed September 20, 2019
2. American Academy of Pediatrics, Committee on Pediatric Emergency Medicine, Council on Clinical Information Technology; American College of Emergency Physicians, Pediatric Emergency Medicine Committee. Policy statement–emergency information forms and emergency preparedness for children with special health care needs. *Pediatrics*. 2010;125(4):829–837. Reaffirmed October 2014
3. Chung S, Baum CR, Nyquist A-C; American Academy of Pediatrics, Disaster Preparedness Advisory Council, Council on Environmental Health, Committee on Infectious Diseases. Technical report: chemical-biological terrorism and its impact on children. *Pediatrics*. 2020;145(2):e20193750
4. Chung S, Foltin G, Schonfeld DJ, et al. *American Academy of Pediatrics, Pediatric Disaster Preparedness and*

Response Topical Collection. Itasca, IL: American Academy of Pediatrics; 2019

5. Behar S, Upperman JS, Ramirez M, Dorey F, Nager A. Training medical staff for pediatric disaster victims: a comparison of different teaching methods. *Am J Disaster Med*. 2008;3(4): 189–199
6. Hewett EK, Nagler J, Monuteaux MC, et al. A hazardous materials educational curriculum improves pediatric emergency department staff skills. *AEM Educ Train*. 2017;2(1):40–47
7. Yan SJ, Chughtai AA, Macintyre CR. Utility and potential of rapid epidemic intelligence from internet-based sources. *Int J Infect Dis*. 2017;63:77–87
8. Rosman Y, Eisenkraft A, Milk N, et al. Lessons learned from the Syrian sarin attack: evaluation of a clinical syndrome through social media. *Ann Intern Med*. 2014;160(9):644–648
9. França UL, McManus ML. Trends in regionalization of hospital care for common pediatric conditions. *Pediatrics*. 2018;141(1):e20171940
10. Remick K, Gausche-Hill M, Joseph MM, Brown K, Snow SK, Wright JL; American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Section on Surgery; American College of Emergency Physicians Pediatric Emergency Medicine Committee; Emergency Nurses Association Pediatric Committee. Pediatric readiness in the emergency department. *Pediatrics*. 2018;142(5):e20182459
11. Gausche-Hill M, Ely M, Schmuhl P, et al. A national assessment of pediatric readiness of emergency departments. *JAMA Pediatr*. 2015;169(6):527–534
12. Custer JW, Watson CM, Dwyer J, Kaczka DW, Simon BA, Easley RB. Critical evaluation of emergency stockpile ventilators in an in vitro model of pediatric lung injury. *Pediatr Crit Care Med*. 2011;12(6):e357–e361
13. Public Health Emergency. HPP funds regional treatment network for Ebola and other special pathogens. Available at: www.phe.gov/Preparedness/planning/hpp/Pages/hpp-pathogens.aspx. Accessed December 13, 2019
14. Davies HD, Byington CL; Committee on Infectious Diseases. Parental presence during treatment of Ebola or other highly consequential infection. *Pediatrics*. 2016;138(3):e20161891
15. Hinton CF, Davies HD, Hocevar SN, et al. Parental presence at the bedside of a child with suspected Ebola: an expert discussion. *Clin Pediatr Emerg Med*. 2016;17(1):81–86
16. Chung S, Charney R, Biddinger P, Krupa R; American Academy of Pediatrics. Family reunification following disasters: a planning tool for health care facilities. 2018. Available at: https://www.aap.org/en-us/Documents/AAP-Reunification-Toolkit.pdf. Accessed June 12, 2019
17. Chung S, Gardner AH, Schonfeld DJ, et al. Addressing children's needs in disasters: a regional pediatric tabletop exercise. *Disaster Med Public Health Prep*. 2018;12(5):582–586
18. So M, Dziuban EJ, Franks JL, et al. Extending the reach of pediatric emergency preparedness: a virtual tabletop exercise targeting children's needs. *Public Health Rep*. 2019;134(4): 344–353
19. Rotenberg JS, Burklow TR, Selanikio JS. Weapons of mass destruction: the decontamination of children. *Pediatr Ann*. 2003;32(4):260–267
20. Fagbuyi DB, Schonfeld DJ; Disaster Preparedness Advisory Council. Medical countermeasures for children in public health emergencies, disasters, or terrorism. *Pediatrics*. 2016;137(2): e20154273
21. US Government Accountability Office. Report to the committee on energy and commerce, house of representatives: efforts to address the medical needs of children in a chemical, biological, radiological, or nuclear incident. 2013. Available at: https://www.gao.gov/assets/660/654264.pdf. Accessed January 17, 2019
22. Rathore MH, Jackson MA; Committee on Infectious Diseases. Infection prevention and control in pediatric ambulatory settings. *Pediatrics*. 2017;140(5): e20172857

Chemical-Biological Terrorism and Its Impact on Children

- *Technical Report*

TECHNICAL REPORT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Chemical-Biological Terrorism and Its Impact on Children

Sarita Chung, MD, FAAP,[a] Carl R. Baum, MD, FACMT, FAAP,[b] Ann-Christine Nyquist, MD, MSPH, FAAP,[c] DISASTER PREPAREDNESS ADVISORY COUNCIL, COUNCIL ON ENVIRONMENTAL HEALTH, COMMITTEE ON INFECTIOUS DISEASES

abstract

Children are potential victims of chemical or biological terrorism. In recent years, children have been victims of terrorist acts such as the chemical attacks (2017–2018) in Syria. Consequently, it is necessary to prepare for and respond to the needs of children after a chemical or biological attack. A broad range of public health initiatives have occurred since the terrorist attacks of September 11, 2001. However, in many cases, these initiatives have not ensured the protection of children. Since 2001, public health preparedness has broadened to an all-hazards approach, in which response plans for terrorism are blended with those for unintentional disasters or outbreaks (eg, natural events such as earthquakes or pandemic influenza or man-made catastrophes such as a hazardous-materials spill). In response to new principles and programs that have evolved over the last decade, this technical report supports the accompanying update of the American Academy of Pediatrics 2006 policy statement "Chemical-Biological Terrorism and its Impact on Children." The roles of the pediatrician and public health agencies continue to evolve, and only their coordinated readiness and response efforts will ensure that the medical and mental health needs of children will be met successfully. In this document, we will address chemical and biological incidents. Radiation disasters are addressed separately.

[a]Division of Emergency Medicine, Boston Children's Hospital and Harvard Medical School, Harvard University, Boston, Massachusetts; [b]Section of Pediatric Emergency Medicine, Departments of Pediatrics and Emergency Medicine, School of Medicine, Yale University, New Haven, Connecticut; and [c]Section of Pediatric Infectious Diseases and Epidemiology, Department of Pediatrics, Children's Hospital Colorado and School of Medicine, University of Colorado, Aurora, Colorado

Dr Chung provided substantial contributions to the conception and design of the work, contributed to drafting and revising it critically for important intellectual content, gives final approval of the version to be published, and agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved; Drs Baum and Nyquist provided substantial contributions to the conception and design of the work and contributed to drafting and revising it critically for important intellectual content; and all authors approved the final manuscript as submitted.

To cite: Chung S, Baum CR, Nyquist A-C, AAP DISASTER PREPAREDNESS ADVISORY COUNCIL, COUNCIL ON ENVIRONMENTAL HEALTH, COMMITTEE ON INFECTIOUS DISEASES. Chemical-Biological Terrorism and Its Impact on Children. Pediatrics. 2020;145(2): e20193750

BACKGROUND INFORMATION

In 2000, the American Academy of Pediatrics (AAP) published the policy statement "Chemical-Biological Terrorism and its Impact on Children." Preceding events such as the 1995 sarin attack in Tokyo, Japan, illustrate the reality that acts of domestic chemical terrorism can occur, with significant impact on the health of children. The subsequent 2006 policy statement highlighted the need for increased awareness and preparedness in response to additional acts of chemical and biological terrorism, including the release of anthrax spores through the US postal system, intentional toxic chemical contamination of food in Michigan and California, and the identification of ricin-laden letters in a post office in

South Carolina. Unfortunately, since the publication of the 2006 policy statement, there have been additional chemical attacks affecting children, such as the 2017 sarin[1] and 2018 chlorine attacks[2] in Syria. These attacks have led to significant pediatric morbidity and mortality. Emerging biological threats, such as Ebola and Zika viruses, have provided opportunities to test the systems of pediatric disaster preparedness nationally and internationally. In the same time frame, there continues to be substantial progress as new chemical and biological medical countermeasures (MCMs) are approved by the US Food and Drug Administration (FDA), additional methods for surveillance are in place, and advances in pediatric disaster preparedness and education are available to assist emergency responders with evidence-based best practices.

Since the September 11, 2001, terrorist attacks and subsequent anthrax releases in the United States, the AAP has recognized the need to strategically address the impact of terrorism (ie, an act designed to frighten, hurt, or kill people) on children at the national, state, and local level. This has led to the appointment of the AAP Disaster Preparedness Advisory Council, which collaborates with federal partners (including the Department of Health and Human Services [DHHS] Office of the Assistant Secretary for Preparedness and Response [ASPR], Centers for Disease Control and Prevention [CDC], Department of Homeland Security [DHS], FDA, Federal Emergency Management Agency, and the National Institute of Child Health and Human Development) as well as more than 70 AAP member disaster preparedness contacts in all AAP chapters who work with their local and state partners to address the needs of children throughout the disaster cycle. The federal government also created the National Commission on Children and Disasters, the National Advisory Committee on Children and Disasters, and the National Biodefense Science Board, all of which included pediatric subject matter experts. The AAP hosts a comprehensive Web site for pediatric health care providers with a page devoted to information on terrorism and its impact on children (www.aap.org/disasters/terrorism). Additional AAP activities to promote pediatric disaster awareness include publication of disaster policy statements such as "Ensuring the Health of Children in Disasters" and "Providing Psychosocial Support to Children and Families in the Aftermath of Disasters and Crises" along with education on specific chemical and biological threats in the AAP manual *Pediatric Environmental Health* (the "Green Book") and the AAP manual *Red Book: 2018 Report of the Committee on Infectious Diseases*.[3–6] The AAP has also promoted pediatric preparedness through implementation of a 2016 regional pediatric and public health tabletop exercise and a 2017 virtual tabletop exercise (www.aap.org/disasters/tabletop).[7]

The unfortunate continuing occurrence of chemical and biological terrorism demonstrates the ongoing need to improve public health and health care system preparedness in all respects, including the detection of covert events, establishment of comprehensive response protocols for children, and implementation of plans for rapid resource mobilization to care for children. At the governmental level, the passage of key federal legislation (Table 1) has facilitated these efforts. However, there remains a need for pediatric health care providers to be knowledgeable about the chemical and biological weapons that could be used against a population that includes children and to be able to provide care during the recovery period. Moreover, principles of the care of children after chemical and biological terrorism are evolving, and these approaches will continue to inform future work.

STATEMENT OF THE PROBLEM

Pediatricians play a pivotal role in providing care in the medical home and supporting the community before, during, and after a chemical or biological event. It is critical for pediatricians and others who care for children in all care settings to continue to educate themselves regarding the pediatric consequences of a chemical or biological attack. Readiness resources and approaches will vary depending on practice setting, such as community hospitals, pediatric hospitals, emergency departments, and office practices. The role of the pediatrician and others who care for children in ensuring the health of children in disasters has been described.[3,8] Specific to chemical and biological terrorism, pediatricians and their staff will need to be prepared to promote and share information on readiness approaches, advise on pediatric decontamination strategies, provide appropriate medical care, offer anticipatory guidance to families, report appearances of unusual disease clusters, and help guide families after events. This technical report summarizes relevant information and evidence. Although the focus of this document is geared toward the US health care system, principles of this technical report can be applied to international health care settings.

NEW INFORMATION

This technical report and its accompanying policy statement[9] replace the 2006 policy statement, with an added focus on identifying and resolving system issues that are paramount to minimizing morbidity and mortality in children after their

TABLE 1 Federal Legislation Enacted Since 2001 To Improve Public Health Response to Bioterrorism and Other Public Health Emergencies

Date	Bill	Legislation
September 2001	Public Law 107-38	2001 Emergency Supplemental Appropriations Act for Recovery From and Response to Terrorist Attacks on the United States
August 2002	Public Law 107-206	2002 Supplemental Appropriations Act for Further Recovery From and Response to Terrorist Attacks on the United States
June 2002	Public Law 107-188	Public Health Security and Bioterrorism Preparedness and Response Act of 2002
November 2002	Public Law 107-296	Homeland Security Act of 2002
April 2003	Public Law 108-20	Smallpox Emergency Personnel Protection Act of 2003
December 2003	Public Law 108-169	United States Fire Administration Reauthorization Act of 2003
July 2004	Public Law 108-276	Project BioShield Act of 2004
October 2004	Public Law 108-324	Military Construction Appropriations and Emergency Hurricane Supplemental Appropriations Act, 2005
December 2004	Public Law 108-494	ENHANCE 911 Act of 2004
May 2005	Public Law 109-13	Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005
September 2005	Public Law 109-72	Flexibility for Displaced Workers Act
September 2005	Public Law 109-62	Second Emergency Supplemental Appropriations Act to Meet Immediate Needs Arising From the Consequences of Hurricane Katrina, 2005
October 2005	Public Law 109-88	Community Disaster Loan Act of 2005
December 2005	Public Law 109-148	Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006
April 2006	Public Law 109-218	Local Community Recovery Act of 2006
September 2006	Public Law 109-288	Child and Family Services Improvement Act of 2006
June 2006	Public Law 109-234	Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery, 2006
December 2006	Public Law 109-417	Pandemic and All-Hazards Preparedness Act
May 2007	Public Law 110-28	US Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007
September 2008	Public Law 110-329	Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009
October 2008	Public Law 110-376	United States Fire Administration Reauthorization Act of 2008
October 2008	Public Law 110-377	Poison Center Support, Enhancement, and Awareness Act of 2008
October 2008	Public Law 110-392	Comprehensive Tuberculosis Elimination Act of 2008
April 2009	Public Law 111-13	Serve America Act
January 2011	Public Law 111-351	Predisaster Hazard Mitigation Act of 2010
March 2013	Public Law 113-5	Pandemic and All-Hazards Preparedness Reauthorization Act of 2013
November 2015	Public Law 114-80	DHS Social Media Improvement Act of 2015
December 2015	Public Law 114-111	Emergency Information Improvement Act of 2015
April 2016	Public Law 114-143	Integrated Public Alert and Warning System Modernization Act of 2015
September 2016	Public Law 114-223	Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act
December 2016	Public Law 114-268	First Responder Anthrax Preparedness Act
December 2016	Public Law 114-255	21st Century Cures Act
December 2016	Public Law 114-326	National Urban Search and Rescue Response System Act of 2016

exposure to a chemical or biological weapon.

REVIEW OF EVIDENCE

Exposure Sources for Chemical and Biological Weapons

Exposure to chemical and biological weapons can occur through several potential sources. Airborne releases of agents have remained the primary concern because large populations can be exposed by this route. Potential mechanisms of exposure include crop-dusting airplanes, tainted letters, and release of agents into confined spaces (eg, subway tunnels, office buildings, theaters). Contamination of the water supply is also a potential source for exposure, although dilution of chemical and biological agents in water is mitigating, and few chemical or biological agents are both water stable and resistant to water-purification techniques that decrease the risk. Finally, the contamination of food that is either unprocessed (eg, uncultivated grain) or processed (eg, a consumer product) is considered a potential means of exposure to chemical or biological weapons.

Specific Vulnerabilities in Children

After events of chemical or biological terrorism, children have a greater risk of both exposure and harm, the result of key developmental, anatomic, and physiologic vulnerabilities. Children have greater life expectancy than adults and, therefore, have more time in which to develop sequelae such as cancer from a variety of sources of exposure (air, water, or food) to chemical or biological weapons. For each source of exposure, children possess a significantly greater likelihood of exposure because of their intake patterns. Children inhale considerably more air on a per-weight basis than adults (400 vs 140 mL/kg per minute, respectively). Consequently, for any concentration of an airborne toxicant, a child will inhale more of the substance on a per-kilogram basis than an adult. Also, substances that are heavier than

air have their highest concentration near the ground, closer to the breathing zone of the child. Because of a proportionately greater body-surface area, children have both greater exposure and an increased likelihood of systemic toxicity to agents that contact their skin. Children have fluid and food intakes that differ significantly from adults. For example, children ingest approximately 100 mL/kg of water per day, whereas adults ingest 40 to 60 mL/kg per day. Children drink more milk than adults, placing them at risk for exposure to agents that can enter the milk supply through contamination of the grass on which cows feed. In the Chernobyl radiation disaster, cows grazed in contaminated pastures, leading to excess radioactivity in their milk. Children drinking this milk sustained significant exposure to radioisotopes, including iodine and strontium.[10] Finally, children not only eat more food on a per-kilogram basis but also have diets that are distinctly different from adults (eg, greater consumption of fruits). Once exposed to a chemical or biological agent, children have numerous physiologic vulnerabilities that could lead to a greater risk of harm. These vulnerabilities include undeveloped self-preservation skills that make them less able to flee danger; an immature immune system that makes them less able to contain infection (eg, plague); less fluid reserve, which can result in a greater risk of severe dehydration after exposure to agents that produce excess gastrointestinal fluid loss (eg, Ebola virus disease); and a greater risk of anxiety reactions and posttraumatic stress disorder after witnessing or being victim to a terrorist act.4 Additionally, with the advent of technology, there is increased availability of social media to children and adolescents, allowing for access to online terrorist information or suggestive material on how to terrorize.

Public Health Preparedness

The All-Hazards Approach

In past years, resources have been provided to public health authorities, including the network of state and regional poison control centers, and first responders (fire officials, police officers, and emergency medical services personnel) to create systems capable of responding to a possible chemical attack. Similarly, emerging and reemerging infections as well as highly contagious organisms such as Ebola have led to a massive public health effort to improve response capability to future acts of biological terrorism. The initiation of these response campaigns revealed large-scale weaknesses in state and local public health infrastructure. Moreover, it became evident that intense effort was being directed toward events that might never occur rather than toward public health threats of much greater likelihood (eg, an unintentional hazardous chemical release). Finally, it became clear that a fragmented and reactive public health response plan is more expensive and inefficient than a single, comprehensive plan. As a result, disaster response agencies and public health authorities have increasingly embraced the concept of the "all-hazards approach." Representing a dramatic paradigm shift in the preparation for chemical and biological terrorism, the all-hazards approach is designed to augment the public health infrastructure, using an integrated model of disaster response. The creation of all-hazards response systems has led to improvements in public health response capabilities. For example, an effective public health response protocol for a sarin release would be equally effective for a hazardous-materials (hazmat) release in the community, such as the 2017 chemical fires in Texas that followed massive flooding and power losses in the wake of Hurricane Harvey.[11] Similarly, the same protocol created to respond to the appearance of smallpox can be modified easily to contain an outbreak of severe acute respiratory syndrome. However, as threats increase and local and state budgets fluctuate, there will continue to be challenges to achieve adequate responses.

Pediatric Disaster Preparedness and Education

Several investigators have studied disaster preparedness and education specific to the needs of children. In 2008, Schobitz et al[12] conducted a study of pediatric and emergency medicine residents at a single institution to assess their baseline knowledge of management of pediatric victims of chemical and biological terrorism. Using an expert-developed, validated test, the investigators determined that the residents of this era were unprepared to manage these victims. The 2010 Pediatric Emergency Mass Critical Care Task Force concluded that mass events place unusual stresses on health care providers, many of whom must provide care outside of their scope of practice, and that education and educational resources can mitigate anxiety and chaos in these contexts.[13] Subsequent research in pediatric disaster triage has demonstrated that a multiple-simulation curriculum can improve prehospital care providers' assessment skills.[14] In addition, studies have revealed an increase in clinical staff's knowledge and confidence with pediatric disaster skills with short, topic-focused educational interventions.[15,16] There are also review articles of pediatric disaster courses to educate health care professionals.[15,17,18]

Agents of Concern

Chemicals

Three traditional assumptions specific to chemical terrorism have proven simplistic. These include the narrow concepts that (1) such weapons were intentionally and specifically manufactured as instruments of mass destruction; (2) chemical terrorism was dramatic and recognized immediately (eg, the sarin

incident in Tokyo); and (3) only well-organized, well-funded terrorist groups were capable of releasing chemical weapons after extensive planning. These concepts have been expanded to include the possibilities that (1) readily available, legitimate chemicals, such as chlorine, can be misused (ie, "weapons of opportunity"); (2) these acts can be covert, with delayed recognition; and (3) a motivated, "lone-wolf" individual with few resources can perpetrate significant releases.

Acts of chemical terrorism involving children illustrate these expanded concepts. In 1999, patrons of a restaurant in Fresno, California, developed severe gastroenteritis. An investigation by public health authorities discovered that the carbamate insecticide methomyl had been added maliciously to the salt. More than 100 adults and children became ill with nausea, vomiting, and diarrhea; a perpetrator was never identified.[19] In 2003, in Grand Rapids, Michigan, a disgruntled grocery store worker placed a nicotine-containing insecticide into ground beef, making it available for purchase by unsuspecting customers. It was not until widespread illness (nausea, mouth burning, vomiting) was reported and there was a recall and analysis of the meat, revealing the presence of nicotine, that this was recognized as an act of terrorism. Ultimately, more than 100 people became ill, including more than 40 children, in what is now considered the largest act of chemical terrorism in US history.[20]

Research in the past decade specific to chemical exposures has been focused on antidotes and resultant injury after exposure. For nerve-agent exposure, 3 classes of medication are used in the treatment of nerve-agent exposure: (1) anticholinergics, usually first-line atropine, to block excess acetylcholine at peripheral muscarinic receptors; (2) oximes, such as pralidoxime, to reactivate inhibited acetylcholinesterase; and (3) anticonvulsants[21] (please refer to the Nerve Agents section for further discussion of clinical effects). Some studies have explored the problem of antidote dosing in children, particularly with respect to prepackaged autoinjectors. Baker[22] noted that adult doses of atropine are well tolerated, even in young children, and recommended the use of the atropine (0.5 or 2 mg) autoinjector for children younger than 1 year after nerve-agent exposures when weight dosing is impractical or not possible to control excessive bronchorrhea and to prevent respiratory failure.[22] In a 2009 review of research on atropine dosing, Sandilands et al[23] considered pharmacokinetic data to balance sufficient and timely dosing of atropine versus the risk of overdose; the authors recommended relatively large initial doses of atropine in children, who are relatively resistant to its adverse effects. Droste et al[21] used a pharmacokinetic model to analyze current CDC and US Army treatment protocols and found that in general, oxime therapy alone was ineffective in alleviating symptoms.[19] The atropine and pralidoxime combination autoinjector can, in theory, be used in children older than 1 year; as of 2018, however, the combination autoinjector was not FDA approved for pediatric patients weighing less than 41 kg. However, authors of an extensive review of antidotes for a variety of chemical agents concluded that the strength of evidence supporting the use of these antidotes is generally weak and that more research is needed.[24]

Other investigators have studied injury related to chemical exposures. Custer et al[25] used an in vitro test lung to simulate pediatric lung injury; the goal was to assess the efficacy of transport and/or emergency ventilators in the setting of mass-casualty respiratory failure. These investigators found that few of the ventilators, chosen from a range of manufacturers, were capable of the minimum alarm and tidal volume function necessary to support the ventilation of pediatric victims.

Additional efforts have focused on improving access to information after chemical exposures. The ASPR, in cooperation with the National Library of Medicine, has developed a Web site that is intended to enable health care professionals to respond to mass-casualty events involving chemicals (https://chemm.nlm.nih.gov/). The resource can be downloaded to a computer or mobile device in advance of an event that might limit or interrupt Internet access.[26]

The analysis of a mass-casualty event may identify 1 or more specific chemicals. The World Health Organization considers the following 6 categories of chemicals to be the most likely threats: nerve agents, blistering agents (vesicants), irritants (corrosives), choking agents, asphyxiants (cyanogens and carbon monoxide), and disabling (incapacitating) agents, including lacrimators (Table 2).[27]

Nerve Agents

Nerve agents are well absorbed through intact skin and even through examination gloves used in clinical settings. All nerve agents act as acetylcholinesterase inhibitors, producing the same symptoms and signs associated with organophosphate poisoning. Manifestations can range from mild (miosis, nausea, diarrhea) to severe (muscle weakness, fasciculations, respiratory failure, coma, and seizures).

In the 1995 sarin episode in Tokyo, the most unanticipated sequela was the degree of injury to health care professionals.[28] Several hundred physicians, nurses, and other health care professionals became ill as a result of 2 factors: handling of sarin-contaminated victims without wearing personal protective equipment (PPE) and entry of contaminated victims into health care facilities, allowing sarin vapor to

enter the ventilation system.[27,29] This event firmly demonstrated the importance of using PPE to protect health care professionals, decontaminating victims before building entry to maintain office or hospital safety, and using environmental controls such as airborne infection isolation rooms (negative-pressure rooms).

Management of nerve-agent exposure includes supportive care and, when indicated, prompt administration of the antidotes atropine and pralidoxime (see the introduction to the previous section, Chemicals, for recent research regarding atropine, pralidoxime, and autoinjectors).[30] Autoinjectors are particularly important in mass-casualty incidents when there is a need to treat large numbers of victims as quickly and efficiently as possible. Until recently, the absence of pediatric autoinjectors complicated the rapid administration of atropine and pralidoxime to children; only the devices approved for adults, containing 2 mg of atropine and 600 mg of pralidoxime, were available. In 2003, the FDA approved new dosage forms of atropine sulfate, approved since 1973 for adults, for use in children and adolescents after nerve-agent exposure.[31] However, the continued absence of a combination pediatric autoinjector in the United States, which is critical to the successful treatment of central nervous system and muscular toxicity from nerve agents, leaves the use of standard, multidose vials as the only therapeutic option. To address this issue, consensus guidelines now recommend that children weighing 13 kg or more (2–3 years of age or older) receive a 600-mg dose of pralidoxime from an autoinjector because this pralidoxime dose falls within the range of safety for the drug.[32] Children weighing less than 13 kg can receive the customary weight-based (20–50 mg/kg) dose, administered from a multidose vial; if the multidose vial is unavailable, an autoinjector could be used. Repeat dosing of atropine may be necessary to mitigate secretions.

Other aspects of care to children who have been exposed to nerve agents are found in recent reviews.[29,33]

Blistering Agents (Vesicants)

Vesicants include sulfur mustard and lewisite, an arsenic-based blistering agent first used in World War I. British antilewisite (dimercaprol) was developed in subsequent years and mitigated the risk to allied soldiers in World War II; it remains useful today as an antidote in some cases of heavy-metal poisoning.[34] The vesicants, released as aerosols, produce erythema, burning, vesiculation, and then desquamation of the skin. Victims of blistering-agent exposure typically develop skin tingling, then burning; within 24 hours, skin sloughing begins to occur, with wounds having the appearance of partial-thickness burns. These agents -are also immunosuppressive, further increasing the risk of severe -infection. Treatment is largely supportive. Important principles of management include topical decontamination and PPE use to protect health care professionals.[35]

TABLE 2 Chemical Weapons of Concern

Agent Classification	Built Weapon	NATO Codes	Weapon of Opportunity
Nerve agents	Tabun	GA	Pesticides
	Sarin	GB	Nicotine
	Soman	GD	Organophosphates
	VX gas	VX	Carbamates
Blistering agents (vesicants)	Lewisite	L	—
	Mustard gas	HD	—
	Nitrogen mustard	—	—
Irritants (corrosives)	—	—	Ammonia
	—	—	Bromine
	—	—	Chlorine
Choking agents	Phosgene	CG	Perfluoroisobutylene (Teflon) and other chemical polymers
	Nitrogen oxides	NOx	Smoke, products of combustion
Asphyxiants	Hydrogen cyanide	AC	Industrial cyanide
	—	—	Sodium azide
	—	—	Carbon monoxide
Disabling agents (incapacitators)	3-quinuclidinyl benzilate	BZ	Anticholinergics
	Cannabinoids	—	—
	Barbiturates	—	—
	Fentanyl derivatives	—	—
	Lacrimators: Chloroacetophenone	CN	Lacrimators
	Chlorobenzylidene	CS	Capsaicin

AC, hydrogen cyanide; BZ, 3-quinuclidinyl benzilate; CG, phosgene; CN, chloroacetophenone; CS, chlorobenzylidene; GA, tabun; GB, sarin; GD, soman; HD, mustard gas; L, lewisite; NATO, North Atlantic Treaty Organization; NOx, nitrogen oxide; —, not applicable. Adapted from World Health Organization. Chemical weapons of concern. Available at: www.who.int/csr/delibepidemics/annex1.pdf. Accessed June 15, 2018. Adapted from Tuorinksy SD, ed. *Medical Aspects of Chemical Warfare.* Washington, DC: Office of the Surgeon General at TMM Publications; 2008: 292–293.

Irritants (Corrosives)

The irritants and corrosives include common chemicals such as ammonia, bromine, and chlorine, which can affect the skin, eyes, mucous membranes, gastrointestinal tract, and predominantly, the upper and lower respiratory tracts. Decontamination includes copious water irrigation of the skin and eyes; management is mainly supportive, but the risk of delayed pulmonary injury remains for 24 hours.[36] The Assad regime in Syria has used chlorine gas against civilians, causing at least 1 pediatric death.[2,37]

Choking Agents

Choking agents are created to produce, usually in delayed fashion, pulmonary injury: bronchospasm, pulmonary edema, and respiratory failure. Immediate symptoms include eye burning, tearing, and blepharospasm. The major agent of this group is phosgene; however, common industrial chemicals, including polytef (Teflon) and other chemical polymers, act as choking agents depending on their ambient concentration. Most choking agents are heavier than air, which could produce higher concentrations at the breathing level of the child. Treatment is supportive.

Asphyxiants (Cyanogens and Carbon Monoxide)

The asphyxiants include the cyanogens and carbon monoxide, often generated in fires. Victims of asphyxiant exposure must be recognized promptly to remove them from the source and to administer life-saving antidotes.

The cyanogens (cyanide salts and sodium azide) interrupt cellular use of oxygen, producing respiratory distress, coma, metabolic acidosis, and lactic acidosis. In the United States, the traditional cyanide antidote "kit" was amyl nitrite inhalation or sodium nitrite injection—which generates methemoglobin—followed by sodium thiosulfate, which reacts with methemoglobin and converts the potentially lethal cyanide ion to the stable thiocyanate ion. Hydroxocobalamin is a newer option that acts more rapidly than thiosulfate and avoids the additional hazard of the methemoglobin intermediate.[38]

Carbon monoxide, a potential weapon of opportunity, binds avidly to hemoglobin and other hemoproteins, interfering with oxygen transport and tissue delivery, and may lead to nonspecific symptoms that mimic viral infections. After immediate removal from carbon monoxide exposure, victims will benefit from receiving 100% oxygen administered via a nonrebreather mask. The degree of illness rather than specific carboxyhemoglobin levels can guide treatment; some experts recommend consultation with a hyperbaric oxygen facility for more severe cases.[39]

Disabling (Incapacitating) Agents

Disabling or incapacitating agents include several different chemical classes (eg, anticholinergic agents, hallucinogens, cannabinoids, and fentanyl derivatives). In the 2002 Russian theater hostage incident, a fentanyl-based disabling agent may have been released during the rescue effort. The agent, although successful in overwhelming the hostage-takers, also killed 127 hostages.[40]

Many disabling agents are weapons of opportunity, easily acquired pharmaceutical agents, or substances of abuse that are added surreptitiously to common sources of food or drink.

Included among disabling agents are lacrimators. Often referred to collectively as Mace or "tear gas," lacrimators include the chemicals chloroacetophenone and chlorobenzylidene as well as capsaicin ("pepper spray"). Lacrimators are designed to produce incapacitation from irritation of the eye and other mucous membranes. Exposure to lacrimators leads to eye burning, tearing, and blepharospasm; victims may become temporarily blind. Inhalation produces mouth pain, shortness of breath, and, in rare cases, laryngospasm. Because capsaicin is widely sold as a nonlethal weapon, episodes of capsaicin release into the ventilation system of schools and buildings are a relatively common prank, although such incidents meet the definition of terrorism.[41]

Biological Agents

Most of the biological agents that could be used as weapons are now discussed in the AAP *Red Book*,[6] although some agents (eg, ricin) are not discussed in detail. Ricin is discussed in a subsequent section of this report.

The biological agents of concern are listed in Table 3. These agents have been placed by the CDC into categories A, B, or C. Thirty-nine agents are included in these 3 categories.

Category A agents are considered the greatest public health threat because of their potential ease of dissemination, resulting high morbidity and mortality, and potential to cause public panic and need for special actions for public health preparedness. Currently, there are 6 agents in this group, including the pathogens that cause anthrax, botulism, plague, smallpox, tularemia, and the viral hemorrhagic fevers, specifically filoviruses (Ebola and Marburg viruses) and arenaviruses (Lassa and Machupo viruses). Detailed descriptions of these agents have been published in the AAP *Red Book* and elsewhere.[6,42] The second highest-priority agents (category B) are moderately easy to disseminate, with moderate morbidity and low mortality. Category B agents also require additional enhancements of

CDC diagnostic and surveillance capabilities (Table 3). Category C agents are of concern because of their future potential to be engineered for mass dissemination, with attendant major health impact with high morbidity and mortality. Mycotoxins are toxins produced by fungi. Agents of primary concern, trichothecenes and aflatoxins, have properties of both chemical weapons and biological weapons and could be used in chemical warfare (Tables 1 and 2).[43,44]

Smallpox (Variola)

Until the Ebola virus epidemic in 2013–2016, the most widely discussed category A agent was Variola major, the agent that causes smallpox. Initial CDC smallpox immunization efforts initiated in 2002 included a "ring immunization" (surveillance and containment) strategy in the United States.[45,46] Subsequently, the CDC recommended a 3-phase plan for smallpox immunization of health care professionals and other individuals, although the program met with only limited success in the first phase of vaccination of health care professionals in acute-care facilities.[42] A high rate of vaccine refusal by health care professionals, concerns about the safety of the vaccine, extensive contraindications to the vaccine, and the appearance of unrecognized adverse effects from the vaccine (eg, fatal cardiac disease)[47,48] hampered the program.[49,50] In 2015, the CDC and AAP published updated clinical guidance for use of the 3 smallpox vaccines in the US Strategic National Stockpile (SNS) for people at risk for smallpox infection after an intentional or accidental release of the virus.[43]

Ricin

Although it is a category B agent, ricin has become a major biological weapon of concern because it is 1 of the most toxic biological agents known. A plant-derived, heat-stable toxin, ricin is an extract of the castor bean (*Ricinus communis*). Ricin acts by inhibition of protein synthesis of cells, ultimately resulting in cell death. Rapidly dividing tissues, particularly the gastrointestinal epithelium, are most susceptible to ricin actions. With these effects, ricin produces severe morbidity and mortality.

Ricin is a versatile agent that can be administered by ingestion, inhalation, or injection. When ingested, it can produce a syndrome of severe gastrointestinal upset, vomiting, hemorrhagic gastroenteritis, shock, and cardiovascular collapse. After inhalation, respiratory distress with a necrotizing pneumonitis may occur. Injection produces rapid shock and cardiovascular collapse. Treatment is supportive. A vaccine against ricin is currently under development.

Ricin has been associated with terrorist activity in the United States on multiple occasions, particularly as an agent sent through the mail. In October 2003, 2 ricin-containing letters were found in the US postal system.[51] In a third incident, ricin was found in the mail sorter of a congressional post office in January 2004. In June 2006, the CDC developed a comprehensive guideline for public health and medical officials in response to a ricin incident.[52] As recently as 2013, the Federal Bureau of Investigation responded to reports of suspicious letters received at mail facilities that contained ricin.[53]

Syndromic Surveillance

Overt acts of chemical and biological terrorism such as the sarin release in Tokyo present the challenge of rapidly identifying the agent and mobilizing the proper interventions. However, acts of chemical and biological terrorism may also be covert. Examples include the cyanide contamination of Tylenol (1982),[54] the release of anthrax (2001), and the nicotine contamination of ground beef (2003).[18] Covert incidents pose a significantly greater public health challenge and are more likely to induce widespread fear than overt events. Mechanisms for early recognition of a covert chemical or biological event, therefore, are necessary to contain the incident and minimize its impact.

TABLE 3 Biological Weapons of Concern

Weapon Category
Category A
Anthrax (*Bacillus anthracis*)
Botulinum (*Clostridium botulinum* toxin)
Plague (*Yersinia pestis*)
Smallpox (*Variola major*)
Tularemia (*Francisella tularensis*)
Viral hemorrhagic fevers (filoviruses [eg, Ebola, Marburg] and arenaviruses [eg, Lassa, Machupo])
Category B
Brucellosis (*Brucella* species)
Epsilon toxin of *Clostridium perfringens*
Food-safety threats (eg, *Salmonella* species, *Escherichia coli* 0157:H7)
Glanders (*Burkholderia mallei*)
Melioidosis (*Burkholderia pseudomallei*)
Psittacosis (*Chlamydia psittaci*)
Q fever (*Coxiella burnetii*)
Ricin toxin from *Ricinus communis* (castor beans)
Staphylococcal enterotoxin B
Typhus (*Rickettsia prowazekii*)
Viral encephalitis (alphaviruses [VEE, EEE, WEE])
Water safety threats (eg, *Vibrio cholerae*, *Cryptosporidium parvum*)
Category C
Emerging threat agents (eg, Nipah virus, hantavirus)

EEE, eastern equine encephalomyelitis; VEE, Venezuelan equine encephalomyelitis; WEE, western equine encephalomyelitis.

Syndromic surveillance, a specialized type of outbreak detection, is a term used to describe mechanisms for monitoring health indices or events that reflect the early stages of a chemical release or of an infection or disease of public health importance to minimize consequences.[55,56] Syndromic surveillance is considered an important means of identifying public health emergencies in their initial stages. Syndromic surveillance techniques, summarized below, can be clinician based or automated. Many syndromic surveillance systems are based in hospital emergency departments.

Astute Clinician

The traditional mechanism of detection of an unusual occurrence has been the clinician who recognizes atypical patterns of symptoms, signs, or disease and reports them to public health authorities. The "astute clinician" principle places all health care professionals (including physicians, advanced practice providers, nurses, paramedics, emergency medical technicians, infection preventionists, laboratorians, pharmacists, epidemiologists, and health educators) in the role of sentinels for the appearance of disease clusters or other clinical abnormalities. It is important to identify and work with those who may already have a defined role in syndromic surveillance. For example, school nurses have an established or particular role in this area, and there are other professionals with these capabilities. The pivotal role of physicians and other health care professionals in surveillance, particularly for acts of terrorism, has led the CDC and other agencies to educate clinicians about chemical and biological weapons release and the diseases they produce. Clinical cues, case definitions, and syndromes for chemical weapons exposure have been published (Table 4) along with numerous resources to expand clinicians' ability to recognize covert terrorist incidents.[25,50,57]

To facilitate uniform reporting among local, state, and federal authorities after unintentional or intentional releases of chemical agents, the CDC has developed case definitions for illness.[51]

Automated Systems

Recently, there has been a rapid increase in the development of real-time, automated syndromic surveillance tools. Such automated decision support uses software to identify sentinel events such as an unusual amount of work or school absenteeism, changes in consumer purchase of over-the-counter products (eg, antipyretics or cough syrups), and changes in the chief-complaint profile among those who visit primary care physicians or hospital emergency departments.[58–60]

The CDC BioSense Platform (www.cdc.gov/nssp/biosense/index.html) is an integrated, national surveillance system that gathers data from diagnosis codes included in electronic medical records to enhance situational awareness for an all-hazards approach. The DHS BioWatch Program (www.dhs.gov/biowatch-program) provides early warning of a bioterrorist attack in more than 30 major metropolitan areas across the country.

A number of surveillance studies have attempted to use the massive volume of data on the Internet to inform rapid epidemic detection. Various surveillance tools, such as the Program for Monitoring Emerging Diseases–Mail (available at www.promedmail.org; International Society for Infectious Diseases) and HealthMap (available at www.healthmap.org; Boston Children's Hospital), which aggregates content from the Program for Monitoring Emerging Diseases–Mail and other sources, are capable of providing alleged outbreak signals ranging from days to months before official reports.[61,62]

Crowdsourcing

An unconventional and unplanned type of syndromic surveillance has arisen in recent years with the advent of mobile devices and social media applications. For example, in the 2013 intentional release of sarin gas near Damascus, Syria, many individuals recorded videos of the atrocity that killed 1400 civilians; Rosman et al[63] searched the YouTube Web site for videos that had been uploaded in the weeks after the release. Many of these videos documented significant clinical signs—including dyspnea, diaphoresis, and syncope—and also revealed problems with the use of PPE, decontamination strategies, and antidote administration. Nonclinicians contributed "crowdsourced" data, in effect, to syndromic surveillance. Although there were no chemical or biological releases at the 2013 Boston Marathon bombings, investigators were able to identify specific keywords that were posted within minutes of the explosions on the social media site Twitter before any reports were issued from public safety officials or traditional news media outlets.[64]

Governmental Roles in Emergency Preparedness

Although emergency preparedness legislation existed before 2001, the passage of additional rules has resulted in efforts by the federal government to improve public health readiness across the nation (Table 1) despite federal budgets remaining flat for more than a decade and state and local budgets declining for public health and emergency response. In contrast, there has been an escalating need to ensure the safety of all US citizens. Established in 2002, the DHS is the main federal agency that leads efforts to protect the US population against chemical, biological, and

TABLE 4 Clinical Syndromes Associated With Chemical and Biological Agents

Category	Clinical Syndrome	Potential Etiologies
Cellular hypoxia	Altered mental status, dyspnea, seizures, and/or metabolic acidosis	Cyanide, carbon monoxide, hydrogen sulfide, and/or sodium azide
Cholinergic crisis	Salivation, diarrhea, lacrimation, bronchorrhea, diaphoresis, miosis, fasciculation, weakness, bradycardia, altered mental status, and/or seizures	Nicotine, nerve agents, and/or organophosphates
Gastrointestinal illness	Abdominal pain, vomiting, profuse diarrhea, hypotension, and/or cardiovascular collapse	Ricin, staphylococcal enterotoxin E, arsenic, and/or Ebola
Lacrimation	Tearing, blepharospasm, and/or incapacitation	Lacrimators (Mace), ammonia, and/or halogens (chlorine, bromine)
Mucosal irritation	Tearing, nose and mouth burning, and/or sore throat	Ammonia and/or halogens
Muscle rigidity	Generalized muscle contractions, painful neck and/or limb spasm, and/or seizurelike activity	Strychnine
Muscle weakness	Generalized muscle weakness, ptosis, and/or respiratory embarrassment	Botulism
Peripheral neuropathy	Muscle weakness or atrophy, "stocking-glove" sensory loss, and/or depressed or absent deep tendon reflexes	Arsenic and/or thallium
Respiratory distress, acute onset	Cough, wheeze, shortness of breath, and/or generalized mucosal irritation	Ammonia and/or halogens
Respiratory distress, delayed	Cough, respiratory distress, wheeze, hypoxia, and/or pulmonary edema	Phosgene and/or sulfur mustard

radiation threats. Specifically, the DHS strives to secure the nation from many threats (eg, aviation, border security, cyber security, and emergency response). Mission areas include preventing terrorism and enhancing security, managing the US borders, administering immigration laws, securing cyberspace, and ensuring disaster resilience. Within the DHHS, the ASPR was established in 2006 to minimize the adverse health consequences from disasters. The ASPR has led the development of the National Health Security Strategy and oversees implementation of the National Biodefense Strategy.[65,66] The ASPR continuously identifies and addresses gaps in coordinating patient care and transportation in disasters, especially for coalitions and states. The ASPR also offers support in this area through the federally funded Hospital Preparedness Program, which is now focused on health care coalition preparedness efforts. The potential benefits of regional disaster health response systems are also being explored. The ASPR also leads the disaster medical assistance teams (DMATs), which provide medical assistance to regions after a large-scale disaster.[67] Although there are individuals on DMATs who have pediatric expertise, personnel on DMATs are trained to provide initial care for both adults and children. The Medical Reserve Corps, another federal effort designed to create community "medical strike teams," has no clearly established pediatric capability or standards (https://mrc.hhs.gov/HomePage).

Other DHHS agencies have undergone change; these include the CDC, FDA, and National Institutes of Health, all of which have reorganized practice, regulatory, and research priorities to include chemical and biological terrorism, along with other public health threats. In 2002, the CDC established the Coordinating Office for Terrorism Preparedness and Emergency Response (later referred to as the Office of Public Health Preparedness and Response and now renamed the Center for Preparedness and Response), and in 2012, the CDC launched the Children's Preparedness Unit to address children's needs in the context of infectious disease outbreaks and other public health emergencies. The CDC also integrated a children's health team into its Emergency Operations Center structure, beginning in 2009 with the H1N1 influenza pandemic and continuing through the responses to the Ebola virus epidemic (2013–2016); the Zika virus outbreak in 2016–2018; the Flint, Michigan, water contamination in 2016; Hurricanes Harvey, Irma, and Maria in 2017; and Hurricane Michael in 2018. At state and local levels, planning for chemical and biological terrorism is now coordinated by multiple agencies, including departments of health, emergency management agencies, poison control centers, and law enforcement authorities.[68] Because there is variability across states, pediatricians can inquire as to which agencies are in charge of planning for and responding to chemical and biological attacks in their local communities.

Poison Control Centers

The network of regional and state poison control centers, funded by federal, state, and local sources, may be the first point of contact for health care providers and members of the public concerned about possible terrorist attacks. Callers can reach poison centers 24 hours a day via a national toll-free number (800-222-1222), and call data are uploaded automatically in nearly real time (currently a median of 9.5 minutes to upload data from all centers) to the National Poison Data System, maintained at the American Association of Poison Control Centers.[69]

SNS and Pediatric MCMs

The SNS has become 1 of the most important initiatives in mass-casualty disaster response.[31] Designed to respond to disasters that overwhelm state and local resources, the SNS includes such capabilities as the delivery of medications and medical supplies to areas of need within a clinically relevant time frame. The SNS supplies include pediatric dosage forms and pediatric sizes of medical supplies as well as instructions for compounding certain tablets and capsules into liquid formulations for some but not all MCMs.[70] Unfortunately, not all MCMs are licensed for use in children, and not all MCMs are available in ideal formulations that are appropriate for younger children. According to the 2013 US Government Accountability Office, 40% of the MCMs in the SNS have not been approved for pediatric use. Of the 60% of MCMs that are approved for children, there are many instances when use is limited to people of specific ages. Currently, unapproved MCMs may be distributed under FDA emergency use authorization or investigational new drug application. If an MCM is considered under the investigational new drug application, additional consent would be needed, which would be challenging to explain to frightened parents and would likely prolong MCM mass distribution efforts during a public health emergency. Ongoing efforts continue within the ASPR to address the MCM needs of pediatric populations in relation to the current medications within the SNS and make prioritized recommendations for formulary additions or changes. The AAP has identified several concerns and recommendations in its policy, "Medical Countermeasures for Children in Public Health Emergencies, Disasters, or Terrorism."[71] Even with an increased awareness of the need, significant barriers remain to developing, testing, procuring, and distributing medications in doses and formulations appropriate for children.[62,72] In addition, state and local plans for medication distribution need to be developed in collaboration with pediatric experts and consider children's needs for maximum effectiveness and efficiency.

The Primary Care Provider and Community Response

Pediatricians play a pivotal role in providing care in the medical home and supporting the community before, during, and after a chemical or biological attack.[4] Most families will seek medical advice from a trusted source such as their pediatrician. Pediatricians can emphasize the need for family disaster preparedness planning before an event and provide resources such as the AAP Family Readiness Kit.[73] After an attack or outbreak, pediatricians and their staff will need to be knowledgeable about the medical course for the agent of concern and provide anticipatory guidance to the families. Although victims of a chemical or biological attack may be treated initially in hospital emergency department settings, victims may also seek care from the medical home. Thus, pediatricians will need to be prepared for a surge in communications with patients and families, have the appropriate PPE (and related training on how to use the equipment), and have developed isolation procedures. Pediatricians will also need to be prepared to help families care for the long-term physical and emotional sequelae. Additional information on the role of the pediatrician in disaster preparedness and response is available.[3,8]

Prehospital and Hospital Preparedness

Hospital protocols for pediatric victims of chemical or biological terrorism must be established in all hospitals. These disaster protocols require an integrated response from the emergency department, ICU, operating rooms, and other key clinical areas within the hospital. Response needs include having an adequate number of pediatric supplies and staff members trained in the care of ill children, including pediatric medication weight-based dosing (milligrams of medication per kilogram of body weight) to minimize morbidity and mortality.[3,31,74,75] The needs of children with chronic health conditions as well as physical and intellectual disabilities need to be considered in the disaster plan. All hospitals should have disaster protocols for pediatric patients, including mobilization of child-life specialists, volunteers, and others such as behavioral health professionals who can provide comfort to and minimize the stress of children, particularly if those children are separated from their parents. For hospitals that do not treat large numbers of children, telehealth and telementoring technologies offer access to information and to pediatric subspecialists to facilitate the care of children.[76] In addition, hospitals participating in a regional coalition may be asked to provide care for victims far away from the affected site.

To be fully prepared for chemical or biological terrorism, pediatric and general hospitals must also have an evacuation plan for times when the hospital environment becomes uninhabitable. Although protocols for "vertical evacuation" (ie, the removal of patients to other areas or floors within the same building) are well established in hospital-based disaster response, comprehensive plans for complete building evacuation are less well developed. Pediatric hospitals requiring full evacuation may have the additional challenge of transporting pediatric patients to health care facilities with relatively few pediatric resources. Nonetheless, memoranda of agreement with

nearby or affiliated institutions and regional alliances are a key part of a comprehensive pediatric hospital disaster plan.

Decontamination

Several investigators have focused on the logistics of prehospital and hospital preparedness. In a study of 2 mass decontamination field exercises, investigators in the United Kingdom used radio-frequency identification tags and detection mats to examine bottlenecks in the process. Computer analysis revealed that bottlenecks occurred at specific phases of the process (eg, the redressing or "rerobing" that followed decontamination showers), and subsequent simulations revealed that shortening the duration of showers and adding capacity in the rerobing area could improve throughput of casualties.[77]

After exposure to a chemical or biological weapon, children may become covered by toxic material that can produce skin injury or be absorbed, producing systemic toxicity. In the case of infectious material, the contamination of skin could be sufficient to represent a threat to health care professionals as well as the victim. When children are covered with unknown but potentially dangerous chemical or infectious material, immediate decontamination is required.[78] To minimize exposure to health care professionals and patients within the health care facility, the child should be disrobed outdoors—as per Occupational Safety and Health Administration regulations—before entering the ambulance or building, with attention to prevention of hypothermia, as noted below. Plans should address the collection of contaminated water. Disrobing alone accounts for more than 85% of topical decontamination and is an extremely effective means of ending exposure. In the Tokyo sarin experience, it was determined that removal of clothing can eliminate pockets of trapped gas.[79] When possible, the victim should disrobe himself or herself to minimize exposure to others. Health care professionals should not assist in disrobing unless they are wearing appropriate PPE.[68]

There is some debate about the merits of dry decontamination (removal of clothing, scraping, absorbent or adsorbent materials, vacuuming, pressurized air, provision of replacement clothing) alone versus wet decontamination, which adds showering to topical decontamination. The decision to use dry versus wet decontamination may depend, for example, on the presence of clearly visible contamination or evidence of a blistering agent.[66]

Showering further removes chemicals, microbes, and debris. As with disrobing, showering usually happens outdoors. However, some institutions may have specially designed indoor hazmat decontamination facilities. Protocols should include strategies for using warm water and low-pressure showers (to avoid trauma to the skin), etc, to prevent hypothermia in children, as well as methods for the collection of contaminated water. Principles of showering include the establishment of 3 management zones in the decontamination staging area (hot [maximum contamination], warm [less contamination]), and cold [no contamination] zones), use of water that has been warmed to a temperature of 100°F, a water pressure of 60 lb psi, and containment of the wastewater. If the toxic material is oily or firmly adherent to the child's skin, a mild soap or shampoo should be used; solutions such as mild bleach should not be used on children because of the risk of skin injury.[31] If an outdoor shower is not available, the child can be simply disrobed before being brought into the health care facility for further care. Decontamination can be a frightening procedure for children, exacerbated by the identity-concealing PPE that clinicians are wearing. Efforts can be made to keep parents nearby and families intact; when possible, parents should remain with their child to offer psychological support and assist with their child's decontamination.[80]

A number of studies have explored various materials—including water—for decontamination. One preliminary study of water-only decontamination of an oil-based, mock chemical-biological agent suggested that 100% of subjects could be decontaminated within 90 seconds.[81] Although proprietary agents are available for specific types of exposures, a review of corrosive dermal exposures found that water is efficacious, widely available, and inexpensive.[82] In specific, known exposures, other decontamination agents may be more effective: a study of the molecular tracer 4-cyanophenol found that decontamination efficiency from porcine skin was 54% with water, up to 70% with dry fuller's earth, and around 90% with a suspension of fuller's earth.[83] In terms of wet versus dry decontamination, another study of absorbent materials in an ex vivo model indicated that dry decontamination was superior to wet methods for removing liquid contaminants but was not effective against particulate matter.[84]

The consensus among investigators, however, is that time is the single most important factor in successful decontamination.[85] In most cases, decontamination is most successful if performed within minutes of exposure, which has the added benefit of mitigating the demand on health care facilities. This has introduced the concept of self-care decontamination and the mnemonic MADE: move and assist, disrobe and decontaminate, evaluate and evacuate.[86]

All health care professionals who assist in decontamination must protect themselves by wearing appropriate PPE.[87] Currently, there are 4 levels of PPE, ranging from level A, which is the highest level of protection, to level D, which consists of a simple gown, gloves, and surgical mask. Many exposed subjects self-present to health care facilities. For hospital personnel, level C PPE (a chemical-resistant suit and gloves, with an air-purifying respirator) is considered adequate for hospital-based management of most contaminated victims. Health care facilities can develop plans for rapid access to PPE equipment and train staff on its use. Other recently published principles of decontamination and PPE are outlined in Table 5.[88,89]

Isolation and Containment

In the current era, hospitals and health clinics need to develop protocols to be vigilant in screening, isolating, and starting treatment of patients with highly contagious emerging infectious diseases. Ideally, integrated communication systems will be in place to help clinicians identify pediatric patients with concerning travel history and possible exposures to an emerging infectious disease. Clinicians can become better prepared by knowing how to contact local and state public health officials if there is concern of a highly contagious pathogen, an emerging infection, or a cluster of illness. Preparation for the 2013–2016 Ebola virus outbreak has led to federally identified biocontainment treatment centers in each US region, including, in some cases, tertiary care pediatric hospitals. Institutions caring for a child with a high-consequence pathogen require policies that include and recognize the developmental and psychological needs of children as well as policies that address parental presence and the use of age-appropriate equipment and supplies.[90,91]

Surge Capacity

An effective response to large-scale chemical or biological terrorism (ie, an incident with more casualties than routine operations can accommodate) requires the creation of surge capacity protocols. Federal, state, and local public health authorities are essential in assisting health facilities during crises of large magnitude. Crisis standards of care have been reviewed and established at all levels.[92] Definitive care of pediatric patients is increasingly dependent on interhospital transfers and referral centers.[93] Lack of disaster planning for children in local health care facilities will impede and complicate the care of children. Because disasters happen locally, all health care systems must consult with pediatric experts and plan for the needs of children during a disaster. Plans for such an event might include (1) the creation of additional bed spaces through cohorting; (2) mechanisms for the rapid discharge of inpatients to increase capacity; (3) an inventory of all sites in the hospital where critical care can be provided; (4) establishment of a site for patient triage, ideally outside of the hospital; (5) identification of care sites for those whose injuries are minor; (6) mechanisms for labeling and tracking patients, particularly children who arrive without personal identification and may not be able to identify their parents; and (7) plans for maintaining hospital security by preventing the entry of contaminated victims and other unauthorized individuals.[94,95] For nonpediatric hospitals, surge capacity plans for a mass-casualty chemical or biological incident involving children can include mechanisms for mobilizing health care professionals with pediatric expertise, including telemedicine. Surge capacity principles are summarized in Table 6.

Pediatric Mental Health

Given that the primary intent of terrorist attacks is to cause psychological distress among victims, witnesses, and the general population, it is to be expected that adjustment reactions will be a major challenge—if not the primary challenge—after chemical and biological terrorism, for both children and adults. Children are among those most at risk for psychological trauma and behavioral difficulties after

TABLE 5 Principles of Decontamination

Principles
All decontamination should occur outside of the health care facility.
All health care professionals should wear appropriate PPE, as determined by their safety officer and occupational health specialist.
All levels of health care professionals should be trained to quickly access and use PPE, including physicians, nurses, clinical assistants, security, and environmental services.
Remove clothing from the victims as quickly as possible. Victims should disrobe themselves when possible.
Discarded clothing should be placed in a labeled plastic bag and stored for possible use by law enforcement.
Consider dry (removal of clothing, scraping, absorbent or adsorbent materials, vacuuming, pressurized air, and/or provision of replacement clothing) versus wet decontamination (addition of showers).
If showering is used, ensure the following:
The water should have a temperature of approximately 100°F and a pressure of 60 psi.
Water alone is used routinely. If the material is oily, a mild soap or shampoo should be added.
Victims should shower for 5 min unless specific alternative recommendations are given.
When possible, water effluent should be contained rather than placing it in the local wastewater stream.
Use heat lamps, blankets, and other mechanisms to prevent hypothermia.
Cover hands, feet, and other exposed areas of the victim if there is evidence of gross contamination.
If there are multiple victims, anticipate the need to perform out-of-hospital triage.

a disaster and will also be influenced by their parents' reactions and by coverage in social and public media. Children may experience short- and long-term effects on their psychological functioning, emotional adjustment, and developmental trajectory. Adjustment reactions may include anxiety, worries, or fears; sadness or depression; difficulties with concentration and learning; developmental or social regression; sleep or eating problems; substance abuse or other risk-taking behavior; posttraumatic reactions and disorders; bereavement when deaths have occurred; and somatization. These reactions may be seen even among children in the community who have had no direct or indirect exposure to the chemical or biological agents. These reactions may persist long after an event, which should be a consideration for those children who have escaped countries where such terrorist attacks are known or believed to have occurred in the past.

Emotional distress may interfere with accurate reporting of symptoms or instead mimic physical responses to the chemical or biological agents. Primary and subspecialty care pediatricians will often be the first to see children experiencing psychological distress in this setting, whether it presents as physical complaints, an adjustment reaction to the terrorist attack, or a combination. Given that virtually all children in a community affected by a terrorist attack are likely to experience some degree of emotional distress and anxiety, it is critical that pediatricians become comfortable in the assessment and acute management of adjustment reactions and mental health problems that may be seen. Pediatricians should be prepared to provide psychosocial support, psychological first aid, and psychoeducation in addition to evaluation and referral to mental health specialists when indicated and resources allow.[5]

TABLE 6 Surge Capacity Principles for Hospitals

Principles
Preparation
Obtain PPE, showers, and other emergency-response equipment
Stockpile pediatric supplies
Stockpile or plan for additional pediatric pharmaceuticals
Perform drills; consider tabletop exercises using pediatric victims
Familiarize with wt-based dosing (eg, milligrams of medication per kilogram of body wt) for pediatric emergency medicines
Response
Anticipate a 1:5:7 ratio of critically ill/urgently ill ("walking wounded")/well ("worried well") casualties[96,97]
Anticipate the "second-wave" phenomenon[98]
Reserve the emergency department for critically ill patients
Perform triage and decontamination outside of the hospital
Put protocols in place to prevent campus security from unauthorized intrusion
Identify and use alternate sites of care; identify transportation options

Pediatricians who live in communities affected by terrorist attacks are likely to be worried about the health of family, friends, and themselves. They may find the delivery of care exhausting and emotionally draining given the surge in health care needs (in most cases predominantly because of the large number of individuals with psychological distress), the uncertainty of providing care during an evolving crisis for which the pediatrician has limited information and experience, and the distress that results from delivering compassionate care and witnessing the suffering of children and their families, pediatric colleagues, and the pediatrician's own family and friends. Attention to self-care and support of professional colleagues is an important component of the response to the crisis throughout the long-term recovery period.[5]

CONCLUSIONS

The threat of a chemical or biological attack remains high. Children can be the intended target or part of the targeted group. Although advances have been made in surveillance, pediatric disaster education, decontamination, and awareness, there continue to be gaps in incorporating children into disaster planning, especially with respect to the use of pediatric MCMs. Pediatric health care providers will need to be knowledgeable of possible agents and sequelae to provide optimal medical and mental health management for children exposed to chemical or biological terrorism. Pediatric health care providers will need to be trained on pediatric decontamination strategies as well as the use of PPE. Pediatric health providers can also help their communities with chemical and biological preparedness and response activities.

LEAD AUTHORS

Sarita Chung, MD, FAAP
Carl R. Baum, MD, FACMT, FAAP
Ann-Christine Nyquist, MD, MSPH, FAAP

DISASTER PREPAREDNESS ADVISORY COUNCIL, 2018–2019

Steven E. Krug, MD, FAAP, Chairperson
Sarita Chung, MD, FAAP
Daniel B. Fagbuyi, MD, FAAP
Margaret C. Fisher, MD, FAAP
Scott Needle, MD, FAAP
David J. Schonfeld, MD, FAAP

LIAISONS

John J. Alexander, MD, FAAP – *US Food and Drug Administration*
Kevin M. Chatham-Stephens, MD, FAAP – *Centers for Disease Control and Prevention*

Daniel Dodgen, PhD – *Office of the Assistant Secretary for Preparedness and Response*
Sangeeta Kaushik, MD, MPH – *US Department of Homeland Security*
Shana Godfred-Cato, DO, FAAP – *Centers for Disease Control and Prevention*
Georgina Peacock, MD, MPH, FAAP – *Centers for Disease Control and Prevention*
Erica Radden, MD, FAAFP – *US Food and Drug Administration*
Robert F. Tamburro, Jr, MD, FAAP – *Eunice Kennedy Shriver National Institute of Child Health and Human Development*

STAFF

Laura Aird, MS
Sean Diederich
Tamar Magarik Haro

COUNCIL ON ENVIRONMENTAL HEALTH EXECUTIVE COMMITTEE, 2018–2019

Jennifer Ann Lowry, MD, FAAP, Chairperson
Samantha Ahdoot, MD, FAAP
Carl R. Baum, MD, FACMT, FAAP
Aaron S. Bernstein, MD, FAAP
Aparna Bole, MD, FAAP
Lori G. Byron, MD, FAAP
Philip J. Landrigan, MD, MSc, FAAP
Steven M. Marcus, MD, FAAP
Susan E. Pacheco, MD, FAAP
Adam J. Spanier, MD, PhD, MPH, FAAP
Alan D. Woolf, MD, MPH, FAAP, FAACT, FACMT

LIAISONS

John M. Balbus, MD, MPH – *National Institute of Environmental Health Sciences*
Nathaniel G. DeNicola, MD, MSc – *American College of Obstetricians and Gynecologists*
Ruth A. Etzel, MD, PhD, FAAP – *US Environmental Protection Agency*
Natalie Villafranco, MD, FAAP – *Section on Pediatric Trainees*
Mary Ellen Mortensen, MD, MS – *Centers for Disease Control and Prevention and National Center for Environmental Health*
Mary H. Ward, PhD – *National Cancer Institute*

STAFF

Paul Spire

COMMITTEE ON INFECTIOUS DISEASES, 2018–2019

Yvonne A. Maldonado, MD, FAAP, Chairperson
Theoklis E. Zaoutis, MD, MSCE, FAAP, Vice Chairperson
Ritu Banerjee, MD, PhD, FAAP
Elizabeth D. Barnett, MD, FAAP
James D. Campbell, MD, MS, FAAP
Jeffrey S. Gerber, MD, PhD, FAAP
Athena P. Kourtis, MD, PhD, MPH, FAAP
Ruth Lynfield, MD, FAAP
Flor M. Munoz, MD, MSc, FAAP
Dawn Nolt, MD, MPH, FAAP
Ann-Christine Nyquist, MD, MSPH, FAAP
Sean T. O'Leary, MD, MPH, FAAP
Mark H. Sawyer, MD, FAAP
William J. Steinbach, MD, FAAP
Tina Q. Tan, MD, FAAP

EX OFFICIO

David W. Kimberlin, MD, FAAP – *Red Book Editor*
Henry H. Bernstein, DO, MHCM, FAAP – *Red Book Online Associate Editor*
H. Cody Meissner, MD, FAAP – *Visual Red Book Associate Editor*

LIAISONS

Amanda C. Cohn, MD, FAAP – *Centers for Disease Control and Prevention*
Jamie Deseda-Tous, MD – *Sociedad Latinoamericana de Infectologia Pediatrica*
Karen M. Farizo, MD – *US Food and Drug Administration*
Marc Fischer, MD, FAAP – *Centers for Disease Control and Prevention*
Natasha B. Halasa, MD, MPH, FAAP – *Pediatric Infectious Diseases Society*
Nicole Le Saux, MD, FRCP(C) – *Canadian Paediatric Society*
Scot Moore, MD, FAAP – *Committee on Practice Ambulatory Medicine*
Neil S. Silverman, MD – *American College of Obstetricians and Gynecologists*
Jeffrey R. Starke, MD, FAAP – *American Thoracic Society*
James J. Stevermer, MD, MSPH, FAAFP – *American Academy of Family Physicians*
Kay M. Tomashek, MD, MPH, DTM – *National Institutes of Health*

STAFF

Jennifer M. Frantz, MPH

ABBREVIATIONS

AAP: American Academy of Pediatrics
ASPR: Office of the Assistant Secretary for Preparedness and Response
CDC: Centers for Disease Control and Prevention
DHHS: Department of Health and Human Services
DHS: Department of Homeland Security
DMAT: disaster medical assistance team
FDA: Food and Drug Administration
MCM: medical countermeasure
PPE: personal protective equipment
SNS: Strategic National Stockpile

DOI: https://doi.org/10.1542/peds.2019-3750

Address correspondence to Sarita Chung, MD, FAAP. E-mail: sarita.chung@childrens.harvard.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: Dr Chung is the codirector for the Disaster Domain of the Emergency Medical Services for Children Innovation and Improvement Center. Dr Baum is the medical director for a grant from the Agency for Toxic Substances and Disease Registry and American College of Medical Toxicology; advisory board

member for the National Biodefense Science Board, American Board of Pediatrics and Medical Toxicology Subboard, Elsevier, and Wolters Kluwer; a shareholder at Biogen Inc; an author at UpToDate; and an expert witness for medical testimony on lead with attorney Michael Foley.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Kingsley P, Barnard A. Banned nerve agent sarin used in Syria chemical attack, -Turkey says. *New York Times*. April 6, 2017. Available at: https://www.nytimes.com/2017/04/06/world/middleeast/chemical-attack-syria.html. Accessed June 28, 2018
2. Ostroukh A. Chlorine gas symptoms seen after blast near Damascus-opposition health authorities. *Reuters*. February 25, 2018. Available at: https://www.reuters.com/article/us-mideast-crisis-syria-ghouta-attack/chlorine-gas-symptoms-seen-after-blast-near-damascus-opposition-health-authorities-idUSKCN1G90ZF. Accessed June 28, 2018
3. Disaster Preparedness Advisory Council; Committee on Pediatric Emergency Medicine. Ensuring the health of children in disasters. *Pediatrics*. 2015;136(5). Available at: www.pediatrics.org/cgi/content/full/136/5/e1407
4. Schonfeld DJ, Demaria T; Disaster Preparedness Advisory Council and Committee on Psychosocial Aspects of Child and Family Health. Providing psychosocial support to children and families in the aftermath of disasters and crises. *Pediatrics*. 2015;136(4). Available at: www.pediatrics.org/cgi/content/full/136/4/e1120
5. American Academy of Pediatrics Council on Environmental Health. In: Etzel RA, Balk SJ, eds. *Pediatric Environmental Health*, 4th ed. Itasca, IL: American Academy of Pediatrics; 2019
6. American Academy of Pediatrics. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*, 31st ed. Itasca, IL: American Academy of Pediatrics; 2018
7. Chung S, Gardner AH, Schonfeld DJ, et al. Addressing children's needs in disasters: a regional pediatric tabletop exercise. *Disaster Med Public Health Prep*. 2018;12(5):582–586
8. Chung S, Foltin G, Schonfeld DJ, et al. *Pediatric Disaster Preparedness and Response Topical Collection*. Itasca, IL: American Academy of Pediatrics; 2019
9. Chung S, Baum CR, Nyquist A-C; American Academy of Pediatrics, Disaster Preparedness Advisory Council, Council on Environmental Health, Committee on Infectious Diseases. Policy statement: chemical-biological terrorism and its impact on children. *Pediatrics*. 2020;145(2):e20193749
10. Hoshi M, Yamamoto M, Kawamura H, et al. Fallout radioactivity in soil and food samples in the Ukraine: measurements of iodine, plutonium, cesium, and strontium isotopes. *Health Phys*. 1994;67(2):187–191
11. Marsh R, Watkins E. As waters recede in Houston, attention turns to chemical facilities. *CNN*. September 1, 2017. Available at: https://www.cnn.com/2017/09/01/politics/environmental-regulation-hurricane-harvey-houston/index.html. Accessed June 28, 2018
12. Schobitz EP, Schmidt JM, Poirier MP. Biologic and chemical terrorism in children: an assessment of residents' knowledge. *Clin Pediatr (Phila)*. 2008;47(3):267–270
13. Tegtmeyer K, Conway EE Jr., Upperman JS, Kissoon N; Task Force for Pediatric Emergency Mass Critical Care. Education in a pediatric emergency mass critical care setting. *Pediatr Crit Care Med*. 2011;12(suppl 6):S135–S140
14. Cicero MX, Whitfill T, Overly F, et al. Pediatric disaster triage: multiple simulation curriculum improves prehospital care providers' assessment skills. *Prehosp Emerg Care*. 2017;21(2):201–208
15. Behar S, Upperman JS, Ramirez M, Dorey F, Nager A. Training medical staff for pediatric disaster victims: a comparison of different teaching methods. *Am J Disaster Med*. 2008;3(4):189–199
16. Hewett EK, Nagler J, Monuteaux MC, et al. A hazardous materials educational curriculum improves pediatric emergency department staff skills. *AEM Educ Train*. 2018;2(1):40–47
17. Siegel D, Strauss-Riggs K, Costello A; National Center for Disaster Medicine and Public Health. Pediatric disaster preparedness curriculum development: conference report. Available at: https://www.usuhs.edu/sites/default/files/media/ncdmph/pdf/pedsconferencereport_1.pdf. Accessed June 15, 2018
18. Johnson HL, Ling CG, Gulley KH; National Center for Disaster Medicine and Public Health. Curriculum recommendations for disaster health professionals: the pediatric population. Available at: https://www.usuhs.edu/ncdmph-learn/Documents/PediatricCurriculumRecommendations-201306.pdf. Accessed June 15, 2018
19. Buchholz U, Mermin J, Rios R, et al. An outbreak of food-borne illness associated with methomyl-contaminated salt. *JAMA*. 2002;288(5):604–610
20. Centers for Disease Control and Prevention (CDC). Nicotine poisoning after ingestion of contaminated ground beef--Michigan, 2003. *MMWR Morb Mortal Wkly Rep*. 2003;52(18):413–416
21. Droste DJ, Shelley ML, Gearhart JM, Kempisty DM. A systems dynamics approach to the efficacy of oxime therapy for mild exposure to sarin gas. *Am J Disaster Med*. 2016;11(2):89–118
22. Baker MD. Antidotes for nerve agent poisoning: should we differentiate children from adults? *Curr Opin Pediatr*. 2007;19(2):211–215
23. Sandilands EA, Good AM, Bateman DN. The use of atropine in a nerve agent response with specific reference to children: are current guidelines too cautious? *Emerg Med J*. 2009;26(10):690–694

24. Rodgers GC Jr., Condurache CT. Antidotes and treatments for chemical warfare/terrorism agents: an evidence-based review. *Clin Pharmacol Ther*. 2010;88(3):318–327

25. Custer JW, Watson CM, Dwyer J, Kaczka DW, Simon BA, Easley RB. Critical evaluation of emergency stockpile ventilators in an in vitro model of pediatric lung injury. *Pediatr Crit Care Med*. 2011;12(6):e357–e361

26. US Department of Health and Human Services. Chemical hazards emergency medical management. Available at: https://chemm.nlm.nih.gov/about.htm. Accessed May 31, 2018

27. World Health Organization. Deliberate chemical release: FAQs. 2017. Available at: www.who.int/environmental_health_emergencies/deliberate_events/chemical_release/en/. Accessed April 4, 2018

28. Okumura T, Suzuki K, Fukuda A, et al. The Tokyo subway sarin attack: disaster management, part 2: hospital response. *Acad Emerg Med*. 1998;5(6):618–624

29. Okumura T, Suzuki K, Fukuda A, et al. The Tokyo subway sarin attack: disaster management, part 1: community emergency response. *Acad Emerg Med*. 1998;5(6):613–617

30. Rotenberg JS, Newmark J. Nerve agent attacks on children: diagnosis and management. *Pediatrics*. 2003;112(3, pt 1):648–658

31. US Food and Drug Administration. *FDA Approves Pediatric Doses of Atropen [Press Release]*. Rockville, MD: US Food and Drug Administration; 2003

32. Markenson D, Reynolds S; American Academy of Pediatrics Committee on Pediatric Emergency Medicine; Task Force on Terrorism. The pediatrician and disaster preparedness. *Pediatrics*. 2006;117(2). Available at: www.pediatrics.org/cgi/content/full/117/2/e340

33. Henretig FM, Cieslak TJ, Eitzen EM Jr.. Biological and chemical terrorism. *J Pediatr*. 2002;141(3):311–326

34. Vilensky JA, Redman K. British anti-Lewisite (dimercaprol): an amazing history. *Ann Emerg Med*. 2003;41(3):378–383

35. Davis KG, Aspera G. Exposure to liquid sulfur mustard. *Ann Emerg Med*. 2001;37(6):653–656

36. Tovar R, Leikin JB. Irritants and corrosives. *Emerg Med Clin North Am*. 2015;33(1):117–131

37. Hemström P, Larsson A, Elfsmark L, Åstot C. l-α-phosphatidylglycerol chlorohydrins as potential biomarkers for chlorine gas exposure. *Anal Chem*. 2016;88(20):9972–9979

38. Parker-Cote JL, Rizer J, Vakkalanka JP, Rege SV, Holstege CP. Challenges in the diagnosis of acute cyanide poisoning. *Clin Toxicol (Phila)*. 2018;56(7):609–617

39. Ng PC, Long B, Koyfman A. Clinical chameleons: an emergency medicine focused review of carbon monoxide poisoning. *Intern Emerg Med*. 2018;13(2):223–229

40. Wax PM, Becker CE, Curry SC. Unexpected "gas" casualties in Moscow: a medical toxicology perspective. *Ann Emerg Med*. 2003;41(5):700–705

41. Haar RJ, Iacopino V, Ranadive N, Weiser SD, Dandu M. Health impacts of chemical irritants used for crowd control: a systematic review of the injuries and deaths caused by tear gas and pepper spray. *BMC Public Health*. 2017;17(1):831

42. Bradley JS, Peacock G, Krug SE, et al; AAP Committee on Infectious Diseases and Disaster Preparedness Advisory Council. Pediatric anthrax clinical management. *Pediatrics*. 2014;133(5). Available at: www.pediatrics.org/cgi/content/full/133/5/e1411

43. Bennett JW, Klich M. Mycotoxins. *Clin Microbiol Rev*. 2003;16(3):497–516

44. Anderson PD. Bioterrorism: toxins as weapons. *J Pharm Pract*. 2012;25(2):121–129

45. Committee on Infectious Diseases. American Academy of Pediatrics. Smallpox vaccine. *Pediatrics*. 2002;110(4):841–845

46. Petersen BW, Damon IK, Pertowski CA, et al. Clinical guidance for smallpox vaccine use in a postevent vaccination program. *MMWR Recomm Rep*. 2015;64(RR):1–26

47. Halsell JS, Riddle JR, Atwood JE, et al; Department of Defense Smallpox Vaccination Clinical Evaluation Team. Myopericarditis following smallpox vaccination among vaccinia-naive US military personnel. *JAMA*. 2003;289(24):3283–3289

48. Centers for Disease Control and Prevention (CDC). Update: adverse events following smallpox vaccination--United States, 2003. *MMWR Morb Mortal Wkly Rep*. 2003;52(13):278–282

49. AAEM/SAEM Smallpox Vaccination Working Group. Smallpox vaccination for emergency physicians. *Acad Emerg Med*. 2003;10(6):681–683

50. Kwon N, Raven MC, Chiang WK, et al; EMERGEncy ID Net Study Group. Emergency physicians' perspectives on smallpox vaccination. *Acad Emerg Med*. 2003;10(6):599–605

51. US Department of Justice Federal Bureau of Investigation. Ricin Letter [Press Release]. Washington, DC: Federal Bureau of Investigation National Press Office; 2004. Available at: https://archives.fbi.gov/archives/news/pressrel/press-releases/ricin-letter. Accessed December 14, 2019

52. US Department of Health and Human Services. Response to a ricin incident: guidelines for federal, state, and local public health and medical officials. Available at: https://emergency.cdc.gov/agent/ricin/pdf/ricin_protocol.pdf. Accessed December 14, 2019

53. The Federal Bureau of Investigation. FBI response to reports of suspicious letters received at mail facilities. Available at: https://archives.fbi.gov/archives/news/pressrel/press-releases/fbi-response-to-reports-of-suspicious-letters-received-at-mail-facilities. Accessed December 14, 2019

54. Dunea G. Death over the counter. *Br Med J (Clin Res Ed)*. 1983;286(6360):211–212

55. Buehler JW, Berkelman RL, Hartley DM, Peters CJ. Syndromic surveillance and bioterrorism-related epidemics. *Emerg Infect Dis*. 2003;9(10):1197–1204

56. Centers for Disease Control and Prevention (CDC). Recognition of illness associated with exposure to chemical agents--United States, 2003. *MMWR Morb Mortal Wkly Rep*. 2003;52(39):938–940

57. Belson MG, Schier JG, Patel MM; CDC. Case definitions for chemical poisoning. *MMWR Recomm Rep*. 2005;54(RR):1–24

58. Mandl KD, Overhage JM, Wagner MM, et al. Implementing syndromic surveillance: a practical guide informed by the early experience. *J Am Med Inform Assoc*. 2004;11(2):141–150

59. Reis BY, Mandl KD. Syndromic surveillance: the effects of syndrome grouping on model accuracy and outbreak detection. *Ann Emerg Med*. 2004;44(3):235–241

60. Beitel AJ, Olson KL, Reis BY, Mandl KD. Use of emergency department chief complaint and diagnostic codes for identifying respiratory illness in a pediatric population. *Pediatr Emerg Care*. 2004;20(6):355–360

61. Yan SJ, Chughtai AA, Macintyre CR. Utility and potential of rapid epidemic intelligence from Internet-based sources. *Int J Infect Dis*. 2017;63:77–87

62. Carrion M, Madoff LC. ProMED-mail: 22 years of digital surveillance of emerging infectious diseases. *Int Health*. 2017;9(3):177–183

63. Rosman Y, Eisenkraft A, Milk N, et al. Lessons learned from the Syrian sarin attack: evaluation of a clinical syndrome through social media. *Ann Intern Med*. 2014;160(9):644–648

64. Cassa CA, Chunara R, Mandl K, Brownstein JS. Twitter as a sentinel in emergency situations: lessons from the Boston Marathon explosions. *PLoS Curr*. 5:ecurrents.dis.ad70cd1c8bc585e9470046cde334ee4b

65. National Health Security; US Department of Health and Human Services. National Health Security Strategy 2019-2022. Available at: https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf. Accessed January 22, 2019

66. US Department of Defense; US Department of Health and Human Services; US Department of Homeland Security; US Department of Agriculture. National Biodefense Strategy. Available at: https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Biodefense-Strategy.pdf. Accessed January 22, 2019

67. Public Health Emergency. Disaster medical assistance teams. Available at: http://www.phe.gov/Preparedness/responders/ndms/ndms-teams/Pages/dmat.aspx. Accessed December 14, 2019

68. Mrvos R, Piposzar JD, Stein TM, Locasto D, Krenzelok EP. Regional pharmaceutical preparation for biological and chemical terrorism. *J Toxicol Clin Toxicol*. 2003;41(1):17–21

69. American Association of Poison Control Centers. National Poison Data System (NPDS). Available at: https://aapcc.org/data-system. Accessed September 24, 2018

70. Public Health Emergency. Strategic National Stockpile. Available at: www.cdc.gov/phpr/stockpile/index.htm. Accessed December 14, 2019

71. Disaster Preparedness Advisory Council. Medical countermeasures for children in public health emergencies, disasters, or terrorism. *Pediatrics*. 2016;137(2):e20154273

72. US Government Accountability Office. 2013 annual report: actions needed to reduce fragmentation, overlap, and duplication and achieve other financial benefits. Available at: https://www.gao.gov/assets/660/653604.pdf. Accessed June 15, 2018

73. American Academy of Pediatrics. Are you prepared for disasters? Family readiness kit. 2016. Available at: https://www.aap.org/en-us/Documents/disasters_family_readiness_kit.pdf. Accessed June 15, 2018

74. Remick K, Gausche-Hill M, Joseph MM, Brown K, Snow SK, Wright JL; American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Section on Surgery; American College of Emergency Physicians Pediatric Emergency Medicine Committee; Emergency Nurses Association Pediatric Committee. Pediatric readiness in the emergency department [published correction appears in *Pediatrics*. 2019;143(3):e20183894]. *Pediatrics*. 2018;142(5):e20182459

75. Barfield WD, Krug SE; Committee on Fetus and Newborn; Disaster Preparedness Advisory Council. Disaster preparedness in neonatal intensive care units. *Pediatrics*. 2017;139(5):e20170507

76. Marcin JP, Rimsza ME, Moskowitz WB; Committee on Pediatric Workforce. The use of telemedicine to address access and physician workforce shortages. *Pediatrics*. 2015;136(1):202–209

77. Egan JR, Amlôt R. Modelling mass casualty decontamination systems informed by field exercise data. *Int J Environ Res Public Health*. 2012;9(10):3685–3710

78. Rotenberg JS, Burklow TR, Selanikio JS. Weapons of mass destruction: the decontamination of children. *Pediatr Ann*. 2003;32(4):260–267

79. Okumura S, Okumura T, Ishimatsu S, Miura K, Maekawa H, Naito T. Clinical review: Tokyo - protecting the health care worker during a chemical mass casualty event: an important issue of continuing relevance. *Crit Care*. 2005;9(4):397–400

80. US Department of Homeland Security; US Department of Health and Human Services. Patient decontamination in a mass chemical exposure incident: national planning guidance for communities. Available at: https://www.dhs.gov/sites/default/files/publications/Patient%20Decon%20National%20Planning%20Guidance_Final_December%202014.pdf. Accessed June 15, 2018

81. Moffett PM, Baker BL, Kang CS, Johnson MS. Evaluation of time required for water-only decontamination of an oil-based agent. *Mil Med*. 2010;175(3):185–187

82. Brent J. Water-based solutions are the best decontaminating fluids for dermal corrosive exposures: a mini review. *Clin Toxicol (Phila)*. 2013;51(8):731–736

83. Roul A, Le CA, Gustin MP, et al. Comparison of four different fuller's earth formulations in skin decontamination. *J Appl Toxicol*. 2017;37(12):1527–1536

84. Kassouf N, Syed S, Larner J, Amlôt R, Chilcott RP. Evaluation of absorbent materials for use as ad hoc dry decontaminants during mass casualty incidents as part of the UK's Initial Operational Response (IOR). *PLoS One*. 2017;12(2):e0170966

85. Kumar V, Goel R, Chawla R, Silambarasan M, Sharma RK. Chemical, biological, radiological, and nuclear decontamination: recent trends and future perspective. *J Pharm Bioallied Sci*. 2010;2(3):220–238

86. Monteith RG, Pearce LD. Self-care decontamination within a chemical exposure mass-casualty incident. *Prehosp Disaster Med*. 2015;30(3):288–296

87. Rathore MH, Jackson MA; Committee on Infectious Diseases. Infection prevention and control in pediatric ambulatory settings. *Pediatrics*. 2017; 140(5):e20172857

88. Occupational Safety and Health Administration. *Best Practices for Hospital-Based First Receivers of Victims From Mass Casualty Incidents Involving the Release of Hazardous Substances*. Washington, DC: Occupational Safety and Health Administration; 2005

89. Hick JL, Hanfling D, Burstein JL, Markham J, Macintyre AG, Barbera JA. Protective equipment for health care facility decontamination personnel: regulations, risks, and recommendations. *Ann Emerg Med*. 2003;42(3):370–380

90. Davies HD, Byington CL; Committee on Infectious Diseases. Parental presence during treatment of Ebola or other highly consequential infection. *Pediatrics*. 2016;138(3):e20161891

91. Hinton CF, Davies HD, Hocevar SN, et al. Parental presence at the bedside of a child with suspected Ebola: an expert discussion. *Clin Pediatr Emerg Med*. 2016;17(1):81–86

92. Institute of Medicine. *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report*. Washington, DC: The National Academies Press; 2009

93. França UL, McManus ML. Trends in regionalization of hospital care for common pediatric conditions. *Pediatrics*. 2018;141(1):e20171940

94. Chung S, Shannon M. Hospital planning for acts of terrorism and other public health emergencies involving children. *Arch Dis Child*. 2005;90(12):1300–1307

95. American Academy of Pediatrics. Family reunification following disasters: a planning tool for health care facilities. 2018. Available at: www.aap.org/en-us/Documents/AAP-Reunification-Toolkit.pdf. Accessed December 16, 2018

96. Beaton R, Stergachis A, Oberle M, Bridges E, Nemuth M, Thomas T. The sarin gas attacks on the Tokyo subway - 10 years later/lessons learned. *Traumatology*. 2005;11(2):103–119

97. Hildebrand S, Bleetman A. Comparative study illustrating difficulties educating the public to respond to chemical terrorism. *Prehosp Disaster Med*. 2007;22(1):35–41

98. Murdoch S, Cymet TC. Treating the victims after disaster: physical and psychological effects. *Compr Ther*. 2006; 32(1):39–42

Children Exposed to Maltreatment: Assessment and the Role of Psychotropic Medication

• *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Children Exposed to Maltreatment: Assessment and the Role of Psychotropic Medication

Brooks Keeshin, MD, FAAP,[a] Heather C. Forkey, MD, FAAP,[b] George Fouras, MD, DFAACAP,[c] Harriet L. MacMillan, CM, MD, MSc, FRCPC,[d] AMERICAN ACADEMY OF PEDIATRICS, COUNCIL ON CHILD ABUSE AND NEGLECT, COUNCIL ON FOSTER CARE, ADOPTION, AND KINSHIP CARE, AMERICAN ACADEMY OF CHILD AND ADOLESCENT PSYCHIATRY, COMMITTEE ON CHILD MALTREATMENT AND VIOLENCE, COMMITTEE ON ADOPTION AND FOSTER CARE

Pediatricians regularly care for children who have experienced child maltreatment. Child maltreatment is a risk factor for a broad range of mental health problems. Issues specific to child maltreatment make addressing emotional and behavioral challenges among maltreated children difficult. This clinical report focuses on 2 key issues necessary for the care of maltreated children and adolescents in pediatric settings: trauma-informed assessments and the role of pharmacotherapy in maltreated children and adolescents. Specific to assessment, current or past involvement of the child in the child welfare system can hinder obtaining necessary information or access to appropriate treatments. Furthermore, trauma-informed assessments can help identify the need for specific interventions. Finally, it is important to take both child welfare system and trauma-informed assessment approaches into account when considering the use of psychotropic agents because there are critical diagnostic and systemic issues that affect the prescribing and discontinuing of psychiatric medications among children with a history of child maltreatment.

INTRODUCTION

Child maltreatment includes physical, sexual, and psychological abuse as well as neglect experienced by children and adolescents. Approximately 700 000 children and adolescents are substantiated victims of maltreatment in the United States each year.[1] The actual number is likely higher because nationally reported child welfare statistics greatly underestimate the prevalence of child maltreatment.[2] Pediatric health care providers routinely care for maltreated children and adolescents, and a disproportionate number of children and adolescents with a history of

abstract

[a]Department of Pediatrics, University of Utah, Salt Lake City, Utah; [b]Department of Pediatrics, University of Massachusetts Medical School, UMass Memorial Children's Medical Center, Worcester, Massachusetts; [c]Los Angeles County Department of Mental Health, Child Welfare Bureau, Continuum of Care Reform Division, Los Angeles, California; and [d]Departments of Psychiatry and Behavioural Neurosciences and Pediatrics, Offord Centre for Child Studies, McMaster University, Hamilton, Ontario, Canada

Drs Keeshin, Forkey, Fouras, and MacMillan were equally responsible for conceptualizing, writing, and revising the manuscript and considering input from all reviewers and the board of directors, and all authors approved the final manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

To cite: Keeshin B, Forkey HC, Fouras G, et al. AAP AMERICAN ACADEMY OF PEDIATRICS, COUNCIL ON CHILD ABUSE AND NEGLECT, COUNCIL ON FOSTER CARE, ADOPTION, AND KINSHIP CARE, AMERICAN ACADEMY OF CHILD AND ADOLESCENT PSYCHIATRY, COMMITTEE ON CHILD MALTREATMENT AND VIOLENCE, COMMITTEE ON ADOPTION AND FOSTER CARE. Children Exposed to Maltreatment: Assessment and the Role of Psychotropic Medication. *Pediatrics.* 2020;145(2): e20193751

maltreatment are likely to experience emotional, behavioral, and developmental problems.[3,4]

Addressing mental health conditions in children and adolescents who have experienced maltreatment involves a comprehensive assessment that is used to guide the provision of follow-up care and treatment. When maltreated children receive treatment of emotional and behavioral problems, emphasis may be placed on pharmacotherapy rather than on a broad range of interventions, including psychotherapy.[5] Each child's case will have its own individual features, and there are situations in which medications are necessary; however, irrespective of mental health diagnosis, maltreated children and adolescents receive more psychotropic medications than comparable populations receiving psychiatric care, suggesting overtreatment.[6,7] Children and adolescents involved with the child welfare system are 2 to 3 times more likely to be treated with psychotropic medication compared with those without such involvement.[8,9] In addition, 33% of all foster children are prescribed a psychotropic medication. Among Medicaid-eligible children, foster children are approximately 4 times more likely to be prescribed a second-generation antipsychotic than children not in foster care,[10] with 10% of foster children receiving 3 or more psychotropic medications at any given time.[11]

The purpose of this clinical report is to provide guidance for pediatric health care providers on the assessment and treatment of mental health conditions commonly experienced by maltreated children and adolescents in both foster care and in-home placement with a particular focus on the appropriate use of psychotropic medication. The report reviews: (1) the potential impact of the child welfare system on mental health assessment and treatment; (2) methods for assessing children and adolescents for traumatic experiences, including trauma- and non–trauma-related symptoms; and (3) approaches to the use of psychotropic medication among maltreated children and adolescents. The latter will include principles and recommendations for the prescribing and discontinuing of psychotropic medications.

ASSESSMENT

Child Welfare System

Understanding key aspects of the child welfare system and how it serves children is important for the assessment of child maltreatment experiences and traumatic stress symptoms as well as treatment planning. Although there is variability among jurisdictions, many of the key decision points are consistent across systems. Contact with child protective services (CPS) begins with a report filed by a mandated reporter, a concerned citizen, or a family member. For substantiated cases with an identified safety or risk issue, a court petition may be filed, which may result in the child becoming a court dependent. In court-dependent cases, service plans or reunification requirements ordered by the court determine the services or "reasonable efforts" that CPS must provide to the family and caregivers of the child. Cases are reviewed periodically to check on the progress of the parents or caregivers as they work toward achieving service plan goals with the aim of eventual reunification of the dependent child with his or her family, if safe to do so.

In court proceedings, the concept of "best interests of the child" is typically used to guide decisions. In addition, the principles of least restrictive settings, maintenance of family or kinship relations, and permanency are important considerations. For children who cannot safely stay at home, placement with a foster or kinship family will be the next step. It is not uncommon in the foster care system for living circumstances to be disrupted and to experience multiple moves within the system. Half of children in foster care are moved to other homes or more restrictive settings while in foster care because of behavioral concerns.[12] After multiple failed placements or when specialized services are needed, children may be moved to residential or congregate care (ie, group homes).

Emotional, Behavioral, and Developmental Problems

A recent clinical report from the American Academy of Pediatrics (AAP), "Clinical Considerations Related to the Behavioral Manifestations of Child Maltreatment,"[13] recognizes that children and adolescents who have been exposed to one or more types of maltreatment may experience a broad range of emotional, behavioral, and developmental problems.[14–17] The clinical report provides a comprehensive overview of these signs and symptoms as well as some of the most commonly associated conditions, such as posttraumatic stress disorder (PTSD).[13] Young children are overrepresented in the maltreated population and may also have emotional and behavioral problems as a result of maltreatment. These clinical problems may include changes in mood, anxiety, sleep, eating or feeding, and behavioral patterns and require that the pediatric health care provider be vigilant for the changes, given developmental stage and limited verbal interactions.[18] Because pediatricians, child psychiatrists, and other health care professionals encounter children in their practices who have been abused and/or neglected, it is important for these pediatric providers to assist children and their families in addressing impairments associated with maltreatment.

Child maltreatment is an experience and not a symptom or disorder. A focused and trauma-informed assessment should be conducted before initiating treatment including referral of a child and/or family to a specific intervention and/or medication. The broad range of conditions and symptoms associated with different forms of child maltreatment show little specificity by type of experience.[2,19] Furthermore, children and adolescents are often exposed to more than one type of maltreatment,[20] and the effects of maltreatment can overlap or be comorbid with non–trauma-related conditions. When available, review of CPS court reports or court reports filed by an assigned court-appointed special advocate can provide valuable assessment information for the pediatric provider. Determination of which aspects of a child's emotional, behavioral, or developmental condition are directly related to specific episodes of child maltreatment versus chronic exposure to maltreatment or other biological, familial, and social factors can be difficult and is generally not possible in the pediatric setting.

Developing a comprehensive picture of a child's exposure to and effects from maltreatment is important because of the pervasive consequences that maltreatment can have on the developing child. Multiple domains of functioning can be affected, including attachment, cognition, self-image, emotional responses, social interactions, and behavior.[21] Affected children and adolescents and their families often interact with professionals from multiple service sectors, including health care, mental health, child welfare, law enforcement, education, and juvenile justice. A number of specific factors may be considered, including the type and timing of exposure to maltreatment as related to developmental stage, the range of symptoms, functional impairment including developmental delay, and how behaviors and symptoms may be related to triggers and reminders of the maltreatment.

Medical, Social, and Trauma Histories

Medical, social, and trauma histories are particularly important in determining the intervention needs of a child and family when history includes child maltreatment. Emphasis on history helps to change the conversation from "What is wrong with you?" to "What happened to you?" This trauma-informed approach is critical to destigmatize and validate the patient and family. The approach will differ depending on the child's living arrangements and access to caregivers. The goal is for the clinician to communicate to the child and family an openness to hearing about past and present events and convey the message that the information is important in formulating decisions about treatment in the present and future. Children and/or family do not necessarily have to provide all details about past injuries, traumas, social services involvement, or foster care placements because this information may be gathered from other sources. Child welfare, school, and previous medical records, when available, can be obtained to inform the history.

Pediatricians should obtain a comprehensive social history to inform a child's treatment needs after exposure to abuse and/or neglect.[22] They should attempt to determine the child's current living arrangements, including any contact with the biological family, foster care placement, residential treatment, or involvement with juvenile justice. The assessment of any ongoing violence, including exposure to intimate partner violence among caregivers, is not only the responsibility of CPS; the pediatrician should be alert to these issues as well as parental mental health problems, including substance use disorder. Pediatricians must emphasize safety as a paramount consideration. It should be made clear that if a child or family is unsafe at any time, an emergency report will be made to CPS.

Assessment of Current Trauma, Social Determinants of Health, and Resilience

Increasingly, pediatric literature supports the practice of being aware of and alert to children's traumatic experiences and social determinants of health because these are important considerations when making decisions about diagnoses and treatments. Traumatic events, including maltreatment, can have a multiplicative effect,[23] and stressors beyond maltreatment, such as poverty and community violence, can contribute to the harm experienced by the child.[24,25] Increasingly, pediatric literature supports taking resilience into account, which allows the pediatric provider to address these issues with a more positive and potentially empowering perspective.[26] Yet, there are no outcome studies indicating benefits of one assessment approach over the other.[27]

It is important for pediatricians to be alert to the possibility of ongoing trauma in children who have experienced past trauma and to demonstrate openness to hearing about ongoing or recurrent experiences of maltreatment. The pediatric provider can spend time with the older child or adolescent individually and ask questions such as, "How are people in the family getting along?" and "Sometimes kids are worried about their safety or the safety of someone at home. What about you?" In some settings, the pediatrician may not be the only professional in a position to ask these questions of the child and may collaborate with another professional, such as a social worker or mental

health clinician. Regardless, questions should be open-ended and appropriate for the child's age and developmental stage and ability to respond appropriately.[28] If the child discloses information about ongoing maltreatment or new exposures not disclosed previously, it is important that the pediatric provider acknowledge and validate the child's disclosure. Information that is critical to providing medical care should be obtained and documented. Medical providers are not investigators like CPS and law enforcement; thus, although medically relevant information should be obtained, questions regarding nonmedical details are not necessary. If the child reveals ongoing or new information, the clinician should support the child, document the disclosure, and tell the child that this information needs to be shared with a child protection worker to help keep the child safe. Children should not be assured of absolute confidentiality when there are safety concerns. Stating this to a child in simple terms early in the visit with a phrase such as, "What you say will be just between you and me unless you are hurting yourself, someone is hurting you, or you are hurting someone else" will help avoid a situation in which a child feels that his or her confidence has been betrayed.

Caregivers can also provide useful information about social determinants of health and safety. Questions about food insecurity and parental mental health provide an opportunity for the practitioner to assess important risk factors but require a practitioner to have a plan to respond to identified family needs. It is essential that such inquiry not put the caregiver at risk; for example, in asking about intimate partner violence, caregivers should only be asked this question during individual interviews.[29] Caregivers should also not be assured of absolute confidentiality because they may provide information that raises concerns about the safety of the child.

Certain questionnaires and instruments have been developed to gather detailed information about exposure to child maltreatment; the National Child Traumatic Stress Network (www.nctsn.org) and the Child Welfare Information Gateway (https://www.childwelfare.gov) maintain updated databases of such tools. These tools have generally been used in research studies; there is no indication that the administration of these measures through screening leads to better outcomes for children.[30] Furthermore, such measures often involve considerable time, making them not feasible for use in the general pediatric setting, and their use may lead to the collection of information that overlaps with what a CPS worker needs to ask about in conducting an assessment.

Trauma-Related Symptoms

Along with screening tools for depression, anxiety, and attention-deficit/hyperactivity disorder (ADHD), specific tools to identify traumatic stress symptoms are available for use in the pediatric setting. The UCLA PTSD Reaction Index Brief Form[31] utilized in a primary care settings is one option for traumatic stress screening that is freely available. Familiarity of the pediatric provider with the tools chosen, specific symptoms or diagnoses screened by each tool, protocols to incorporate their use into office flow, and ability to address patient or family responses are all important. One example of how this can be done is the Intermountain Healthcare Pediatric Traumatic Stress Care Process Model.[32] As discussed in the AAP clinical report on the behavioral manifestations of child maltreatment, psychiatric diagnoses, including PTSD; internalizing problems, such as depression and anxiety; externalizing problems, including disruptive behavioral disorders (oppositional defiant and conduct disorders); substance use disorder; suicidal behavior; and ADHD are associated with maltreatment.[13] The term "complex trauma" is used to describe the effects of multiple or chronic traumatic experiences, which result in a wide range of cognitive, emotional, and behavioral changes that do not fit easily into common diagnostic categories. For children and adolescents who have suffered from severe, pervasive, or prolonged maltreatment, symptoms of complex trauma can result. These include intense emotional distress; disturbed sleep; attention and concentration problems; anger; aggressive, destructive, or reckless behavior; withdrawal; intrusive thoughts; exaggerated emotional response to stimuli; hypervigilance; risk-taking; and difficulty with emotional regulation.

For the symptoms of complex trauma noted above, trauma-specific measures, such as the Trauma Symptom Checklist for Children,[33] or broad behavioral assessment tools, such as the Child Behavior Checklist, may be used. The need for additional and improved tools in primary care or specialty settings to assess for complex trauma and distinguish it from other diagnoses has been noted. However, until new methods are developed and validated, children and adolescents at risk for complex trauma require comprehensive evaluations that lead to thoughtful and parsimonious formulations rather than a laundry list of diagnoses. The National Child Traumatic Stress Network (www.nctsn.org) has commonly used standardized measures for providers to assess these patients, along with specifics regarding the domains evaluated by the measure, targeted age, format, completion time, and source of more information.

The purpose of any measures used during the assessment should be discussed with the child and caregiver. Where appropriate, feedback to the child and/or family that highlights the child's strengths should be provided. Areas in which the caregiver and child agree or disagree can be discussed during the feedback. If opinions are consistent, this is a potential strength, indicating that child and caregiver are "on the same page." Discussing discrepancies may help family members to understand that children and caregivers have different perceptions of the same symptom. The feedback process can be used to provide some psychoeducation to families and patients. It can be helpful to explore the past strategies used to address behaviors, such as strong emotions. The family can be educated about triggers of certain behaviors and advised about how treatment can potentially relieve those symptoms. These approaches assist families to consider a child's actions using a "trauma lens," which can help families and children to understand behaviors and reduce stress. The National Child Traumatic Stress Network has a number of resources specifically for families and caregivers to further their understanding of the effects of trauma.

Although beyond the scope of this clinical report, information and practical guidance in integration of these components into pediatric practice, including preparing the practice, difficult conversations, managing office flow, and coding and billing, are available in the AAP guide "Helping Foster and Adoptive Families Cope with Trauma," the AAP's "Trauma Toolbox for Primary Care" (both available at https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/healthy-foster-care-america/Pages/Trauma-Guide.aspx), and Johns Hopkins University's "Improving the Capacity of Primary Care to Serve Children and Families Experiencing Trauma and Chronic Stress: A Toolkit" (available at http://web.jhu.edu/pedmentalhealth/PICC%20TOOLKIT%201.pdf).

TREATMENT

A stable home environment with responsive and nurturing caregiving is most important for children who have experienced maltreatment with resultant emotional and behavioral difficulties. In addition, such children need to receive evidence-based treatments (EBTs) demonstrated effective in this population. An overview of the evidence-based individual and family-based psychotherapeutic interventions for maltreated children and adolescents is provided in the AAP clinical report on the behavioral manifestations of child maltreatment.[13] A 2016 AAP technical report, "Addressing Early Childhood Emotional and Behavioral Problems," outlines services for the treatment of young children[18] because young, even nonverbal, children can be significantly affected by child maltreatment–related trauma. Because access to such interventions may be limited and, even when available, may be accessed only after long waitlists, pediatric providers should provide guidance and strategies to help families bridge the time until EBT can begin. Psychoeducation, relaxation training, encouraging parent-child communication, and parenting supports are features common to EBTs. Through pediatric anticipatory guidance, pediatric providers may support families with such approaches while waiting for EBT to become available. Helping nonoffending caregivers and patients learn relaxation techniques such as using belly breathing, guided imagery, meditation, yoga, stretching, and massage can be useful in dealing with traumatic stress symptoms after maltreatment.[34]Providing guidance on the importance of adequate sleep and exercise is also important. Referrals to community resources for mindfulness programs and parenting support can be useful in supporting children and families.

Sometimes, in an attempt to preserve existing foster care placements and reduce failure of caregiving arrangements, providers will turn to psychotropic medication in an attempt to control disruptive behaviors that threaten a placement. A Government Accounting Office report from 2011 reviewed Medicaid claims data for children and adolescents both in foster care and not in foster care in 5 states: Florida, Massachusetts, Michigan, Oregon, and Texas.[35] In this report, children and adolescents in foster care were found to be prescribed psychotropic medications at rates 2.7 to 4.5 times higher than those who were not in foster care. The report also cited high rates of polypharmacy, high doses of medications, and young age at initiation of medication therapy.[35] A follow-up report from 2012 examined Medicaid and private insurance claims data and found that children and adolescents enrolled in Medicaid were more likely to be on psychotropic medication without psychosocial interventions, such as psychotherapy. In response to the increased use of psychotropic medications in foster care, child welfare agencies have adopted programs to provide psychotropic medication oversight.[36] Detailed discussion of these programs is beyond the scope of this clinical report, but they commonly include a review by a medical practitioner with a recommendation to the child welfare agency and/or the courts for action. In some jurisdictions, parents or other stakeholders may also be given the opportunity to contest the administration of medication during a court hearing.

General Pharmacotherapy Considerations

Ideally, pediatricians work closely with therapists and psychiatrists when treating maltreated children in need of pharmacotherapy. Some pediatricians work in integrated care settings that may provide colocated or collaborative care. These models tend to enhance coordination and continuity of care and are well suited to address the clinical and system-level complexity of children exposed to child maltreatment.[37] However, primary care providers are often not in a position to provide integrated mental health care, nor do they necessarily have access to evidence-based trauma-focused interventions for maltreated children. This lack of access may lead to underuse of trauma-informed, evidence-based psychotherapies and may be one of many factors leading to the increased prescription of psychotropic medication among maltreated children and adolescents.

Having to consider the use of a medication to treat symptoms in maltreated children is a reality faced by primary care providers. Therefore, it is critical for pediatric providers to remember the following key concepts when considering the use of medications:

1. Maltreated children are more likely to have complex trauma including multiple or chronic traumatic experiences that result in a wide range of cognitive, emotional, and behavioral changes that do not easily fit into common diagnostic categories. Unidentified complex trauma may lead to children and adolescents being given multiple psychiatric diagnoses in an effort to capture the many manifestations of the trauma.[38]
2. Even when phenotypically similar to common disorders, individuals with a history of child maltreatment constitute a distinct "ecophenotype" (as described by Teicher and Sampson[4]) with different underlying biological changes and, thus, may not respond in predictable ways to treatments traditionally prescribed for mental health conditions.[4] This phenomenon may be especially true for young children.[18]
3. Maltreated children and adolescents may be more susceptible to adverse effects associated with psychotropic medication, such as excessive weight gain and suicidality.[39,40] It is essential that pediatricians are cautious when considering the use of psychotropic treatments in maltreated children.
4. Accurate diagnosis of both trauma- and non–trauma-specific conditions is crucial for choosing a treatment plan to alleviate symptoms in maltreated patients.
5. When starting, continuing, or discontinuing a medication, shared decision-making and informed consent are used for the child's given placement (home, kinship, or foster care) with the appropriate caregiver or proxy (which may vary by state in foster placements) as well as assent, when indicated. Before prescribing, providers will need to consider, identify, and obtain the consents required in their locality according to the placement status of the child.[41]

Ongoing Trauma Exposure

The biological aspects of trauma-specific disorders are discussed in the AAP clinical report on the behavioral manifestations of child maltreatment.[13] When considering treatment options, it is important to remember that behaviors such as increased reactivity, hyperarousal, and poor attention to stimuli (such as school work) in the presence of ongoing danger are not pathologic but a normal stress response.[42] Furthermore, in situations in which maltreated children continue to be at risk, there is little value in a pharmacotherapy trial for possible comorbidities until the danger has been mitigated.[43] Medication trials for the child's developmentally normal response to an ongoing threat are inappropriate and invalidating to the child. In addition, focusing on medication rather than the family distracts from approaches aimed at collaboration with child welfare and other community agencies to enhance overall safety and develop enhanced safety skills for the child, which is a core component of most evidence-based trauma psychotherapies.[43]

Sleep Disturbances

Children and adolescents who have experienced maltreatment often have sleep problems that can be a manifestation of specific trauma-related symptoms or may result from poor sleep hygiene and inadequate environmental and family supports for healthy sleep.[44] When maltreated children present with sleep problems, pediatricians should begin with providing psychoeducation on the connection between traumatic exposures and sleep difficulties.[45] Along with general sleep guidance (hygiene), such as limiting screen time and decreasing caffeine intake, other strategies specific to a history of trauma may include encouraging the family to reestablish routines around bedtime that calm the child (eg, warm bath, chamomile tea, story time), enhancing the child's feelings of safety at night (eg, parent staying in room at first while child falls asleep, use of a night light), and actively decreasing distress experienced by the child through use of techniques such as focused breathing and guided imagery.[34]

There is little evidence on effective medications for the treatment of sleep problems in children and adolescents.[46] Sleep problems should prompt the clinician to assess for disorders common in maltreated

children, including PTSD, anxiety, depression, and behavioral problems. Referral to mental health providers should be made if there is an inadequate response to primary sleep interventions, sleep problems that are frequent or severe and/or worsening over time, or the identification of psychiatric comorbidity that has persisted after trauma (eg, PTSD, anxiety, depression, behavioral issues). After attempting nonpharmacologic interventions, concurrent with or before a mental health referral for persistent sleep difficulties, a trial of melatonin can be considered.[46] Melatonin has been found to be efficacious in pediatric populations at risk for insomnia, such as those with ADHD and autism spectrum disorders.[47,48] Additionally, treatment of comorbidities should be considered to avoid the risk of polypharmacy.[49] Because of the lack of evidence and the option of safer alternatives, as well as significant adverse effects and risks, first- and second-generation antipsychotics and benzodiazepines are not recommended for the treatment of sleep problems in children and adolescents.[43]

PTSD

Evidence-based psychotherapies are the most effective treatment of children with PTSD[50] and should always be considered first before initiating medication trials.[13,34] To date, no medication is approved by the US Food and Drug Administration (FDA) for treatment of trauma-specific symptoms or PTSD in children and adolescents.[43] In 2 separate randomized controlled trials evaluating the efficacy of sertraline (an FDA-approved selective serotonin reuptake inhibitor [SSRI] for PTSD in adults) in the treatment of PTSD among pediatric patients, no benefit was found, either as monotherapy or in combination with evidence-based psychotherapy.[51,52] In adults with PTSD, prazosin has been demonstrated as effective in treating nightmares and sleep disturbances.[53] Prazosin may be considered for children and adolescents with PTSD and severe sleep difficulties, according to expert consensus guidelines such as the "Florida Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents," on the basis of a review of retrospective data (Table 1).[54] However, given the substantial evidence supporting the efficacy of certain psychotherapeutic approaches for the treatment of trauma-exposed children and the paucity of rigorous studies evaluating pharmacologic agents in children with PTSD,[34,50] there is at present no evidence to support the use of medications without first providing evidence-based psychotherapies in the treatment of pediatric PTSD.

Other Diagnostic Considerations

Children and adolescents with a history of maltreatment are at increased risk of disorders that are not trauma specific and for which judicious use of medication may be indicated. Common disorders such as anxiety, depression, and ADHD are overrepresented in children with histories of child maltreatment and other types of adversity.[3,4,55,56] Depending on the experience and expertise of the pediatric health care provider, the provider should use standardized measures to assess the wide array of possible psychiatric diagnoses or refer to a child psychiatrist.[49]

Although some of the information that follows may seem outside the scope of practice for pediatricians, in fact, pediatric health care providers may be the only resource available for this type of care because of the limited availability of psychiatrists. It is often difficult to distinguish between anxiety, depression, disruptive behavior, and trauma-specific disorders, especially when the symptoms could be indicative of comorbidity or syndromic overlap (Table 2). For example, the intrusive and hyperarousal symptoms of PTSD can appear similar to symptoms of anxiety or ADHD in a child brought to primary care for possible psychotropic medication management. Assessing for additional traumatic stress symptoms, inquiring about the temporal relationship between maltreatment experiences and the onset and exacerbation of symptoms, and poor responses to previous pharmacologic interventions may provide important insights. For example, symptoms initially identified by caregivers as related to anxiety or ADHD may be better explained by PTSD and, therefore, may not be appropriate for pharmacotherapy, as described in the preceding section on PTSD. The revised PTSD criteria in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, include negative or decreased cognition and mood with many specific symptoms, such as negative beliefs toward self, self-blame, negative emotional state, loss of interest in previously enjoyable activities, and feeling detached.[57] Determining symptoms of depression versus PTSD and possible comorbidity has significant treatment implications. Over time, when disorders such as anxiety, depression, and ADHD are clearly identified, monotherapy trials of psychotropic medications may be warranted (Table 1).

Suicidal ideation and suicide attempts are often related to the presence of mental illness generally[58] and not limited to depression alone. Older children and adolescents who have been maltreated are at increased risk of suicidality and self-harm.[59] Asking questions regarding self-harm and suicidal ideation is critical because patients may not appear suicidal in the clinical setting. Measures such as the Columbia Suicide Severity Rating Scale[60] can assist practices in standardizing their approach to

TABLE 1 Pharmacologic Treatment Considerations in Maltreated Children and Adolescents

Disorder	Initial Considerations	Ongoing Monitoring Strategy	Second-Line Considerations	Treatments Pitfalls To Avoid
General pediatric mental health concerns	Start with psychosocial treatment. Nonoffending parental involvement is essential, with involvement of other caregivers and school-based interventions as needed. In mild cases, attempt at least 12 wk of psychosocial interventions before medication.	Monitor response to treatment by using reliable and valid measures. If medications are being considered, first reassess the diagnosis and diagnostic formulation. Weigh the risks and benefits of initiating treatment with psychotropic medications.	When starting medication: • Initiate with monotherapy • When using medication, initiate at a low dose and slowly titrate (start low, go slow) • Continue psychosocial treatment during treatment with medication • Monitor for suicidality • Monitor for adverse effects of medications	• Polypharmacy • Antipsychotics should be restricted to schizophrenia, mania or bipolar disorder, psychotic depression, drug-induced psychosis, tic disorders, and severe aggression.
PTSD	The greatest level of evidence supports exposure-based therapies, of which, TF-CBT has the most data and is the most widely used. In children <6 y, may consider TF-CBT (4 mo) or CPP (6 mo) as first-line treatment.	Monitor for treatment response. When TF-CBT is not readily available or effective, consider: • Prolonged exposure therapy • Eye movement desensitization and reprocessing • Trauma and grief components therapy for adolescents • Child and family traumatic stress intervention (PTSD prevention therapy)	• For PTSD symptoms that impair sleep (eg, nightmares, nighttime hyperarousal), may consider psychotherapy augmentation with prazosin • For persistent intrusive or arousal or reactivity, may consider psychotherapy augmentation with clonidine or guanfacine	• Pharmacotherapy-absent trauma-focused psychotherapy • Polypharmacy • Antipsychotics • Benzodiazepines • Multiple antihypertensive medications
Depression	Psychoeducation and psychosocial interventions including but not limited to self-help materials, active listening or relationship building, school involvement, mood monitoring, opportunities for play and recreational activities, cognitive restructuring, family conflict reduction, sleep hygiene, and exercise.	• Psychotherapy for mild to moderate depression • For moderate to severe depression, fluoxetine or combination of CBT or IPT with fluoxetine • May consider escitalopram for patients 12 y and older	• If no clinical response to the medication in first trial, switch to other SSRI • Reassess diagnosis or medication adverse effects • Increase psychosocial intervention and medication dose if tolerated • Augment with alternate psychosocial intervention (either CBT or IPT)	• Polypharmacy • Antipsychotics • Benzodiazepines
Anxiety	Initiate treatment with exposure-based CBT. If CBT is not available, consider other evidence-based psychosocial interventions.	• If moderate to severe anxiety disorder or inadequate response to CBT, initiate treatment with fluoxetine or sertraline alone or with CBT • Treatment with CBT has been shown to be more effective than medication alone	• If first trial with fluoxetine or sertraline is not effective and/or there are treatment-limiting adverse effects, switch to the other SSRI not previously used and initiate or continue CBT	• Polypharmacy • Antipsychotics • Benzodiazepines
ADHD	When clinically feasible, observe for potential traumatic stress symptom overlap in children exposed to maltreatment. If unsafe, or if ADHD symptoms persist with EBTs for traumatic stress and home stabilization, proceed with ADHD treatment.	• Psychostimulant monotherapy (methylphenidate class or amphetamine class, either short- or long-acting) • If first choice is ineffective, try monotherapy with another stimulant or alpha-2 agonist	• Combination of extended-release alpha-2 agonist with psychostimulant or trial of atomoxetine	• Antipsychotics • Multiple concurrent antihypertensive medications

Adapted from 2018–2019 Florida Best Practice Psychotherapeutic Medication Guidelines for Children and Adolescents (Available at: http://www.medicaidmentalhealth.org/_assets/file/Guidelines/2018-19%20FL%20Best%20Practice%20Medication-Child-Adolescent_Online1.pdf). CBT, cognitive-behavioral therapy; CPP, Child-Parent Psychotherapy; IPT, interpersonal psychotherapy; TF-CBT, trauma-focused cognitive-behavioral therapy.

identifying and then assessing suicidality. Although most suicide screening and assessment processes have been validated for adolescents, they can be adapted for older children. When there is indication of suicidal ideation or suicidal behavior, using a standardized clinical approach may be helpful. Evidence-based approaches, such as the Family Intervention for Suicide Prevention, use behavioral assessments and family-based considerations when determining risk and protective factors for suicide and have been shown to increase linkage with ongoing mental health care for suicidal adolescents.[61] Although

TABLE 2 Potential for Diagnostic Overlap With Trauma- and Non–Trauma-Specific Symptoms

Traumatic stress and depression		
PTSD symptom clusters may mimic symptoms commonly considered indications of depression	**Negative cognition and mood sypmtoms** of PTSD include depressive similar symptoms: negative belief toward self, self-blame, negative emotional state, loss of interest, detachment	**Hyperarousal and increased reactivity** in PTSD include depressive similar symptoms[a]: irritable and angry, reckless and self-destructive behavior, poor concentration, sleep disturbances
Traumatic stress and anxiety		
Panic attacks may not indicate panic disorder if attacks are triggered by trauma reminders, better explained as intrusive and hyperarousal symptoms of PTSD	Separation challenges may be similar to **separation anxiety** but could be trauma specific depending on context of traumatic experience(s) and association with trauma reminders	**Generalized and social anxiety** are often independent of trauma-specific context and reminders; however, still important to consider symptoms in context of traumatic experiences
Traumatic stress and ADHD		
Many overlapping symptoms make differentiating trauma and ADHD symptoms in the presence of traumatic stress nearly impossible, especially in younger children	**Collateral information** from multiple settings may help clarify if symptoms are specific/exacerbated by certain relationships/settings or are more universal	**Reevaluation after treatment for traumatic stress** and reduction of trauma symptoms for possible ADHD may be needed to make diagnosis

[a] Suicidal ideation is a well-recognized symptom of major depressive disorder. However, suicidal ideation and nonsuicidal self-injurious behavior can be observed in a number of conditions in addition to depression that disproportionally affect maltreated children, including, but not limited to, PTSD, anxiety, substance use disorder, and personality, mood, and psychotic disorders.

many maltreated adolescents with significant suicidality or self-harm ideation may benefit from evidence-based therapies, such as Trauma-Focused Cognitive Behavior Therapy,[62] stabilization and enhancing safety must occur before the child can receive trauma-specific therapies in the outpatient setting. When indicated, more intensive levels of care, such as inpatient hospitalization, day treatment, or intensive outpatient treatments (such as Dialectical Behavior Therapy), are necessary before the initiation of trauma-specific outpatient therapies.[63] Of note, crisis interventions like the Family Intervention for Suicide Prevention or more intensive interventions as described above are, as of now, intended for adolescents and nonoffending family and caregivers and should be an important consideration when working with maltreated adolescents.

Discontinuing Medication

In 2009, the American Academy of Child and Adolescent Psychiatry (AACAP) identified principles to follow, including developing a specific plan, when discontinuing psychiatric medications.[49] Over the last 2 decades, there has been interest among some child psychiatrists in refinement of processes for appropriate discontinuation of medications, reflecting the frequency of psychotropic prescriptions given to children and adolescents as well as the rate of psychotropic polypharmacy.[64] Especially in vulnerable populations, such as maltreated children and adolescents, it is a priority to identify the reasons for the use of psychotropic medications.[35] The AACAP and other organizations indicate that if evidence-based prescribing practices were used and systems of care were strengthened, the use of psychotropic treatment and medication burden among maltreated children and adolescents could be lessened.[65,66]

Discontinuing medications is the process of identifying and then tapering off medications that are no longer indicated or when the existing or potential risks outweigh the existing or potential benefits.[64] Safe medication discontinuation is an area in need of further research and clear policies and practice guidance because it pertains to children and adolescents. However, pediatricians are often confronted with challenging clinical issues for which clear guidelines or definitive evidence about how to respond is absent. For example, the use of a psychotropic medication may be necessitating the administration of another psychotropic to address effects of the first medication (ie, the addition of a sleep medication to treat insomnia that has developed after beginning a psychotropic medication).[29,49] Additionally, children, adolescents, and/or families may be advocating for a simplification of the pharmacotherapy and desiring guidance as to how best to proceed.

A practical and safe approach to medication discontinuation is not simply medication cessation but rather assessing for the minimal effective dose and number of medications. Because there can be multiple reasons for prescribing psychotropic medications to children with a history of maltreatment, a broad and thoughtful approach is crucial. When a complete clinical picture is not available, pediatricians may be hesitant to reduce even substantial medication regimens because of a concern about escalation in symptoms.[67] However, it is

important to recognize that discontinuing medication is not necessarily a static, one-time event but should be considered part of an ongoing treatment plan.[64] Periodic reassessment of the diagnosis, formulation, and treatment plan is necessary as new information becomes available and in response to the currently provided treatment.[64]

Unfortunately, for many psychotropic medications, there is no standardized approach to determining when psychotropic medications are no longer required. However, Bellonci et al[64] have provided guidance and considerations on the process:

1. Ascertaining the complete medication history, which requires a comprehensive assessment in which a review of previous records is essential to assess what has been tried in the past and the basis for the current regimen.
2. Considering the risk and adverse effect profile of the current medication regimen.
3. Assessing each medication currently being prescribed in light of the comprehensive assessment.
4. Creating an order priority for each medication to be either decreased or discontinued.
5. Implementing the treatment plan.
6. Monitoring treatment plan effects and reassessing.

Additionally, when selecting medications to decrease or discontinue, factors to consider include (1) medications for which there is no clear or valid indication; (2) medications that are part of a prescribing cascade, which may occur when an adverse effect of a medication(s) is used as the basis for another diagnosis and a new medication added; (3) when actual harm or potential harm is greater than the benefits; (4) medications that appear to be duplicative, redundant, or ineffective or the symptoms have resolved; (5) medications that are preventive (prophylactic) in nature; and (6) medications that are imposing an unacceptable treatment burden for the patient and family.[64] The off-label use of medication may pose a concern to pediatric providers and their patients in clinical practice. However, the off-label use of medication is not synonymous with a lack of evidence to support its use. Levels of evidence, ranging from a lower level, such as a case series, to a higher level, such as a randomized controlled trial or a meta-analysis, provide the basis of support or indication for the off-label use of a medication. With regard to medication discontinuation, it is the level of evidence of support for the treatment, in addition to the other factors noted, that should drive the decision-making process, rather than simply basing it on whether a medication is FDA approved.[49]

As suggested by Bellonci et al,[64] this process of discontinuing psychotropic medication may be operationalized by (1) beginning with a medication that has the least evidence of efficacy or has the greatest evidence for adverse effects, (2) focusing on medications that are being prescribed at supratherapeutic doses with no reasonable justification, (3) focusing on medications that are being given in subtherapeutic doses with no evidence of effectiveness, and (4) addressing only 1 medication at a time so that there is clarity, should an adverse effect develop or symptoms return.

When to Refer to Child Psychiatry

Access to mental health assessments by psychiatrists can be difficult, often because many regions do not have enough child psychiatrists to meet the demand. Child psychiatry referrals should be made for children with diagnostic uncertainty and for those in whom multiple trials of medications have failed or who are taking 2 or more psychotropic medications (or 1 medication, if the medication is an antipsychotic).[49] Referral to child psychiatry should be considered when parents or guardians of maltreated children are advocating for treatment regimens beyond the pediatrician's regular scope of practice or the pediatrician believes that addressing the needs of child and family are beyond his or her capability.[49] Furthermore, it is important for pediatricians to routinely monitor for adverse effects from psychiatric medications. Monitoring is not limited to medications that pediatricians initiate because adverse effects of a medication initiated by a mental health provider may prompt a medical, rather than psychiatric, visit. Referral to child psychiatry should not take the place of referral to a trained therapist who can evaluate and initiate evidence-based therapies for traumatic stress.[45]

CONCLUSIONS

Children and adolescents who experience maltreatment are at great risk of revictimization and mental health sequelae, and it is incumbent on the pediatric primary care provider to work collaboratively with families and the child welfare system and to participate in the assessment, management, and appropriate referral for trauma-related conditions common among maltreated children and adolescents. Although no studies to date demonstrate that early intervention with EBT mitigates the long-term sequelae associated with child maltreatment, reducing symptoms and promoting return to healthy functioning at school and at home have important implications for quality of life and overall well-being. It is, therefore, essential that pediatric providers conduct comprehensive assessments whenever feasible to determine where EBT strategies apply and avoid the use of medications that have little or no likely benefit. There is a clear need for controlled trials of interventions

including pharmacologic agents to help determine evidence-based approaches to reducing impairment in children and adolescents exposed to maltreatment. Although medications have a role, the evidence to date is limited, and nonpharmacologic approaches are preferred.

Clinical Considerations for the Pediatrician

1. Children who experience child maltreatment are best served by providers and systems that use trauma-informed approaches to care.
2. Interactions with child welfare can be complex and can result in treatment barriers and issues.
3. When assessing traumatic experiences and symptoms, ensure that there are approaches in place to respond to the information obtained so that children who have experienced maltreatment and their families can be supported. This support could be provided by the pediatrician and/or by referrals, depending on the setting and context.
4. Treatment that is primarily focused on psychosocial interventions rather than medications and tailored to the unique needs of the child is often of greatest value and least risk to children with a history of child maltreatment.

Key Action Statements

- Pediatricians should communicate to the children and families an openness to hearing about past and present events and convey the message that the information is important in formulating decisions about treatment in the present and future.
- The pediatrician should obtain a comprehensive social history to inform a child's treatment needs after exposure to abuse and/or neglect.
- The pediatrician must be alert to ongoing trauma and violence, including exposure to intimate partner violence among caregivers, and parental mental health problems, including substance use disorder.
- Pediatricians must emphasize safety as a paramount consideration and make it clear that if a child or family is unsafe at any time, an emergent report will be made to CPS.
- Pediatricians should not assure children or caregivers of absolute confidentiality.
- Before the initiation of psychosocial or medication interventions, a focused assessment of the child should be conducted by a clinician trained in the assessment of children exposed to maltreatment.
- Children who have experienced maltreatment with resultant emotional and behavioral difficulties should receive evidence-based psychotherapies and treatments with demonstrated effectiveness.
- Pediatric providers should provide resources to bridge the period until EBT can begin, including psychoeducation, relaxation training, encouraging parent-child communication, and parenting supports.
- Pediatricians should refer children with sleep disorders after trauma to mental health providers if there is an inadequate response to primary sleep interventions.
- First- and second-generation antipsychotics and benzodiazepines should not be used for the treatment of sleep problems in children and adolescents and are not generally indicated for the treatment of the most common disorders found among maltreated children, specifically, PTSD, anxiety, depression, and ADHD.
- When anxiety, depression, or ADHD is suspected, pediatric health care providers should consider that traumatic stress may better explain the symptoms of concern and use standardized measures to assess the possible psychiatric diagnoses or refer to a child psychiatrist.
- Pediatricians should ask maltreated children and adolescents questions regarding self-harm and suicidal ideation, even if patients may not appear suicidal, preferably using standardized tools such as the Columbia Suicide Severity Rating Scale.
- Pediatricians who are considering discontinuing medications should employ evidence-based protocols that incorporate principles of optimizing the medication regimen (ie, focusing on medications with significant risk, limited evidence, or no clear clinical or symptom improvement).
- Pediatricians should make referrals to child psychiatry (if available) for children when there is diagnostic uncertainty and for those in whom multiple trials of medications have failed or who are taking 2 or more psychotropic medications (or 1 medication, if the medication is an antipsychotic).

LEAD AUTHORS

Brooks Keeshin, MD, FAAP
Heather C. Forkey, MD, FAAP
George Fouras, MD, DFAACAP
Harriet L. MacMillan, MD, MSc, FRCPC

AAP COUNCIL ON CHILD ABUSE AND NEGLECT, 2017–2018

Emalee G. Flaherty, MD, FAAP, Co-Chairperson
Andrew P. Sirotnak, MD, FAAP, Co-Chairperson
Ann E. Budzak, MD, FAAP
CAPT Amy R. Gavril, MD, MSCI, FAAP
Suzanne B. Haney, MD, FAAP
Sheila M. Idzerda, MD, FAAP

ABBREVIATIONS

AAP: American Academy of Pediatrics
ADHD: attention-deficit/hyperactivity disorder
CPS: child protective services
EBT: evidence-based treatment
FDA: US Food and Drug Administration
PTSD: posttraumatic stress disorder
SSRI: selective serotonin reuptake inhibitor

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

DOI: https://doi.org/10.1542/peds.2019-3751

Address correspondence to Brooks Keeshin, MD, FAAP. E-mail: Brooks.Keeshin@hsc.utah.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Children's Bureau, Administration for Children and Families. Child maltreatment. 2016. Available at: https://www.acf.hhs.gov/sites/default/files/cb/cm2016.pdf. Accessed January 1, 2010
2. Finkelhor D, Turner HA, Shattuck A, Hamby SL. Prevalence of childhood exposure to violence, crime, and abuse: results from the national survey of children's exposure to violence. *JAMA Pediatr*. 2015;169(8):746–754
3. Gilbert R, Widom CS, Browne K, Fergusson D, Webb E, Janson S. Burden and consequences of child

maltreatment in high-income countries. *Lancet*. 2009;373(9657):68–81

4. Teicher MH, Samson JA. Childhood maltreatment and psychopathology: a case for ecophenotypic variants as clinically and neurobiologically distinct subtypes. *Am J Psychiatry*. 2013; 170(10):1114–1133
5. Pecora PJ, Jensen PS, Romanelli LH, Jackson LJ, Ortiz A. Mental health services for children placed in foster care: an overview of current challenges. *Child Welfare*. 2009;88(1): 5–26
6. Keeshin BR, Strawn JR, Luebbe AM, et al. Hospitalized youth and child abuse: a systematic examination of psychiatric morbidity and clinical severity. *Child Abuse Negl*. 2014;38(1): 76–83
7. Leslie LK, Raghavan R, Zhang J, Aarons GA. Rates of psychotropic medication use over time among youth in child welfare/child protective services. *J Child Adolesc Psychopharmacol*. 2010; 20(2):135–143
8. Raghavan R, Brown DS, Allaire BT, Garfield LD, Ross RE. Medicaid expenditures on psychotropic medications for maltreated children: a study of 36 states. *Psychiatr Serv*. 2014;65(12):1445–1451
9. Matone M, Localio R, Huang Y-S, dosReis S, Feudtner C, Rubin D. The relationship between mental health diagnosis and treatment with second-generation antipsychotics over time: a national study of U.S. Medicaid-enrolled children. *Health Serv Res*. 2012;47(5): 1836–1860
10. Kreider AR, Matone M, Bellonci C, et al. Growth in the concurrent use of antipsychotics with other psychotropic medications in Medicaid-enrolled children. *J Am Acad Child Adolesc Psychiatry*. 2014;53(9):960–970.e2
11. Raghavan R, McMillen JC. Use of multiple psychotropic medications among adolescents aging out of foster care. *Psychiatr Serv*. 2008;59(9): 1052–1055
12. Connell CM, Vanderploeg JJ, Flaspohler P, Katz KH, Saunders L, Tebes JK. Changes in placement among children in foster care: a longitudinal study of child and case influences. *Soc Serv Rev*. 2006;80(3):398–418
13. Sege RD, Amaya-Jackson L; American Academy of Pediatrics Committee on Child Abuse and Neglect, Council on Foster Care, Adoption, and Kinship Care; American Academy of Child and Adolescent Psychiatry Committee on Child Maltreatment and Violence; National Center for Child Traumatic Stress. Clinical considerations related to the behavioral manifestations of child maltreatment. *Pediatrics*. 2017; 139(4):e20170100
14. Nelson EC, Heath AC, Madden PAF, et al. Association between self-reported childhood sexual abuse and adverse psychosocial outcomes: results from a twin study. *Arch Gen Psychiatry*. 2002; 59(2):139–145
15. Anda RF, Felitti VJ, Bremner JD, et al. The enduring effects of abuse and related adverse experiences in childhood. A convergence of evidence from neurobiology and epidemiology. *Eur Arch Psychiatry Clin Neurosci*. 2006; 256(3):174–186
16. Edwards VJ, Holden GW, Felitti VJ, Anda RF. Relationship between multiple forms of childhood maltreatment and adult mental health in community respondents: results from the adverse childhood experiences study. *Am J Psychiatry*. 2003;160(8):1453–1460
17. Felitti VJ, Anda RF, Nordenberg D, et al. Relationship of childhood abuse and household dysfunction to many of the leading causes of death in adults. The Adverse Childhood Experiences (ACE) Study. *Am J Prev Med*. 1998;14(4): 245–258
18. Gleason MM, Goldson E, Yogman MW; Council on Early Childhood; Committee on Psychosocial Aspects of Child and Family Health; Section on Developmental and Behavioral Pediatrics. Addressing early childhood emotional and behavioral problems. *Pediatrics*. 2016;138(6):e20163025
19. Macmillan HL, Wathen CN, Barlow J, Fergusson DM, Leventhal JM, Taussig HN. Interventions to prevent child maltreatment and associated impairment. *Lancet*. 2009;373(9659): 250–266
20. Turner HA, Finkelhor D, Ormrod R. Poly-victimization in a national sample of children and youth. *Am J Prev Med*. 2010;38(3):323–330
21. Kendall-Tackett K. The health effects of childhood abuse: four pathways by which abuse can influence health. *Child Abuse Negl*. 2002;26(6–7):715–729
22. Pierce MC, Kaczor K, Thompson R. Bringing back the social history. *Pediatr Clin North Am*. 2014;61(5):889–905
23. Ford JD, Elhai JD, Connor DF, Frueh BC. Poly-victimization and risk of posttraumatic, depressive, and substance use disorders and involvement in delinquency in a national sample of adolescents. *J Adolesc Health*. 2010;46(6):545–552
24. Johnson SB, Riley AW, Granger DA, Riis J. The science of early life toxic stress for pediatric practice and advocacy. *Pediatrics*. 2013;131(2):319–327
25. Johnson SB, Riis JL, Noble KG. State of the art review: poverty and the developing brain. *Pediatrics*. 2016; 137(4):e20153075
26. Traub F, Boynton-Jarrett R. Modifiable resilience factors to childhood adversity for clinical pediatric practice. *Pediatrics*. 2017;139(5):e20162569
27. Ahern NR, Kiehl EM, Sole ML, Byers J. A review of instruments measuring resilience. *Issues Compr Pediatr Nurs*. 2006;29(2):103–125
28. Christian CW; Committee on Child Abuse and Neglect, American Academy of Pediatrics. The evaluation of suspected child physical abuse. *Pediatrics*. 2015; 135(5). Available at: www.pediatrics.org/cgi/content/full/135/5/e1337
29. MacMillan HL, Wathen CN. Children's exposure to intimate partner violence. *Child Adolesc Psychiatr Clin N Am*. 2014; 23(2):295–308
30. Gilbert R, Kemp A, Thoburn J, et al. Recognising and responding to child maltreatment. *Lancet*. 2009;373(9658): 167–180
31. Rolon-Arroyo B, Oosterhoff B, Layne CM, Steinberg AM, Pynoos RS, Kaplow JB. The UCLA PTSD Reaction Index for DSM-5 Brief Form: a screening tool for trauma-exposed youths. *J Am Acad Child Adolesc Psychiatry*. 2019;S0890-8567–8569
32. Intermountain Healthcare. Diagnosis and management of traumatic stress in

pediatric patients (in press). Available at: https://intermountainphysician.org/clinical/Pages/Care-Process-Models-(CPMs).aspx. Accessed Jan 7, 2020

33. Briere J. *Trauma Symptom Checklist for Children (TSCC): Professional Manual*. Odessa, FL: PAR, Psychological Assessment Resources; 1996
34. Cohen JA, Bukstein O, Walter H, et al; AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with posttraumatic stress disorder. *J Am Acad Child Adolesc Psychiatry*. 2010;49(4):414–430
35. Kutz GD. *Foster Children: HHS Guidance Could Help States Improve Oversight of Psychotropic Prescriptions*. Washington, DC: US Government Accountability Office; 2011
36. Mackie TI, Hyde J, Palinkas LA, Niemi E, Leslie LK. Fostering psychotropic medication oversight for children in foster care: a national examination of states' monitoring mechanisms. *Adm Policy Ment Health*. 2017;44(2):243–257
37. Asarnow JR, Rozenman M, Wiblin J, Zeltzer L. Integrated medical-behavioral care compared with usual primary care for child and adolescent behavioral health: a meta-analysis. *JAMA Pediatr*. 2015;169(10):929–937
38. Forkey H, Szilagyi M. Foster care and healing from complex childhood trauma. *Pediatr Clin North Am*. 2014; 61(5):1059–1072
39. Keeshin BR, Luebbe AM, Strawn JR, Saldaña SN, Wehry AM, DelBello MP. Sexual abuse is associated with obese children and adolescents admitted for psychiatric hospitalization. *J Pediatr*. 2013;163(1):154–159.e1
40. Singh AB, Bousman CA, Ng CH, Berk M. High impact child abuse may predict risk of elevated suicidality during antidepressant initiation. *Aust N Z J Psychiatry*. 2013;47(12):1191–1195
41. Szilagyi MA, Rosen DS, Rubin D, Zlotnik S; Council on Foster Care, Adoption, and Kinship Care; Committee on Adolescence; Council on Early Childhood. Health care issues for children and adolescents in foster care and kinship care. *Pediatrics*. 2015; 136(4). Available at: www.pediatrics.org/cgi/content/full/136/4/e1142
42. Pynoos RS, Steinberg AM, Ornitz EM, Goenjian AK. Issues in the developmental neurobiology of traumatic stress. *Ann N Y Acad Sci*. 1997;821:176–193
43. Keeshin BR, Strawn JR. Psychological and pharmacologic treatment of youth with posttraumatic stress disorder: an evidence-based review. *Child Adolesc Psychiatr Clin N Am*. 2014;23(2):399–411
44. Pynoos RS, Steinberg AM, Layne CM, Briggs EC, Ostrowski SA, Fairbank JA. DSM-V PTSD diagnostic criteria for children and adolescents: a developmental perspective and recommendations. *J Trauma Stress*. 2009;22(5):391–398
45. Cohen JA, Kelleher KJ, Mannarino AP. Identifying, treating, and referring traumatized children: the role of pediatric providers. *Arch Pediatr Adolesc Med*. 2008;162(5):447–452
46. Owens JA, Mindell JA. Pediatric insomnia. *Pediatr Clin North Am*. 2011; 58(3):555–569
47. Bendz LM, Scates AC. Melatonin treatment for insomnia in pediatric patients with attention-deficit/hyperactivity disorder. *Ann Pharmacother*. 2010;44(1):185–191
48. Gringras P, Nir T, Breddy J, Frydman-Marom A, Findling RL. Efficacy and safety of pediatric prolonged-release melatonin for insomnia in children with autism spectrum disorder. *J Am Acad Child Adolesc Psychiatry*. 2017;56(11): 948–957.e4
49. Walkup J; Work Group on Quality Issues. Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents. In: *J Am Acad Child Adolesc Psychiatry*, vol. 48. 2009: 961–973
50. Morina N, Koerssen R, Pollet TV. Interventions for children and adolescents with posttraumatic stress disorder: a meta-analysis of comparative outcome studies. *Clin Psychol Rev*. 2016;47:41–54
51. Robb AS, Cueva JE, Sporn J, Yang R, Vanderburg DG. Sertraline treatment of children and adolescents with posttraumatic stress disorder: a double-blind, placebo-controlled trial. *J Child Adolesc Psychopharmacol*. 2010; 20(6):463–471
52. Cohen JA, Mannarino AP, Perel JM, Staron V. A pilot randomized controlled trial of combined trauma-focused CBT and sertraline for childhood PTSD symptoms. *J Am Acad Child Adolesc Psychiatry*. 2007;46(7): 811–819
53. George KC, Kebejian L, Ruth LJ, Miller CW, Himelhoch S. Meta-analysis of the efficacy and safety of prazosin versus placebo for the treatment of nightmares and sleep disturbances in adults with posttraumatic stress disorder. *J Trauma Dissociation*. 2016; 17(4):494–510
54. Keeshin BR, Ding Q, Presson AP, Berkowitz SJ, Strawn JR. Use of prazosin for pediatric PTSD-associated nightmares and sleep disturbances: a retrospective chart review. *Neurol Ther*. 2017;6(2):247–257
55. Hussey JM, Chang JJ, Kotch JB. Child maltreatment in the United States: prevalence, risk factors, and adolescent health consequences. *Pediatrics*. 2006; 118(3):933–942
56. Trickett PK, Noll JG, Putnam FW. The impact of sexual abuse on female development: lessons from a multigenerational, longitudinal research study. *Dev Psychopathol*. 2011; 23(2):453–476
57. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed. Arlington, TX: American Psychiatric Association; 2013
58. Brent DA, Kalas R, Edelbrock C, Costello AJ, Dulcan MK, Conover N. Psychopathology and its relationship to suicidal ideation in childhood and adolescence. *J Am Acad Child Psychiatry*. 1986;25(5):666–673
59. Brent DA, Greenhill LL, Compton S, et al. The Treatment of Adolescent Suicide Attempters study (TASA): predictors of suicidal events in an open treatment trial. *J Am Acad Child Adolesc Psychiatry*. 2009;48(10): 987–996
60. Posner K, Brown GK, Stanley B, et al. The Columbia-Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *Am J Psychiatry*. 2011;168(12): 1266–1277

61. Hughes JL, Asarnow JR. Enhanced mental health interventions in the emergency department: suicide and suicide attempt prevention in the ED. *Clin Pediatr Emerg Med*. 2013;14(1):28–34

62. Cohen JA, Mannarino AP. Psychotherapeutic options for traumatized children. *Curr Opin Pediatr*. 2010;22(5):605–609

63. Ougrin D, Tranah T, Stahl D, Moran P, Asarnow JR. Therapeutic interventions for suicide attempts and self-harm in adolescents: systematic review and meta-analysis. *J Am Acad Child Adolesc Psychiatry*. 2015;54(2):97–107.e2

64. Bellonci C, Baker M, Huefner JC, Hilt RJ. Deprescribing and its application to child psychiatry. *Child Adolesc Psychopharmacol News*. 2016;21(6):1–9

65. American Academy of Child and Adolescent Psychiatry. Recommendations about the use of psychotropic medications for children and adolescents involved in child-serving systems. 2015. Available at: https://www.aacap.org/App_Themes/AACAP/docs/clinical_practice_center/systems_of_care/AACAP_Psychotropic_Medication_Recommendations_2015_FINAL.pdf. Accessed July 7, 2019

66. Reeve E, Thompson W, Farrell B. Deprescribing: a narrative review of the evidence and practical recommendations for recognizing opportunities and taking action. *Eur J Intern Med*. 2017;38:3–11

67. Lee T, Fouras G, Brown R; American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter for the assessment and management of youth involved with the child welfare system. *J Am Acad Child Adolesc Psychiatry*. 2015;54(6):502–517

Children With Intellectual and Developmental Disabilities as Organ Transplantation Recipients

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Children With Intellectual and Developmental Disabilities as Organ Transplantation Recipients

Mindy B. Statter, MD, MBE,[a] Garey Noritz, MD,[b] COMMITTEE ON BIOETHICS, COUNCIL ON CHILDREN WITH DISABILITIES

The demand for transplantable solid organs far exceeds the supply of deceased donor organs. Patient selection criteria are determined by individual transplant programs; given the scarcity of solid organs for transplant, allocation to those most likely to benefit takes into consideration both medical and psychosocial factors. Children with intellectual and developmental disabilities have historically been excluded as potential recipients of organ transplants. When a transplant is likely to provide significant health benefits, denying a transplant to otherwise eligible children with disabilities may constitute illegal and unjustified discrimination. Children with intellectual and developmental disabilities should not be excluded from the potential pool of recipients and should be referred for evaluation as recipients of solid organ transplants.

INTRODUCTION

The American Academy of Pediatrics policy statement "Pediatric Organ Donation and Transplantation" published in 2010 provides recommendations to promote awareness for increased organ donation and the role of organ donation as an integral part of end-of-life care but does not discuss recipient candidacy and eligibility.[1] The demand for transplantable solid organs far exceeds the supply of deceased donor organs. Patient selection criteria are determined by individual transplant programs. Given the scarcity of solid organs for transplant, organs are allocated to those most likely to experience maximal benefit, taking into consideration both medical and psychosocial factors. Historically, patients with intellectual and developmental disabilities (IDDs) have often been excluded as potential recipients of organ transplants. The issue of intellectual disability (ID) in donors is not in the scope of this statement. IDD is defined as "a group of developmental conditions characterized by significant impairment of cognitive functions, which are associated with limitations of learning, adaptive behaviour and skills."[2] Patients with an

abstract

[a]*Division of Pediatric Surgery, Department of Surgery, Children's Hospital at Montefiore, Bronx, New York; and* [b]*Department of Pediatrics and Center for Pediatric Bioethics, The Ohio State University and Nationwide Children's Hospital, Columbus, Ohio*

DOI: https://doi.org/10.1542/peds.2020-0625

Address correspondence to Mindy B. Statter, MD, MBE. E-mail: mstatter@montefiore.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

To cite: Statter MB, Noritz G, AAP COMMITTEE ON BIOETHICS, COUNCIL ON CHILDREN WITH DISABILITIES. Children With Intellectual and Developmental Disabilities as Organ Transplantation Recipients. *Pediatrics.* 2020; 145(5):e20200625

autism spectrum disorder can also be considered to have an IDD. IDDs may be secondary to genetic syndromes, chromosomal abnormalities, exposures during pregnancy (fetal alcohol syndrome, exposure to teratogenic drugs or toxins), congenital anomalies, intrauterine insult (stroke, placental problems), or postnatal insults (infections, trauma).

Intellectual impairment refers to deficits in general mental abilities, including reasoning, planning, problem-solving, abstract thinking, academic learning, and learning from experience, and is commonly defined as an IQ of ≤ 70. Adaptive functioning deficits refer to impairments in social, conceptual, and practical skills needed for self-care, self-direction, communication, home living, use of community resources, and functional academic skills.[3] In the case of developmental disabilities, it is recognized that cognitive testing alone is inadequate to characterize a person's level of disability. More important is the individual's level of adaptive functioning, which describes the skills with which an individual lives in his or her environment.[4]

People may function at, above, or below what would be expected on the basis of their cognitive ability, largely as a result of the quality of the environmental supports they receive. In this way, disability is a social construct; people with a physical or cognitive difference are also disabled by the inability of society to support them. Studies that do not take into account adaptive capabilities find a higher prevalence of ID than those taking into account a person's adaptive capability or level of functioning.[5] It is this larger view of adaptive functioning that should be examined as part of the transplant evaluation.

Richards et al[6] highlighted the inconsistencies across major pediatric transplant centers in how the presence of IDD is used as a criterion in the listing decisions for solid organ transplant. Thirty-nine percent of programs stated that they consider IDD "rarely" or "never" in the listing process, whereas 43% of programs "always" or "usually" do. The degree of a patient's delay also affects the listing decision, with 14% of programs reporting mild or moderate IDD as a relative contraindication to listing and 22% reporting that IDD was "irrelevant" to the listing decision. There was also discordance among the solid organ programs (heart, liver, and kidney). Heart programs tend to consider neurodevelopmental status more often in their listing decisions compared to liver and kidney programs, which use IQ more restrictively.[6] The official guidance from the International Society for Heart and Lung Transplantation does specifically mention "mental retardation" as a relative contraindication to heart transplant.[7] The inconsistencies among programs serve to highlight that the use of the criterion of neurodevelopmental delay for listing is heterogeneous, likely reflecting individual programmatic biases.[6]

The Americans with Disabilities Act (ADA)[8] and the Rehabilitation Act[9] prohibit disability-based discrimination by doctors' offices, state-run hospitals, and recipients of federal funding, including health care providers who are paid through Medicaid or Medicare and organizations funded through federal contracts such as the United Network for Organ Sharing (UNOS). The Organ Procurement and Transplantation Network (OPTN) is the nation's organ procurement, donation, and transplant system.[1] It is overseen by the US Department of Health and Human Services (HHS). UNOS is the nonprofit organization that operates the OPTN under a contract from the federal government. All organ procurement organizations and transplant programs in the United States are OPTN and/or UNOS members and follow OPTN policies.[1]

Discrimination under the ADA includes both the refusal to provide services to qualified individuals with disabilities and refusal to make reasonable modifications in policies and practices that are necessary to ensure people with disabilities may access services. When transplant is likely to provide significant health benefits, denying transplant to otherwise eligible people with disabilities may constitute illegal and unjustified discrimination.[8]

In 1995, Sandra Jensen, a 34-year-old woman with Down syndrome and congenital heart disease was initially refused a heart-lung transplant solely because she had trisomy 21 and mental retardation (current terminology at the time). She, with her family and other advocates, mounted a national campaign to protest this discrimination. She subsequently received her transplant on January 23, 1996, and became the first person in the world with trisomy 21 to do so. Dr William Bronston, a state rehabilitation administrator and coordinator of the campaign, in a speech delivered to the National Down Syndrome Society after Sandra's transplant in 1996, said, "Sandra's story has opened a window into the chaos and incompetence of the national transplant system as it currently exists."[10]

STATEMENT OF THE PROBLEM

Transplant centers contend with conflicting priorities that may affect the evaluation and listing of recipients with IDDs, including the need to have high transplant success rates for accreditation and to remain in payer networks. Transplant centers want to allocate limited resources to those most likely to benefit but also want to avoid negative media attention around the perception of discrimination in the referral,

acceptance, or listing processes for solid organ transplant.[11]

Among transplant centers, there is inconsistency in defining IDDs, which affects referral and listing and excludes patients from the qualifying pool of recipients. The use of IDD as a medical criterion by transplant centers is inconsistent and varied. When transplant centers use IDD as a social value criterion rather than a medical criterion, they make implicit rationing decisions that favor candidates without an IDD.[12]

The study of "implicit bias" helps us understand how unconscious assumptions about groups of people may influence perception and decision-making.[12] Tests have been designed to assess implicit bias toward individuals with developmental disabilities,[13] and unsurprisingly, clinicians are susceptible to such biases.[14] Just as transplant centers need to ensure that implicit bias does not influence decisions because of race, ethnicity, or sex, clinicians need to be aware of the existence of implicit bias toward individuals with disabilities and thoughtfully examine this bias in listing decisions for organ transplant.[15]

There is the misconception that transplant recipients with disabilities are unable to comply with posttransplant medical regimens, lack adequate support systems to ensure such compliance, have decreased life expectancy, and have a lower likelihood of transplant success.[12] There is the biased presumption that people with disabilities have a lower quality of life than those without disabilities and, therefore, do not receive as much benefit from the transplant as a person without disabilities or that they cannot be expected to derive any benefit by having their life extended by a transplant. For children with IDDs, a social value criterion focuses on their limitations and discounts the contributions that these children make to their families and society.[12] The variance in the defining of IDD and the inconsistent use of IDD as a medical criterion result in the unjustified exclusion of children with IDDs from access to solid organ transplant.

Correspondence in October 2016 from the US Congress to Jocelyn Samuels, the director of the Office for Civil Rights in the HHS, urged the agency to address what congress called "persistent" organ transplant discrimination. The letter called for guidance from the HHS clarifying that denying an organ transplant on the basis of a person's disability would violate the ADA.[16]

The most appropriate outcomes to consider when determining if a patient should be evaluated or listed for transplant are organ and patient survival with the same minimum thresholds for all patients with or without developmental disability.[17] In the determination of a qualifying pool of potential recipients, the literature suggests that there is no substantial difference in patient or organ survival between children with and without IDDs.[17,18] Studies have shown that patients with developmental or intellectual disabilities and appropriate posttransplant support have outcomes comparable to those of children without disabilities.[18]

Benedetti et al[19] described an institutional experience from 1968 to 1996 in renal transplant in adult recipients with ID. A psychologist and a social worker assessed the ability and commitment of the primary support person (the individual from the family or from the institution caring for the patient in charge of the daily medications and clinical follow-up). Only patients with expected long-term survival with a "cooperative" personality or a qualified primary support person were accepted as candidates. The average IQ was 56, chronological age range was 17 to 45 years, and average developmental age was 7.7 years (range: 3–14 years). The 1- and 5-year patient and graft survival was 100%. They found that kidney transplant in properly selected patients with ID provided excellent patient and graft survival rates and that patient quality of life and health, as judged by the primary support people, was highly improved after kidney transplant in comparison with dialysis or advanced chronic renal failure. The authors concluded that the presence of ID should not be considered a contraindication to kidney transplant.[19]

Ohta et al[20] reported data from 8 Japanese institutions from 1988 to 2004; 522 pediatric kidney transplants were performed, including 25 (4.8%) in recipients ID. Follow-up data revealed all 25 grafts were functioning during a mean observation period of 41.1 months. All people providing primary support for these children were satisfied with the transplant and believed that quality of life was improved for both the transplant recipients and themselves.[20]

Galante et al[21] reported results of renal transplant in recipients with ID; graft survival and long-term renal function was equivalent to recipients without ID. They also concluded that renal transplant may offer significant advantages when compared to the need for dialysis in patients with ID.[21]

TRANSPLANT ETHICS

In transplant ethics, the ethical principles directly applicable to the allocation of organs for transplant are respect for persons, utility, and justice.[22] Respect for persons embraces respect for autonomy; this necessitates transparency of processes and allocation rules to enable stakeholders to make informed decisions. Utility describes the effort to maximize the greatest benefit for the greatest number of

patients.[23] Utility applied to the allocation of organs should maximize the net overall good, balancing benefits and harms, thereby incorporating beneficence and nonmaleficence. For example, commonly accepted medical contraindications to transplant incorporate utility by excluding individuals whose diseases can be expected to recur after transplant, diseases that may be worsened by posttransplant immunosuppression, or diseases that make surgery unsafe for the patient.[24] In public policies related to allocation of organs, there is consensus that the social worth or value of individuals should not be considered. IDD as a social value criterion results in implicit and explicit bias that may reflect the values of the decision-makers and affect rationing decisions. For children with IDDs, a social value criterion focuses on their limitations and discounts the contributions that these children make to their families and society.[12] Justice refers to fairness in the pattern of distribution of the benefits and burdens of an organ procurement and allocation program. Equitable access to the transplant waiting list is the basis of equitable organ allocation. Justice requires that criteria for candidacy are applied in an equal manner. Equitable allocation incorporates efficiency and equity, as specified in the Final Rule implemented in 2000, "distributing organs over as broad a geographic area as feasible…and in order of decreasing medical urgency."[24]

Excluding children with disabilities from the qualifying pool of potential recipients violates these ethical principles. Children with disabilities can be deceased organ donors and contribute to the supply of solid organs, so it would be unfair to categorically exclude them as recipients of organ transplants.

Beneficence and nonmaleficence apply not only to the pediatric patient being referred, accepted, or listed for transplant but also to the family construct. The family, in addition to the patient, is a stakeholder and must be educated in the benefits, risks, and harms of transplant and collaborate with the transplant team in the decision-making process. Evaluation for transplant includes determining if there are significant medical comorbidities that unduly limit transplant survival; transplant is not offered to any patient who will be harmed by the procedure.

One pediatric transplant center stated that developmental disability alone should not preclude transplant; however, "biological survival is not a sufficient goal for transplantation. Survival for the purpose of having continued conscious experience is a minimum goal of transplantation."[25] The center's neurodevelopmental task force, drawing on federal and expert consensus guidelines, defined terms including minimally conscious state and persistent vegetative state. As such, the center's policy is to not offer transplants to patients in persistent vegetative states. The task force concluded that a scarce resource should not be used to prolong the survival of people who very likely have no conscious experience. The task force sought assistance from a community ethics committee that used an absolute lack of benefit argument, claiming that it is ethically justifiable to exclude patients in persistent vegetative state from receiving transplants.[25]

In balancing beneficence and nonmaleficence, the benefits, risks, and harms of transplant to pediatric patients with developmental disabilities, it is necessary to acknowledge that the transplant can add to or reduce the burden of treatment. The pediatric patient with disabilities may have the burden of other organ system disease in addition to the failed organ. Many children are already dependent on technology for survival, such as a feeding tube or tracheostomy. For these children with medical complexity, certain inherent aspects of the disability, such as recurrent tracheitis or pneumonia, may pose a more significant risk after transplant because of the required immunosuppression.[26]

Transplant teams have the responsibility of educating families about the benefits, risks, and possible harms of organ transplant and collaboratively making the best decision possible. Although many parents will naturally subordinate their own interests and the interests of siblings when dealing with the interests of their child with organ failure being evaluated for transplant, it is helpful to remind parents that it is acceptable to directly consider their own interests and the interests of other children when making decisions for and about their sick child. It is beneficial to have parents openly acknowledge the sacrifices associated with various treatment options and the effect on their own lives and the lives of their other children.[27] It is ethically permissible for some families to decide that because of the degree of IDD, their children may not attain enough benefit to warrant the immediate and lifelong burdens of transplant.

QUALITY OF LIFE

A core issue in the discussion of organ transplant for children has to do with the concept of quality of life. The World Health Organization defines quality of life as an "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."[28] By its very nature, quality of life is individualistic, and although many attempts have been made to measure and monitor quality of life for groups of people, one must not lose sight of the individual's

understanding of his or her own quality of life.

As commonly defined, quality of life goes well beyond health-related matters and includes physiologic, psychological, and social factors.[29] Likewise, disability is commonly understood to cross multiple domains, including body functions, body structures, activity and participation, and environmental factors,[30] all of which affect an individual's assessment of his or her quality of life. This complicated interplay of medical and nonmedical factors is challenging to families and physicians who must decide whether to proceed with transplant for a child with a disability.

It is well known that many individuals with disabilities rate their own quality of life similarly to individuals without disabilities[31–33] and higher than their families or physicians do when using proxy measurements.[31,34,35] This has been called the "disability paradox"[34]; individuals with disabilities tend to base their assessment of quality of life on factors beyond their physical and mental functioning, whereas proxy reporters tend to focus on the disability.[29] Clinicians' bias as a result of their own perception of the disability may undervalue the actual quality of life of the patient. As stated by Graham and Robinson,[36] "while quality of life considerations should be considered when assessing the benefits and burdens of medical care, there is the concern that many clinicians may unconsciously use the phrase 'quality of life' to mask a set of more complicated, unspoken assumptions about the lives of the disabled." Many clinicians working in an inpatient setting may not recognize that their assessments of quality of life are based on an incomplete clinical picture and are, therefore, limited. The child's condition and function during a hospitalization provides limited insight into a patient's overall quality of life and the family's experiences, which may contribute to bias on the part of clinicians. Professional attitudes then conflict with parental assertions about the appropriateness of an intervention, not because of ethical or moral differences, but because of different perceptions about the baseline quality of life of the child.[36]

EVALUATION FOR TRANSPLANT

The evaluation for solid organ transplant is a multidisciplinary assessment that includes a psychosocial evaluation, the goal of which is to identify patient and family strengths and risk factors that may affect posttransplant outcomes. Transplant evaluations for all individuals also include an assessment of the psychosocial milieu in which the individual exists.[1] The degree of psychosocial support available to the individual is part of this determination. In transplant evaluations for all young children and for older children with disabilities, the presence of caring, able, and committed caregivers is of paramount importance. These caregivers must be committed to the immediate and long-term care of the individual and his or her medical and psychosocial needs. The American Academy of Pediatrics policy statement emphasized the goal of keeping the family unit intact during and after the transplant process.[1] For patients with disabilities, caregivers often include a number of people outside the immediate family and may include the extended family, home nurses, therapists, clergy, and educators. Developmental specialists may be of particular importance for making the individual "come alive" for the transplant committee, demonstrating how the individual functions within his or her psychosocial setting.[37] The commitment of this extended caregiving team should be taken into account when considering an individual for transplant.

The OPTN encourages individual transplant centers to develop their own criteria for these "nonmedical" evaluations, although some guidance is given.[38] For instance, they suggest addressing problems with adherence, such as for an organ failure caused by behaviors such as smoking and alcohol use, but do not give strict criteria for exclusion from transplant consideration.

The likelihood of nonadherence to posttransplant regimens and medical care is commonly cited as a disqualifying barrier for patients with disabilities. However, nonadherence is highly prevalent in other populations, particularly adolescents.[39] Patients with disabilities often require assistance with their medication regimen and, thus, have a high degree of oversight, which may improve the likelihood of adherence.[40]

The presence of behavioral and emotional problems seems to be a more important predictor of low quality of life among children with disabilities than the extent of the physical disability.[41] In typically developing children, behavioral and emotional problems would be an important determinant of eligibility for organ transplant[42] because such problems can affect the ability to adhere to complex posttransplant medical recommendations and should likewise be considered a factor for individuals with disability. Many children with chronic illnesses, particularly those with IDDs, have distress with medical visits or phlebotomy, often because of past painful interactions with the medical system.[43] Patients with these issues often respond to child life and other therapies to allow for medical tasks to take place.[44] However, if children cannot be accustomed to simple medical procedures such as phlebotomy, they would be poor transplant candidates because of the chronic and continuing need for blood tests. For such patients,

posttransplant care is not likely to be practical, regardless of the presence or absence of a developmental disability.

Although patients with disabilities commonly report good quality of life, their caregivers often report poorer quality of life, which may be related to the intensity of the care that is necessary.[45,46] The caregiving burden is often more closely related to the extent of behavioral and emotional problems than the severity of the motor or cognitive impairment.[47] The psychosocial evaluation in these circumstances should include the functioning of the broadly defined family unit rather than only the individual to receive the transplant. The family of a child with disabilities might experience an increase or decrease in the caregiving burden, and this should be explored individually.

The lack of standardized mechanisms for transplant centers to assess cognitive development and adaptive functioning was noted by Wightman et al.[48] In a large (N = 2076) retrospective cohort analysis of children receiving a first kidney-alone transplant in the UNOS data set from 2008 to 2011, they reported 16% of the recipients were children identified as having definite or probable ID. For the purpose of the study, the authors created a definition of ID on the basis of information in the UNOS data set because of the lack of standardized mechanisms for transplant centers to assess cognitive development, academic level, or academic activity. Short-term (3-year) graft and patient survival were similar between children with definite or probable ID and without ID. The authors acknowledged that their study did not assess children listed for transplant who remain on the list, patients with end-stage kidney disease not referred to a transplant center, or those refused listing by a transplant center, thereby underestimating the number of children with disabilities eligible for consideration for kidney transplant.[48] The standardization of the definition of disability including both intellectual functioning and adaptive behavior may be helpful in predicting the outcome after transplant.

SUMMARY

When transplant is likely to provide significant health benefits, denying transplant to people with disabilities on the basis of their supposed lower quality of life may constitute illegal and unjustified discrimination.[8] The decision to initiate transplant must include consideration of both the individual patient's current quality of life with the diseased organ and the potentially improved quality of life with the transplanted organ, albeit with the burdens of surgery, immunosuppression, and other posttransplant therapies.[49,50]

The notion that children with disabilities have a lower quality of life than children with typical development is both incorrect and ethically problematic in decisions regarding organ transplant. Care must be taken to ensure that medical and psychosocial factors that may affect the transplant outcome are not confused with judgments of an individual's social worth. Children without disabilities have no more claims to scarce resources, such as organ transplants, than do children with disabilities.

To address concerns regarding the fairness of transplant evaluations for patients with IDDs, a framework for transplant centers is necessary to ensure procedural consistency and transparency. The definition and assessment of ID, including the evaluation of cognitive development and adaptive functioning, and the criteria for recipient candidacy and selection require standardization and transparency, making transplant centers accountable for their decisions. One pediatric transplant center used a multidisciplinary approach to develop a center-wide transplant policy. To increase transparency and accountability with respect to candidacy decisions for patients with developmental disabilities, the task force recommended the formation of a transplant listing advisory committee. The purpose of such a committee is to ensure that institutional transplant selection criteria are fair and nondiscriminatory and that patients declined for evaluation or listing were granted a fair and unbiased review, particularly with respect to characteristics that identify vulnerable or protected classes of people, such as those with disabilities, who may be protected under the ADA.[25]

In adhering to the ethical principles of respect for persons, utility, and justice, children with IDDs should not be excluded from the potential pool of recipients and should be referred for evaluation as recipients of organ transplants. IDD alone should not be a contraindication to the referral, acceptance, or listing for solid organ transplant. The presence of an IDD is relevant but should not be the determinative factor.

RECOMMENDATIONS

1. Patients should not be excluded from consideration for solid organ transplant solely on the basis of an intellectual or developmental disability. When transplant is likely to provide significant health benefits, denying transplant to people with disabilities on the basis of their supposed lower quality of life may constitute illegal and unjustified discrimination.
2. Transplant programs should standardize the definition and assessment of ID so that transplant decisions can be individualized, equitable, and transparent. The transplant team

should consider both the cognitive and adaptive skills of the individual. Consistency in defining IDD allows the use of IDD as a medical criterion to prevent unjustified exclusion of children from access to solid organ transplant. There should be concordance among the respective solid organ transplant programs within an institution in defining IDD to avoid individual programmatic biases. The transplant team should consider both the cognitive and adaptive skills of the individual. Cognitive testing alone is inadequate to characterize a person's level of disability. The individual's level of adaptive functioning must be taken into account; specifically, the skills with which an individual lives within his or her environment (eg, the social, conceptual, and practical skills needed for self-care, self-direction, communication, home living, use of community resources, and functional academic skills) must be considered. Failure to consider adaptive functioning as part of the transplant evaluation results in an inaccurate assessment of ID.

3. The transplant evaluation is a collaborative process that should occur in person rather than by medical record review and should include caregivers such as therapists and developmental specialists who can illustrate the patient's degree of function. Evaluations for transplant to an individual with ID should include professionals with expertise in the evaluation and management of individuals with ID.[51]

LEAD AUTHORS

Mindy B. Statter, MD, MBE
Garey Noritz, MD

COMMITTEE ON BIOETHICS, 2019–2020

Robert Conover Macauley, MD, MDiv, FAAP, Chairperson
Ratna Basak, MD, FAAP
Gina Marie Geis, MD, FAAP
Naomi Tricot Laventhal, MD, FAAP
Douglas J. Opel, MD, MPH, FAAP
Mindy B. Statter, MD, FAAP

LIAISONS

Mary Lynn Dell, MD, DMin – *American Academy of Child and Adolescent Psychiatry*
Douglas S. Diekema, MD, MPH, FAAP – *American Board of Pediatrics*
Nanette Elster, JD, MPH – *Legal Consultant*
David Shalowitz – *American College of Obstetricians and Gynecologists*

STAFF

Florence Rivera, MPH

COUNCIL ON CHILDREN WITH DISABILITIES EXECUTIVE COMMITTEE, 2019–2020

Dennis Z. Kuo, MD, MHS, FAAP, Chairperson
Susan Apkon, MD, FAAP
Lynn F. Davidson, MD, FAAP
Kathryn A. Ellerbeck, MD, MPH, FAAP
Jessica E.A. Foster, MD, MPH, FAAP
Susan L. Hyman, MD, FAAP
Garey H. Noritz, MD, FAAP
Mary O'Connor Leppert, MD, FAAP
Barbara S. Saunders, DO, FAAP
Christopher J. Stille, MD, MPH, FAAP
Larry Yin, MD, MSPH, FAAP

FORMER COUNCIL ON CHILDREN WITH DISABILITIES EXECUTIVE COMMITTEE MEMBERS

Kenneth W. Norwood Jr, MD, FAAP, Immediate Past Chairperson
Timothy Brei, MD, FAAP
Beth Ellen Davis, MD, MPH, FAAP

LIAISONS

Cara Coleman, JD, MPH – Family Voices
Marie Mann, MD, MPH, FAAP – Maternal and Child Health Bureau
Edwin Simpser, MD, FAAP – *Section on Home Care*
Peter J. Smith, MD, MA, FAAP – *Section on Developmental and Behavioral Pediatrics*
Marshalyn Yeargin-Allsopp, MD, FAAP – Centers for Disease Control and Prevention

STAFF

Alexandra Kuznetsov, RD

ACKNOWLEDGMENT

We acknowledge Dr. Aviva Katz for her leadership, insight, and guidance in the development of this policy.

ABBREVIATIONS

ADA: Americans with Disabilities Act
HHS: US Department of Health and Human Services
ID: intellectual disability
IDD: intellectual and developmental disability
OPTN: Organ Procurement and Transplantation Network
UNOS: United Network for Organ Sharing

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Committee on Hospital Care, Section on Surgery, and Section on Critical Care. Policy statement–pediatric organ donation and transplantation. *Pediatrics*. 2010;125(4):822–828
2. Salvador-Carulla L, Reed GM, Vaez-Azizi LM, et al. Intellectual developmental disorders: towards a new name, definition and framework for "mental retardation/intellectual disability" in ICD-11. *World Psychiatry*. 2011;10(3):175–180
3. Papazoglou A, Jacobson LA, McCabe M, Kaufmann W, Zabel TA. To ID or not to ID? Changes in classification rates of

intellectual disability using DSM-5. *Intellect Dev Disabil*. 2014;52(3):165–174

4. Tassé MJ, Schalock RL, Balboni G, et al. The construct of adaptive behavior: its conceptualization, measurement, and use in the field of intellectual disability. *Am J Intellect Dev Disabil*. 2012;117(4): 291–303

5. Maulik PK, Mascarenhas MN, Mathers CD, Dua T, Saxena S. Prevalence of intellectual disability: a meta-analysis of population-based studies. *Res Dev Disabil*. 2011;32(2):419–436

6. Richards CT, Crawley LM, Magnus D. Use of neurodevelopmental delay in pediatric solid organ transplant listing decisions: inconsistencies in standards across major pediatric transplant centers. *Pediatr Transplant*. 2009;13(7): 843–850

7. Mehra MR, Kobashigawa J, Starling R, et al. Listing criteria for heart transplantation: International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplant candidates–2006. *J Heart Lung Transplant*. 2006;25(9):1024–1042

8. Americans with Disabilities Act, Pub L No. 101–336, 104 Stat 328 (1990), amended Pub L No. 110–325 (2008)

9. Rehabilitation Act of 1973 (section 504). 29 USC §701 (1973)

10. Pelka F. Running the transplant gauntlet: discrimination against people with disabilities when they seek organ transplant. *Exceptional Parent*. 2004;34: 30–33

11. Lefkowitz DS, Fitzgerald CJ, Zelikovsky N, Barlow K, Wray J. Best practices in the pediatric pretransplant psychosocial evaluation. *Pediatr Transplant*. 2014; 18(4):327–335

12. Wightman A, Smith J, Diekema D. Neurodevelopmental Status as a Criterion for Solid Organ Transplant Eligibility. In: Greenberg RA, Goldberg AM, Rodriquez-Arias D, eds. *Ethical Issues in Pediatric Organ Transplantation*. Switzerland: Springer; 2016:215–236

13. Project Implicit. Implicit Association Test. Disability IAT. Available at: https://implicit.harvard.edu/implicit/. Accessed March 12, 2020

14. Maina IW, Belton TD, Ginzberg S, Singh A, Johnson TJ. A decade of studying implicit racial/ethnic bias in healthcare providers using the implicit association test. *Soc Sci Med*. 2018;199:219–229

15. White AA III, Stubblefield-Tave B. Some advice for physicians and other clinicians treating minorities, women, and other patients at risk of receiving health care disparities. *J Racial Ethn Health Disparities*. 2017;4(3):472–479

16. Diament M. Disability no reason to deny organ transplants, lawmakers say. *Disability Scoop*. October 24, 2016. Available at: https://www.disabilityscoop.com/2016/10/24/disability-organ-lawmakers/22920/. Accessed October 14, 2018

17. Panocchia N, Bossola M, Vivanti G. Transplantation and mental retardation: what is the meaning of a discrimination? *Am J Transplant*. 2010;10(4):727–730

18. Martens MA, Jones L, Reiss S. Organ transplantation, organ donation and mental retardation. *Pediatr Transplant*. 2006;10(6):658–664

19. Benedetti E, Asolati M, Dunn T, et al. Kidney transplantation in recipients with mental retardation: clinical results in a single-center experience. *Am J Kidney Dis*. 1998;31(3):509–512

20. Ohta T, Motoyama O, Takahashi K, et al. Kidney transplantation in pediatric recipients with mental retardation: clinical results of a multicenter experience in Japan. *Am J Kidney Dis*. 2006;47(3):518–527

21. Galante NZ, Dib GA, Medina-Pestana JO. Severe intellectual disability does not preclude renal transplantation. *Nephrol Dial Transplant*. 2010;25(8):2753–2757

22. Organ Procurement and Transplantation Network. *Ethical Principles in the Allocation of Human Organs*. Washington, DC: US Department of Health and Human Services; 2015

23. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 6th ed. New York, NY: Oxford University Press; 2009:197

24. Allocation of Organs. 42 CFR §121.8 (1999). Available at: https://www.gpo.gov/fdsys/search/pagedetails.action?browsePath=Title+42%2FChapter+I%2FSubchapter+K%2FPart+121%2FSection+121.8&granuleId=CFR-2002-title42-vol1-sec121-8&packageId=CFR-2002-title42-vol1&collapse=true&fromBrowse=true&collectionCode=CFR. Accessed November 15, 2018

25. Kamin DS, Freiberger D, Daly KP, et al. What is the role of developmental disability in patient selection for pediatric solid organ transplantation? *Am J Transplant*. 2016;16(3):767–772

26. Cohen E, Kuo DZ, Agrawal R, et al. Children with medical complexity: an emerging population for clinical and research initiatives. *Pediatrics*. 2011; 127(3):529–538

27. Groll D. Four models of family interests. *Pediatrics*. 2014;134(suppl 2):S81–S86

28. The WHOQOL Group. The World Health Organization Quality of Life assessment (WHOQOL): position paper from the World Health Organization. *Soc Sci Med*. 1995;41(10):1403–1409

29. Anthony SJ, Pollock SP, Ng VL. Quality of life after pediatric solid organ transplantation. *Pediatr Clin North Am*. 2010;57(2):559–574

30. World Health Organization. *International Classification of Functioning, Disability and Health*. Geneva, Switzerland: World Health Organization; 2001

31. Dickinson HO, Parkinson KN, Ravens-Sieberer U, et al. Self-reported quality of life of 8-12-year-old children with cerebral palsy: a cross-sectional European study. *Lancet*. 2007;369(9580): 2171–2178

32. Mezgebe M, Akhtar-Danesh G-G, Streiner DL, Fayed N, Rosenbaum PL, Ronen GM. Quality of life in children with epilepsy: how does it compare with the quality of life in typical children and children with cerebral palsy? *Epilepsy Behav*. 2015;52(pt A): 239–243

33. Calley A, Williams S, Reid S, et al. A comparison of activity, participation and quality of life in children with and without spastic diplegia cerebral palsy. *Disabil Rehabil*. 2012;34(15):1306–1310

34. Albrecht GL, Devlieger PJ. The disability paradox: high quality of life against all odds. *Soc Sci Med*. 1999;48(8):977–988

35. White-Koning M, Arnaud C, Dickinson HO, et al. Determinants of child-parent

agreement in quality-of-life reports: a European study of children with cerebral palsy. *Pediatrics*. 2007;120(4). Available at: www.pediatrics.org/cgi/content/full/120/4/e804

36. Graham RJ, Robinson WM. Integrating palliative care into chronic care for children with severe neurodevelopmental disabilities. *J Dev Behav Pediatr*. 2005;26(5):361–365
37. Magnus D. Should developmentally delayed children be listed for solid organ transplants? [Video presentation.] Presented at: 2007 Pediatric Bioethics Conference; July 13–14, 2007; Seattle, WA. Available at: https://www.youtube.com/watch?v=TInpTN3c4IQ&feature=youtu.be. Accessed March 12, 2020
38. US Department of Health and Human Services. General considerations in assessment for transplant candidacy. Available at: https://optn.transplant.hrsa.gov/resources/ethics/general-considerations-in-assessment-for-transplant-candidacy/. Accessed October 14, 2018
39. Dobbels F, Ruppar T, De Geest S, Decorte A, Van Damme-Lombaerts R, Fine RN. Adherence to the immunosuppressive regimen in pediatric kidney transplant recipients: a systematic review. *Pediatr Transplant*. 2010;14(5):603–613
40. Dobbels F. Intellectual disability in pediatric transplantation: pitfalls and opportunities. *Pediatr Transplant*. 2014;18(7):658–660
41. Chen K-L, Tseng M-H, Shieh J-Y, Lu L, Huang C-Y. Determinants of quality of life in children with cerebral palsy: a comprehensive biopsychosocial approach. *Res Dev Disabil*. 2014;35(2):520–528
42. Corbett C, Armstrong MJ, Parker R, Webb K, Neuberger JM. Mental health disorders and solid-organ transplant recipients. *Transplantation*. 2013;96(7):593–600
43. Evans DW, Canavera K, Kleinpeter FL, Maccubbin E, Taga K. The fears, phobias and anxieties of children with autism spectrum disorders and Down syndrome: comparisons with developmentally and chronologically age matched children. *Child Psychiatry Hum Dev*. 2005;36(1):3–26
44. Davit CJ, Hundley RJ, Bacic JD, Hanson EM. A pilot study to improve venipuncture compliance in children and adolescents with autism spectrum disorders. *J Dev Behav Pediatr*. 2011;32(7):521–525
45. Basaran A, Karadavut KI, Uneri SO, Balbaloglu O, Atasoy N. The effect of having a children with cerebral palsy on quality of life, burn-out, depression and anxiety scores: a comparative study. *Eur J Phys Rehabil Med*. 2013;49(6):815–822
46. Murphy N, Caplin DA, Christian BJ, Luther BL, Holobkov R, Young PC. The function of parents and their children with cerebral palsy. *PM R*. 2011;3(2):98–104
47. Lowes L, Clark TS, Noritz G. Factors associated with caregiver experience in families with a child with cerebral palsy. *J Pediatr Rehabil Med*. 2016;9(1):65–72
48. Wightman A, Young B, Bradford M, et al. Prevalence and outcomes of renal transplantation in children with intellectual disability. *Pediatr Transplant*. 2014;18(7):714–719
49. Anthony SJ, Hebert D, Todd L, et al. Child and parental perspectives of multidimensional quality of life outcomes after kidney transplantation. *Pediatr Transplant*. 2010;14(2):249–256
50. Qvist E, Jalanko H, Holmberg C. Psychosocial adaptation after solid organ transplantation in children. *Pediatr Clin North Am*. 2003;50(6):1505–1519
51. Association of University Centers on Disabilities. UCEDDs. Available at: https://www.aucd.org/template/page.cfm?id=24. Accessed February 25, 2018

Diagnosis, Management, and Treatment of Female Genital Mutilation or Cutting in Girls

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Diagnosis, Management, and Treatment of Female Genital Mutilation or Cutting in Girls

Janine Young, MD, FAAP,[a] Nawal M. Nour, MD, MPH, FACOG,[b] Robert C. Macauley, MD, FAAP,[c] Sandeep K. Narang, MD, JD, FAAP,[d] Crista Johnson-Agbakwu, MD, MSc, FACOG,[e] SECTION ON GLOBAL HEALTH, COMMITTEE ON MEDICAL LIABILITY AND RISK MANAGEMENT, COMMITTEE ON BIOETHICS

Female genital mutilation or cutting (FGM/C) involves medically unnecessary cutting of parts or all of the external female genitalia. It is outlawed in the United States and much of the world but is still known to occur in more than 30 countries. FGM/C most often is performed on children, from infancy to adolescence, and has significant morbidity and mortality. In 2018, an estimated 200 million girls and women alive at that time had undergone FGM/C worldwide. Some estimate that more than 500 000 girls and women in the United States have had or are at risk for having FGM/C. However, pediatric prevalence of FGM/C is only estimated given that most pediatric cases remain undiagnosed both in countries of origin and in the Western world, including in the United States. It is a cultural practice not directly tied to any specific religion, ethnicity, or race and has occurred in the United States. Although it is mostly a pediatric practice, currently there is no standard FGM/C teaching required for health care providers who care for children, including pediatricians, family physicians, child abuse pediatricians, pediatric urologists, and pediatric urogynecologists. This clinical report is the first comprehensive summary of FGM/C in children and includes education regarding a standard-of-care approach for examination of external female genitalia at all health supervision examinations, diagnosis, complications, management, treatment, culturally sensitive discussion and counseling approaches, and legal and ethical considerations.

abstract

[a]Department of General Pediatrics, Denver Health Refugee Clinic, and Human Rights Clinic, Denver Health and Hospitals and School of Medicine, University of Colorado Denver, Denver, Colorado; [b]African Women's Health Center, Department of Obstetrics and Gynecology, Brigham and Women's Hospital and Harvard Medical School, Harvard University, Boston, Massachusetts; [c]Department of Pediatrics, Oregon Health and Science University, Portland, Oregon; [d]Division of Child Abuse Pediatrics, Ann and Robert H. Lurie Children's Hospital of Chicago and Department of Pediatrics, Feinberg School of Medicine, Northwestern University, Chicago, Illinois; and [e]Refugee Women's Health Clinic, Department of Obstetrics and Gynecology, Valleywise Health Medical Center and Office of Refugee Health, Southwest Interdisciplinary Research Center, School of Social Work, Watts College of Public Service and Community Solutions, Arizona State University, Phoenix, Arizona

To cite: Young J, Nour NM, Macauley RC, et al. AAP SECTION ON GLOBAL HEALTH, AAP COMMITTEE ON MEDICAL LIABILITY AND RISK MANAGEMENT, AAP COMMITTEE ON BIOETHICS. Diagnosis, Management, and Treatment of Female Genital Mutilation or Cutting in Girls. *Pediatrics.* 2020;146(2):e20201012

BACKGROUND

Female genital mutilation or cutting (FGM/C)* is currently outlawed in much of the world. The United Nations,[1] the World Health Organization (WHO),[2] the International Federation of Obstetrics and Gynecology,[3] and the American Medical Association[4] are among multiple organizations that unequivocally oppose all forms of FGM/C (see Table 1).

FGM/C involves medically unnecessary cutting of parts or all of the external female genitalia, including the clitoris, prepuce, labia minora, and labia majora. FGM/C may be associated with significant morbidity and mortality and is not associated with any medical benefit. Notwithstanding this morbidity, it is still performed and has been practiced in many cultures for thousands of years, predating Judaism, Christianity, and Islam.[5] Historically and in present-day, FGM/C is a cultural practice not directly tied to any specific religion, ethnicity, or race and has been reported to still occur throughout the world, including in the United States, but with higher prevalence in parts of the Middle East, Asia, and Africa (see Fig 1). Reasons why FGM/C is performed vary by region and culture and may include a belief that it increases marriageability, preserves virginity, improves hygiene, perpetuates a traditional rite of passage, and/or upholds prescribed religious beliefs (although no sacred texts recommend this practice).[6,7] FGM/C is predominantly performed on children and adolescents ranging in age from newborn infants to 15 years; the typical age varies by region of the world, country, state, province, and even town or village[8] (see Fig 2). However, the vast majority of medical literature, teaching, and research is focused on chronic issues affecting women of childbearing age and on the management of FGM/C during pregnancy and the peripartum and postpartum periods.[9,10]

To date, there are neither national nor international clinical practice guidelines that are specifically focused on FGM/C in infants and prepubertal and pubertal girls.

This clinical report's primary goal is to educate pediatric health care providers on the continued occurrence of FGM/C, the populations that it affects, diagnosis, complications, treatment options, and the provision of culturally sensitive counseling, all while taking into consideration the legal and ethical aspects of a practice that is illegal in the United States and much of the world (see Table 2).

PREVALENCE

National and international data on the prevalence of FGM/C in children and adolescents are difficult to obtain and are based on either maternal report or estimates derived from data on the adult female population who present mainly for obstetrical care. The United Nations Children's Fund estimated that in 2018, 200 million girls and women alive at that time had undergone FGM/C worldwide.[11] Some authors estimate that more than 500 000 girls and women who live in the United States (as of 2012) have had FGM/C performed or are at risk for having FGM/C performed, but these estimates are projections based on country of origin prevalence data and may, therefore, not be precise or accurate.[13] To date, no reliable data exist quantifying the true number of girls and women residing in the United States who have had FGM/C performed.[13]

The majority of FGM/C occurs in 30 African and Middle Eastern countries, with highest prevalence in Egypt, Somalia, Guinea, Djibouti, Mali, Sierra Leone, Sudan, and Eritrea.[14] However, FGM/C also occurs with unknown frequency in Yemen, Oman, the United Arab Emirates, Bahrain, northern Iraq, India, Malaysia, and Indonesia[15] and has been reported to occur sporadically in Russia[16,17] and Colombia.[18] The practice of FGM/C is not uniformly performed throughout any given country and may be clustered on the basis of economic status, level of education, rural versus urban geographic location, ethnic and/or tribal affiliation, and religious beliefs. In half of the countries with available data on FGM/C prevalence, most girls have had FGM/C performed before 5 years of age (see Fig 2).

Although it is illegal in the United States, FGM/C has been reported in the United States in sporadic cases over the past several years.[19,20] The federal Department of Justice prosecuted its first case against a US physician accused of having performed FGM/C across state lines in up to 100 children (see The Law and FGM/C in Minors in the United States for further current case details).[21] At of time of writing, the charges were dismissed by the district judge of the Eastern District of Michigan.[22] This specific case is focused on the practice of FGM/C in the Dawoodi Bohra community in India and among a subset of the Dawoodi Bohra immigrant community in the United States. The illegal practice of US families sending their children abroad to have FGM/C

* Currently, there are few experts in the United States who care for children and teenagers with FGM/C (see Table 4 for a link to access regional specialists). As such, it is of utmost importance to identify regional specialists, including child abuse pediatricians, gynecologists, urologists, and mental health providers, with whom to collaborate if providing medical care for children and teenagers affected by or at risk for FGM/C. FGM/C is an accepted term adopted by many international organizations and in medical research papers and, as such, will be used throughout this document.[9,12,16] Infibulation refers to type III FGM/C (see FGM/C Types and Classification in addition to Fig 4). Defibulation refers to a surgical procedure that opens the scar formed in patients with type III FGM/C (see Defibulation).

TABLE 1 FGM/C Recommendations

Recommendations
FGM/C is illegal in the United States.
FGM/C is a violation of human rights.
FGM/C has no medical benefit.
FGM/C is associated with serious and potentially life-threatening complications that can have lifelong impacts on health.
Health care providers should not perform any type of FGM/C on female infants, girls, or teenagers.
Health care providers caring for girls at risk for FGM/C should actively counsel families against performing FGM/C, including when families travel to countries where FGM/C is practiced.
A genital examination allows health care professionals to identify FGM/C and other medical findings of significance.
If genital examination findings are equivocal for the presence of FGM/C and risk factors for FGM/C are present, a specialist trained in identification of FGM/C should be consulted (see Table 4).
The management of FGM/C should include complete documentation of clinical findings and the use of ICD-10 coding.
Health care providers should recommend defibulation for all girls and teenagers with type III FGM/C, irrespective of whether complications are currently present.

performed (also known as "vacation cutting") is also presumed to occur.[23,24] However, prevalence data are nonexistent to date.[13]

FGM/C TYPES AND CLASSIFICATION

The WHO has classified FGM/C into four distinct types (see Table 3), with type III associated with the most significant long-term morbidity (see Complications and Management) (Figs 3–11). To better delineate specific findings, the WHO has also included subtypes of FGM/C, categorized as Ia and Ib, IIa–IIc, and IIIa and IIIb (see Fig 12). However, the practice of FGM/C is not standardized, and physical findings may overlap between types and subtypes (see Figs 5 and 6). Type I FGM/C is classified as cutting of the glans or part of the body of the clitoris and/or prepuce; type II includes excision of the clitoris and labia minora, with or without excision of the labia majora; type III, infibulation, includes cutting and apposing the labia minora and/or majora over the urethral meatus and vaginal opening to significantly narrow it and may include clitoral excision (Figs 10 and 11); and type IV includes piercing, scraping, nicking, stretching, or otherwise injuring the external female genitalia without removing any genital tissue and includes practices that do not fall into the other three categories (Fig 13).

FIGURE 1
FGM/C global prevalence. Countries where FGM/C is practiced with unknown frequency and not pictured on this map include Oman, the United Arab Emirates, Bahrain, India, Malaysia, Russia, and Colombia.[15–18] South Sudan seceded from Sudan in 2011 but is not noted on this map.[107] Reproduced with permission from United Nations Population Fund. *Demographic Perspectives on Female Genital Mutilation.* Copyright © United Nations Population Fund 2015.

Prevalence of FGM/C subtypes is mainly influenced by ethnicity and region. Surveys of girls and women older than 15 years reveal that approximately 10% of cases are FGM/C type III, or infibulation, although these numbers are based on self-report and likely under- or

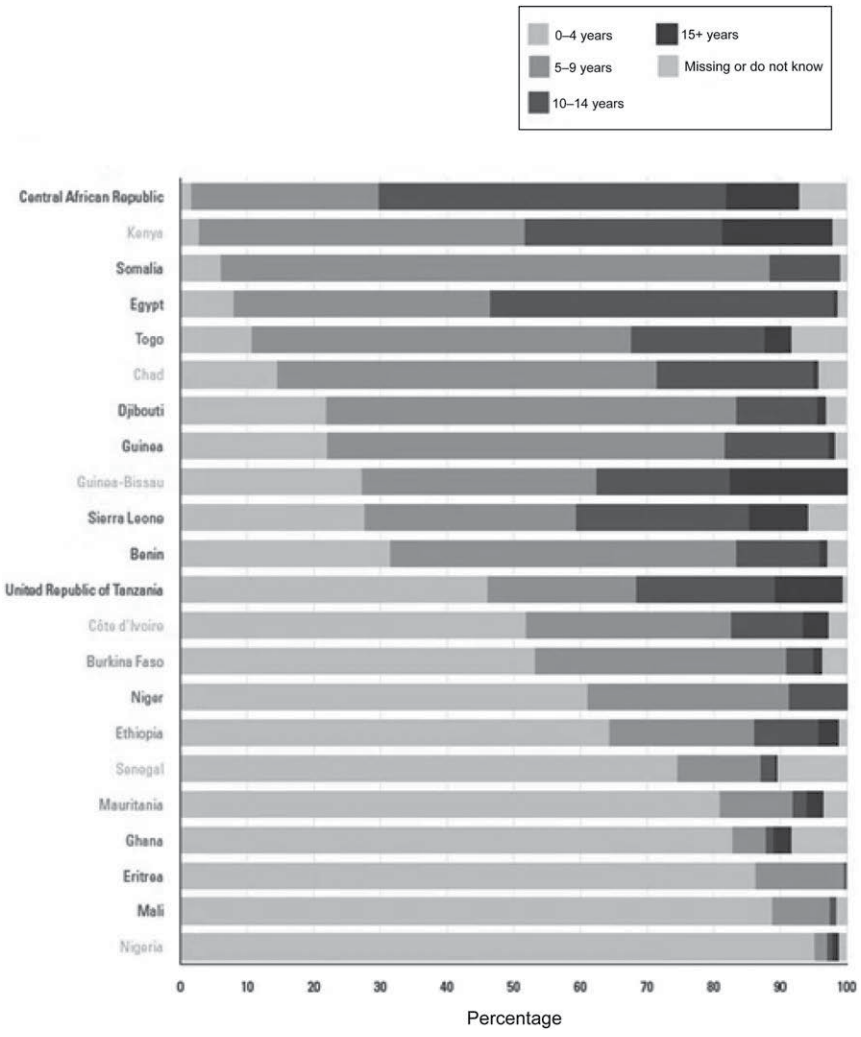


FIGURE 2
Maternal report of age that girls have undergone FGM/C, by country. Reproduced with permission from UNICEF. *Female Genital Mutilation/Cutting: A Statistical Overview and Exploration of the Dynamics of Change*. New York, NY: UNICEF; 2013:41. Copyright © United Nations Children's Fund 2013.

overestimate the actual prevalence of type III FGM/C.[8] The practice of infibulation, the removal and apposition of the labia minora and/or labia majora with or without cutting of the clitoris, is concentrated in northeastern Africa in Djibouti, Eritrea, and Somalia. Data extrapolated from 2004 to 2008 East African regional surveys of girls and women 15 years and older revealed that 82% to 99% reported to have had undergone FGM/C, and of these cases, 34% to 79% were type III (Somalia having the highest prevalence of type III).[25]

KNOWLEDGE OF, ATTITUDE ABOUT, AND PRACTICE OF FGM/C IN THE UNITED STATES

Knowledge of FGM/C is believed to be limited among US pediatric providers because there are no nationally required courses on diagnosis of type, management, or treatment of FGM/C for medical students, residents, or fellows in general pediatrics, family medicine, adolescent medicine, child abuse pediatrics, urology, or gynecology.[9,26–28] Instead, existing studies from the United States are focused on nurse midwives and obstetricians and gynecologists and note the lack of training in diagnosis, management, and cultural and legal aspects of care in adult women.[29–32] One recent US study revealed that of 79 general pediatricians surveyed, 73% had received no previous FGM/C education, 89% did not feel confident in their ability to identify FGM/C types, and frequency of performing external genital examinations on female patients at health supervision visits was inversely related to the age of the patient (with 75% performing examinations on infants, down to only 8% in 17- to 18-year-olds).[28] In literature from other high-income countries with immigrant populations from regions where FGM/C is prevalent, pediatricians have reported identifying FGM/C in pediatric patients, managing complications from remote and recent procedures, and, in some instances, being asked to perform FGM/C in children.[9,33,34] However, one survey conducted in Australia revealed that of pediatricians surveyed, most reported neither discussing nor examining children for FGM/C.[34,35]

CLINICAL HISTORY TAKING

For children with possible risk factors for FGM/C (eg, mother or sibling with a history of FGM/C, country of origin, birth country, and/or history of travel to a country where FGM/C is practiced), it is recommended that clinical assessment of FGM/C status be integrated into routine pediatric care. Nonetheless, it can be challenging. It is of utmost importance for the pediatric health care provider to establish a trusting relationship with the child or teenager and her family to allow for nonjudgmental questions and ongoing counseling. Experts suggest that health care providers ask the patient or parent the term they use to name female genital cutting. Use of the word mutilation is not recommended when discussing FGM/C with patients and

TABLE 2 Timeline of International Legislation Against FGM/C

Country	Year Legislation Enacted[a]
Benin	2003
Burkina Faso	1996
Central African Republic	1966, 1996[b]
Chad	2003
Côte d'Ivoire	1998
Djibouti	1995, 2009[b]
Egypt	2008
Eritrea	2007
Ethiopia	2004
The Gambia	2015[108]
Ghana	1994, 2007[b]
Guinea	1965, 2000[b]
Guinea-Bissau	2011
Iraq (Kurdistan region)	2011
Kenya	2001, 2011[b]
Mauritania	2005
Niger	2003
Nigeria (some states)	1999–2006
Senegal	1999
Somalia	2012
Sudan (some states)	2008–2009
Togo	1998
Uganda	2010
United Republic of Tanzania	1998
Yemen	2001

Reproduced with permission from United Nations Children's Fund. Female *Genital Mutilation/Cutting: A Statistical Overview and Exploration of the Dynamics of Change*. New York, NY: United Nations Children's Fund; 2013:9. Copyright © UNICEF 2013.

[a] Bans outlawing FGM/C were passed in some African countries, including Kenya and Sudan, during colonial rule. This table includes only legislation that was adopted by independent African nations and does not reflect earlier rulings.

[b] Later dates reflect amendments to the original law or new laws.

caregivers because it is potentially inflammatory and also difficult to translate (and may not be understood).

Given that girls who had FGM/C performed at a young age may not recall being cut (as well as the fact that parents or primary guardians may not reveal a history of FGM/C to their children), obtaining a history of FGM/C from the girl alone may yield little relevant clinical information. Instead, it is advisable that the FGM/C clinical history taking include both the girl and parent or guardian once rapport has been established. Similarly, some parents or guardians may not be aware that FGM/C performed in the country of origin before immigration is not prosecutable in the United States (see The Law and FGM/C in Minors in the United States) or may fear judgment from US medical providers, so they may initially withhold information about previous FGM/C.

When caring for girls with or at risk for FGM/C, it is important to approach FGM/C discussion, physical examination, and counseling with cultural sensitivity. Girls' genitalia may have never been examined before, although they may have had multiple physical examinations in the United States or abroad.[28] Girls and mothers who have been cut may be afraid to seek care from a health care provider because of concerns about disapproval or previous negative experiences being used to teach trainees or other health care providers about FGM/C; many will seek a physician's care only if there is a health problem. Irrespective of their culture, girls' and mothers' knowledge of female anatomy, reproductive health, family planning, and sexually transmitted infections may also be very limited. Understanding each girl's and mother's current knowledge and perception of FGM/C, addressing fears, providing age-appropriate education about pelvic anatomy, and sharing information about the importance of the annual physical examination can facilitate ongoing rapport and engagement with health care. In addition, some girls or parents may request a female health care provider as well as a female interpreter. For girls at risk for FGM/C, it is advisable that efforts be made to honor this request, if at all possible, given social and cultural expectations.

It is important for health care providers to assess each patient individually and make no assumptions about her and her parents' beliefs regarding FGM/C. Mothers and fathers may or may not hold discordant views about FGM/C, and some clinical experts suggest that mothers who have themselves undergone FGM/C may nonetheless oppose subjecting their daughters to this practice. Instead, treating patients and caregivers with respect, sensitivity, and professionalism will encourage them to return and supports health-seeking behavior.

In families with risk factors for FGM/C, including having a mother and/or other girls who have already been cut in the family, it is advisable to inquire, in a nonthreatening manner, whether the parents are planning to perform FGM/C on their daughter. Raising such a sensitive topic may elicit various emotions, but this is a vital educational opportunity to reiterate child safety, the morbidity and mortality associated with FGM/C, and its legal consequences. Such discussions may occur over multiple visits, and it is recommended to revisit these discussions, particularly if the child is being seen before a trip to countries where FGM/C is still practiced. Whether to have this discussion in front of the girl depends on the developmental age of the child,

TABLE 3 FGM/C ICD-10 Coding and WHO Classification

FGM/C Type	ICD-10 Code[109]	WHO Classification (2016)
Female genital mutilation, unspecified	N90.810	
Female genital mutilation, type I	N90.811	Partial excision of the clitoris and/or prepuce
	—	Ia: removal of prepuce only
	—	Ib: partial or total[a] removal of clitoris and prepuce
Female genital mutilation, type II	N90.812	Partial or total[a] removal of the clitoris and labia minora, with or without excision of the labia majora
	—	IIa: removal of labia minora only
	—	IIb: partial removal of the clitoris and labia minora
	—	IIc: partial removal of the clitoris, labia minora and majora
Female genital mutilation, type III	N90.813	Infibulation: narrowing of the vaginal orifice by cutting and apposing the labia minora and/or labia majora over the vaginal opening; may include excision of the clitoris
	—	IIIa: removal and apposition of the labia minora
	—	IIIb: removal and apposition of the labia majora
Other female genital mutilation	N90.818	Unclassified (all other harmful procedures for non-medical purposes), including piercing
	—	IV

—, not applicable.

[a] Although WHO classification describes total removal of the clitoris, it is the glans or the glans and part of the body of the clitoris that is cut.[110]

her degree of understanding, and the dynamics within the family. Encouraging parents to reevaluate this practice in a nonjudgmental manner and impressing on them that FGM/C causes medical complications, has no medical indications, and is also against the law (with associated legal consequences) will hopefully facilitate reconsideration of this practice. It is also essential to document these discussions in the medical chart so that health care providers are both aware that education about FGM/C medical complications and illegality has been discussed and aware of what specific issues have and have not been discussed. Similarly, given that FGM/C performed overseas and before US emigration does not constitute a violation of US law, it is of utmost importance to document past history and timing of FGM/C in the chart so that it is clear that there are no legal ramifications for the family.

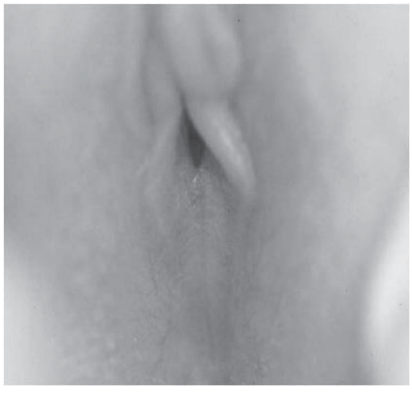


FIGURE 3
Prepubertal female with labial adhesions, no FGM/C. (Reprinted with permission from American Academy of Pediatrics. *Visual Diagnosis of Child Abuse on CD-ROM.* 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2008.)

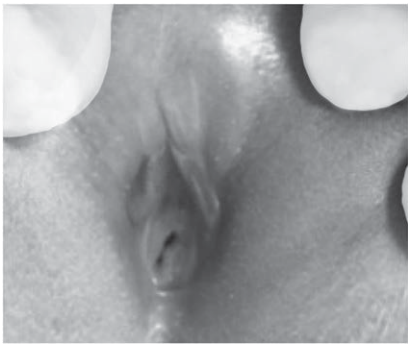


FIGURE 4
Periclitoral adhesions, 18-month-old female patient, no FGM/C (photo credit: J.Y.).

EXTERNAL FEMALE GENITAL EXAMINATION: STANDARDS AND DOCUMENTATION

Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition, recommends that "each visit include a complete physical examination." A complete physical examination includes assessment of genitalia from birth to age 21.[36]

It is recommended that pediatricians and other health care providers include genital inspection as part of all health supervision examinations and be knowledgeable about the variants of normal genital anatomy and the signs of previous genital cutting.[33]

The external genital examination in girls should include the identification of the prepuce, clitoris, and labia minora and majora (see Figs 14–16), and the examination should be performed in frog-leg position with chaperone use documented, per recommendations of the American Academy of Pediatrics.[37] In prepubertal girls, it may be more difficult to identify the clitoris, and in these cases, the prepuce may need to be partially retracted to facilitate

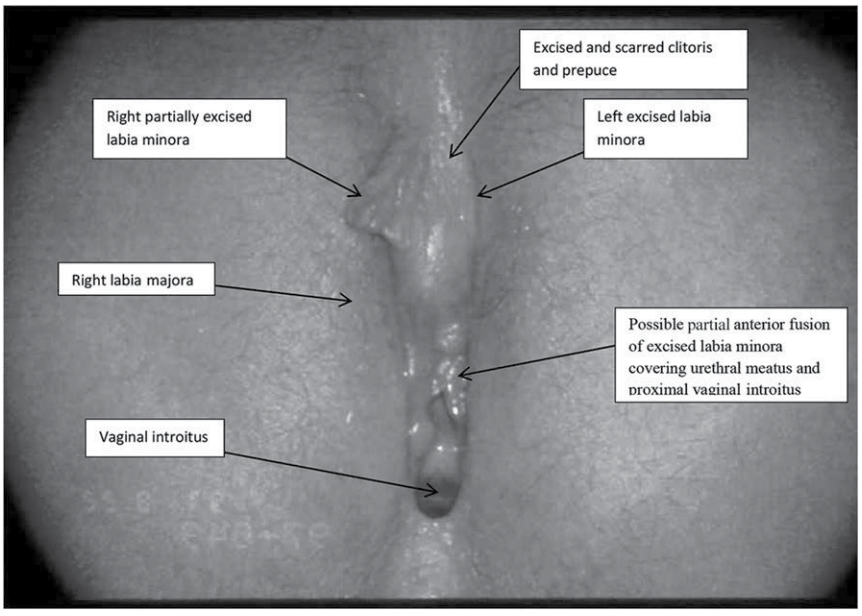


FIGURE 5
Type IIb or IIIa FGM/C in a prepubertal girl (excised clitoris, prepuce, partially excised right labia minora, absent left labia minora, and possible partial anterior fusion of excised labia minora covering urethral meatus and proximal vaginal introitus). This photo was reviewed by three FGM/C experts (J. Abdulcadir, C.J.A, and J.Y), and consensus was either type IIb or IIIa. Arrows were added by J.Y. (Reprinted with permission from Graham EA. Ritual female genital cutting [RFGC] PowerPoint slides. 2014. Available at: https://ethnomed.org/resource/ritual-female-genital-cutting-rfgc-powerpoint-slides/. Accessed April 30, 2020.)

identification. Similarly, the labia minora is less developed, and it is advisable that efforts be made to identify this structure as well. Although not systematically studied, anecdotal experience by some experts suggests that types I, II, and IV FGM/C and even some type III subtypes may be difficult to recognize during the physical examination, particularly in prepubertal girls. Similarly, prepubertal labial adhesions may be miscategorized as FGM/C (see Figs 3–6). If genital examination findings are equivocal for the presence of FGM/C and risk factors for FGM/C are present, a specialist trained in identification of FGM/C should be consulted, although currently, there are few such specialists in the United States (see Table 4 for a link to access regional specialists). However, given the subtleties of some FGM/C, it is assumed that not all cases will be identified.

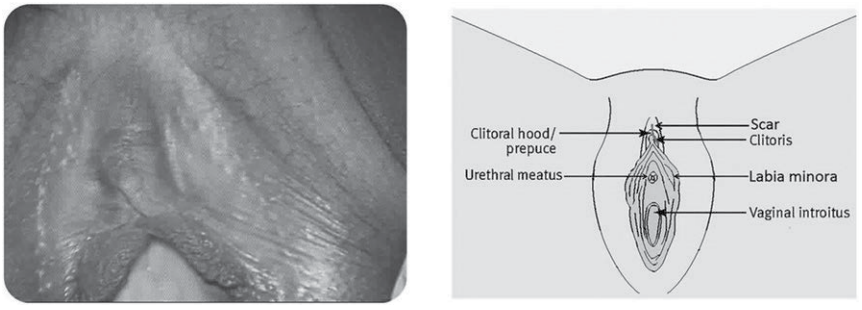


FIGURE 6
Type Ib FGM/C, scarring with excised clitoris and prepuce, or type IV FGM/C with linear scar from superficial cutting with adhesions, Tanner stage 5 female patient. This photo was reviewed by three FGM/C experts (J. Abdulcadir, C.J.A., and J.Y.), and it was unclear if it was type 1b or type IV on the basis of photos. The author of the source of the photo identifies the photo as type IV FGM/C. (Reprinted with permission from Creighton SM, Dear J, de Campos C, Williams L, Hodes D. Multidisciplinary approach to the management of children with female genital mutilation [FGM] or suspected FGM: service description and case series. *BMJ Open*. 2016;6[2]:e010311.)

If FGM/C is suspected to have occurred recently, it may also be difficult to confirm on physical examination without prompt evaluation by a specialist. The genitalia are highly vascularized tissues, healing occurs quickly, and less invasive cutting may easily be missed in some cases, given minimal or only subtle scarring.

If FGM/C is identified on examination, it is advisable that the clinician discuss findings with the caregiver and/or child if the child is old enough to participate in medical decision-making. Medical complications, depending on the type of FGM/C diagnosed, should be reviewed with the caregiver and/or child, as well as when to return for care if any of these complications develop (see Complications and Management). If an older child or teenager is unaware that she has had FGM/C performed (as may be the case if a girl had FGM/C performed at a young age), it is important that a culturally sensitive approach be taken to further discuss her diagnosis with her (see the Appendix for further guidance). Although not systematically studied, FGM/C is a community practice, and in some cultures, aunts, grandparents, or other figures of authority may make the decision to perform FGM/C on a child.[38] In these cases, theoretically, a parent may also not know of a child's previous FGM/C. It is suggested that a thoughtful, supportive discussion occur with the primary caregivers to inform them of the diagnosis, associated potential medical issues, and treatment, when clinically indicated. Given that such information may be distressing, it is advised to offer mental health

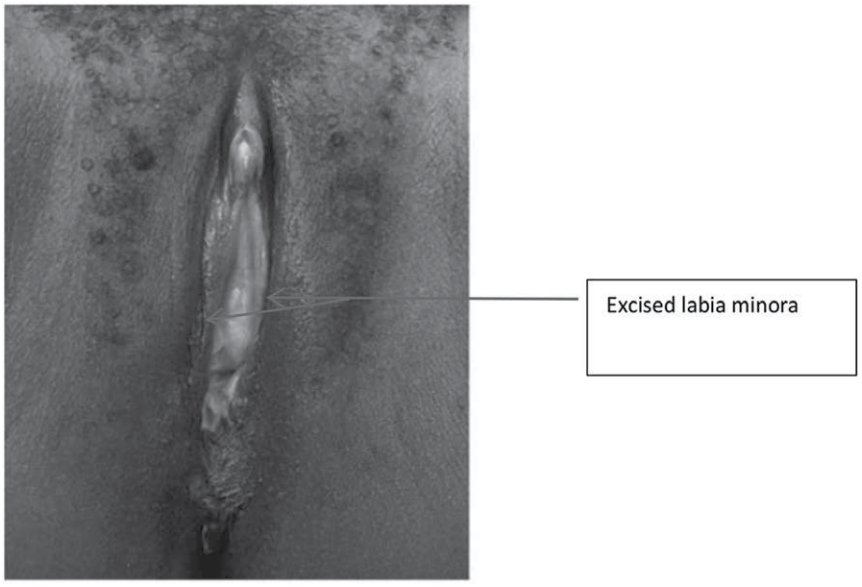


FIGURE 7
Type IIa FGM/C, excision of labia minora only, Tanner stage 5 female patient. (Reprinted with permission of Jasmine Abdulcadir. Copyright © Jasmine Abdulcadir. Also published in Abdulcadir J, Catania L, Hindin MJ, Say L, Petignat P, Abdulcadir O. Female genital mutilation: a visual reference and learning tool for health care professionals. *Obstet Gynecol.* 2016;128[5]:959.)

professional support to caregivers, as indicated.

CODING AND DOCUMENTATION

The management of FGM/C should include complete documentation of clinical findings and use of the *International Classification of Diseases, 10th Revision* (ICD-10) coding,[39] as indicated. A guide to ICD-10 coding and definitions and descriptions of FGM/C subtypes is provided in Table 3. In the future, appropriate coding will allow for better estimates of pediatric FGM/C prevalence. Additionally, clinical documentation of FGM/C findings may facilitate timely referral to gynecologic or urologic specialists, if needed. However, a recent review of state-level hospital discharge data in Arizona revealed that from 2008 to 2014, only 243 cases of FGM/C had been documented, as identified by *International Classification of Diseases, Ninth Revision* and ICD-10 codes, and that of these 243 cases, none were documented in children younger than 18 years (C.J.A, unpublished observations). As context, the Population Reference Bureau estimates that 7459 women and children are at risk for FGM/C in Arizona, suggesting that FGM/C is not being documented consistently by health care providers.[40]

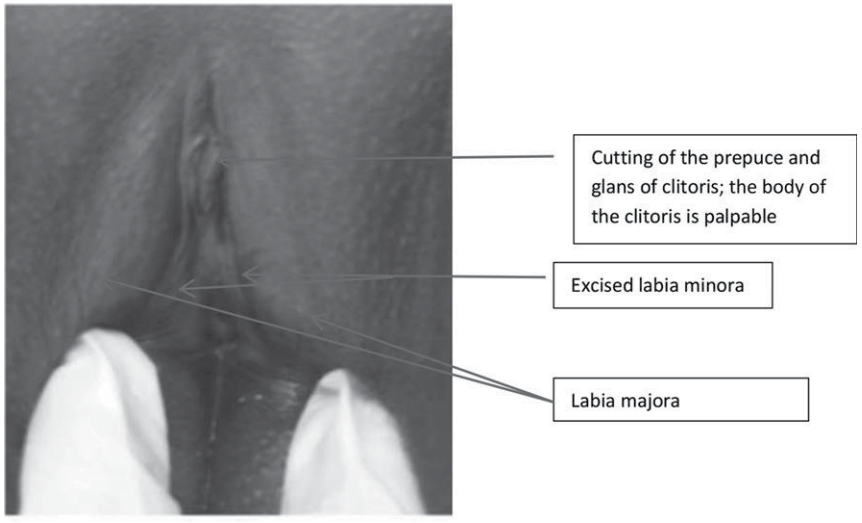


FIGURE 8
Type IIb FGM/C, partial or total clitoridectomy and excision of labia minora, Tanner stage 5 woman. (Reprinted with permission of Jasmine Abdulcadir. Copyright © Jasmine Abdulcadir. Also published in Abdulcadir J, Catania L, Hindin MJ, Say L, Petignat P, Abdulcadir O. Female genital mutilation: a visual reference and learning tool for health care professionals. *Obstet Gynecol.* 2016;128[5]:959.)

COMPLICATIONS AND MANAGEMENT

Immediate Health Complications

Health care providers who work with children and live in countries with intermediate and high prevalence of FGM/C are likely to see immediate health complications; however, such a situation is likely rare in the United States.[41] Exceptions will be newly arrived immigrants who underwent FGM/C just before entering the United States, girls who have recently returned to the United States after undergoing FGM/C while temporarily overseas, or FGM/C that has been performed in the United States. In general, medical complications become more severe with progression from type I to type III, tending to reflect the amount of tissue being removed. If the clitoral dorsal artery or labial branches of the pudendal artery are cut, hemorrhage has been documented in the range of 4% to 19%. Active hemorrhage, subsequent hypotension, hypovolemic shock, and death may occur in these cases.[42,43]

Given the potential use of traditional nonsterile instruments, girls with FGM/C are at risk for acute infections. Girls with type III FGM/C most often have their legs bound for up to

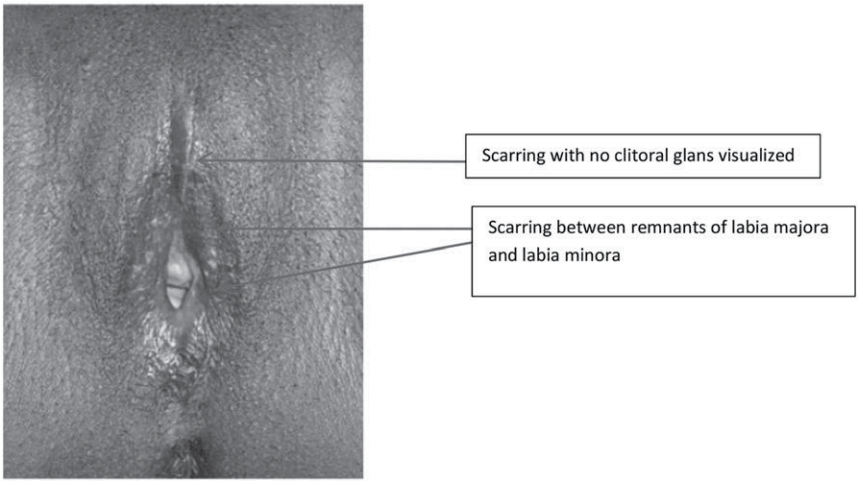


FIGURE 9
Type IIc FGM/C, partial or total clitoridectomy, excision of the labia minora and majora, Tanner stage 5 woman. (Reprinted with permission of Jasmine Abdulcadir. Copyright © Jasmine Abdulcadir. Also published in Abdulcadir J, Catania L, Hindin MJ, Say L, Petignat P, Abdulcadir O. Female genital mutilation: a visual reference and learning tool for health care professionals. *Obstet Gynecol*. 2016; 128[5]:959.)

1 week after cutting (standard practice in type III cases, reportedly to facilitate scar formation). Such prolonged binding facilitates bacterial overgrowth and prevents wound healing. Girls may suffer from cellulitis or wound abscesses; gangrene, septic shock, and tetanus have also been reported. Difficulty urinating, both from pain and deliberate decreased liquid intake, is common.[41] The urethra, vagina, and/or rectum may also be inadvertently cut during FGM/C. Fractures of the clavicle, femur, or humerus also have been reported, resulting from the need to restrain a girl who was not anesthetized during the procedure[42] (Table 5).

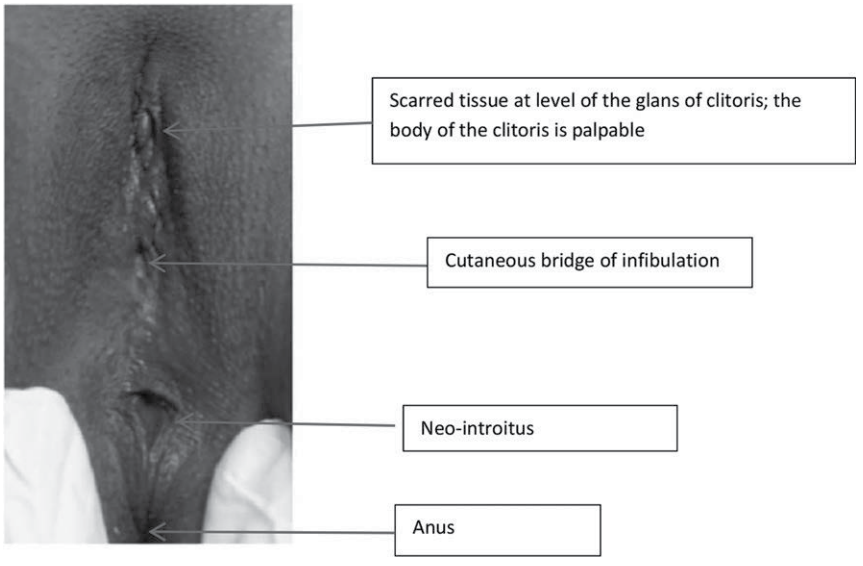


FIGURE 10
Type IIIb FGM/C, with significant narrowing of the introitus from stitching of the labia minora, Tanner stage 5 woman. (Reprinted with permission of Jasmine Abdulcadir. Copyright © Jasmine Abdulcadir. Also published in Abdulcadir J, Catania L, Hindin MJ, Say L, Petignat P, Abdulcadir O. Female genital mutilation: a visual reference and learning tool for health care professionals. *Obstet Gynecol*. 2016; 128[5]:961.)

If a girl is seen with any immediate complications, it is recommended that the health care provider refer for appropriate emergency care and the patient receive vaccination against tetanus. Once stabilized, it is recommended to consult a health provider with FGM/C expertise (see Table 4) to determine the need for medical and/or surgical management. Although there are no data that directly link FGM/C to acquisition of HIV, hepatitis B, or hepatitis C, some clinical experts recommend testing for these infections at the initial visit and at least 6 months after cutting has occurred.[44] As in all children, it is advised that hepatitis B vaccination be offered to girls with FGM/C if they are neither immune nor infected.

In cases in which a girl has been recently cut, it is recommended to offer mental health supports for her, as indicated. Refer to Reporting Child Abuse and Ethical Analysis regarding scenarios in which child abuse reports are recommended.

Long-Term Complications

Studies reveal that girls and women with type III FGM/C are also at higher risk of long-term health complications than those with type I, II, or IV FGM/C. A systematic review of the literature reveals that long-term health complications include dysmenorrhea as well as psychosexual, infertility, and urinary problems.[42] However, physical and psychological complications are not necessarily proportionate to the FGM/C type. Although the authors of one study state that the relative risk of obstetric complications (including increased cesarean delivery rates), of the need for infant resuscitation, of stillbirths, and of infants with low birth weight increases with the severity of FGM/C, data are limited, and it is likely that the combination of obstructed labor and substandard

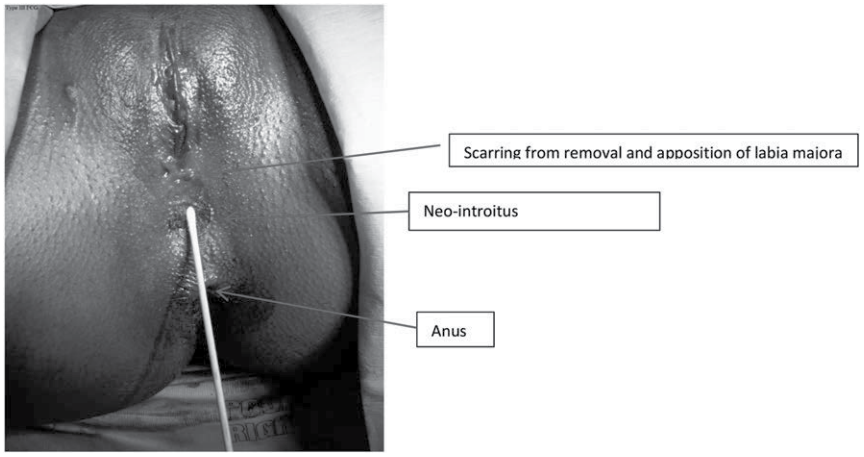


FIGURE 11
Type IIIb FGM/C in a Tanner stage 5 17-year-old with severe dysmenorrhea preventing her from going to school during menstrual flow (photo courtesy of N.N.).

health care systems contribute to such complications (Tables 6 and 7).[45]

Secondary analysis of cesarean delivery rates has revealed that health care provider unfamiliarity with defibulation and/or other management options for FGM/C may increase the risk of cesarean deliveries in some cases.[46,47]

Long-term complications can be placed into 7 major categories: pain, urinary issues, infections, scarring, infertility, sexual dysfunction,[42,48] mental health issues,[49,50] and other (Table 5).

Pain

Pain is a common long-term complication after type III FGM/C and can also be present in patients with type I and II FGM/C. In type III FGM/C, the narrow neo-introitus creates a closed environment that can obstruct urinary and menstrual flow. Because of the scarring that obstructs the introitus, the menstrual flow of women and teenagers with infibulation can last longer than usual, rendering them unable go to school during this time (see Fig 11). Menstruation may be painful and may become dark and foul smelling because of the retention of blood. In very rare cases, hematocolpos and hematometra have been documented.

Other painful complications arise when remnant foreign bodies are left in the scar during the initial procedure. These can produce sharp pains when sitting and walking. Cut or trapped nerve fibers have also been documented, creating very painful neuromas. In both of these situations, defibulation and removal of the foreign body or neuroma are recommended.[51]

Dyspareunia in sexually active teenagers with type III FGM/C has been seen (see Future Infertility) and treatment includes defibulation.[52]

One study followed 40 Somali women whose primary indications for defibulation were pregnancy (30%), dysmenorrhea (30%), apareunia (20%), or dyspareunia (15%). Of the 32 patients surveyed, 94% stated they would highly recommend defibulation to others; 100% of patients were pleased with the results, felt their appearance had improved, and were sexually satisfied, suggesting that the symptoms of teenagers who have undergone FGM/C and are experiencing dysmenorrhea will also be improved by defibulation.[52]

Urinary Issues

The narrow neo-introitus and scar in type III FGM/C create a dark, moist, and unventilated area surrounding the urethra. Urine can stagnate beneath the scar and promote abnormal bacterial growth. As a result, girls who are infibulated can experience chronic urinary tract infections. With recurrence of UTI, suppressive antimicrobial medication is an option, although defibulation is preferable; however, currently there are no known systematic studies evaluating the efficacy of prophylactic antibiotic treatment or defibulation in preventing recurrent UTIs associated with FGM/C.[53]

In general, clinical experience indicates that girls who are infibulated may describe their urinary stream as being slow and having a dripping quality. As the urine exits the urethra, it trickles under the scar and then drips past the neo-introitus. Patients also may complain of overactive bladder on the one hand or straining and urinary retention on the other. These issues may be attributable to injury of the urethra, resulting in urinary strictures and stenosis and requiring cystoscopy or urethral dilation. It is also possible for the obstructing scar to enable urinary crystals to deposit and, as a result, form urinary stones.[54] These patients routinely experience sharp pains and require defibulation for stone removal.

Scarring and Other Postinflammatory Reactions

Keloid formation is rare, although not unknown in FGM/C cases. The main problem with the infibulated scar is its obstructive nature. However, other complications in type II FGM/C include unintended labial fusions and cysts (fluid-filled, sebaceous, or inclusion cysts or abscesses). There are multiple case reports documenting epidermal cysts associated with all types of FGM/C.

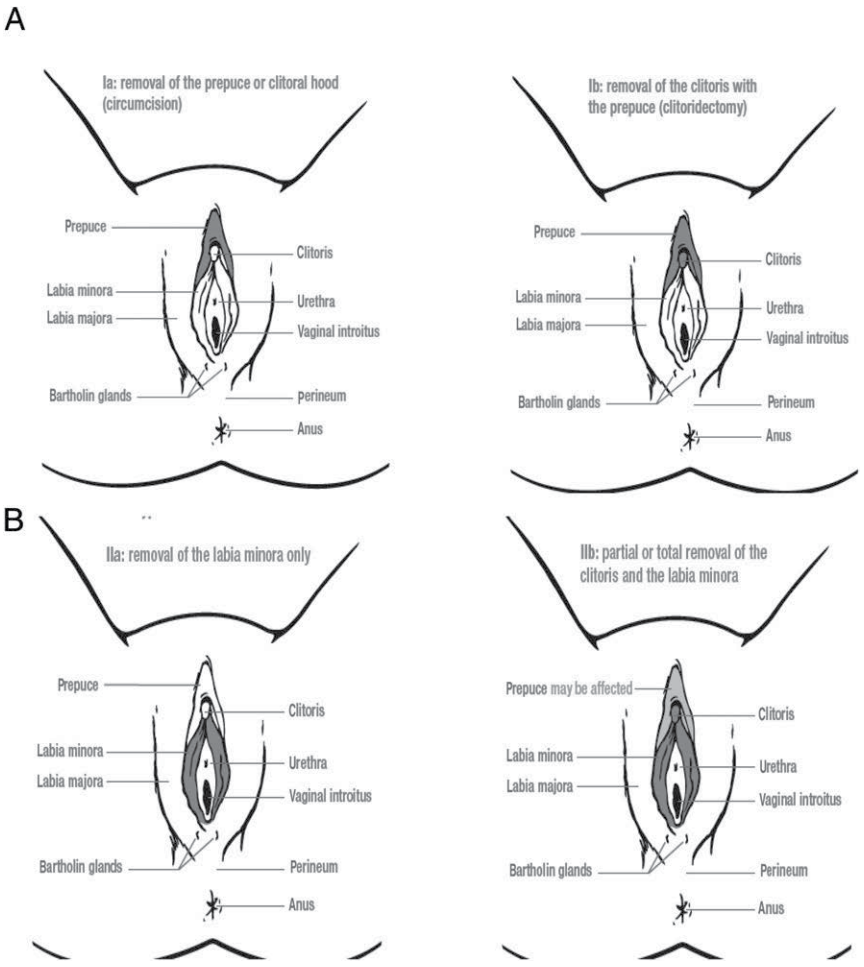


FIGURE 12

WHO FGM/C subtype diagrams. A, Female genital mutilation (FGM) type 1. B, FGM type 2. World Health Organization. Copyright © World Health Organization 2016. Also published in Abdulcadir J, Catania L, Hindin MJ, Say L, Petignat P, Abdulcadir O. Female genital mutilation: a visual reference and learning tool for health care professionals. *Obstet Gynecol.* 2016;128(5):959–960.

Some cysts have been documented to grow up to 12 cm in size and are not only extremely painful but also become problematic for ambulation and sitting.[55,56] Dissecting the cyst and defibulating the patient is necessary in these cases (see Fig 17).

Other Infections

Given the infibulated scar, this enclosed environment fosters bacterial and fungal growth and predisposes girls to chronic or recurrent vaginal infections. In these cases, oral antifungal and antimicrobial medications are recommended. If the patient's neo-introitus is not too small and she is comfortable with introducing vaginal suppositories, this is an alternative treatment. For girls and teenagers with chronic infections, defibulation by an adolescent or general gynecologist experienced with managing FGM/C is recommended.

A study in rural Gambia of teenagers and women (15–54 years) with clinically diagnosed type I or II FGM/C (N = 671) also revealed a higher prevalence of bacterial vaginosis and herpes simplex virus 2 compared with teenagers and women without FGM/C but did not reveal an increased risk for perineal or anal damage, vulvar tumors, dyspareunia, infertility, organ prolapse, or other reproductive tract infections.[57]

Of note, large epidemiologic studies conducted in low- or middle-income countries where both FGM/C and HIV and/or hepatitis B are prevalent have not revealed an association between FGM/C and HIV and/or hepatitis B infections.[44,58,59] The authors of these studies did not evaluate risk around the time of cutting but months to years after the cutting occurred. To our knowledge, no studies have specifically addressed hepatitis C infection risks. However, given that FGM/C is often performed with unsterile equipment that may be shared between patients, some experts recommend testing girls with FGM/C for these blood-borne infections.

Future Infertility

Infertility for women with type III FGM/C is influenced by anatomic and psychological barriers as well as from possible recurrent gynecologic infections. In a Sudanese case-control hospital-based study of 99 women without hormonal, iatrogenic, or male-partner risk factors for infertility a diagnostic laparoscopy was performed, and it was found that primary infertility was associated with the increased anatomic damage inflicted by FGM/C.[60] Repeated attempts at penetration through the infibulated scar may be painful and difficult, and stretching of the infibulated introitus may take months. The learned association between sexuality and pain may a have significant negative effect on the woman's willingness to have intercourse and, thereby, on fertility. In general, if there are any issues related to FGM/C that negatively affect sexual health, referral to appropriate mental health supports is advisable for both women and their partners.

Sexuality

There are currently no studies that have been specifically focused on sexuality in teenagers with FGM/C. The impact of FGM/C on female

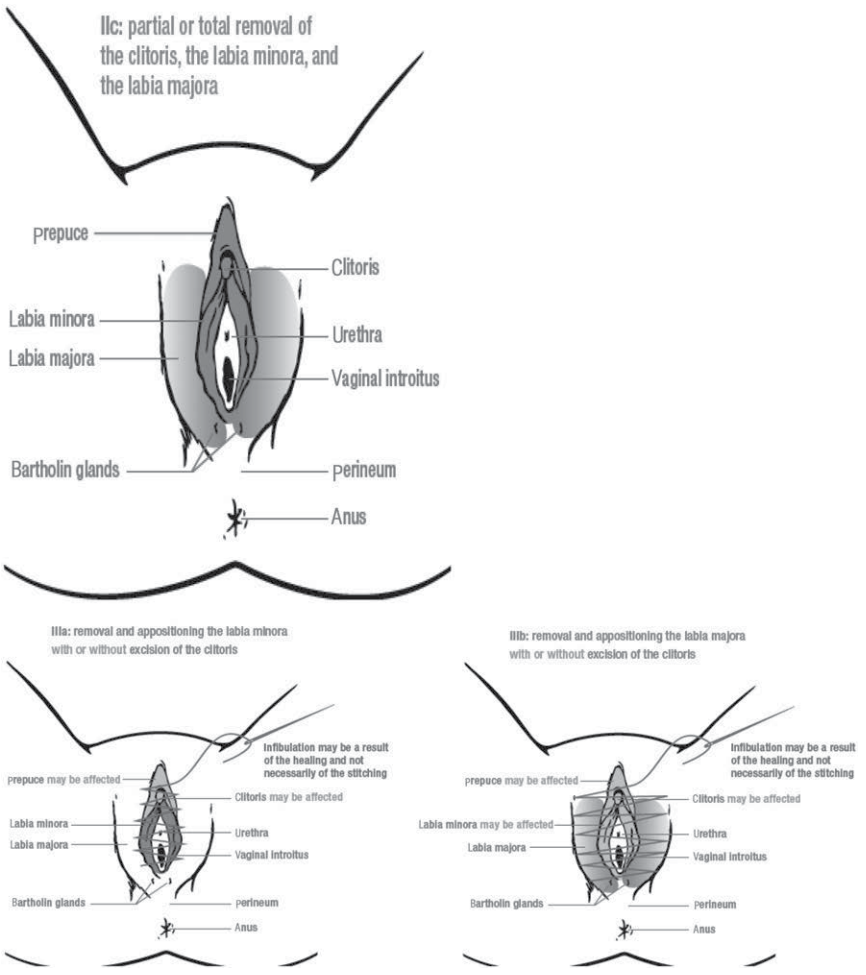


FIGURE 12
Continued.

sexuality has been evaluated in a few studies in adult women. However, the lack of standardization of FGM/C subtype studied and the use of nonvalidated questionnaires make interpretation of results difficult. Some studies reveal that women with FGM/C have reported less sexual desire, arousal, orgasms, and satisfaction compared with women without FGM/C[61] as well as increased rates of dyspareunia.[62] Other research has revealed no association between FGM/C and sexual intercourse frequency and that women with FGM/C also initiated sexual intercourse more than women without FGM/C.[63,64]

Surgical clitoral reconstruction is an emerging area of study. However, to date, there are no conclusive results revealing long-term benefits. If teenagers inquire about the option of reconstructive surgical repair, it is important to review the fact that there is still inadequate data that assure successful outcomes, including a decrease in pain and increased sexual pleasure.[65,66]

Mental Health

There has been limited high-quality research on the effects of FGM/C on the mental health of girls and women. One 2010 systematic review of the literature included 17 studies of women with and without FGM/C (*N* = 12 755) and revealed insufficient evidence to support or refute the link of FGM/C to specific mental health diagnoses.[48] In a more recent 2017 small cross-sectional study of Egyptian women and girls (*N* = 204, ages 14–19 years), those with and without FGM/C were compared, and a significantly higher prevalence of somatization, depression, and anxiety was found in those with FGM/C.[49]

Defibulation

Defibulation, also known as deinfibulation, is the procedure that opens the infibulated scar in type III FGM/C and exposes the vaginal introitus and urethral opening. In general, in some regions of the world, including Djibouti, defibulation is most often performed in newly married teenagers by a traditional birth attendant or midwife so that sexual intercourse may occur. In other regions, including North Sudan, Somalia, and areas in southern Egypt, the husband opens the neo-introitus over time through ongoing attempts at penetration. However, some teenagers and women who have access to medical care may have defibulation performed by a medical professional at marriage or after their official engagement.

Teenagers who are infibulated may present to health care providers requesting defibulation. Given the significant morbidity associated with type III FGM/C, experts believe that defibulation should be recommended for all girls and teenagers with type III FGM/C, particularly when complications are currently present. Similarly, teenagers who are pregnant should also be counseled regarding risks during and after pregnancy and should be strongly encouraged to undergo defibulation.

Of note, given that girls and teenagers who are infibulated have varying degrees of obstruction of urinary or menstrual flow, have varying degrees of pain, and/or have risks for normal vaginal delivery, such signs and symptoms should underscore the medical necessity for treatment. Given the medical necessity of

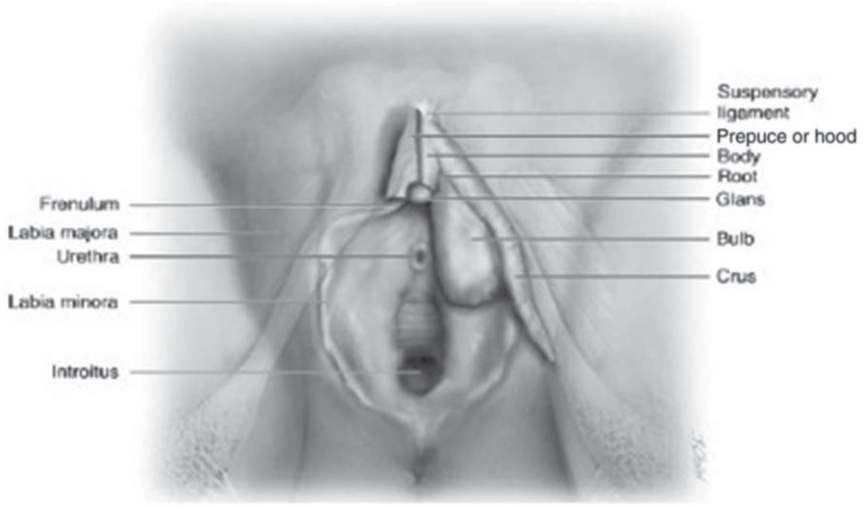


FIGURE 13
Female genital anatomic structures. Clitoral excision refers to the cutting of the glans (which is the distal part of the body of the clitoris) or the glans and part of the body. In all cases, part of the clitoral body remains intact, with scarring overlying the remaining body. The bulbs and crura, two other sexual erectile structures, have not been noted to be affected in FGM/C cases. Reprinted with permission from Abdulcadir J, Botsikas D, Bolmont M, et al. Sexual anatomy and function in women with and without genital mutilation: a cross-sectional study. *J Sex Med.* 2016;13(2):227–237 and Pauls RN. Anatomy of the clitoris and the female sexual response. *Clin Anat.* 2015;28(3):376–384.

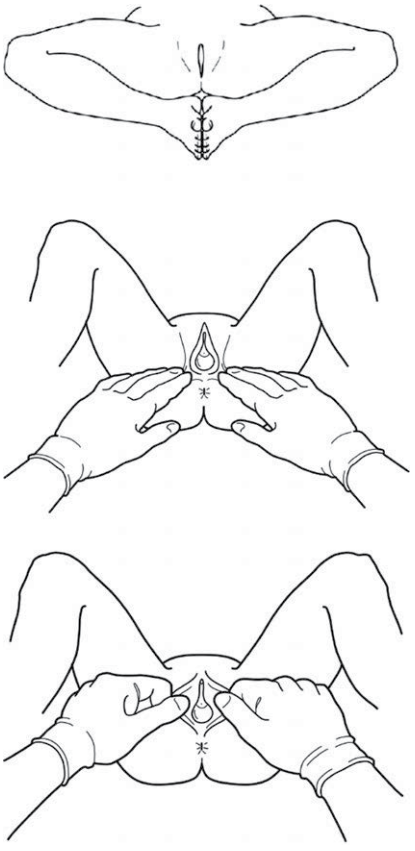


FIGURE 16
Clinical approach to external female genital examination. (Reprinted with permission from American Academy of Pediatrics. *Visual Diagnosis of Child Abuse on CD-ROM.* 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2008.)

treatment in these cases, Medicaid should cover the defibulation.

In all cases of defibulation, it is advised that an experienced pediatric gynecologist (for young children), gynecologist (for older children and teenagers), urologist, or urogynecologist be identified to perform the procedure. One challenge is that there are currently few trained specialists with experience in managing FGM/C, particularly in young children. Similarly, it may be difficult to refer a girl or teenager to a male provider, and much discussion and support will need to be provided to facilitate successful care. Counseling patients who do not want to be defibulated, despite current complications, may be challenging given social and cultural pressures. This counseling may take multiple visits, and it may be necessary to dispel fears of loss of virginity in cases of defibulation.[67] Mental health and social issues may arise and need to be addressed through counseling and support. Multiple legal and ethical issues may also arise in cases in which a teenager desires defibulation but she does not want her parents to know because of fear of stigma and/or refusal by her parents (see The Law and FGM/C in Minors in the United States, Ethical Analysis, and Case 2 in the Appendix for further information).

For young children who are defibulated, general anesthesia is recommended in all cases.

If a teenager is pregnant, defibulating her under spinal anesthesia during

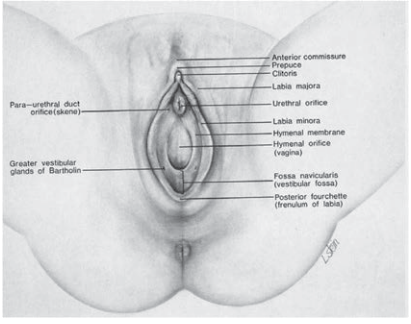


FIGURE 14
Normal prepubertal female anatomy. Labia minora is often less well-developed than pictured in prepubertal girls.[110] (Reprinted with permission from Graham EA. Ritual female genital cutting [RFGC] PowerPoint slides. 2014. Available at: https://ethnomed.org/resource/ritual-female-genital-cutting-rfgc-powerpoint-slides/. Accessed April 30, 2020.)

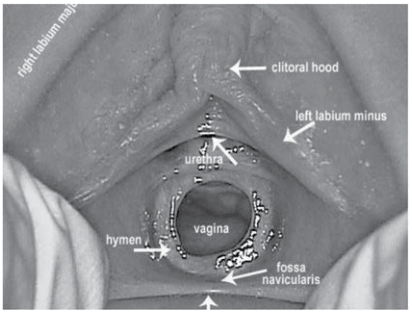


FIGURE 15
Prepubertal female introitus. (Reprinted with permission from American Academy of Pediatrics. *Visual Diagnosis of Child Abuse on CD-ROM.* 3rd ed. Elk Grove Village, IL: American Academy of Pediatrics; 2008.)

TABLE 4 Resources

Title or Description	Source
Care of Girls and Women Living with Female Genital Mutilation: A Clinical Handbook.	WHO[111]
To find a regional FGM/C expert, please go to the US End FGM/C Network Web site	https://endfgmnetwork.org/
Female Genital Mutilation/Cutting: Existing Federal Efforts to Increase Awareness Should Be Improved	US Government Accountability Office[112]
WHO Guidelines on the Management of Health Complications From Female Genital Mutilation	WHO[113]
Eliminating Female Genital Mutilation: An Interagency Statement: OHCHR, UNAIDS, UNDP, UNECA, UNESCO, UNFPA, UNHCR, UNIFEM, WHO	WHO[2]
Female Genital Mutilation/cutting: A Statistical Overview and Exploration of the Dynamics of Change	United Nations Children's Fund[16]
Female Genital Mutilation (FGM) Frequently Asked Questions	United Nations Population Fund[114]
Background information and educational pamphlets in Amharic, Arabic, French, Somali, Swahili, and Tigrinya	US Citizenship and Immigration Services[115]
Guidelines for the US Domestic Medical Examination for Newly Arriving Refugees	Centers for Disease Control and Prevention[116]
Immigrant Child Health Toolkit	American Academy of Pediatrics[117]
Female Genital Mutilation. A Visual Reference and Learning Tool for Health Care Professionals	Abdulcadir et al[118]; video available at https://www.youtube.com/watch?v=XRid7jlUzMY
Defibulation: A Visual Reference and Learning Tool	Abdulcadir et al[68]
Female Genital Mutilation/Cutting and Violence Against Women and Girls: Strengthening the Policy Linkages Between Different Forms of Violence	United Nations Entity for Gender Equality and the Empowerment of Women[12]
Overview: Female Genital Mutilation (FGM)	National Health Service[119]
Female genital mutilation (FGM): Resources for Healthcare Staff	National Health Service, Department of Health and Social Care[120]
FGM: Mandatory Reporting in Healthcare	National Health Service, Department of Health and Social Care[121]
Canadian FGM/C statement	Canadian Paediatric Society[122]
Australian FGM/C statement	The Royal Australasian College of Physicians[123,124]
New Zealand FGM/C statement	The FGM Education Programme[124]

the second trimester is advised. In countries where spinal anesthesia may not available, local anesthesia may be used, if necessary. This allows ample time for healing and will facilitate providing care during labor. However, some teenagers may present late in the third trimester. They can still be defibulated up to 34 weeks' gestation, which will allow for the neo-vulva to heal adequately before labor. Otherwise, defibulating the patient preferably in the first stage of labor or when the baby is crowning are options and are the routine approaches in some African countries, although these approaches have not been systematically studied. Defibulation in the first stage of labor does facilitate pelvic examinations, catheterization, and general monitoring during labor while also allowing for procedures on less edematous tissues and quicker delivery. If a teenager is not pregnant, she can be defibulated under regional or general anesthesia. Although the WHO recommends local anesthesia as best practice, this recommendation is not based on strong evidence. Local anesthesia is not recommended (unless in a country where spinal and general anesthesia may not be available),[68] because women may report flashback memories from the day when they were cut, as noted in one case report.[69]

For type III FGM/C, timing and complications of defibulation have not been systematically studied in prepubertal girls. For prepubertal girls with complications, including pain, obstruction of urinary stream, and recurrent urinary tract infections, and teenagers with dysmenorrhea related to FGM/C, it is important that the health care provider begin conversations with the parents and/or child regarding the need for defibulation to treat these medical complications and associated morbidity as well as whether the girl would benefit from mental health counseling.

COMMUNITY ENGAGEMENT

Within the United States, emerging evidence indicates a misunderstanding and distrust among immigrant communities with fears of deportation, criminalization, raids by Immigration and Customs Enforcement, and fear of being reported to Child Protective Services (CPS).[70–74] Some health care and social service providers may also not understand the long-term physical and mental health-related morbidity associated with the practice of FGM/C.[75] In addition, language barriers may complicate patient-provider communication and have been demonstrated to negatively affect health-seeking behavior and health services use.[30,76,77]

A grassroots community-based and community-led approach is essential when working with affected populations to ensure that policies, preventive interventions, and advocacy are all informed by the perspectives, experiences, and needs

TABLE 5 FGM/C Immediate and Long-Term Complications

Immediate Complications		Long-term Complications	
Category	Description	Category	Description
Bleeding	Hemorrhage[41]	Urinary	Urethral strictures[41]
	Anemia	—	Meatal obstruction[41]
	Hypotension	—	Chronic urinary tract infection[125]
	Hypovolemic shock	—	Pyelonephritis
	Death[41]	—	Meatitis
	—	—	Urinary crystals
Infection	Cellulitis	Infection	Chronic yeast infections
	Abscess[41]	—	Chronic bacterial vaginitis[41]
	Fever[41]	—	Herpes simplex virus
	Pelvic inflammatory disease	—	Vulvar or periclitoral abscess[41]
	Tetanus	—	No definitive data on risks for hepatitis B, hepatitis C, or HIV[44,126]
	Gangrene	—	—
	Septic shock	—	—
	Poor healing[41]	—	—
Oliguria	Dehydration	Scarring	Fibrosis[41]
	Urethral injury[41]	—	Keloids[41]
	Urethral edema[41]	—	Partial fusion
	Urinary retention[41]	—	Complete fusion
	—	—	Hematocolpos[41]
	—	—	Inclusion or sebaceous cyst[41]
Fractures	Clavicle	Pain	Neuromas
	Femur	—	Chronic vaginal infections[41]
	Humerus	—	Dyspareunia[41]
	—	—	Vaginismus
	—	—	Dysmenorrhea[41]
	—	Infertility	Vaginal stenosis
	—	—	Infibulated scar
	—	—	Dyspareunia[41]
	—	—	Apareunia
	—	Mental health	Anxiety disorders[a]
	—	—	Depression[a]
	—	—	Posttraumatic stress disorder[a]
	—	—	Somatisation[a]

—, not applicable.

[a] Large systematic studies are lacking. Some small studies have revealed an association between FGM/C and mental health diagnoses.[49]

of those directly affected by FGM/C.[78] There are varying approaches to engage FGM/C-affected communities that need to be culturally and linguistically tailored on the basis of availability of local expertise, resources, infrastructure, and personnel. It is important to assess whether local efforts already exist because it will be much easier to build and/or expand on these partnerships. If there are no preexisting relationships, new community-based partnerships may need to be explored and created. It is recommended that pediatric health care professionals nurture meaningful partnerships with FGM/C-affected communities to foster greater trust, open dialogue, counseling, education, and community outreach to enhance culturally sensitive care for affected populations and to prevent FGM/C among female minors. In the past, the focus of outreach efforts has principally targeted women, who have been at the forefront of the perpetuation of FGM/C. However men, as husbands, fathers, brothers, sons, community leaders, and religious figures, also play a critical role in changing social norms; encouraging greater dialogue with

TABLE 6 Obstetric Difficulties in Type III FGM/C

Obstetric Difficulties
Prolonged labor
Increased risk of perineal tears or episiotomy
Perineal wound infection
Difficult episiotomy repairs
Postpartum hemorrhage
Sepsis
Difficulty placing fetal scalp electrode, Foley catheter, or intrauterine pressure catheter
Difficulty performing fetal scalp pH

Adapted from Nour NM. Female genital cutting: clinical and cultural guidelines. *Obstet Gynecol Surv.* 2004; 59(4):272–279.

TABLE 7 Perinatal Complications of FGM/C

Perinatal Complications
Increased cesarean deliveries
Stillbirth
Low birth wt (data inconclusive)[a]
Increase rates of infant resuscitation

Adapted from Banks E, Meirik O, Farley T, Akande O, Bathija H, Ali M; WHO Study Group on Female Genital Mutilation and Obstetric Outcome. Female genital mutilation and obstetric outcome: WHO collaborative prospective study in six African countries. *Lancet.* 2006; 367(9525):1835–1841.

[a] One recent multicenter prospective study in the Gambia revealed no association between FGM/C and infants with low birth wt but a statistically significant increased risk of perinatal death and need for infant resuscitation (n = 1208).[127]

and engagement of their wives, daughters, and sisters in health services use; and supporting efforts toward eventual abandonment of the practice of FGM/C.[77,79] Consequently, it is critically important to include both men and women in strategies to enhance health services use and improve experiences with care while supporting community-wide FGM/C prevention efforts.

It is advisable that clinicians seek to engage within and across health care systems and multispecialty provider teams instead of staying within isolated profession-specific silos. Such multidisciplinary teams may comprise child abuse specialists, gynecologists, urologists, and general surgeons in addition to nurses, social workers, teachers, psychologists, counselors, case managers, certified medical interpreters, patient navigators, community health workers, refugee resettlement agencies, and public health departments. In addition, culturally appropriate and language-congruent resources, such as written information on FGM/C, should be made available in health care settings in the form of posters, pamphlets, or leaflets placed in private areas, such as women's restrooms, and made available in relevant languages.

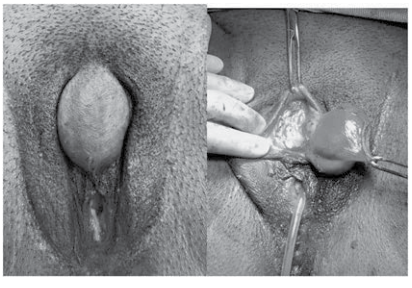


FIGURE 17
Type IIb FGM/C with large cyst, Tanner stage 5 female patient (photo courtesy of N.N.).

Since 2015, mandatory reporting legislation in the United Kingdom has come under increased scrutiny for the lack of consistent, reliable, high-quality data as well as for the lack of a routine system of monitoring.[80–83] Stigmatization of FGM/C-affected communities and distrust of law enforcement have resulted in underreporting, along with a lack of professional awareness and training.[84] Within the context of migration, the impact of acculturation, education, and length of stay on changing attitudes toward the practice are critical considerations when determining girls at risk for FGM/C[85–87] The first dedicated multispecialty clinic in the United Kingdom for girls affected by FGM/C and girls at risk with complex health needs uses a pediatric child abuse expert, a pediatric adolescent gynecologist with expertise in FGM/C, a child psychotherapist, and a specialist nurse in pediatric and adolescent gynecology, along with interpreters.[33] Referrals to this dedicated clinic are evaluated promptly with genital as well as colposcopy examinations, followed by further testing, counseling, and engagement of additional social and legal support services, as needed.

It is advised that attention also be paid to ensuring that the next generation of health care providers and scholars gain critical skills and exposure to culturally appropriate approaches to care for this population during their training. Hence, students, including medical and nursing students, residents, and fellows across various health, social science, and public health professions, should also be engaged in clinical care, counseling, education, and community outreach on FGM/C in such a way that is respectful of patients, caregivers, and communities. Models of established training guidelines and evidence-based educational competencies specific to FGM/C are lacking across all levels of health professions training. A proposed approach to instituting clinician competencies includes convening a multidisciplinary team of experts comprising key stakeholders from clinical medicine, medical education, public health, and research. Their expertise in competency development processes as well as in FGM/C would address FGM/C-specific knowledge and skills for clinical practice, patient care and handling ethical conundrums, communication skills, interprofessional collaboration (including partnering with community activists), and prevention efforts engaging individual families as well as FGM/C-affected communities.[32] Thereafter, evaluative performance metrics could be used to assess whether clinician competencies and patient care outcomes are being optimized. Moreover, an integrated team-based approach to health care delivery may more effectively address the multidimensional facets of providing holistic care, recognizing the intersection of ethnicity, migration, sex, and gender, which underlies the social construct of FGM/C.[88] Efforts to directly engage FGM/C-affected communities to engender trust, educate, promote continuity of care, and empower women and girls may enhance their health literacy and self-efficacy in seeking care for FGM/C-related concerns, navigating the health care system, and preventing future FGM/C.

ETHICAL ANALYSIS

Some have attempted to defend FGM/C by an appeal to cultural relativity, noting divergent mores and expectations in countries where it is frequently practiced.[89] Such a defense cannot overcome the fact that, as a rule, FGM/C may be physically and emotionally damaging, seriously affecting a girl's reproductive, sexual, and mental health. It is intrinsically a violation of the girl's human rights, compromising her bodily integrity without any medical benefit, without her consent (or, frequently, even her assent). It represents an extreme case of sex discrimination through attempting to control a woman's sexuality.[3] For these reasons, the practice is condemned by a vast number of health care organizations.[3,90,91]

While condemning the practice itself, as discussed previously, it is important to show cultural sensitivity to those who practiced FGM/C in their home countries. Some parents may not have felt they had a choice, given prevailing cultural expectations, believing that FGM/C gave their daughters the best chance of succeeding in a society where it was a prerequisite for marriage and acceptance.[92] Other parents might not have been fully aware of what was going to happen to their children or believed it had some medical benefit. Thus, the fact that a girl underwent this procedure is not a sign that her parents do not care about her or that they are more likely to engage in other forms of abuse.

So, although it is important to take active steps to prevent children from subsequently being subjected to FGM/C, it is also important to treat families whose children have already undergone FGM/C with compassion. Experience suggests that building rapport with parents increases the probability that they will give permission for remedial interventions. Such an approach may also help persuade the family to forgo FGM/C with their other children and perhaps enable advocacy efforts with their local community as well as extended family in their country of origin.

FGM/C performed by health care providers is not uncommon, representing 18% of cases from all countries with available data. In some countries, health care providers are responsible for three-quarters of FGM/C procedures.[93] If asked to perform the procedure, even health care professionals who are morally opposed to FGM/C might agree to do so out of a sense of cultural respect or because they believe the alternative (ie, the family seeking the procedure from traditional practitioners) to be even worse.

By agreeing to perform the procedure, however, health care providers are granting it medical legitimacy, which not only undercuts the moral prohibition on the procedure but also contributes to its spread and ongoing societal acceptance. As the WHO notes, "It can also lead some health-care providers to develop a professional and financial interest in upholding the practice,"[15] and although the immediate risks could be reduced if the procedure were performed by a trained professional, the risks of the previously noted long-term complications remain.

THE LAW AND FGM/C IN MINORS IN THE UNITED STATES

Within the United States, there are several legal issues that confront health care providers in the context of a suspected FGM/C case, including the following:

1. applicable federal and state laws;
2. consent and assent;
3. reporting child protection and/or criminal activity concerns;
4. confidentiality; and
5. documentation.

Outside the United States, many countries have laws in place that criminalize the practice of FGM/C (see Table 2).

Applicable US Federal and State Laws

The Federal Prohibition of Female Genital Mutilation Act of 1996 made it illegal to perform FGM/C in the United States on children and teenagers younger than 18 years. The act criminalizes circumcising, excising, or infibulating "the whole or any part of the labia majora or labia minora or clitoris of another person who has not attained the age of 18 years," unless deemed medically necessary, and recognizes no religious or cultural exemption for the practice of any type of FGM/C. However, a recent federal district court decision, *United States v Nagarwala*,[21,94] has found the statute unconstitutional. Despite this federal court decision invalidating the federal statute, at the time of this writing, 35 states have also enacted specific state criminal statutes against FGM/C[95,96] (see Table 8).

Although FGM/C performed in another country before US immigration is not reportable or prosecutable, transporting a child out of the United States for the purpose of FGM/C (so-called vacation cutting) was criminalized in the Transport for Female Genital Mutilation Act of 2013. When a child is at risk for FGM/C, including when traveling to a country where FGM/C prevalence is high and in cases in which the girl's mother and/or sisters have already had FGM/C performed before US immigration, it is recommended that health care providers have an open and supportive conversation with the parents regarding the significant medical complications of FGM/C (see Complications and Management) and legal implications to parents or other caregivers if they have FGM/C performed on their child.

TABLE 8 FGM/C Laws, by State (as of July 12, 2019)

State	Applicable Law	Only Applies to Minors (<18 Unless Otherwise Specified)	Vacation Cutting Provision (Bans Travel Outside State for FGM/C)	Duty To Report (Including FGM as Child Abuse)	Cultural and Ritual Reasons and/or Consent Not a Defense	Parent or Guardian and Circumciser Subject to Prosecution	Sentence
Arkansas	A.C.A. 5-14-135, 12-18-103, 16-118-116, 17-80-121, 20-82-101, 20-82-102	X	X	X	X	X	Imprisonment 3–10 y
Arizona	A.R.S. §§ 12-513, 13-705, 13-1214, 13-3620,	X	X	X	—	—	Imprisonment 5.25–35 y and fine up to $25 000
California[a]	Cal. Pen. Code § 273a, 273.4	X	—	—	—	X	Imprisonment 1–6 y
Colorado[b]	Col. Rev. Stat. § 18-6-401	<16	—	—	X	X	Imprisonment minimum 4 y
Delaware	Del. Code Tit. 11, § 780	X	—	—	X	X	Imprisonment up to 5 y
Florida	Fla. Stat. § 794.08	X	X	—	X	X	Imprisonment up to 15 y and/or fine up to $10 000
Georgia[c]	O.C.G.A. § 16-5-27	X	X	—	X	X	Imprisonment 5–20 y
Idaho	I.C 18-1506B, I.C. 19-402	X	—	—	X	—	Imprisonment up to life
Illinois	720 Ill. Comp. Stat. 5/12-34; 325 Ill. Comp. Stat. 5/3, 5/4	—	—	X	X	X	Imprisonment 6–30 y
Iowa	I.C.A. 708.16	X	X	X	X	—	Imprisonment for up to 5 y and fine of $750–$7500
Kansas	K.S.A. § 21-5431	X	X	—	X	X	Imprisonment 89–100 mo
Louisiana	La. R.S. 14:43.4	X	X	—	X	X	Imprisonment up to 15 y
Maryland	Md. Code Health-Gen. § 20-601, 602	X	—	—	X	X	Imprisonment up to 5 y and/or fine up to $5000
Michigan	1931 PA 328 § 136 1978 PA 368 § 9159	X	X	—	X	X	Imprisonment up to 15 y
Minnesota	Minn. Stat. § 144.3872, 609.2245	—	—	—	X	—	Imprisonment up to 5 y and/or fine to $10 000
Missouri	Mo. Rev. Stat. § 568.065	Under 17	—	—	X	X	Imprisonment 5–15 y
Nevada	Nev. Rev. Stat. § 200.5083	X	X	—	X	X	Imprisonment 2–10 y and/or fine up to $10 000
New Hampshire	N.H. Rev State.§ 632-A:10-d	X	—	X	X	—	Imprisonment up to 7 y
New Jersey	N.J. Stat. § 2C:24-10	X	X	—	X	X	Imprisonment 3–5 y
New York	N.Y. Penal Law § 130.85; N.Y. Public Health Law § 207(k)	X	—	—	X	X	Imprisonment up to 4 y
North Dakota	N.D. Cent. Code § 12.1-36-01	X	—	—	X	—	Imprisonment up to 5 y and/or fine up to $10 000
Ohio	OH ST §§ 2903.32, 2929.14, 2929. 18	X	—	X	X	—	Imprisonment 2–8 y, fine up to $40 000, and/or a fine up to $15 000 and an additional fine up to $25 000
Oklahoma	21 Okl. St. § 760	—	—		X	—	Imprisonment 3 y to life and/or fine up to $20 000
Oregon	Or. Rev. Stat. § 163.207	X	—		X	X	Imprisonment up to 10 y
Pennsylvania	18 Pa. C.S.A. 3132	X	X	X	X	X	Imprisonment for >10 y
Rhode Island[d]	R.I. Gen. Laws § 11-5-2	—	—	—	—	—	Imprisonment up to 20 y

TABLE 8 Continued

State	Applicable Law	Only Applies to Minors (<18 Unless Otherwise Specified)	Vacation Cutting Provision (Bans Travel Outside State for FGM/C)	Duty To Report (Including FGM as Child Abuse)	Cultural and Ritual Reasons and/or Consent Not a Defense	Parent or Guardian and Circumciser Subject to Prosecution	Sentence
South Carolina	Code 1976 16-3-2210-2240	X	X	X	X	X	Imprisonment up to 20 y and/or fine up to $20 000
South Dakota	S.D.C.L. §§ 22-18-37, 22-18-38, 22-18-39	X	X	—	X	X	Imprisonment up to 10 y and fine up to $20 000
Tennessee	Tenn. Code § 39-13-110, 38-1-101	—	—	X	X	—	Imprisonment 2–12 y and/or fine up to $5000
Texas	Tex. Health & Safety Code § 167.001	X	X	—	X	X	Imprisonment 6 mo to 2 y and/or fine up to $10 000
Utah	U.C.A. 1953 76-5-701, 76-5-702, 76-5-703, 76-5-704	X	X	X	X	X	Imprisonment up to 5 y and/or fine up to $5000
Virginia	Va. Code §§ 8.01-42.5, 18.2-51.7	X	X	—	—	X	Imprisonment up to life and/or fine up to $100 000
West Virginia	W. Va. Code § 61-8D-3A	X	—	—	X	X	Imprisonment 2–10 years and fine $1000–5000
Wisconsin	Wis. Stat. § 146.35	X	—	—	X	—	Imprisonment 6 y and/or fine up to $10 000

States with no existing FGM/C laws (as of July 12, 2019): Alabama, Alaska, Connecticut, Hawaii, Indiana, Kentucky, Maine, Massachusetts, Mississippi, Montana, Nebraska, New Mexico, North Carolina, Vermont, Washington, and Wyoming. Adapted from Equality Now. Female genital mutilation in the United States. Available at: https://www.equalitynow.org/factsheets. Accessed May 25, 2018 and from Mishori R, Warren N, Reingold R. Female genital mutilation or cutting. *Am Fam Physician*. 2018; 97(1):52A. X, existing law; —, no current legislation addressing this issue.

[a] California: enhanced penalty for FGM/C under "Abandonment and Neglect of Children" (Penal Code).

[b] Colorado: within child abuse law and one of few states where doctor-patient and husband-wife privileges are inapplicable in prosecutions for FGM/C.

[c] Georgia: one of few states where husband-wife and other statutory privileges are inapplicable in prosecutions for FGM.

[d] Rhode Island: within assault statute.

Consent and Assent

Before discussing consent and assent issues as they pertain to FGM/C, it is appropriate to review these concepts. Informed consent is the legal authorization to provide medical care to an individual. Minor children generally lack sufficient decision-making capacity to provide true informed consent, with three notable exceptions. The first involves the so-called "minor treatment statutes,"[97] which vary by state but generally permit minors to consent to treatment of sexually transmitted infections, mental illness, substance abuse, or matters related to reproductive health (including contraception, abortion, prenatal care, and pregnancy). If treatment qualifies under a state's minor treatment statute, a minor may consent to that specific treatment but not to others that fall outside the scope of the statute. Evaluation for FGM/C and treatment of its complications could impact reproductive health and, thus, may fall under the minor treatment statute of some states.

The second exception involves a minor patient who is legally emancipated. Emancipation[98] may be automatically conferred by taking a specific action, which varies by state, such as getting married or serving in the active duty military, or may be declared by a court after the minor fulfills specific requirements such as being self-supporting and either being enrolled in high school or having obtained one's diploma.

The third exception involves being deemed a "mature minor"[99] after being assessed for relevant factors such as reasoning ability and intellectual capacity.[100]

Again, state laws vary as to the precise requirements for a minor to be deemed sufficiently mature to make her own health care decisions. It is recommended that health care providers not assume a minor is

mature unless provided with clear court documentation. Unlike the minor treatment statutes, emancipated and mature minors are granted the right to make all their own medical decisions, which would include not only evaluation of FGM/C but also interventions to treat it and its complications.

Outside these specific exceptions, parents are tasked with making nonemergency medical decisions for their minor children, which is termed "parental permission." But even if a child is incapable of informed consent, she still has a role in medical decision-making. It is recognized that a child's decisional capacity evolves over time, and so "assent" refers to a pediatric patient's agreement to evaluation and treatment to the degree that she is able to comprehend what is being proposed. This involves developmentally appropriate awareness of the nature of the condition, appreciation of what to expect with tests or treatments, and being free of inappropriate pressure.[101] In nonemergency situations, the older child and adolescent should give assent to evaluation and/or treatment.

There are two other situations in which parental permission is not required for the evaluation and treatment of a child. The first is when abuse is suspected, such as FGM/C that occurred in the United States, or as vacation cutting after immigration to the United States. Most states grant immunity to a provider who assists or participates in an investigation of allegation of maltreatment (ie, conducts a nonemergency evaluation for abuse, including the physical examination, and taking necessary photographs or radiographs and performing medically relevant tests) from any civil or criminal liability related to that participation.[102] It is prudent for health care professionals to be knowledgeable of their state-specific child maltreatment legislation (see Table 8). If questions arise, it may be wise to consult with a child abuse pediatrician.

Even if parental permission is not required for the reasons noted here, if the patient is old enough to provide assent, it is advisable to obtain this before proceeding. Additionally, maintaining open lines of communication with the patient's parents is helpful, which may include informing them of what is being performed and why.

The other context in which parental permission is not required is emergent situations such as active hemorrhage or imminent delivery with infibulation. If the parents are unavailable to provide permission, consent may be presumed if three conditions hold:

1. there is a serious and immediate threat to life or health;
2. there is a need for urgent intervention (delay in care is not safe); and
3. the health care provider administers only care and treatment of emergency conditions that pose an immediate threat to the child.[103]

In such situations in which the parents are available yet withhold permission, evaluation and treatment may proceed on the basis of the presumption of medical neglect and the duty of the state to protect the patient from harm (the doctrine of parens patriae).

Reporting Child Abuse

Health care providers in the United States are mandated reporters of suspected child maltreatment, which includes FGM/C that occurred in the United States or as vacation cutting outside the United States after this practice was criminalized in 2013. Physical examination findings suggestive of FGM/C, with previous documentation of normal genitalia, should prompt reporting to CPS. FGM/C that occurred before immigration to the United States does not meet the legal requirement for breaching confidentiality by reporting to state agencies. Furthermore, reporting past or current FGM/C runs the risk of damaging not only the therapeutic relationship with an individual patient and her family but also with the immigrant community to which that family may belong. If health care providers are perceived not only as judgmental (ie, culturally insensitive) but also as agents of the state, families may be less likely to seek out needed medical care for their children. The opportunity for advocacy to prevent future potential instances of FGM/C may also be lost.

Most states also require a report to be made if there exists reasonable cause to believe that child abuse may occur in the future. Immediate or imminent risk warrants notification of local law enforcement authorities as well. If a child experienced FGM/C before immigration to the United States, which is not reportable, health care providers might, in some cases, be concerned for other female children in the home who might subsequently be subjected to FGM/C. It is important that these situations be evaluated individually and on the basis of a culturally sensitive discussion with the child's primary care givers and child, if developmentally appropriate. It is advisable that the dialogue include a review of health risks and complications as well as legal repercussions of FGM/C. As needed, it is important that cultural concerns be addressed and that community organizations be engaged to enhance parental understanding. This dialogue should be recorded in the child's medical record.

After such education and dialogue, if a health care provider has reasonable cause to believe that a child may subsequently be subjected to FGM/C, CPS should be notified. As mentioned previously, what constitutes

reasonable cause to believe is a nuanced and case-specific question. However, it is advised that health care providers remember that the threshold for reporting maltreatment does not require incontrovertible certainty, just a reasonable suspicion. Studies have revealed that pediatricians have multiple reasons for either delaying or not reporting suspected maltreatment (ie, mistrust of the child welfare investigative system and familiarity with the family, to name a few) and that physicians sometimes require inordinately high degrees of certainty before reporting suspected maltreatment.[104]

If a clinician is uncertain whether the fact pattern of a particular case reaches the threshold of reasonable cause to believe, it is appropriate to consult a child abuse pediatrician. Expressed intention to engage in FGM/C, either in the United States or abroad, should prompt a report to CPS if the child's parent or caregiver cannot be dissuaded.

To avoid stereotyping, as well as harm to the therapeutic relationship, it is important to avoid making assumptions and to be attentive to implicit biases. Many families who originate from countries with high prevalence of FGM/C may travel back to the country of origin for many reasons wholly unrelated to FGM/C. Although some communities accept FGM/C as a sign of cultural identity or enhancing marriageability, anecdotal expert experience suggests that many mothers from high-prevalence countries do not want to subject their daughters to FGM/C. This may be particularly true when the mother herself has suffered medical complications, although this situation has not been systematically studied. Recognizing this, it is appropriate to engage in an open and supportive discussion with the family about their beliefs about FGM/C. This may involve inquiring as to the family's plans for their daughter (see Appendix). Laws and regulations regarding child abuse reporting are different in other countries. It is prudent for health care providers to be cognizant of their country-specific requirements.

Confidentiality

In the adolescent patient with past, current, or future FGM/C concerns, it is important for health care providers to have a comprehensive discussion with the patient about the expectations and limitations of confidentiality. FGM/C that occurred in the United States or as vacation cutting after it was criminalized in 2013 is subject to federal and state reporting laws.

Documentation

Objective and thorough documentation is extremely important in potential (and actual) child maltreatment circumstances. The following recommendations (Do's and Don't's) may assist health care providers in ensuring appropriate clinical documentation in the FGM/C scenario.

Do's

1. Document in the medical record the particulars regarding informed consent or permission (ie, who gave it, when it was given, for what purpose, etc).
2. For children able to assent, obtain their assent before proceeding with examination of external genitalia.
3. Carefully and objectively document any examination limitations or mishaps in the record.
4. Describe physical findings in detail. When possible, and after attaining appropriate consent, photo-document abnormal genital findings and maintain them in a secure fashion in compliance with privacy rules of the Health Insurance Portability and Accountability Act. Given that external genital examination and, particularly, photography of a girl or teenager may be difficult to explain to families from other cultures, photographs may be reserved for those times when there are concerns that suspected FGM/C constitutes child abuse.
5. Report impressions objectively, comprehensively, and in as simple language as possible. When applicable, report alternative diagnoses considered relevant to the findings and impression, such as labial adhesions or normal anatomic variants. In cases in which either identification of the diagnosis of FGM/C is not clear, it is strongly recommended to consult a health care provider who is well versed in diagnosis of FGM/C in prepubertal or pubertal girls, depending on the case, given that type I and II FGM/C may be difficult to diagnose (see Table 4). Such consultation is highly recommended before reporting to CPS, especially if the family is amenable.
6. If FGM/C has been recently performed in the United States, or abroad and after initial immigration, create the CPS report in a timely fashion, and as soon after evaluation as possible.
7. Document (in reasonable detail), where appropriate, all consultations with colleagues, patients and/or parents, and multidisciplinary partners.

Don't's

1. Insert language into the record or a report that is inflammatory, superfluous, or highly subjective (ie, "profoundly," "faulty," "sloppy," "terrible," "negligent," "careless," "horrible," "uncaring," "pathetic," "horrific," "barbaric," etc).
2. State conclusions that are not supported by specific facts or by the medical literature, especially if

the identification or diagnosis of FGM/C is unclear or uncertain.

3. Record information in the record or a report that has primarily legal implications and minimal or no patient care value.

Legal Right to Asylum Protection in the United States and FGM/C

FGM/C presents one other legal consideration for clinicians, that of US asylum protection. US asylum protection may be granted to someone who has left their native country because of persecution or fear that they will suffer from persecution,[105] including because of membership in a particular social group, in this case being female and living in a country where FGM/C is practiced. To be granted asylum, a person must either be physically present in the United States or at a port of entry to the United States, and certain other conditions must be met through a formal process with US Citizenship and Immigration Services.

The 1996 US ruling, the *Matter of Kasinga,* established the right of asylum protection for women and children potentially facing FGM/C.[106] However, the scenarios of past FGM/C and parents seeking asylum on the basis that their daughters would be subjected to FGM/C if they returned to their home country are more nuanced and case specific. It is prudent for clinicians to recognize this potential protection for their patients and to direct families to an immigration law attorney if such issues arise.

CONCLUSIONS

FGM/C in children is a complex issue with potential medical, mental health, and legal ramifications. It has no clinical benefits and is associated with significant morbidity and mortality. Health care providers caring for diverse patient populations may identify FGM/C in their patients; however, FGM/C will only be identified if primary care providers become adept at performing external genital examinations on all children at every health supervision appointment. It is recommended that health care providers who are not comfortable with making an FGM/C diagnosis or discussing treatment options consult a specialist who is trained in addressing pediatric FGM/C. Open and culturally sensitive discussions among health care providers, parents, and children regarding FGM/C is of utmost importance in addressing FGM/C that has already occurred as well as in preventing future FGM/C from occurring.

RECOMMENDATIONS

1. Health care providers should not perform any type of FGM/C on female infants, girls, or teenagers.
2. Health care providers caring for girls at risk for FGM/C should actively counsel families against performing FGM/C, including when families travel to countries where FGM/C is practiced.
3. With consent and/or assent of the guardian and/or child documented in the patient's chart, all children should have external genitalia examined at all health supervision examinations, including the identification of the prepuce, clitoris, and labia minora and majora.
4. For children with risk factors for FGM/C, it is recommended that clinical assessment of FGM/C status be integrated into routine pediatric care and that a history of FGM/C before US immigration be documented in the health record.
5. It is recommended that health care providers who are not comfortable with making an FGM/C diagnosis or discussing treatment options consult a specialist who is trained in addressing pediatric FGM/C (see Table 4).
6. If genital examination findings are equivocal for the presence of FGM/C and risk factors for FGM/C are present, a specialist trained in identification of FGM/C should be consulted (see Table 4).
7. The management of FGM/C should include complete documentation of clinical findings and the use of ICD-10 coding.
8. Health care providers should recommend defibulation for all girls and teenagers with type III FGM/C, particularly when complications are currently present.
9. In all cases in which defibulation is recommended, an experienced pediatric gynecologist (for young children), gynecologist (for older children and teenagers), urologist, or urogynecologist should be identified to perform the procedure.
10. Standardized training related to the identification, treatment, management, and culturally appropriate communication approaches needs to be developed and provided to health care providers who care for FGM/C-affected communities.
11. If FGM/C is suspected to have occurred in the United States, or as vacation cutting after immigration to the United States, the child should be evaluated for potential abuse. Expressed intention to engage in FGM/C, either in the United States or abroad, should also prompt a report to CPS if the child's parent or caregiver cannot be dissuaded.

ACKNOWLEDGMENT

We acknowledge the contribution of Zeinab Eyega (founder and executive director, Sauti Yetu Center for African

Women and Families) for her expert analysis of the case examples presented in the Appendix.

APPENDIX: CASE EXAMPLES AND EXPERT ANALYSIS

An example of an approach when discussing FGM/C with the child or teenager's mother may include statements such as the following:

I am learning about cultural practices in your country and understand that female genital cutting is done in your country. Were you cut as a child? Were your daughters cut while you were still living there? The reason I ask is that I am a physician and female genital cutting may have severe medical complications, including recurrent urinary tract infections, painful menstruation, and severe scarring blocking the flow of urine and menstrual blood. I want to make sure that you and your daughters are not having these issues because they can be treated. I also want to make sure that you understand that it is illegal to have a girl cut once she is living in the United States. This includes not sending her to another country to have her cut once she has been living in the United States.

Consider discussing FGM/C with the mother at the end of the visit after obtaining a history and performing the physical examination. Introducing a conversation regarding FGM/C early in a visit may serve as a barrier to establishing trust and rapport.

CASE 1

The patient is a 16-year-old teenaged refugee born in Mali and living in Mauritania before US arrival. She has established care with her primary care pediatrician, who explains that she needs to perform a full physical examination, including examination of her external genitalia. The teenager assents to the examination and is found to have type IIb FGM/C. The girl does not know that she has been cut and has no recollection of the procedure having occurred. She is confused and does not understand what her FGM/C means for her and how she will discuss this with her parents and boyfriend.

J.Y., General Pediatrician

Some girls do not recall undergoing FGM/C, particularly if it occurred at a young age. Expert opinion suggests that some parents do not inform their daughters of having been cut. In this case, it is important to explain physical findings to the patient and use diagrams, such as the one in Fig 4. She will need to be supported in understanding why she was cut, and it is recommended that the care provider explore how and if she would like to discuss her FGM/C with her mother, either with the medical provider present or not. If the patient is contemplating a sexual relationship, she may be concerned about her genitalia appearing different. She may also have questions about sexual function. These questions may be addressed either at this visit or at follow-up visits over time. Referral for culturally appropriate mental health supports may also be warranted in this case. If this patient has female siblings, it is recommended that they also have head-to-toe physical examinations, including external genitalia, and physical findings should be documented. It is recommended that a culturally sensitive discussion occur with the mother and father regarding the medical issues associated with FGM/C and that FGM/C performed in the United States or as vacation cutting is illegal. These discussions should be documented in the patient's chart, and the diagnosis of FGM/C should be included in the patient's past medical history as having occurred before arrival in the United States.

Zeinab Eyega, Founder and Executive Director, Sauti Yetu Center for African Women and Families

The pediatrician should ask how the patient feels about her diagnosis of FGM/C, if the teenager has questions about the practice, and if she has ever heard about FGM/C at school or through friends or family and if so, what she learned and thought. It is essential to determine the teenager's support network, whether peers, a teacher, or a counselor, that can provide regular guidance and help as needed. The teenager's boyfriend may be from within or outside of her cultural group. Over time, it is important to discuss with the teenager whether she is concerned about her appearance because of her FGM/C. If she does not have any current health issues or concerns and there are no medical problems, the discussion may be left and revisited if concerns arise.

S.K.N., Child Abuse and Legal Expert

An honest but respectful discussion needs to occur, exploring the family's current beliefs regarding FGM/C, education about medical complications and/or risks, and education about US laws prohibiting the practice. It is important to remember to obtain more history about when the family came to the United States and whether there are other female siblings who may be at risk. A private discussion with the mother is recommended to learn of when and where the FGM/C occurred. If it occurred outside US jurisdiction, FGM/C is not grounds for reporting, but the safety of other younger female siblings in the house at future risk should be considered.

R.C.M., Medical Ethics Expert

The important ethical issues (including the patient's right to understand her condition and the obligation to protect female siblings who might be at risk) are well addressed in the preceding commentaries.

CASE 2

The patient is a 17-year-old Sudanese girl with type III FGM/C performed before US immigration who has severe dysmenorrhea from partial obstruction of menstrual flow. She wants to undergo defibulation. The

teenager gives permission for the pediatrician to discuss the issue with her parents and the medical recommendation to undergo defibulation because of medical complications. The parents are very concerned about defibulation and reluctant to give permission.

J.Y., General Pediatrician

With the teenager's consent, it is recommended to arrange a meeting with the parents to discuss the complications their daughter is having from her FGM/C, including severe pain with menstruation from partial obstruction of menstrual flow. Consider initiating the conversation with the parents by asking what their understanding of FGM/C is and exploring why it is or is not important to them. It is recommended to show diagrams of the teenager's anatomy and explain the issues that the infibulation is causing as well as her risk for future complications, including possible issues with scarring, chronic pain, and infertility. Several meetings may be required to review the medical issues and the recommendation to defibulate the teenager to relieve symptoms, both short- and long-term. As with case 1, if there are other female siblings in the home, it is recommended to make arrangements to perform a full physical examination on the other female siblings, including visualization of the external genitalia, and findings should be clearly documented in the chart. A frank but culturally sensitive discussion should occur with the parents, explaining medical complications and the illegality of future FGM/C documented in the chart as well as documentation of FGM/C having occurred overseas, before immigration, in the past medical history.

Zeinab Eyega, Founder and Executive Director, Sauti Yetu Center for African Women and Families

If the teenager consents to allowing a discussion with her parents, the pediatrician should facilitate a meeting with both the teenager and parents present. It is important to learn from the parents if they have noted the medical issues, including pain, that their daughter has had because of her type III FGM/C and that the recommended treatment is defibulation. Some parents (most likely the mother) may be concerned that if their daughter is defibulated, the procedure would affect her virginity. It is important to address this concern to ensure that the teenager continues to have support from her parents after defibulation so that she does not feel isolated from her parents and other family members, both of which could negatively affect her emotional well-being. The parents may need time to process the information, and another appointment should be offered as well as the option to meet with a counselor to discuss the issue with the counselor.

S.K.N., Child Abuse and Legal Expert, and R.C.M, Medical Ethics Expert

This scenario is nuanced and could constitute medical neglect by the parents (depending on the severity of symptoms and degree of obstruction). If possible, the general pediatrician should consult a child abuse pediatrician because they will know the local CPS personnel and procedures well and may be able to provide an idea of their potential response. Furthermore, the general pediatrician should have an honest and respectful discussion with parents about the teenager's medical need for defibulation and about their failure to consent possibly requiring a report to CPS for intervention.

Although 18 years is the age of majority in nearly every state, some younger patients may possess sufficient decision-making capacity to make informed and voluntary health care decisions.[101] If her condition represents a current threat to her health (in terms of pain, suffering, or risk of morbidity or mortality), her parents' unwillingness to give permission to defibulation could represent medical neglect. Even if her condition is not an emergency, the patient could be declared by the court to be a mature minor, depending on the laws of her state,[99] and could thus have the legal right to consent to the procedure herself.

CASE 3

A 10-year-old girl born in the United States in 2008 to Ethiopian refugee parents presents for well-child care. She had a documented normal physical examination, with normal female genitalia, at her newborn visit. Well-child care examinations at 4, 6, and 8 years of age occurred with the genital examination marked as "deferred" at each visit. Of note, the girl traveled to Ethiopia in 2012 to visit relatives with her mom. A full physical examination, including external genitalia, reveals type Ib FGM/C. Once the child is dressed, the mother is separately asked if her child had FGM/C performed. She denies any knowledge of her child being cut abroad.

J.Y., General Pediatrician

It is important to ask the 10-year-old whether she recalls having been cut. If she does remember being cut, she will be able to provide more information regarding when and where it happened as well as who was involved. If she is unable to provide any information about the cutting, it is important to document this information in her medical chart. Although more likely the FGM/C occurred overseas on her visit with relatives, it is theoretically possible that she had FGM/C performed in the United States. In this case, it would be reasonable to consult with a child abuse specialist in your state. As with cases 1 and 2, if there are other female siblings in the house, these children should be examined, and physical findings and medical and

legal education regarding FGM/C should be clearly documented in the patient's health record.

Zeinab Eyega, Founder and Executive Director, Sauti Yetu Center for African Women and Families

The pediatrician should start by speaking with the parents separately from the child and explaining that her examination reveals FGM/C that was performed after she was born in the United States. It is important to show diagrams revealing the difference between a cut and uncut child so that the parents understand. Ask questions about other family members and if they have also had FGM/C. In some cases, biological parents may not be involved in the decision to circumcise their daughter and may not know that she was cut. In such cases, a respected elder in the community, such as a grandmother or aunt, may make this decision for the girl and have her cut.

S.K.N., Child Abuse and Legal Expert

Although this scenario may not be prosecutable as vacation cutting or reportable, as in case 1, it is advisable to gather more psychosocial history about the family makeup and the family's current beliefs about FGM/C.

R.C.M., Medical Ethics Expert

Although the patient is unable to provide informed consent for evaluation and treatment, she is developing the capacity for assent and thus is entitled to an explanation of her condition, provided in a nonjudgmental and developmentally appropriate fashion, with her questions welcomed and consistent promises of ongoing support. The pediatrician should also strive to establish rapport with the family, who may be denying knowledge because of fear of repercussions or may truly be unaware.

CASE 4

The patient is a 5-year-old female refugee from Somalia via a Kenyan refugee camp who had type IIIb FGM/C performed 6 months before US immigration. The child has her urethral opening covered by labia minora, and urinary stream occurs through a 2 × 2 mm opening in the otherwise sealed labia minora. The patient has reported delay in bladder emptying and pain, per maternal report. She has no report of past urinary tract infections, prolonged fever, or vomiting.

J.Y., General Pediatrician

A supportive discussion should occur with the parents regarding the pain and medical complications associated with the child's type III FGM/C, including risk for recurrent urinary tract infections and renal scarring. Diagrams should be used to demonstrate the issues associated with acute urinary obstruction. This discussion may take several visits, with strict return precautions reviewed each time, including the need to bring the child immediately for medical evaluation if the following conditions are present: fever, vomiting, dysuria, or urgency to urinate, frequency of urination, and/or the inability to pass urine. With consent of the parents, a trusted leader in the Somali community may need to be called on to help support the parents in deciding to allow their child to undergo defibulation.

Zeinab Eyega, Founder and Executive Director, Sauti Yetu Center for African Women and Families

It is important to use diagrams to review the physical findings of female genital cutting with the parents and to explain why the child is having problems emptying her bladder and has pain. Explain that it is recommended to have the child defibulated and that this will not affect her virginity or her ability in the United States to marry later in life. If there are other daughters, they should also be examined.

S.K.N., Child Abuse and Legal Expert

A thorough psychosocial history should be obtained to assess the social dynamics of the family. An honest and respectful discussion should occur that, as in case 2, should highlight the possible need to report to CPS if permission is denied for the health and safety of the child. Again, if available, consultation with a child abuse pediatrician is advised because that individual will know the local CPS personnel, procedures, and responses well.

R.C.M., Medical Ethics Expert

The patient has a condition that leads to pain and impaired urinary outflow. Irrespective of the cause, this needs to be addressed. The clinical situation should be explained to the parents as well as recommendations made to treat the urinary retention and pain. Parental refusal of the intervention to address these problems suggests they are not acting in the best interest of the child.

LEAD AUTHORS

Janine Young, MD, FAAP
Nawal M. Nour, MD, MPH, FACOG
Robert C. Macauley, MD, FAAP
Sandeep K. Narang, MD, JD, FAAP

CONTRIBUTING AUTHOR

Crista Johnson-Agbakwu, MD, MSc, FACOG

SECTION ON GLOBAL HEALTH EXECUTIVE COMMITTEE, 2019–2020

Patrick T. McGann, MD, MS, FAAP, Chairperson
Chiquita Palha De Sousa, MD, MPH, FAAP
Heather Haq, MD, MHS, FAAP
Alcy R. Torres, MD, FAAP
Ifelayo P. Ojo, MBBS, MPH, FAAP
Nicole E. St. Clair, MD, FAAP
Parminder Suchdev, MD, MPH, FAAP, Immediate Past Chairperson

FORMER MEMBERS OF THE SECTION

Linda D. Arnold, MD, FAAP
Kevin J. Chan, MD, MPH, FAAP
Cynthia R. Howard, MD, MPH, FAAP
Katherine Yun, MD, MHS, FAAP

COMMITTEE ON BIOETHICS, 2019–2020

Robert Conover Macauley, MD, MDiv, FAAP, Chairperson
Ratna Basak, MD, FAAP

ACKNOWLEDGMENTS

The authors acknowledge the contribution of Zeinab Eyega, Founder and Executive Director, Sauti Yetu, Center for African Women and Families, for her expert analysis of the case examples presented in the Appendix.

ABBREVIATIONS

CPS: child protective services
FGM/C: female genital mutilation or cutting
ICD-10: *International Classification of Diseases, 10th Revision*
WHO: World Health Organization

DOI: https://doi.org/10.1542/peds.2020-1012

Address correspondence to Janine Young, MD, FAAP. E-mail: janine.young@dhha.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: Dr Johnson-Agbakwu has a grant relationship with Arizona State University from the 2018 copyright of "Female Genital Mutilation/Cutting (FGM/C): A Visual Reference and Learning Tool for Health Care Professionals."

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Dr Johnson-Agbakwu has a grant relationship with Arizona State University from the 2018 copyright of "Female Genital Mutilation/Cutting (FGM/C): A Visual Reference and Learning Tool for Health Care Professionals."

REFERENCES

1. Committee on the Elimination of Discrimination against Women. *Convention on the Elimination of All Forms of Discrimination Against Women: General Recommendation No. 14: Female Circumcision*. New York, NY: United Nations; 1990
2. World Health Organization. *Eliminating Female Genital Mutilation: An Interagency Statement: OHCHR, UNAIDS, UNDP, UNECA, UNESCO, UNFPA, UNHCR, UNIFEM, WHO*. Geneva, Switzerland: World Health Organization; 2008
3. FIGO Committee for the Study of Ethical Aspects of Human Reproduction and Women's Health. *Ethical Issues in Obstetrics and Gynecology*. London, United Kingdom: International Federation of Gynecology and Obstetrics; 2012
4. Council on Scientific Affairs, American Medical Association. Female genital mutilation. *JAMA*. 1995;274(21): 1714–1716
5. United Nations Population Fund. Female genital mutilation. Available at: https://www.unfpa.org/female-genital-mutilation. Accessed May 24, 2018
6. World Health Organization. Female genital mutilation. 2018. Available at: https://www.who.int/news-room/fact-sheets/detail/female-genital-mutilation. Accessed May 24, 2018
7. Kopelman LM. Female circumcision/genital mutilation and ethical relativism. *Second Opin*. 1994;20(2): 55–71
8. World Health Organization. Female genital mutilation (FGM). 2013. Available at: www.who.int/reproductivehealth/topics/fgm/prevalence/en/. Accessed May 24, 2018

9. Zurynski Y, Sureshkumar P, Phu A, Elliott E. Female genital mutilation and cutting: a systematic literature review of health professionals' knowledge, attitudes and clinical practice. *BMC Int Health Hum Rights*. 2015;15:32

10. Creighton SM, Hodes D. Female genital mutilation: what every paediatrician should know. *Arch Dis Child*. 2016; 101(3):267–271

11. United Nations Children's Fund. Female genital mutilation (FGM). Available at: https://data.unicef.org/topic/child-protection/female-genital-mutilation/. Accessed May 12, 2019

12. United Nations Entity for Gender Equality and the Empowerment of Women. *Female Genital Mutilation/ Cutting and Violence Against Women and Girls: Strengthening the Policy Linkages Between Different Forms of Violence*. New York, NY: United Nations Entity for Gender Equality and the Empowerment of Women; 2017

13. Goldberg H, Stupp P, Okoroh E, Besera G, Goodman D, Danel I. Female genital mutilation/cutting in the United States: updated estimates of women and girls at risk, 2012. *Public Health Rep*. 2016; 131(2):340–347

14. United Nations Children's Fund. Female genital mutilation/cutting: a global concern. Available at: https://www.unicef.org/media/files/FGMC_2016_brochure_final_UNICEF_SPREAD.pdf. Accessed May 24, 2018

15. World Health Organization. An Update on WHO's Work on Female Genital Mutilation (FGM): Progress Report. Geneva, Switzerland: World Health Organization; 2011. Available at: https://www.who.int/reproductivehealth/publications/fgm/rhr_11_18/en/. Accessed April 29, 2020

16. United Nations Children's Fund. *Female Genital Mutilation/Cutting: A Statistical Overview and Exploration of the Dynamics of Change*. New York, NY: United Nations Children's Fund; 2013

17. BBC News. Russia furore over FGM in mainly Muslim Dagestan. BBC News. August 18, 2016. Available at: https://www.bbc.com/news/world-europe-37115746.Accessed April 29, 2020

18. Ross CT, Campiño PJ, Winterhalder B. Frequency-dependent social transmission and the interethnic transfer of female genital modification in the African diaspora and indigenous populations of Colombia. *Hum Nat*. 2015;26(4):351–377

19. Victor D. Father imprisoned for genital cutting is deported to Ethiopia. *The New York Times*. March 14, 2017. Available at: https://www.nytimes.com/2017/03/14/us/father-imprisoned-for-genital-cutting-is-deported-to-ethiopia.html. Accessed May 24, 2018

20. Burstyn L. Female circumcision comes to America. *The Atlantic*. October 1, 1995. Available at: https://www.theatlantic.com/magazine/archive/1995/10/female-circumcision-comes-to-america/306051/. Accessed May 24, 2018

21. Belluck P. Michigan case adds U.S. dimension to debate on genital mutilation. *The New York Times*. June 10, 2017. Available at: https://www.nytimes.com/2017/06/10/health/genital-mutilation-muslim-dawoodi-bohra-michigan-case.html. Accessed May 24, 2018

22. Hicks M. Judge dismisses most serious remaining charge against doctor accused of genital mutilation. The Detroit News. March 5, 2020. Available at: https://www.detroitnews.com/story/news/local/michigan/2020/03/05/judge-dismisses-charge-against-doctor-female-genital-mutilation/4960323002/. Accessed April 29, 2020

23. Semu-Banda P. For many girls, school holidays means FGM "cutting season." 2017. Available at: https://www.unfpa.org/cuttingseason. Accessed May 24, 2018

24. Sanctuary for Families. *Female Genital Mutilation in the United States. Protecting Girls and Women in the U.S. From FGM and Vacation Cutting*. New York, NY: Sanctuary for Families; 2013

25. Population Reference Bureau. *Female Genital Mutilation/Cutting: Data and Trends*. Washington, DC: Population Reference Bureau; 2010

26. Tamaddon L, Johnsdotter S, Liljestrand J, Essén B. Swedish health care providers' experience and knowledge of female genital cutting. *Health Care Women Int*. 2006;27(8):709–722

27. Kaplan-Marcusan A, Torán-Monserrat P, Moreno-Navarro J, Castany Fàbregas MJ, Muñoz-Ortiz L. Perception of primary health professionals about female genital mutilation: from healthcare to intercultural competence. *BMC Health Serv Res*. 2009;9(1):11

28. Young J, Rodrigues KK, Imam B, Johnson-Agbakwu C. Female genital mutilation/cutting-pediatric physician knowledge, training, and general practice approach [published online ahead of print October 10, 2019]. *J Immigr Minor Health*. doi:10.1007/s10903-019-00938-x

29. Hess RF, Weinland J, Saalinger NM. Knowledge of female genital cutting and experience with women who are circumcised: a survey of nurse-midwives in the United States. *J Midwifery Womens Health*. 2010;55(1): 46–54

30. Lazar JN, Johnson-Agbakwu CE, Davis OI, Shipp MP. Providers' perceptions of challenges in obstetrical care for Somali women. *Obstet Gynecol Int*. 2013; 2013:149640

31. Jacoby SD, Smith A. Increasing certified nurse-midwives' confidence in managing the obstetric care of women with female genital mutilation/cutting. *J Midwifery Womens Health*. 2013;58(4): 451–456

32. Atkinson HG, Geisler A. Developing physician educational competencies for the management of female genital cutting: a call to action. *J Womens Health (Larchmt)*. 2019;28(7):997–1003

33. Creighton SM, Dear J, de Campos C, Williams L, Hodes D. Multidisciplinary approach to the management of children with female genital mutilation (FGM) or suspected FGM: service description and case series. *BMJ Open*. 2016;6(2):e010311

34. Zurynski Y, Phu A, Sureshkumar P, Cherian S, Deverell M, Elliott EJ; for Australian Paediatric Surveillance Unit Female Genital Mutilation Study Steering Committee. Female genital mutilation in children presenting to Australian paediatricians. *Arch Dis Child*. 2017;102(6):509–515

35. Sureshkumar P, Zurynski Y, Moloney S, Raman S, Varol N, Elliott EJ. Female genital mutilation: survey of paediatricians' knowledge, attitudes

and practice. *Child Abuse Negl*. 2016;55:1–9

36. Hagan JF, Shaw JS, Duncan PM, eds. *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*, 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017
37. Committee on Practice and Ambulatory Medicine. Use of chaperones during the physical examination of the pediatric patient. *Pediatrics*. 2011;127(5):991–993
38. Shell-Duncan B, Hernlund Y, Wander K, Moreau A. *Contingency and Change in the Practice of Female Genital Cutting: Dynamics of Decision Making in Senegambia. Summary Report*. Seattle, Washington: Department of Anthropology, University of Washington; 2010
39. World Health Organization. International Statistical classification of diseases and Related Health Problems 10th Revision. 2016. Available at: https://icd.who.int/browse10/2016/en. Accessed xx xx, xxxx
40. Population Reference Bureau. Women and girls at risk of female genital mutilation/cutting in the United States. 2016. Available at: https://www.prb.org/us-fgmc/. Accessed May 25, 2018
41. Berg RC, Underland V, Odgaard-Jensen J, Fretheim A, Vist GE. Effects of female genital cutting on physical health outcomes: a systematic review and meta-analysis. *BMJ Open*. 2014;4(11):e006316
42. Nour NM. Female genital cutting: clinical and cultural guidelines. *Obstet Gynecol Surv*. 2004;59(4):272–279
43. Berg RC, Underland V. *Immediate health consequences of Female Genital Mutilation/Cutting (FGM/C)*. Oslo, Norway: Knowledge Centre for the Health Services at The Norwegian Institute of Public Health; 2014. Available at: www.ncbi.nlm.nih.gov/books/NBK464798/. Accessed August 30, 2019
44. Brewer DD, Potterat JJ, Roberts JM Jr., Brody S. Male and female circumcision associated with prevalent HIV infection in virgins and adolescents in Kenya, Lesotho, and Tanzania. *Ann Epidemiol*. 2007;17(3):217–226
45. Banks E, Meirik O, Farley T, Akande O, Bathija H, Ali M; WHO Study Group on Female Genital Mutilation and Obstetric Outcome. Female genital mutilation and obstetric outcome: WHO collaborative prospective study in six African countries. *Lancet*. 2006;367(9525):1835–1841
46. Rodriguez MI, Say L, Abdulcadir J, Hindin MJ. Clinical indications for cesarean delivery among women living with female genital mutilation. *Int J Gynaecol Obstet*. 2017;139(1):21–27
47. Rodriguez MI, Seuc A, Say L, Hindin MJ. Episiotomy and obstetric outcomes among women living with type 3 female genital mutilation: a secondary analysis. *Reprod Health*. 2016;13(1):131
48. Berg RC, Denison E, Fretheim A. *Psychological, Social and Sexual Consequences of Female Genital Mutilation/Cutting (FGM/C): A Systematic Review of Quantitative Studies*. Oslo, Norway: Knowledge Centre for the Health Services at The Norwegian Institute of Public Health; 2010
49. Ahmed MR, Shaaban MM, Meky HK, et al. Psychological impact of female genital mutilation among adolescent Egyptian girls: a cross-sectional study. *Eur J Contracept Reprod Health Care*. 2017;22(4):280–285
50. Knipscheer J, Vloeberghs E, van der Kwaak A, van den Muijsenbergh M. Mental health problems associated with female genital mutilation. *BJPsych Bull*. 2015;39(6):273–277
51. Abdulcadir J, Tille JC, Petignat P. Management of painful clitoral neuroma after female genital mutilation/cutting. *Reprod Health*. 2017;14(1):22
52. Nour NM, Michels KB, Bryant AE. Defibulation to treat female genital cutting: effect on symptoms and sexual function. *Obstet Gynecol*. 2006;108(1):55–60
53. Effa E, Ojo O, Ihesie A, Meremikwu MM. Deinfibulation for treating urologic complications of type III female genital mutilation: a systematic review. *Int J Gynaecol Obstet*. 2017;136(suppl 1):30–33
54. Nour NM. Urinary calculus associated with female genital cutting. *Obstet Gynecol*. 2006;107(2 pt 2):521–523
55. Rouzi AA. Epidermal clitoral inclusion cysts: not a rare complication of female genital mutilation. *Hum Reprod*. 2010;25(7):1672–1674
56. Victoria-Martínez AM, Cubells-Sánchez L, Martínez-Leborans L, Sánchez-Carazo JL, de Miquel VA. Vulvar epidermal inclusion cyst as a long-term complication of female genital mutilation. *Indian J Dermatol*. 2016;61(1):119
57. Morison L, Scherf C, Ekpo G, et al. The long-term reproductive health consequences of female genital cutting in rural Gambia: a community-based survey. *Trop Med Int Health*. 2001;6(8):643–653
58. Brady M. Female genital mutilation: complications and risk of HIV transmission. *AIDS Patient Care STDS*. 1999;13(12):709–716
59. Reisel D, Creighton SM. Long term health consequences of female genital mutilation (FGM). *Maturitas*. 2015;80(1):48–51
60. Almroth L, Elmusharaf S, El Hadi N, et al. Primary infertility after genital mutilation in girlhood in Sudan: a case-control study. *Lancet*. 2005;366(9483):385–391
61. Thabet SM, Thabet AS. Defective sexuality and female circumcision: the cause and the possible management. *J Obstet Gynaecol Res*. 2003;29(1):12–19
62. Chalmers B, Hashi KO. 432 Somali women's birth experiences in Canada after earlier female genital mutilation. *Birth*. 2000;27(4):227–234
63. Stewart H, Morison L, White R. Determinants of coital frequency among married women in Central African Republic: the role of female genital cutting. *J Biosoc Sci*. 2002;34(4):525–539
64. Okonofu FE, Larsen U, Oronsaye F, Snow RC, Slanger TE. The association between female genital cutting and correlates of sexual and gynaecological morbidity in Edo State, Nigeria. *BJOG*. 2002;109(10):1089–1096
65. Berg RC, Taraldsen S, Said MA, Sørbye IK, Vangen S. The effectiveness of surgical interventions for women with FGM/C: a systematic review. *BJOG*. 2018;125(3):278–287

66. Abdulcadir J, Rodriguez MI, Say L. A systematic review of the evidence on clitoral reconstruction after female genital mutilation/cutting. *Int J Gynaecol Obstet*. 2015;129(2):93–97

67. Abdulcadir J, Marras S, Catania L, Abdulcadir O, Petignat P. Defibulation: a visual reference and learning tool. *J Sex Med*. 2018;15(4):601–611

68. American College of Obstetricians and Gynecologists. *Female Genital Cutting: Clinical Management of Circumcised Women*, 2nd ed. Washington, DC: American College of Obstetricians and Gynecologists; 2008

69. Abdulcadir J, Bianchi Demicheli F, Willame A, Recordon N, Petignat P. Posttraumatic stress disorder relapse and clitoral reconstruction after female genital mutilation. *Obstet Gynecol*. 2017; 129(2):371–376

70. Pierce S, Bolter J, Selee A. *U.S. Immigration Policy Under Trump: Deep Changes and Lasting Impacts*. Washington, DC: Migration Policy Institute; 2018

71. Hacker K, Chu J, Leung C, et al. The impact of Immigration and Customs Enforcement on immigrant health: perceptions of immigrants in Everett, Massachusetts, USA. *Soc Sci Med*. 2011; 73(4):586–594

72. Redden M. Undocumented immigrants avoid vital nutrition services for fear of deportation. *The Guardian*. May 9, 2017. Available at: https://www.theguardian.com/us-news/2017/may/09/undocumented-immigrants-wic-nutrition-services-deportation. Accessed June 5, 2019

73. Medina J. Too scared to report sexual abuse. The fear: deportation. *The New York Times*. April 30, 2017. Available at: https://www.nytimes.com/2017/04/30/us/immigrants-deportation-sexual-abuse.html. Accessed June 5, 2019

74. Hoffman J. Sick and afraid, some immigrants forgo medical care. *The New York Times*. June 26, 2017. Available at: https://www.nytimes.com/2017/06/26/health/undocumented-immigrants-health-care.html. Accessed June 5, 2019

75. Vissandjée B, Denetto S, Migliardi P, Proctor J. Female genital cutting (FGC) and the ethics of care: community engagement and cultural sensitivity at the interface of migration experiences. *BMC Int Health Hum Rights*. 2014;14(1): 13

76. Vissandjée B, Kantiébo M, Levine A, N'Dejuru R. The cultural context of gender, identity: female genital, excision and infibulation. *Health Care Women Int*. 2003;24(2):115–124

77. Johnson-Agbakwu CE, Helm T, Killawi A, Padela AI. Perceptions of obstetrical interventions and female genital cutting: insights of men in a Somali refugee community. *Ethn Health*. 2014; 19(4):440–457

78. Baillot H, Murray N, Connelly E, Howard N. Addressing female genital mutilation in Europe: a scoping review of approaches to participation, prevention, protection, and provision of services. *Int J Equity Health*. 2018;17(1): 21

79. Varol N, Turkmani S, Black K, Hall J, Dawson A. The role of men in abandonment of female genital mutilation: a systematic review. *BMC Public Health*. 2015;15(1):1034

80. Creighton SM, Samuel Z, Otoo-Oyortey N, Hodes D. Tackling female genital mutilation in the UK. *BMJ*. 2019;364:l15

81. Macfarlane A. Misleading use of FGM statistics compounds concerns about their reliability. *BMJ*. 2019;364:l927

82. Karlsen S, Mogilnicka M, Carver N, Pantazis C. Female genital mutilation: empirical evidence supports concerns about statistics and safeguarding. *BMJ*. 2019;364:l915

83. Seven days in medicine: 28 November to 4 December 2018. *BMJ*. 2018;363: k5126

84. Gangoli G, Gill A, Mulvihill N, Hester M. Perception and barriers: reporting female genital mutilation. *J Aggress Confl Peace Res*. 2018;10(4):251–260

85. Vogt S, Efferson C, Fehr E. The risk of female genital cutting in Europe: comparing immigrant attitudes toward uncut girls with attitudes in a practicing country. *SSM Popul Health*. 2017;3:283–293

86. Wahlberg A, Johnsdotter S, Ekholm Selling K, Källestål C, Essén B. Factors associated with the support of pricking (female genital cutting type IV) among Somali immigrants - a cross-sectional study in Sweden. *Reprod Health*. 2017; 14(1):92

87. Wahlberg A, Johnsdotter S, Selling KE, Källestål C, Essén B. Baseline data from a planned RCT on attitudes to female genital cutting after migration: when are interventions justified? *BMJ Open*. 2017;7(8):e017506

88. Agency for Healthcare Research and Quality. Community-driven clinic for refugee women enhances access to comprehensive, culturally sensitive care across the reproductive life span. 2014. Available at: https://innovations.ahrq.gov/profiles/community-driven-clinic-refugee-women-enhances-access-comprehensive-culturally-sensitive. Accessed February 1, 2018

89. Mendelsohn N. At the crossroads: the case for and against a cultural defense to female genital mutilation. *Rutgers Law Rev*. 2004;56(4):1011–1038

90. World Health Organization. Eliminating female genital mutilation. An Interagency statement. 2008. Available at: https://www.un.org/womenwatch/daw/csw/csw52/statements_missions/Interagency_Statement_on_Eliminating_FGM.pdf. Accessed April 30, 2020

91. Choudhary I, Mishori R, Kim S. Words matter: charting the landscape of US and international health profession organizations' public statements about FGM/C. *J Immigr Minor Health*. 2019; 21(4):893–904

92. Alavi R. Female genital mutilation: a capabilities approach. *Auslegung J Philos*. 2003;26(2):1–25

93. Joint United Nations Programme on HIV and AIDS; United Nations Development Programme; United Nations Population Fund. *Global Strategy to Stop Health-Care Providers From Performing Female Genital Mutilation*. Geneva, Switzerland: World Health Organization; 2010

94. United States v. Nagarwala, 350 F Supp 3d 613 (ED Mich 2018)

95. Equality Now. US laws against FGM—state by state. Available at: https://www.equalitynow.org/us_laws_against_fgm_state_by_state. Accessed April 30, 2020

96. AHA Foundation. FGM legislation by state. Available at: https://www.

theahafoundation.org/female-genital-mutilation/fgm-legislation-by-state/. Accessed March 7, 2019

97. Boonstra H, Nash E. Minors and the right to consent to health care. *Issues Brief (Alan Guttmacher Inst)*. 2000;(2): 1–6

98. Cornell Law School. Emancipation of minors - laws.. 2008. Available at: https://www.law.cornell.edu/wex/table_emancipation. Accessed May 25, 2018

99. Coleman DL, Rosoff PM. The legal authority of mature minors to consent to general medical treatment. *Pediatrics*. 2013;131(4):786–793

100. Driggs AE. The mature minor doctrine: do adolescents have the right to die? *Health Matrix Clevel*. 2001;11(2): 687–717

101. Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2): e20161484

102. Child Welfare Information Gateway. *Immunity for Reporters of Child Abuse and Neglect*. Washington, DC: US Department of Health and Human Services, Children's Bureau; 2019

103. Committee on Pediatric Emergency Medicine and Committee on Bioethics. Consent for emergency medical services for children and adolescents. *Pediatrics*. 2011;128(2):427–433

104. Levi BH, Brown G. Reasonable suspicion: a study of Pennsylvania pediatricians regarding child abuse. *Pediatrics*. 2005; 116(1) Available at: www.pediatrics.org/cgi/content/full/116/1/e5

105. US Citizenship and Immigration Services. Asylum. 2019. Available at: https://www.uscis.gov/humanitarian/refugees-asylum/asylum. Accessed February 4, 2018

106. US Department of Justice, Executive Office for Immigration Review, Board of Immigration Appeals. In re Fauziya Kasinga, applicant. 1996. Available at: https://www.justice.gov/sites/default/files/eoir/legacy/2014/07/25/3278.pdf. Accessed February 4, 2017

107. Kimenyi MS. The long road to South Sudan's secession vote. 2010. Available at: https://www.brookings.edu/opinions/the-long-road-to-south-sudans-secession-vote/. Accessed March 1, 2020

108. United Nations Population Fund. Analysis of legal frameworks on female genital mutilation in selected countries in West Africa. 2018. Available at: https://wcaro.unfpa.org/sites/default/files/pub-pdf/UNFPA-ANALYSIS-ON-FGM-WEB.pdf. Accessed January 10, 2019

109. Centers for Disease Control and Prevention. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). 2019. Available at: https://www.cdc.gov/nchs/icd/icd10cm.htm. Accessed December 14, 2017

110. Abdulcadir J, Botsikas D, Bolmont M, et al. Sexual anatomy and function in women with and without genital mutilation: a cross-sectional study. *J Sex Med*. 2016;13(2):226–237

111. World Health Organization. *Care of Girls and Women Living with Female Genital Mutilation: A Clinical Handbook*. Geneva, Switzerland: World Health Organization. Available at: www.who.int/reproductivehealth/publications/health-care-girls-women-living-with-FGM/en/. Accessed May 29, 2019

112. US Government Accountability Office. Female genital mutilation/cutting: existing federal efforts to increase awareness should be improved. 2016. Available at: https://www.gao.gov/products/GAO-16-645. Accessed September 10, 2019

113. World Health Organization. *WHO Guidelines on the Management of Health Complications from Female Genital Mutilation*. Geneva, Switzerland: World Health Organization. Available at: www.who.int/reproductivehealth/topics/fgm/management-health-complications-fgm/en/. Accessed September 10, 2019

114. United Nations Population Fund. Female genital mutilation (FGM) frequently asked questions. Available at: https://www.unfpa.org/resources/female-genital-mutilation-fgm-frequently-asked-questions. Accessed April 30, 2020

115. US Citizenship and Immigration Services. Female genital mutilation or cutting (FGM/C). 2018. Available at: https://www.uscis.gov/fgmc. Accessed November 13, 2017

116. Centers for Disease Control and Prevention. Guidelines for the US domestic medical examination for newly arriving refugees. 2019. Available at: https://www.cdc.gov/immigrantrefugeehealth/guidelines/domestic/domestic-guidelines.html. Accessed September 10, 2019

117. American Academy of Pediatrics. Immigrant child health toolkit. Available at: www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Immigrant-Child-Health-Toolkit/Pages/Clinical-Care.aspx. Accessed September 10, 2019

118. Abdulcadir J, Catania L, Hindin MJ, Say L, Petignat P, Abdulcadir O. Female genital mutilation: a visual reference and learning tool for health care professionals. *Obstet Gynecol*. 2016; 128(5):958–963

119. National Health Service. Overview: female genital mutilation (FGM). 2017. Available at: https://www.nhs.uk/conditions/female-genital-mutilation-fgm/. Accessed November 3, 2017

120. National Health Service, Department of Health and Social Care. Female genital mutilation (FGM): resources for healthcare staff. 2015. Available at: https://www.gov.uk/government/collections/female-genital-mutilation-fgm-guidance-for-healthcare-staff. Accessed August 12, 2019

121. National Health Service, Department of Health and Social Care. FGM: mandatory reporting in healthcare. 2017. Available at: https://www.gov.uk/government/publications/fgm-mandatory-reporting-in-healthcare. Accessed September 11, 2019

122. Canadian Paediatric Society. Female genital mutilation/cutting. 2019. Available at: https://www.kidsnewtocanada.ca/screening/fgm. Accessed September 11, 2019

123. The Royal Australasian College of Physicians. *Female Genital Mutilation/Cutting*. Sydney, Australia: The Royal Australasian College of Physicians; 2012

124. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Female genital mutilation (FGM). 2017. Available at: https://ranzcog.edu.au/RANZCOG_SITE/media/RANZCOG-MEDIA/Women%27s%20Health/Statement%20and%20guidelines/Clinical%20-%

20Gynaecology/Female-Genital-Mutilation-(C-Gyn-1)-Nov17.pdf?ext=.pdf. Accessed April 30, 2020

125. Almroth L, Bedri H, El Musharaf S, et al. Urogenital complications among girls with genital mutilation: a hospital-based study in Khartoum. *Afr J Reprod Health*. 2005;9(2):118–124

126. Diouf K, Nour N. Female genital cutting and HIV transmission: is there an association? *Am J Reprod Immunol*. 2013;69(suppl 1):45–50

127. Armitage AJ, Bittaye M, Agbala S, Idoko P. Neonatal outcomes of female genital mutilation/cutting (fgm/c) in the Gambia: results from a multicentre prospective observational study. *Arch Dis Child*. 2018;103(suppl 1):A107

Digital Advertising to Children

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Digital Advertising to Children

Jenny Radesky, MD, FAAP,[a] Yolanda (Linda) Reid Chassiakos, MD, FAAP, FACP,[b] Nusheen Ameenuddin, MD, MPH, MPA, FAAP,[c] Dipesh Navsaria, MPH, MSLIS, MD, FAAP,[d] COUNCIL ON COMMUNICATION AND MEDIA

Advertising to children and teenagers is a multibillion-dollar industry. This policy statement reviews the forms of advertising that children and teenagers encounter, including newer forms of digital marketing, such as sponsored content, influencers, data collection, persuasive design, and personalized behavioral marketing driven by machine learning. Parents and pediatric health care providers need to be aware of the ways different marketing messages reach children and teenagers, including Internet sites, social media, and mobile apps. Evidence suggests that exposure to advertising is associated with unhealthy behaviors, such as intake of high-calorie, low-nutrient food and beverages; use of tobacco products and electronic cigarettes; use of alcohol and marijuana; and indoor tanning. Children are uniquely vulnerable to the persuasive effects of advertising because of immature critical thinking skills and impulse inhibition. School-aged children and teenagers may be able to recognize advertising but often are not able to resist it when it is embedded within trusted social networks, encouraged by celebrity influencers, or delivered next to personalized content. This policy statement expresses concern about the practice of tracking and using children's digital behavior to inform targeted marketing campaigns, which may contribute to health disparities among vulnerable children or populations. Pediatricians should guide parents and children to develop digital literacy skills to prevent or mitigate negative outcomes, but it is equally important that policy makers and technology companies embrace digital design, data collection, and marketing practices within today's broad digital environment that support healthier decision-making and outcomes.

THE CHANGING LANDSCAPE OF MARKETING TO CHILDREN

Advertising to children and teenagers via various forms of media has occurred for decades, with expenditures of $3.2 billion for nondigital and $900 million for digital advertising in the United States in 2018.[1] Children and teenagers encounter advertising through television, radio, print media, the Internet, and their mobile phones. Advertising can take many forms, including images, videos, and games that advertise specific brands.

abstract

[a]Department of Pediatrics, Medical School, University of Michigan, Ann Arbor, Michigan; [b]Department of Pediatrics, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, California; [c]Mayo Clinic, Rochester, Minnesota; and [d]Department of Pediatrics, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin

Dr Radesky drafted the initial policy statement, wrote sections of the manuscript, and critically revised the manuscript on the basis of reviewer feedback; Drs Chassiakos, Ameenuddin, and Navsaria wrote sections of the manuscript and revised the manuscript on the basis of reviewer feedback; and all authors approved the final manuscript as submitted.

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-1681

Address correspondence to Jenny Radesky, MD, FAAP. E-mail: jradesky@med.umich.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Radesky J, Chassiakos Y(LR, Ameenuddin N, et al. AAP COUNCIL ON COMMUNICATION AND MEDIA. Digital Advertising to Children. *Pediatrics*. 2020;146(1):e20201681

However, since the introduction of mobile media and Internet-connected devices (eg, virtual assistants, Internet-connected toys), advertising now comprises a wider range of marketing approaches for which influences on child behavior have not been well described. The purpose of this policy statement is to review the developmental science explaining how children and teenagers are vulnerable to advertising, review the emerging research on novel marketing approaches and evidence regarding advertising and child health, and offer guidance to parents, pediatric health care providers, industry, and policy makers about the needs and rights of children in the modern digital media environment.

CHILDREN'S UNIQUE VULNERABILITY TO ADVERTISING

Research on children's understanding of television advertising[2] demonstrates that children 7 years and younger have limited ability to understand the persuasive intent (ie, that someone else is trying to change their thoughts and behavior) of the advertiser. From ages 7 to 11 years, children can start to recognize television advertising and persuasive intent with their parents' assistance but lack the abstract thinking skills that help individuals recognize advertising as a larger commercial concept. At ~12 years of age and older, teenagers were able to identify television advertisements (ads) and advertisers' intention to change behavior (which is why some countries, such as Sweden and Brazil, have laws banning advertising to children younger than 12 years).

However, recognition of persuasive intent does not necessarily lead to the ability to resist marketing, especially with highly appealing products. Marketers use emotional or subconscious approaches[3] to engage children, such as using trusted characters[4] or celebrities. At as young as age 2, a child can easily identify a familiar character as well as correctly connect them with an endorsed product.[5]

Most importantly, most research on children's understanding of advertising involves television and print ads only, but newer forms of advertising found in mobile and interactive media and smart technologies, often powered by personal data, are more difficult to identify. They do not necessarily occur in a predictable manner and are often integrated into the content.[6] Advertising may also be linked to rewards or be embedded in trusted social networks or personalized digital platforms, which may undermine children's abilities to identify or critically think about advertising messages. Regulations on television advertising[7] have not yet been updated for the modern digital environment.

NEW MARKETING APPROACHES

The nature of media used by children and teenagers has changed dramatically in the past decade, and children now spend more time on the Internet, social media, user-created content, video games, mobile applications (apps), virtual or augmented reality, virtual assistants, and Internet-connected toys. The Internet allows advertisers to contact, track, and influence users, as guided by behavioral data collection; a user's digital trail of location, activities, in-app behavior, likes, and dislikes contributes to a digital profile shared among many companies that can be used to make advertising messages more effective.

Sponsored Content and Influencers

User-created content on social media platforms and video-streaming services (eg, TikTok, YouTube) frequently involves commercial content and marketing messages. Examples include the highly popular unboxing and toy-play videos as well as influencers reviewing or using products with sponsorship from companies. Child advocacy groups have highlighted the large amount of child-directed influencer marketing, often undisclosed, which is not allowed on children's television (ie, "host selling," using stars of a television program in commercials airing during that program) because it is harder for children to identify or resist.[8]

Data and Privacy

Data collection for commercial purposes includes use of cookies in a user's browser, which record and follow Web page history; the collection of posts, likes, purchases, and viewing history by apps such as Facebook and Instagram or search engines such as Google[9]; and collection of data via apps granted permission to track device data, such as location or contacts. Software mines such data from user accounts, devices, and virtual assistants and often shares data with third-party companies to develop a profile of the user, which informs the delivery of targeted ads.[10] Collection of mobile device-derived data has been found to be highest in news and children's apps,[11] many of which evade privacy rules of the Children's Online Privacy and Protection Act (COPPA) (1998; revised in 2013) by stating that their apps are for general audiences. User data can be aggregated and stored, sold to third parties, and used to infer personal characteristics, such as sexual orientation or health problems.[12] Livingstone et al,[12] in their review of the limited literature on "datafication" of children, conclude that school-aged children up to teenagers do not comprehend the full complexity of how digital data are collected, analyzed, and used for commercial purposes. For example, studies suggest that teenagers have a more interpersonal, and less technical, conceptualization of privacy, so they may not be as aware of the ramifications of sharing data with governments or corporations

compared with sharing private information with friends or parents. Young children are more trusting of privacy-invasive technologies, such as location trackers,[13] likely because of their convenience. In a recent report commissioned by the UK Information Commissioner's Office, children and parents reported not reading the terms and conditions or privacy notices in platforms, feeling pressured to accept cookies to use Web sites, and feeling uncomfortable with their data being used for targeted advertising.[14] In addition, preschool-aged children up to teenagers in this study believed they should have the right to erase or limit the use of their digital data.[14] However, data-brokering services are highly complex, using evolving algorithms across multiple platforms, with business practices that are intentionally opaque, which even adults do not fully understand.[15]

Beyond advertising, it is also important for families to understand how data collection influences the information that reaches them through the Internet. Previous online behaviors shape what is delivered to users via news, notifications, and social media feeds, creating a filter bubble in which all input, unbeknownst to users, is tailored to their interests and creates false norms that can undermine healthy behaviors.

In the United States, COPPA is meant to "place parents in control over what information is collected from their young children online" and limit the data that child-directed Web sites, apps, or other online services collect, use, or disclose to third parties in the absence of parental consent.[16] However, COPPA leaves open many gaps in its protection. It generally does not protect children when they are using Web sites or apps that are considered targeted to a general audience, nor does it apply after a child is 13 years of age. In addition, the law has not being enforced reliably.[11] The European Union's General Data Protection Regulation (2018) is more ambitious in protecting user privacy, and the UK Information Commissioner's Office has recently introduced an age-appropriate design code to address children's vulnerabilities regarding data collection and persuasive design.[17]

Persuasive Design and Behavioral Marketing

Design elements intended to nudge users into specific behaviors (by constraining choices, highlighting preferred buttons to click, or providing rewards for preferred behavior) are now a common part of digital design.[18] These design elements extend digital engagement in ways that increase exposure to advertising, which children and teenagers may not be able to identify or resist. This targeted marketing also results in different products being advertised to different populations, which may accentuate existing disparities.[12]

Gamified Ads and In-App Purchases

Newer Internet marketing practices in the 2000s included gamified advertising ("advergames"), which rewards users for watching ads or buying products,[19] but have evolved to include advertising that is less evident to the child. For example, an analysis of the most-downloaded free apps for children younger than 5 years on Google Play revealed that 96% contained commercial content, including hidden ads, interstitial ads that pop up automatically, and ads that, when viewed, provided incentives, such as more game tokens or making gameplay easier.[6] App characters were noted to encourage in-app purchases in some games.[6]

Artificial Intelligence and Machine Learning

Artificial intelligence and machine learning form the core of many technologies accessed by children and teenagers, including virtual assistants. It is unclear how much data are being collected, how data are being processed or used to shape query responses for the purposes of marketing to children, or how parents can access the information. Young children attribute more animism to and place more trust in these artificial intelligence agents and are more likely to share information with them.[20]

SPECIFIC HEALTH-RELATED CONCERNS

Food Advertising and Childhood Obesity

Food marketing funding today is less dependent on television and is instead concentrated on integrated marketing campaigns and cross-platform promotion to spur children's requests and demands for products,[21] as highlighted in the recent comprehensive report by the University of Connecticut Rudd Center for Food Policy and Obesity.[22] Food advertising has been linked to higher obesity risk via ads for high-calorie, low-nutrient food and beverages (which influence diet and purchases).[23] Screen media consumption is inversely correlated with fruit and vegetable intake and directly correlated with energy-dense, nutrient-poor snacks, drinks, and food.[24] Ads also promote intake of foods that contribute to dental caries.[25] More fast food and sugar beverages are advertised in African American, Hispanic, and low-income communities, according to the Rudd report,[26] as are candy and cereals. Nearly 40% of ads on television targeted to African American and Hispanic populations are for fast food and other restaurants. Unhealthy food advertising in 13- to 17-year-olds is also correlated with development of media-driven norms that supersede healthier family norms.[27] Influencers can sway teenagers toward unhealthy choices; Bragg et al[28] identified popular music stars endorsing 18%

of surveyed ads; 49 (71%) promoted sugar-sweetened beverages, and 21 (80.8%) endorsed foods were energy dense and nutrient poor. In an experimental study, Coates et al,[29] found that school-aged children who viewed mock profiles of influencers promoting unhealthy snacks showed a significant increase in intake of unhealthy snacks and total calories compared with children who viewed influencers promoting nonfood items. Folkvord et al[30] observed increased caloric intake in 7- to 10-year-olds playing advergames as well, which children with high impulsivity had an especially hard time inhibiting.

Tobacco and Electronic Cigarette Advertising

Multiple studies have revealed that in teenagers, attention and receptivity to cigarette advertising is correlated with both current and future use.[31] Cigarette ads on television and radio were banned in 1971 for this reason. This correlation has been found with emerging tobacco products, such electronic cigarettes (e-cigarettes),[32,33] to which the majority of middle and high school students have been exposed.[34] E-cigarette companies have used social media influencers, hashtags, music videos, and other informal social media presence to advertise their products,[35] although companies have deleted their own official social media accounts.

Alcohol Advertising

Studies have revealed increased exposure to alcohol content for middle and high school youth via social media,[36] banner ads, and video ads, with disparate exposure for African American,[37] Hispanic, and American Indian youth.[38] A review by Jernigan et al[39] of 12 longitudinal studies published from 2009 to 2015 demonstrated a positive correlation between marketing exposure and receptivity and alcohol consumption in youth, and the authors concluded that "existing self-regulatory systems do not meet their intended goal of protecting vulnerable populations from alcohol marketing."

Marijuana Advertising

The legalization of marijuana in many states has led to media and point-of-sale advertising seen by people younger than 21 years[40] or increased exposure through social media mentions, sometimes accompanied by cartoon characters or other design elements attracting to children.[41] Point-of-service advertising has been found to be more common in areas of lower socioeconomic status and minority populations.[42] Marijuana advertising exposure is associated with heavier use, use of marijuana concentrates and edibles in young adults,[43] and higher probability of marijuana use and intentions in middle schoolers.[44]

Cultural Biases, Body Appearance, and Teenager Self-image

By presenting ideals of body appearance, ads can convey cultural biases, such as skin color (eg, skin-lightening products), hair traits (eg, hair-straightening products), or unhealthy body weight ideals (eg, diet products or muscle-building supplements). In addition, ads for indoor tanning salons often target teenagers. Because indoor tanning is considered a class 2 carcinogen, such advertising is restricted over traditional media. For this reason, tanning salons actively use social media as a strategy for attracting and retaining customers,[45] encouraging high-frequency tanning,[46] and lowering the perception of the risks of tanning.[47]

DIGITAL LITERACY

Digital literacy requires that children, teenagers, and parents understand that technology is created by other humans with their own agendas and that they can accept or reject its messages, identify advertising and persuasive intent, reflect on their own reactions to media, and engage with media on the basis of their own intentions (rather than reacting to engagement-promoting design). However, Livingstone et al[12] identified disparities in knowledge about technology and privacy among parents of different socioeconomic status or digital skills. For example, parents from lower-income backgrounds were more likely to place credence in the learning value of apps marketed as educational for their young children,[48] despite a lack of evidence-based data for most such products.[49] Thus, differences in digital literacy skills and knowledge by socioeconomic status may contribute to digital disparities.

Digital literacy programs have been developed to teach children how to think about technology, not just how to use it. For example, Zarouali et al[10] showed that teenagers responded more favorably to specifically targeted rather than nontargeted ads, but teenagers who understood the privacy intrusions that led to such targeted advertising were more skeptical and less likely to purchase the product. Educational programs and campaigns are recommended, in combination with the design changes discussed below, to mitigate this influence and persuasion.

CONCLUSIONS

Many digital media resources, including apps, programs, games, and educational materials, are subsidized and supported by advertising dollars. Children's and teenagers' unique developmental needs make them more vulnerable to negative physical, mental, and financial health effects of digital marketing. Although parents play a large role in helping their children be critical of media messages, identify surreptitious advertising approaches, and resist their influence, it is also crucial that there are measures in place in children's digital media environments to protect their needs.

RECOMMENDATIONS

For Parents

Excessive media use has been linked with negative health outcomes in children and teenagers. American Academy of Pediatrics (AAP) policies regarding media[50,51] provide guidance for parents and families regarding limiting media use and engaging in healthy conversation about media messages. However, parents should not be the only ones held responsible for child privacy in a digital environment that is predicated on a business model of advertising and data collection in which the default settings serve to compromise user privacy or potentiate disparities. Parents can be effective in teaching children and teenagers to think critically about digital media, but this AAP policy statement places the primary duty to protect children on technology developers and policy makers, who should create a digital environment in which families can access content that provides opportunities rather than delivers profits.

To empower parents to help their children, the following steps and resources are recommended:

1. Build digital, privacy, and design savviness. Know what your children are downloading and accessing so that you can help them be an informed consumer, and demand better-designed digital products for children (helpful resources: https://www.childrenscommissioner.gov.uk/wp-content/uploads/2018/11/who-knows-what-about-me-infographic.pdf and https://www.consumerreports.org/digital-security/online-security-and-privacy-guide/).
2. Enhance and monitor privacy settings on personal devices, apps, social media, virtual assistants, and wireless networks. Understand the differences between privacy settings that determine what other users can see about you and the platform collecting data about you (helpful resource: https://www.commonsensemedia.org/privacy-and-internet-safety).
3. Create a family media use plan that intentionally uses high-quality media content that has as few ads as possible, limits data collection, and encourages discussion about privacy (helpful resource: https://www.healthychildren.org/English/media/Pages/default.aspx).
4. Teach children to analyze the ads they see, identify algorithms that affect their streaming content, understand what personal data are collected, and be savvy about the persuasive intent behind the design of the technologies they use (helpful resource: Digital literacy toolkit from Sonia Livingstone: www.myprivacy.uk).
5. Talk to school administrators and teachers about the digital privacy of the technology tools they use (helpful resources: Campaign for a Commercial-Free Childhood parent toolkit for student privacy [https://commercialfreechildhood.org/pf/parent-toolkit-student-privacy/] and Common Sense Media privacy evaluations of educational technology products https://privacy.commonsense.org/evaluations/1]).

The best thing parents can do to encourage digital literacy in their children is to talk openly and critically about media from the time children are young. For example, when watching a television show or using mobile technology, parents can express their skepticism or ask children their opinions. Alternatively, when children ask to buy a specific product, parents can ask questions to explore how advertising might have contributed to that desire. Parents can speak with younger children about what ads are trying to sell or why their favorite app has design features, such as autoplay, that keep them watching longer. For older children, discussions can revolve around influencers, unpacking messages about consumerism, or whether they understand all of their privacy settings. These are just a few examples of how such discussions allow parents to understand the extent of their children's literacy (or lack thereof), help to align children's media use with their family values, and help children to feel comfortable reaching out to their parents when they have concerns about online content or privacy.

For Providers

The AAP recommends the following:

1. Understand how children and teenagers are targeted by advertisers, and help parents understand children's specific vulnerability to persuasive design and targeted ads. Encourage parents to be discerning consumers of their child's media and demand better design and data collection practices.
2. Ask patients and families about any media use concerns as a part of routine health maintenance. Encourage families to use the AAP family media use plan to set media use limits, adopt privacy-preserving behaviors, and engage in parent-child communication regarding digital media.
3. Provide educational materials and references (listed above) to help parents and patients build digital literacy, as developmentally appropriate. Consider using a parent or child's use of a mobile device during visits as a teachable moment to identify ads or persuasive design (helpful resource: *AAP News* article on building digital literacy: https://www.aappublications.org/news/2019/04/24/masteringmedia042419).
4. Recommend parents to think of themselves as role models for

digital media use, digital citizenship, and digital literacy. Encourage discussions about Internet privacy and persuasive design, and recommend settings or filters to reduce ads and improve privacy.

5. Advocate for policies and regulations that limit advertising and data collection from children and teenagers. Pediatricians can advocate with local schools to avoid educational technology that is commercial and does not protect children's privacy. Pediatricians and parents can also ask for the establishment of digital literacy curricula in public schools so that children from all socioeconomic backgrounds can build equitable understanding of digital marketing and persuasive design.

For Industry and Policy Makers

The AAP recommends the following:

1. Policy makers and technology companies should adopt stricter privacy regulations for all users (including children and teenagers), which include data collection from home technologies, mobile devices, and other Internet-connected devices or toys. Disclosure of such collection should be prominently provided at appropriate literacy and developmental levels, and technology companies should report what data will be collected, how the data will be used, with whom data might be shared, and the risks and benefits to the consumer. Information about blocking this data collection and deleting personal information permanently should be provided. Default settings for platforms, programs, apps, and Internet-connected toys should be set at the highest level of privacy.
2. Strengthen COPPA enforcement to prohibit personal and location data collection from apps and Web sites clearly used by children younger than 13 years without parental consent and by anyone 13 to 17 years of age without the user's consent. For Web sites and apps used by multiple age groups, such as search engines and YouTube, provide alternative services that do not collect or aggregate data and that limit advertising. Ban targeted (ie, data-driven behavioral) advertising to individuals younger than 18 years.
3. Ban all commercial advertising to children younger than 7 years, and limit advertising to older children and teenagers. All advertising should be clearly labeled as such (eg, as sponsored content).
4. Prohibit in-app host selling and purchases, including loot boxes that pressure gamers to spend money during game play. Require clear separation of content and advertising in media designed for children, including product placement in child-directed videos.
5. Reduce advertising of unhealthy foods and beverages to children and teenagers, particularly targeted advertising that exacerbates disparities when combined with structural sources of inequality (eg, healthy food scarcity, public underinvestment in opportunities for exercise or play).
6. In accordance with the AAP policy statement on tobacco,[52] depictions of tobacco products (including e-cigarettes), tobacco product use, and images associated with tobacco product brands in movies and video games should be restricted. Internet sales of tobacco products should be banned because they are easily accessed by minors.
7. In accordance with previous AAP policy statements on marijuana[53] and alcohol,[54] limit access and marketing of these substances to youth (eg, by using mascots, cartoon characters, or influencers popular with children and teenagers).
8. Require and fund digital literacy curricula in schools. Prohibit use of digital media that contain advertising in the classroom.
9. Fund and promote research on the effects of advertising in digital media in children and teenagers to further identify risks inherent in data collection, digital profiling, and selective targeting of disadvantaged communities and to inform age-appropriate design guidance.
10. Increase efforts to promote digital equity by improving access to quality commercial-free content.

ABBREVIATIONS

AAP: American Academy of Pediatrics
COPPA: Children's Online Privacy and Protection Act
e-cigarette: electronic cigarette

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Jenny Radesky is a paid consultant and board member for Melissa & Doug. The other authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Statista. Spending on advertising to children worldwide from 2012 to 2021, by format (in billion US dollars). Available at: https://www.statista.com/statistics/750865/kids-advertising-spending-worldwide/. Accessed August 26, 2019
2. John DR. Consumer socialization of children: a retrospective look at twenty-five years of research. *J Consum Res*. 1999;26(3):183–213
3. Nairn A, Fine C. Who's messing with my mind? The implications of dual-process models for the ethics of advertising to children. *Int J Advert*. 2008;27(3):447–470
4. Hoffner C. Children's wishful identification and parasocial interaction with favorite television characters. *J Broadcast Electron Media*. 1996;40(3):389–402
5. Neeley SM, Schumann DW. Using animated spokes-characters in advertising to young children: does increasing attention to advertising necessarily lead to product preference? *J Advert*. 2004;33(3):7–23
6. Meyer M, Adkins V, Yuan N, Weeks HM, Chang YJ, Radesky J. Advertising in young children's apps: a content analysis. *J Dev Behav Pediatr*. 2019;40(1):32–39
7. Beales JH III. *Advertising to Kids and the FTC: A Regulatory Retrospective That Advises the Present*. Washington, DC: US Federal Trade Commission; 2004. Available at: https://www.ftc.gov/sites/default/files/documents/public_statements/advertising-kids-and-ftc-regulatory-retrospective-advises-present/040802adstokids.pdf. Accessed August 26, 2019
8. Campaign for a Commercial-Free Childhood, Center for Digital Democracy, and Public Citizen. Complaint, request for investigation, and request for policy guidance on the deceptive practice of influencer marketing directed to children. 2016. Available at: www.commercialfreechildhood.org/sites/default/files/FTCInfluencerComplaint.pdf. Accessed August 26, 2019
9. Goldfarb A. What is different about online advertising? *Rev Ind Organ*. 2014;44:115–129
10. Zarouali B, Ponnet K, Walrave M, Poels K. "Do you like cookies?" Adolescents' skeptical processing of retargeted Facebook-ads and the moderating role of privacy concern and a textual debriefing. *Comput Human Behav*. 2017;69:157–165
11. Binns R, Lyngs U, Van Kleek M, Zhao J, Libert T, Shadbolt N. Third party tracking in the mobile ecosystem. 2018. Available at: https://arxiv.org/pdf/1804.03603.pdf. Accessed October 1, 2019
12. Livingstone S, Stoilova M, Nandagiri R. *Children's Data and Privacy Online: Growing up in a Digital Age. An Evidence Review*. London: London School of Economics and Political Science; 2019
13. Gelman SA, Martinez M, Davidson NS, Noles NS. Developing digital privacy: children's moral judgments concerning mobile GPS devices. *Child Dev*. 2018;89(1):17–26
14. UK Information Commissioner's Office. Towards a better digital future: informing the age appropriate design code. 2019. Available at: https://ico.org.uk/media/about-the-ico/consultations/2614763/ico-rr-report-0703.pdf. Accessed August 26, 2019
15. Yao Y, Lo Re D, Wang Y. Folk models of online behavioral advertising. In: *Proceedings of the 2017 ACM Conference on Computer Supported Cooperative Work and Social Computing*; February 25–March 1, 2017; Portland, OR
16. US Federal Trade Commission. Complying with COPPA: frequently asked questions. Available at: https://www.ftc.gov/tips-advice/business-center/guidance/complying-coppa-frequently-asked-questions#General%20Questions. Accessed August 26, 2019
17. UK Information Commissioner's Office. Age appropriate design: a code of practice for online services: consultation document. 2019. Available at: https://ico.org.uk/media/about-the-ico/consultations/2614762/age-appropriate-design-code-for-public-consultation.pdf. Accessed August 26, 2019
18. Fogg BJ. *Persuasive Technology: Using Computers to Change What We Think and Do*. San Francisco, CA: Morgan Kaufmann Publishers; 2002
19. Verhellen Y, Oates C, De Pelsmacker P, Dens N. Children's responses to traditional versus hybrid advertising formats: the moderating role of persuasion knowledge. *J Consum Policy*. 2014;37:235–255
20. Druga S, Williams R, Breazeal C, Resnick M. "Hey Google is it OK if I eat you?": initial explorations in child-agent interaction. In: *Proceedings of the 2017 Conference on Interaction Design and Children*; June 27-30, 2017; Stanford, CA
21. US Federal Trade Commission. Review of food marketing to children and adolescents – follow-up report. Available at: https://www.ftc.gov/reports/review-food-marketing-children-adolescents-follow-report. Accessed August 26, 2019
22. Frazier WC, Harris JL. *Trends in Television Food Advertising to Young People: 2015 Update*. Hartford, CT: University of Connecticut Rudd Center for Food Policy & Obesity; 2016
23. Thai CL, Serrano KJ, Yaroch AL, Nebeling L, Oh A. Perceptions of food advertising and association with consumption of energy-dense nutrient-poor foods among adolescents in the United States: results from a national survey. *J Health Commun*. 2017;22(8):638–646
24. Pearson N, Biddle SJ. Sedentary behavior and dietary intake in children, adolescents, and adults. A systematic

review. *Am J Prev Med*. 2011;41(2):178–188

25. Rodd HD, Patel V. Content analysis of children's television advertising in relation to dental health. *Br Dent J*. 2005;199(11):710–712; discussion 713
26. Harris JL, Shehan C, Gross R, et al. *Food Advertising Targeted to Hispanic and Black Youth: Contributing to Health Disparities*. Hartford, CT: Rudd Center for Food Policy & Obesity; 2015
27. Beaudoin CE. The mass media and adolescent socialization: a prospective study in the context of unhealthy food advertising. *Journal Mass Commun Q*. 2014;91(3):544–561
28. Bragg MA, Miller AN, Elizee J, Dighe S, Elbel BD. Popular music celebrity endorsements in food and nonalcoholic beverage marketing. *Pediatrics*. 2016;138(1):e20153977
29. Coates AE, Hardman CA, Halford JC, Christiansen P, Boyland EJ. Social media influencer marketing and children's food intake: a randomized trial. *Pediatrics*. 2019;143(4):e20182554
30. Folkvord F, Anschütz DJ, Nederkoorn C, Westerik H, Buijzen M. Impulsivity, "advergames," and food intake. *Pediatrics*. 2014;133(6):1007–1012
31. Perks SN, Armour B, Agaku IT. Cigarette brand preference and pro-tobacco advertising among middle and high school students - United States, 2012–2016. *MMWR Morb Mortal Wkly Rep*. 2018;67(4):119–124
32. Agaku IT, Ayo-Yusuf OA. The effect of exposure to pro-tobacco advertising on experimentation with emerging tobacco products among US adolescents. *Health Educ Behav*. 2014;41(3):275–280
33. Mantey DS, Cooper MR, Clendennen SL, Pasch KE, Perry CL. E-cigarette marketing exposure is associated with e-cigarette use among US youth. *J Adolesc Health*. 2016;58(6):686–690
34. Singh T, Marynak K, Arrazola RA, Cox S, Rolle IV, King BA. Vital signs: exposure to electronic cigarette advertising among middle school and high school students - United States, 2014. *MMWR Morb Mortal Wkly Rep*. 2016;64(52):1403–1408
35. Huang J, Kornfield R, Szczypka G, Emery SL. A cross-sectional examination of marketing of electronic cigarettes on Twitter. *Tob Control*. 2014;23(suppl 3):iii26-iii30
36. Jernigan DH, Rushman AE. Measuring youth exposure to alcohol marketing on social networking sites: challenges and prospects. *J Public Health Policy*. 2014;35(1):91–104
37. D'Amico EJ, Martino SC, Collins RL, et al. Factors associated with younger adolescents' exposure to online alcohol advertising. *Psychol Addict Behav*. 2017;31(2):212–219
38. Alaniz ML, Wilkes C. Pro-drinking messages and message environments for young adults: the case of alcohol industry advertising in African American, Latino, and Native American communities. *J Public Health Policy*. 1998;19(4):447–472
39. Jernigan D, Noel J, Landon J, Thornton N, Lobstein T. Alcohol marketing and youth alcohol consumption: a systematic review of longitudinal studies published since 2008. *Addiction*. 2017;112(suppl 1):7–20
40. Fiala SC, Dilley JA, Firth CL, Maher JE. Exposure to marijuana marketing after legalization of retail sales: Oregonians' experiences, 2015-2016. *Am J Public Health*. 2018;108(1):120–127
41. Cabrera-Nguyen EP, Cavazos-Rehg P, Krauss M, Bierut LJ, Moreno MA. Young adults' exposure to alcohol- and marijuana-related content on Twitter. *J Stud Alcohol Drugs*. 2016;77(2):349–353
42. Siahpush M, Farazi PA, Kim J, et al. Social disparities in exposure to point-of-sale cigarette marketing. *Int J Environ Res Public Health*. 2016;13(12):E1263
43. Krauss MJ, Sowles SJ, Sehi A, et al. Marijuana advertising exposure among current marijuana users in the U.S. *Drug Alcohol Depend*. 2017;174:192–200
44. D'Amico EJ, Miles JN, Tucker JS. Gateway to curiosity: medical marijuana ads and intention and use during middle school. *Psychol Addict Behav*. 2015;29(3):613–619
45. Ricklefs CA, Asdigian NL, Kalra HL, et al. Indoor tanning promotions on social media in six US cities #UVTanning #tanning. *Transl Behav Med*. 2016;6(2):260–270
46. Myrick JG, Noar SM, Kelley D, Zeitany AE. The relationships between female adolescents' media use, indoor tanning outcome expectations, and behavioral intentions. *Health Educ Behav*. 2017;44(3):403–410
47. Gall Myrick J, Noar SM, Sontag JM, Kelley D. Connections between sources of health and beauty information and indoor tanning behavior among college women. *J Am Coll Health*. 2020;68(2):163–168
48. Radesky JS, Eisenberg S, Kistin CJ, et al. Overstimulated consumers or next-generation learners? Parent tensions about child mobile technology use. *Ann Fam Med*. 2016;14(6):503–508
49. Callaghan MN, Reich SM. Are educational preschool apps designed to teach? An analysis of the app market. *Learn Media Technol*. 2018;43(3):280–293
50. Council on Communications and Media. Media and young minds. *Pediatrics*. 2016;138(5):e20162591
51. Reid Chassiakos YL, Radesky J, Christakis D, Moreno MA, Cross C; Council on Communications and Media. Children and adolescents and digital media. *Pediatrics*. 2016;138(5):e20162593
52. Farber HJ, Nelson KE, Groner JA, Walley SC; Section on Tobacco Control. Public policy to protect children from tobacco, nicotine, and tobacco smoke. *Pediatrics*. 2015;136(5):998–1007
53. Committee on Substance Abuse; Committee on Adolescence. The impact of marijuana policies on youth: clinical, research, and legal update. *Pediatrics*. 2015;135(3):584–587
54. Quigley J; Committee on Substance Use and Prevention. Alcohol use by youth. *Pediatrics*. 2019;144(1):e20191356

Drugs Used to Treat Pediatric Emergencies

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Drugs Used to Treat Pediatric Emergencies

Rohit P. Shenoi, MD, FAAP,[a] Nathan Timm, MD, FAAP,[b] COMMITTEE ON DRUGS, COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE

abstract

This clinical report is a revision of "Preparing for Pediatric Emergencies: Drugs to Consider." It updates the list, indications, and dosages of medications used to treat pediatric emergencies in the prehospital, pediatric clinic, and emergency department settings. Although it is not an all-inclusive list of medications that may be used in all emergencies, this resource will be helpful when treating a vast majority of pediatric medical emergencies. Dosage recommendations are consistent with current emergency references such as the *Advanced Pediatric Life Support* and *Pediatric Advanced Life Support* textbooks and American Heart Association resuscitation guidelines.

[a]*Texas Children's Hospital and Department of Pediatrics, Baylor College of Medicine, Houston, Texas; and* [b]*Cincinnati Children's Hospital Medical Center and Department of Pediatrics, College of Medicine, University of Cincinnati, Cincinnati, Ohio*

Drs Shenoi and Timm prepared, reviewed, revised, and approved the final manuscript, including the drug tables and references; and all authors approved the final manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2019-3450

Address correspondence to Rohit Shenoi. E-mail: rshenoi@bcm.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

To cite: Shenoi RP, Timm N, AAP COMMITTEE ON DRUGS, AAP COMMITTEE ON DRUGS, AAP COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE. Drugs Used to Treat Pediatric Emergencies. *Pediatrics.* 2020;145(1):e20193450

INTRODUCTION

Most children present for emergency medical care in physicians' offices, the prehospital setting, or the emergency department (ED). Roughly 28 million (27%) of the annual ED visits in the United States are by children younger than 19 years.[1] Approximately 7% of these children reach the hospital via emergency medical services (EMS).[1] EMS agencies provide the majority of out-of-hospital emergency care to children. Of the 4800 general and short-stay hospitals with 24-hour EDs in the United States during 2006, the majority (87%) admitted children, but only 10% were children's hospitals or had PICUs. A majority (84%) of hospitals would send pediatric patients requiring intensive care to another hospital.[2] Approximately 30% of emergency pediatric visits occurred in children's hospitals.[2] Medical emergencies may occur between once or more per week and once or more per month in pediatricians' offices.[3,4] Given the scope of pediatric emergency care in the United States and to facilitate consistency in the pharmacotherapy of medical emergencies in children, it is incumbent that all health providers who manage critically ill or injured children be knowledgeable of the medications used to treat pediatric emergencies. Changes in the pattern and scope of practice, changes in the dosages and indications of medications, availability of newer drugs, and the discontinuation of older pharmacotherapeutic agents make it necessary to stay updated.

This document will be helpful to medical practitioners in the clinic, prehospital setting, and ED. The Supplemental Information contains several tables, each listing medications used to treat pediatric emergencies on the basis of organ system or context (eg, drugs used in disasters). The indications, dosing, and practical points regarding drug administration are described. Description of medication adverse effects is limited. Some drugs may be listed in multiple places because of overlapping indications. Antimicrobial agents (except for in disaster situations), vaccines, and chemotherapeutic agents are not included. The practitioner is referred to the American Academy of Pediatrics (AAP) *Red Book: Report of the Committee on Infectious Diseases* for the treatment of infections.[5] In addition, some drugs that are used to treat pediatric emergencies in consultation with an appropriate medical subspecialist (eg, tissue plasminogen for stroke, intravenous [IV] methylprednisolone for transverse myelitis) are not listed. Dosages are generally provided as milligrams per kilogram. The format for presented dosages is consistent with AAP recommendations for reducing medication errors.[6] Some high-potency drugs, such as prostaglandins, vasopressors, nitroprusside, and fentanyl, have their dosages provided in μg per kilogram. The reader is referred to resources for the safe prescription, administration, and monitoring of medications in their patients.[6]

The IV route is preferred for the administration of medications in an emergency. However, when prompt IV access is not possible, emergency intraosseous administration is an acceptable alternative. The practitioner is advised to consult the pharmacist on the appropriate infusion system whenever possible. Certain drugs (lidocaine, epinephrine, atropine, naloxone [memory aid: LEAN]) can be administered by the endotracheal tube (ET) if no vascular access can be obtained. However, intratracheal drug administration results in lower, less predictable drug concentrations than intravascular administration and is not preferred. If the ET route is used, the drug should be administered with or diluted in 1 to 5 mL of isotonic saline solution followed by manual ventilations. ET administration of naloxone is not recommended for neonates. Newer methods of drug administration in children include the intranasal and intrabuccal routes. These are especially useful in sedation, analgesia, and seizure control. When administering drugs by the intranasal route, it is preferable to use a mucosal atomizer to mist the drug rather than a syringe to drip the medication into the nostrils.

To date, the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act have resulted in expanded labeling with pediatric-specific information for more than700 drugs.[7] However, gaps in pediatric labeling and dosing information still exist.[8] The reader is encouraged to consult package inserts, drug labels, and medical literature for more information. In some situations, pediatricians may need to prescribe certain medications "off label" for important illnesses. A drug's off-label status does not imply an improper or experimental use. The decision to prescribe these medications off label should be based on expert opinion or evidence for the medication's use in a different population. The reader is referred to the AAP policy statement "Off-Label Use of Drugs in Children"[9] and the US Food and Drug Administration (FDA) for changes in pediatric labeling of drugs.[7]

The information in this document is based on literature review and consensus opinion. References for individual drug indications and dosing are provided. Dosing should be individualized, taking into account the patient's weight in kilograms, medical illness, age, concurrently administered drugs, and drug hypersensitivity history. Within each table, the drugs are listed alphabetically and not by importance of use. The selection of a particular drug may depend on practice variability and drug availability (ie, hospital formulary or drug shortages).

The committees recommend the use of current *Advanced Pediatric Life Support*[10] and *Pediatric Advanced Life Support*[11] textbooks, updated American Heart Association guidelines,[12–14] and additional references for more detailed information on pediatric resuscitation algorithms, rapid-sequence intubation (RSI), procedural sedation,[15] and medical management in disasters.[16,17] In addition, the reader is referred to published treatment guidelines[18]; clinical reports, technical reports, and policy statements[19–31]; and consensus opinion.[32] Practitioners should consult the *Textbook of Neonatal Resuscitation* and updated American Heart Association guidelines for detailed information concerning the management of neonatal emergencies and appropriate drugs, dosages, and routes of administration.[33] The Neonatal Resuscitation Program is focused on care of the newly born infant, and there is no clear evidence to guide when it is appropriate to use *Advanced Pediatric Life Support* guidelines in the care of an infant. General recommendations are currently to decide which drug to use on the basis of the likely etiology of the problem. The use of preprinted weight-based medication cards and/or length-based resuscitation tapes[34] is recommended when treating an emergency regardless of location (prehospital, ED, hospital ward, outpatient, or community clinic).

Note that doses listed are not comprehensive, and variations in dosing may be indicated for specific patients and/or clinical situations.

LEAD AUTHORS

Rohit Shenoi, MD, FAAP
Nathan Timm, MD, FAAP

COMMITTEE ON DRUGS, 2016–2019

Bridgette Jones, MD, FAAP, Chairperson
Kathleen Neville, MD, MS, MBA, FAAP, Past Chairperson
Jennifer Foster, MD, FAAP
Connie Houck, MD, FAAP
Matthew Laughon, MD, FAAP
Ian Paul, MD, FAAP
Routt J. Reigart, MD, FAAP
Rohit Shenoi, MD, FAAP
Janice Sullivan, MD, FAAP
John van den Anker, MD, PhD, FAAP

LIAISONS

John J. Alexander, MD, MPH, FAAP – *Food and Drug Administration*
Janet D. Cragan, MD, MPH, FAAP – *Centers for Disease Control and Prevention*
Angela Gantt, MD – *American College of Obstetricians and Gynecologists*
Phillip Heine, MD – *American College of Obstetricians and Gynecologists*
Michael Rieder, MD, FAAP – *Canadian Paediatric Society*
Adelaide Robb, MD – *American Academy of Child and Adolescent Psychiatry*
Hari Sachs, MD, FAAP – *Food and Drug Administration*
Geert W. 't Jong, MD, PhD – *Canadian Paediatric Society*
Timothy Wilens, MD – *American Academy of Child and Adolescent Psychiatry*
Anne Zajicek, MD, PharmD, FAAP – *National Institutes of Health*
Perdita Taylor-Zapata, MD – *National Institutes of Health*

STAFF

Raymond J. Koteras, MHA
James Baumberger
Tamar Margarik Haro

COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE, 2016–2019

Joseph Wright, MD, MPH, FAAP, Chairperson
Terry Adirim, MD, MPH, FAAP
James Callahan, MD, FAAP
Michael Agus, MD, FAAP
Javier Gonzalez del Rey, MD, MEd, FAAP
Toni Gross, MD, MPH, FAAP
Madeline Joseph, MD, FAAP
Natalie Lane, MD, FAAP
Lois Lee, MD, MPH, FAAP
Elizabeth Mack, MD, FAAP
Prashant Mahajan, MD, MPH, MBA, FAAP
Jennifer Marin, MD, FAAP
Suzan Mazor, MD, FAAP
Nathan Timm, MD, FAAP

LIAISONS

Elizabeth Edgerton, MD, MPH, FAAP – *US Department of Health and Human Services, Maternal and Child Health Bureau*
Andrew Eisenberg, MD, MHA – *American Academy of Family Physicians*
Mary Fallat, MD, FAAP – *American College of Surgeons and American Academy of Pediatrics Section on Surgery*
Marianne Gausche-Hill, MD, FAAP – *National Pediatric Readiness Project*
Cynthiana Lightfoot – *Family Partnerships Network*
Charles Macias, MD, MPH, FAAP – *Emergency Medical Services for Children Innovation and Improvement Center*
Brian Moore, MD, FAAP – *National Association of EMS Physicians*
Diane Pilkey, RN, MPH – *US Department of Health and Human Services, Maternal and Child Health Bureau*
Katherine Remick, MD, FAAP – *National Association of Emergency Medical Technicians*
Mohsen Saidinejad, MD, MBA, FAAP – *American College of Emergency Physicians*
Sally Snow, RN, BSN – *Emergency Nurses Association*
David Tuggle, MD, FAAP – *American College of Surgeons and American Academy of Pediatrics Section on Surgery*
Cynthia Wright-Johnson, MSN, RNC – *National Association of State EMS Officials*

STAFF

Sue Tellez

ABBREVIATIONS

AAP: American Academy of Pediatrics
ED: emergency department
EMS: emergency medical services
ET: endotracheal tube
FDA: Food and Drug Administration
IV: intravenous
RSI: rapid-sequence intubation

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Cottrell EK, O'Brien K, Curry M, et al. Understanding safety in prehospital emergency medical services for children. *Prehosp Emerg Care*. 2014;18(3):350–358
2. Schappert SM, Bhuiya F. Availability of pediatric services and equipment in emergency departments: United States, 2006. *Natl Health Stat Rep*. 2012;(47):1–21
3. Pendleton AL, Stevenson MD. Outpatient emergency preparedness: a survey of pediatricians. *Pediatr Emerg Care*. 2015;31(7):493–495
4. Santillanes G, Gausche-Hill M, Sosa B. Preparedness of selected pediatric offices to respond to critical emergencies in children. *Pediatr Emerg Care*. 2006;22(11):694–698
5. American Academy of Pediatrics. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*, 31st ed. Itasca, IL: American Academy of Pediatrics; 2018
6. Benjamin L, Frush K, Shaw K, Shook JE, Snow SK; American Academy of Pediatrics Committee on Pediatric Emergency Medicine; American College of Emergency Physicians

Pediatric Emergency Medicine Committee; Emergency Nurses Association Pediatric Emergency Medicine Committee. Pediatric medication safety in the emergency department. *Pediatrics*. 2018;141(3): e20174066

7. US Food and Drug Administration. New pediatric labeling information database. Available at: http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=labelingdatabase. Accessed May 18, 2017
8. Smith MC, Williamson J, Yaster M, Boyd GJC, Heitmiller ES. Off-label use of medications in children undergoing sedation and anesthesia. *Anesth Analg*. 2012;115(5):1148–1154
9. Frattarelli DA, Galinkin JL, Green TP, et al; American Academy of Pediatrics Committee on Drugs. Off-label use of drugs in children. *Pediatrics*. 2014; 133(3):563–567
10. American Academy of Pediatrics, American College of Emergency Physicians. In: Fuchs S, Yamamoto L, eds. *The Pediatric Emergency Medicine Resource*, 5th ed. Burlington, MA: Jones and Bartlett Learning; 2012
11. American Heart Association, Subcommittee on Pediatric Resuscitation. *PALS (Pediatric Advanced Life Support) Provider Manual*. Dallas, TX: American Heart Association; 2011
12. de Caen AR, Berg MD, Chameides L, et al. Part 12: pediatric advanced life support: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2015;132(18, suppl 2): S526–S542
13. Maconochie IK, de Caen AR, Aickin R, et al; Pediatric Basic Life Support and Pediatric Advanced Life Support Chapter Collaborators. Part 6: pediatric basic life support and Pediatric Advanced Life Support: 2015 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. *Resuscitation*. 2015; 95:e147–e168
14. Kleinman ME, Chameides L, Schexnayder SM, et al. Part 14: pediatric advanced life support: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2010;122(18, suppl 3): S876–S908
15. Coté CJ, Wilson S; American Academy of Pediatrics; American Academy of Pediatric Dentistry. Guidelines for monitoring and management of pediatric patients before, during, and after sedation for diagnostic and therapeutic procedures: update 2016. *Pediatrics*. 2016;138(1):e20161212
16. Disaster Preparedness Advisory Council. Medical countermeasures for children in public health emergencies, disasters, or terrorism. *Pediatrics*. 2016;137(2):e20154273
17. Foltin GL. Pediatric Terrorism and Disaster Preparedness Resource (PTDPR). Available at: http://slideplayer.com/slide/6305475/. Accessed April 28, 2017
18. National Asthma Education and Prevention Program. *Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Publication 08-5846*. Bethesda, MD: National Institutes of Health, National Heart, Lung and Blood Institute; 2007
19. Frush K; American Academy of Pediatrics Committee on Pediatric Emergency Medicine. Preparation for emergencies in the offices of pediatricians and pediatric primary care providers. *Pediatrics*. 2007;120(1): 200–212
20. Puopolo KM, Benitz WE, Zaoutis TE; Committee on Fetus and Newborn; Committee on Infectious Diseases. Management of neonates born at ≤34 6/7 weeks' gestation with suspected or proven early-onset bacterial sepsis. *Pediatrics*. 2018;142(6):e20182896
21. Puopolo KM, Benitz WE, Zaoutis TE; Committee on Fetus and Newborn; Committee on Infectious Diseases. Management of neonates born at ≥35 0/7 weeks' gestation with suspected or proven early-onset bacterial sepsis. *Pediatrics*. 2018;142(6):e20182894
22. Sullivan JE, Farrar HC; Section on Clinical Pharmacology and Therapeutics, Committee on Drugs. Fever and antipyretic use in children. *Pediatrics*. 2011;127(3):580–587
23. Chun TH, Mace SE, Katz ER; American Academy of Pediatrics; Committee on Pediatric Emergency Medicine; American College of Emergency Physicians; Pediatric Emergency Medicine Committee. Executive summary: evaluation and management of children and adolescents with acute mental health or behavioral problems. Part I: common clinical challenges of patients with mental health and/or behavioral emergencies. *Pediatrics*. 2016;138(3): e20161571
24. Bradley JS, Peacock G, Krug SE, et al; AAP Committee on Infectious Diseases and Disaster Preparedness Advisory Council. Pediatric anthrax clinical management. *Pediatrics*. 2014;133(5). Available at: www.pediatrics.org/cgi/content/full/133/5/e1411
25. Crawford-Jakubiak JE, Alderman EM, Leventhal JM; Committee on Child Abuse and Neglect; Committee on Adolescence. Care of the adolescent after an acute sexual assault. *Pediatrics*. 2017;139(3): e20164243
26. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep*. 2015;64(RR-03):1–137
27. Bradley JS, Byington CL, Shah SS, et al. The management of community-acquired pneumonia in infants and children older than 3 months of age: clinical practice guidelines by the Pediatric Infectious Diseases Society and the Infectious Diseases Society of America. *Clin Infect Dis*. 2011;53(7): e1–e52
28. Fein JA, Zempsky WT, Cravero JP; American Academy of Pediatrics; Committee on Pediatric Emergency Medicine, Section on Anesthesiology and Pain Medicine. Relief of pain and anxiety in pediatric patients in emergency medical systems. *Pediatrics*. 2012;130(5). Available at: www.pediatrics.org/cgi/content/full/130/5/e1391
29. Yamamoto LG, Manzi S; Committee on Pediatric Emergency Medicine. Dispensing medications at the

hospital upon discharge from an emergency department. *Pediatrics*. 2012;129(2). Available at: www.pediatrics.org/cgi/content/full/129/2/e562

30. Rogers JJ; American College of Emergency Physicians. Policy compendium 2016 edition. Available at: https://www.acep.org/search.aspx?searchtext=policy%20compendium. Accessed August 15, 2016
31. Ralston SL, Lieberthal AS, Meissner HC, et al; American Academy of Pediatrics. Clinical practice guideline: the diagnosis, management, and prevention of bronchiolitis. *Pediatrics*. 2014;134(5). Available at: www.pediatrics.org/cgi/content/full/134/5/e1474
32. Dart RC, Goldfrank LR, Erstad BL, et al. Expert consensus guidelines for stocking of antidotes in hospitals that provide emergency care. *Ann Emerg Med*. 2018;71(3):314–325.e1
33. Wyckoff MH, Aziz K, Escobedo MB, et al. Part 13: neonatal resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2015;132(18, suppl 2):S543–S560
34. Resources for Management of Circulatory Emergencies. *Pediatric Advanced Life Support (PALS) Provider Manual. Dallas, TX: American Heart Association*. Elk Grove Village, IL: American Academy of Pediatrics; 2016:237–238

Electronic Documentation in Pediatrics: The Rationale and Functionality Requirements

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Electronic Documentation in Pediatrics: The Rationale and Functionality Requirements

Heather C. O'Donnell, MD, MSc, FAAP,[a,b] Srinivasan Suresh, MD, MBA, FAAP,[c] COUNCIL ON CLINICAL INFORMATION TECHNOLOGY

Clinical documentation is a fundamental component of the practice of medicine. It has significantly evolved over the past decade, largely because of the growth of health information technology and electronic health records. Although government agencies and other professional organizations have published position statements on the structure and use of electronic documentation, few have specifically addressed the documentation needs for the care of children. A policy statement on electronic documentation of clinical care by general pediatric and subspecialist providers by the American Academy of Pediatrics is needed. This statement provides insight on the unmet needs of key stakeholders to direct future research and development of the electronic media necessary to enhance the wellness of children and improve health care delivery. It also addresses the challenges and opportunities for efficient and effective clinical documentation in pediatrics.

BACKGROUND INFORMATION

The move from paper charting to electronic documentation has created a need for guidance to facilitate pediatricians' ability to effectively communicate the clinical picture while accurately reflecting the extent and quality of care provided. The American College of Physicians and the American Medical Informatics Association have published guiding principles regarding clinical documentation, focusing on the primary role of documentation for patient-centered clinical care and improving outcomes.[1–3] In addition to advancing these principles, more methods to reduce documentation burden and manage information overload are warranted. Furthermore, there are unique requirements for pediatric documentation that should be clarified for pediatric generalists and subspecialists, such as means to record adolescent information confidentially and to communicate medical history with schools.

abstract

[a]Department of Pediatrics, Children's Hospital at Montefiore and Albert Einstein College of Medicine, Bronx, New York; [b]Pediatric Physicians' Organization at Children's Hospital, Boston Children's Hospital, Brookline, Massachusetts; and [c]Divisions of Health Informatics and Emergency Medicine, Department of Pediatrics, University of Pittsburgh School of Medicine and UPMC Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania

Drs O'Donnell and Suresh equally contributed as coauthors to draft, review, and revise the manuscript with input of all reviewers and the Board of Directors, and both authors approved the final manuscript as submitted.

DOI: https://doi.org/10.1542/peds.2020-1682

Address correspondence to Heather C. O'Donnell, MD, MSc, FAAP. E-mail: heather.odonnell@childrens.harvard.edu

To cite: O'Donnell HC, Suresh S, AAP COUNCIL ON CLINICAL INFORMATION TECHNOLOGY. Electronic Documentation in Pediatrics: The Rationale and Functionality Requirements. *Pediatrics*. 2020;146(1):e20201682

The Agency for Healthcare Research and Quality technical brief on core functionality in pediatric electronic health records (EHRs), the Health Level Seven International Child Health Functional Profile for EHR Systems, and a few American Academy of Pediatrics (AAP) policy statements comprehensively delineate specific EHR functionality needs of pediatricians.[4–8] However, specific guidelines on documentation content and workflow in existing and future systems are imperative to align documentation tasks with the core tenets of pediatric care.

This policy statement addresses the common barriers that pediatric practitioners face in dealing with clinical documentation. A clear policy will serve as a guiding force in prioritizing the key elements of a patient note, navigating the complex world of electronic documentation implementation and enhancement, and focusing research efforts on ideas that show promise in decreasing clinical burden and improving care. The accompanying technical report provides a background for the recommendations in this statement.[9]

STATEMENT OF PROBLEM

Electronic clinical documentation is a requirement for the Centers for Medicare & Medicaid Services' Meaningful Use program (renamed Promoting Interoperability)[10] and has been adopted by the majority of hospitals and clinics in the United States,[11,12] but current certification and implementation standards for EHRs provide few specific guidelines on documentation content and workflows. In addition, the documentation needs of child health providers are often different from those of providers caring for adults. Yet, there has not been a unique focus on defining the best practices for electronic clinical documentation in pediatric populations.

The change from paper-based to electronic documentation has had many benefits but has introduced additional regulatory requirements, presented new threats to the utility of patient notes, and galvanized both the desire and opportunity to use clinical documentation for additional purposes. Multiple stakeholders with differing priorities (clinical, regulatory, research, quality, and economic) and varying abilities of some providers to interact efficiently with electronic systems have contributed to increased documentation burden and physician burnout.[13–16] Considering these issues, clear guidance on clinical documentation is needed.

SUMMARY AND CONCLUSIONS

Clinical communication and, hence, documentation are at the heart of the practice of medicine. Electronic documentation, now broadly adopted, has been accepted as the standard medium. A great deal has been learned during the transition to electronic documentation, including the opportunity to discover the unintended consequences of various tools and workflows. Importantly, we have recognized that paper notes of the past cannot be directly translated into an EHR format. Although it has offered many advantages, the transition to electronic notes has changed the very nature of the structure, workflow, and use of documentation.[17] The roles and use of documentation have expanded, but its primary role to support clinical reasoning and communication should always be paramount. Building on this knowledge, this is an opportune time for the AAP to implement guidance to direct care and clinical documentation in the 21st century to best serve the needs of pediatric providers, patients, and families.

Multiple barriers must be overcome to implement these recommendations. In local and vendor EHR development, there will always be competing priorities to this primary function of supporting clinical reasoning and communication, including regulatory obligations[18] and requirements tied to fiscal reimbursement.[10] In addition, there may be difficulty engaging vendors in pediatric-specific projects because children represent a smaller percentage of overall health care usage and burden. Gaining a consensus among child health care providers on needs and priorities and advocacy from pediatric organizations could be helpful in this regard. As part of the implementation of the 21st Century Cures Act, the Office of the National Coordinator for Health Information Technology has proposed new criteria to support voluntary certification of health information technology for use by pediatric clinicians; this may advance the recognition and prioritization of pediatric needs by EHR vendors.[19]

One of the key recommendations is ensuring representation from all stakeholders when considering electronic documentation implementation, changes, and enhancements. However, convening a large group of stakeholders and gaining consensus can be time consuming and laborious. In addition, clinical providers often do not have dedicated time or a percentage of full-time equivalents allotted for this work. Yet, the early and complete engagement of clinical providers and/or end users is critical to the successful development and implementation of electronic documentation.

Ideally, clinical informaticists should facilitate clinical documentation improvement. They can bridge the gap of understanding between frontline clinicians and health information technology professionals and vendors. Clinical informaticists

can also provide expertise on the best practices on clinical documentation improvement. When having a trained clinical informaticist is not feasible, such as in smaller health care settings, the role of EHR vendor user groups and professional clinical informatics organizations, such as the AAP Council on Clinical Information Technology and the American Medical Informatics Association, becomes vital.

This policy statement stresses the importance of research of documentation structure, content workflows, and functionalities to determine best practices. However, such evaluations may be arduous because of the difficulty in assessing documentation quality and its ability to effectively communicate information to stakeholders. Although standard measures of documentation quality are being developed,[20] they often require manual review of notes. Automated methods to continuously monitor documentation quality would be more efficient.

RECOMMENDATIONS

1. EHR documentation functionalities, including documentation templates, data entry, and display, need to support the pediatric care core values of age-based, longitudinal, and family-centered care. To address this, professional pediatric-focused organizations and health care institutions should conduct the following:
   a. work with stakeholders to build consensus on documents that should be standardized, such as school forms, for integration into all EHRs;
   b. continue to advocate for pediatric-specific documentation needs to EHR vendors and developers;
   c. support the creation and dissemination of models and best practice guidelines for pediatric electronic documentation; and
   d. promote the development of policies and methods to facilitate the seamless sharing of electronic documentation tools (eg, templates and workflows) and data across child health providers nationally.
2. Models of shared documentation among health care providers and with patients, caregivers, and other key stakeholders (eg, adolescents, schools, and immunization registries) should continue to be explored as a means to improve clinical communication among care teams, facilitate health outcomes tracking, and potentially reduce documentation burden for providers. Effective models could be incorporated in developing health information exchanges.
3. Tools and strategies aimed at relieving documentation burden should be developed and researched to understand their impact on documentation time and clinical care as well as on satisfying evaluation and management codes and other regulatory requirements. Examples of potential tools and strategies include the following:
   a. automated data entry (eg, device integration and barcoding);
   b. documentation task distribution (eg, integration of patient-generated health data);
   c. elimination of redundancy that is consistent with family-centered care (eg, linkages for family and social history); and
   d. alternative documentation methods (eg, speech recognition and scribes).
4. Mechanisms to mitigate information overload, such as enhanced data displays, search tools, and streamlined and standardized note structures, need to be developed and studied.
5. Professional organizations and health care institutions should refine pediatric data definitions and partner with EHR vendors to integrate these standards into electronic systems.
6. The reuse of clinical documentation to support regulatory requirements, evaluation and management codes, research, and quality improvement efforts should be supported. However, there must also be clear understanding and mitigation of any negative impacts on the clinical narrative, usefulness as a clinical communication tool, and documentation burden.
   a. Guidelines for the appropriate attainment of data from clinical documentation should continue to be developed and propagated. For example, the completion of a task within the EHR should be captured as its own documentation. Additional documentation that the task was completed should not be required.
   b. Although complete discrete data are often most useful for reuse, the documentation of incomplete discrete data should be enabled if clinically relevant, for example, the ability to record that a patient received a vaccine even if the exact preparation or month and day of receipt are unknown.
   c. National research organizations and the health information technology industry should support research in alternative models and technology to facilitate the reuse of clinical data (eg, natural language understanding).
7. All documentation implementation and improvement initiatives should include representation from medical providers including trainees and attending physicians as well as, if possible, patient and family representatives and specialists in health information management, quality

improvement, reporting, research, billing, and clinical informatics.

8. Medical schools, residency programs, and physician licensing boards should integrate continuing electronic documentation training into their curricula using Accreditation Council for Graduate Medical Education program requirements as a guide. Attending physicians should provide timely and frequent feedback to trainees regarding documentation quality. In addition, EHRs should support clear delineation of trainee documentation and attending attestation.

LEAD AUTHORS

Heather C. O'Donnell, MD, MSc, FAAP
Srinivasan Suresh, MD, MBA, FAAP

COUNCIL ON CLINICAL INFORMATION TECHNOLOGY EXECUTIVE COMMITTEE, 2018–2019

Emily Chui Webber, MD, FAAP
Gregg M. Alexander, DO
Sandy Lee Chung, MD, FAAP
Alexander M. Hamling, MD, MBA, FAAP
Eric S. Kirkendall, MD, MBI, FAAP
Ann M. Mann, MD, FAAP
Heather C. O'Donnell, MD, MSc, FAAP
Reza Sadeghian, MD, MBA, MSc, FAAP
Eric Shelov, MD, MBI, FAAP
Srinivasan Suresh, MD, MBA, FAAP
Andrew M. Wiesenthal, MD, SM, FAAP

LIAISONS

Dale C. Alverson, MD, FAAP – *Section on Telehealth Care*
Francis Dick-Wai Chan, MD, FAAP – *Section on Advances in Therapeutics and Technology*
Melissa S. Van Cain, MD, FAAP – *Section on Pediatric Trainees*

STAFF

Lisa Krams, MAHS

ABBREVIATIONS

AAP: American Academy of Pediatrics
EHR: electronic health record

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Kuhn T, Basch P, Barr M, Yackel T; Medical Informatics Committee of the American College of Physicians. Clinical documentation in the 21st century: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med*. 2015;162(4):301–303
2. Cusack CM, Hripcsak G, Bloomrosen M, et al. The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting. *J Am Med Inform Assoc*. 2013;20(1):134–140
3. McGowan JJ, Cusack CM, Bloomrosen M. The future of health IT innovation and informatics: a report from AMIA's 2010 Policy Meeting. *J Am Med Inform Assoc*. 2012;19(3):460–467
4. Dufendach KR, Eichenberger JA, McPheeters ML; Agency for Healthcare Research and Quality. Core functionality in pediatric electronic health records. Available at: https://effectivehealthcare.ahrq.gov/topics/pediatric-ehr/technical-brief. Accessed January 10, 2018
5. Health Level Seven International. HL7 EHR Child Health Functional Profile (CHFP), release 1. Available at: www.hl7.org/implement/standards/product_brief.cfm?product_id=15. Accessed January 10, 2018
6. American Academy of Pediatrics Council on Clinical Information Technology. Policy statement: Electronic prescribing in pediatrics: toward safer and more effective medication management. *Pediatrics*. 2013;131(4):824–826
7. Spooner SA; Council on Clinical Information Technology, American Academy of Pediatrics. Special requirements of electronic health record systems in pediatrics. *Pediatrics*. 2007;119(3):631–637
8. Lehmann CU; Council on Clinical Information Technology. Pediatric aspects of inpatient health information technology systems. *Pediatrics*. 2015;135(3). Available at: www.pediatrics.org/cgi/content/full/135/3/e756
9. O'Donnell HC, Suresh S; Council on Clinical Information Technology. Electronic documentation in pediatrics: the rationale and functionality requirements. *Pediatrics*. 2020;146(1):e20201684
10. Office of the National Coordinator for Health Information Technology. Promoting interoperability. Available at: https://www.healthit.gov/topic/meaningful-use-and-macra/promoting-interoperability. Accessed June 4, 2020
11. Charles D, Gabriel M, Searcy T; Office of the National Coordinator for Health Information Technology. Adoption of electronic health record systems among U.S. non-federal acute care hospitals: 2008-2014. 2015. Available at: https://www.healthit.gov/sites/default/files/data-brief/2014HospitalAdoptionDataBrief.pdf. Accessed January 12, 2018
12. Office of the National Coordinator for Health Information Technology. Office-based physician electronic health record adoption. Available at: https://dashboard.healthit.gov/quickstats/pages/physician-ehr-adoption-trends.php. Accessed January 12, 2018

13. Tutty MA, Carlasare LE, Lloyd S, Sinsky CA. The complex case of EHRs: examining the factors impacting the EHR user experience [published correction appears in *J Am Med Inform Assoc*. 2019;26(11):1424]. *J Am Med Inform Assoc*. 2019;26(7): 673–677

14. Gardner RL, Cooper E, Haskell J, et al. Physician stress and burnout: the impact of health information technology. *J Am Med Inform Assoc*. 2019;26(2):106–114

15. Shanafelt TD, Dyrbye LN, Sinsky C, et al. Relationship between clerical burden and characteristics of the electronic environment with physician burnout and professional satisfaction. *Mayo Clin Proc*. 2016;91(7):836–848

16. Joukes E, Abu-Hanna A, Cornet R, de Keizer NF. Time spent on dedicated patient care and documentation tasks before and after the introduction of a structured and standardized electronic health record. *Appl Clin Inform*. 2018;9(1):46–53

17. Cimino JJ. Improving the electronic health record–are clinicians getting what they wished for? *JAMA*. 2013; 309(10):991–992

18. The Joint Commission. Interpreting Joint Commission standards: FAQs. Available at: https://www.jointcommission.org/standards_information/jcfaq.aspx. Accessed January 16, 2018

19. Department of Health and Human Services; Office of the Secretary. 21st Century Cures Act: interoperability, information blocking, and the ONC Health IT Certification Program. *Fed Regist*. 2019;84(42):7424–7610. Available at: https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf. Accessed June 4, 2020

20. Stetson PD, Morrison FP, Bakken S, Johnson SB; eNote Research Team. Preliminary development of the Physician Documentation Quality Instrument. *J Am Med Inform Assoc*. 2008;15(4):534–541

Electronic Documentation in Pediatrics: The Rationale and Functionality Requirements

- *Technical Report*

TECHNICAL REPORT

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Electronic Documentation in Pediatrics: The Rationale and Functionality Requirements

Heather C. O'Donnell, MD, MSc, FAAP,[a,b] Srinivasan Suresh, MD, MBA, FAAP,[c] COUNCIL ON CLINICAL INFORMATION TECHNOLOGY

Clinical documentation has dramatically changed since the implementation and use of electronic health records and electronic provider documentation. The purpose of this report is to review these changes and promote the development of standards and best practices for electronic documentation for pediatric patients. In this report, we evaluate the unique aspects of clinical documentation for pediatric care, including specialized information needs and stakeholders specific to the care of children. Additionally, we explore new models of documentation, such as shared documentation, in which patients may be both authors and consumers, and among care teams while still maintaining the ability to clearly define care and services provided to patients in a given day or encounter. Finally, we describe alternative documentation techniques and newer technologies that could improve provider efficiency and the reuse of clinical data.

Clinical documentation is defined as the capturing and recording of clinical information, often in real time while the patient is present (eg, during consultation, assessment, imaging, and treatment).[1] However, clinical documentation has grown to encompass more than just provider notes at the time of a patient visit. Patient care activities often take place outside in-person encounters and include events involving care coordination and communication with patients and caregivers. The records of such events also represent clinical documentation. In addition, newer technologies, including patient portals, connected home monitoring devices, and patient-controlled mobile devices, potentially enable patients and families to act as authors of clinical documentation, a title previously assigned only to health care providers.[2]

Clinical documentation is primarily intended to facilitate the synthesis of patient information, develop medical care and wellness plans, and communicate patient information. Initially, documentation was intended for sharing information among various health care providers but has since

abstract

[a]Department of Pediatrics, Children's Hospital at Montefiore and Albert Einstein College of Medicine, Bronx, New York; [b]Pediatric Physicians' Organization at Children's Hospital, Boston Children's Hospital, Brookline, Massachusetts; and [c]Divisions of Health Informatics and Emergency Medicine, Department of Pediatrics, University of Pittsburgh School of Medicine and UPMC Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania

Drs O'Donnell and Suresh equally contributed as coauthors to draft, review, and revise the manuscript with input of all reviewers and the Board of Directors; and both authors approved the final manuscript as submitted.

Technical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, technical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All technical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-1684

Address correspondence to Srinivasan Suresh, MD, MBA, FAAP. Email: suresh@chp.edu

To cite: O'Donnell HC, Suresh S, AAP COUNCIL ON CLINICAL INFORMATION TECHNOLOGY. Electronic Documentation in Pediatrics: The Rationale and Functionality Requirements. *Pediatrics.* 2020;146(1):e20201684

expanded to include communication with patients and their caregivers as integral members of the care team. In pediatrics, clinical care teams also include adolescents who may have the right to manage their own reproductive health, substance use, and mental health issues and the school systems that serve as important caregivers for pediatric patients. Clinical documentation also serves other important roles, including the record of patient care and services provided for billing purposes, a means to protect the legal interest of providers and patients, a resource for research data for quality monitoring and improvement, and an educational tool for health care provider trainees.[3]

The transition of clinical documentation from paper to electronic health records (EHRs) has provided many positive opportunities in clinical care and documentation but has also introduced new challenges. Most importantly, electronic clinical documentation is more accessible and legible than paper records, may include more structured data elements contained elsewhere in the medical record, and is available remotely to health care providers, patients, and other stakeholders.

One downside with electronic documentation is that providers may be overwhelmed with large amounts of textual and tabular data. In addition, nonclinical stakeholders may have a more direct influence on the design and content of clinical documentation. For example, electronic documentation tools can remind or even require (required fields, forced fields, or hard stops) an author to include specific items in his or her documentation. Interventions on paper were much less invasive (education or reminders that could be avoided) and likely less effective at changing documentation behavior. This additional input can lead to increasing documentation burden, especially when some of these requirements are redundant or not relevant to the clinical narrative, and can have the effect of blurring the understanding of the purpose of a note. There is increasing recognition that documentation burden can lead to clinician burnout, and new federal legislation is aimed at developing strategies to reduce documentation burden.[4]

Electronic clinical documentation may also be more onerous than using paper. Efficient typing and navigation of the electronic record may not be skills possessed by all providers. Documentation tools such as copying functions, templates and scripts (allowing for clicking rather than typing), or the importation of data from other areas in the medical record can alleviate some of the burden. However, these tools may introduce new unintended consequences of their own, including increased length and decreased effectiveness of notes ("note bloat") and inaccurate documentation.[5–7]

The American Academy of Pediatrics (AAP) has addressed several topics related to EHRs, including electronic prescribing systems,[8] health information technology and the medical home,[9] standards for health information technology to ensure adolescent privacy,[10] pediatric aspects of inpatient health information technology systems,[11] and electronic communication of the health record and information with pediatric patients and their guardians.[12] Although these areas cover aspects of electronic documentation, there is a lack of a single unified AAP policy statement or technical report that provides an overall view of clinical documentation of pediatric care. In this technical report, we aim to review electronic clinical documentation in pediatrics and provide background information for the recommendations in the accompanying policy statement[13] to maximize the benefits of such technology to improve the care of children as well as to mitigate the potential negative aspects.

CONTENT AND STRUCTURE REQUIREMENTS FOR RECORDING CLINICAL INFORMATION

Similar to what has been emphasized in AAP policy statements and technical reports,[9–14] an Agency for Healthcare Research and Quality technical brief,[15] and the Children's EHR Format,[16,17] pediatric care providers need certain core functionalities in EHRs, including the ability to document in a manner that supports and facilitates the care of pediatric patients. Templates or similar tools designed to guide providers through the task of documentation should facilitate longitudinal, preventive, team-based, and age- and condition-specific care central to the core of pediatric medicine (Table 1).[18] In addition, pediatric care providers have long been on the forefront of family-centered care,[19] but many EHRs lack the ability to support the hallmarks of this aspect of care, such as team-based documentation and documentation of familial connections.[9] For example, familial linkages in the EHR and the ability to share certain parts of documentation, such as family and social histories, across family members could increase the robustness of this information and strengthen the delivery of family-centered care (Table 1). This feature could also serve as a method to reduce redundant documentation tasks.

Discrete Data

Similar to other medical specialties, the documentation needs of pediatric providers include both discrete (conforming to a predefined or conventional syntactic organization) and nondiscrete documentation needs as well as the need for some flexibility between the two.[20] The value of discrete data includes

TABLE 1 Clinical Documentation Framework Based on Core Components of Pediatric Care

Core Component of Pediatric Care	Examples of Supporting EHR Documentation
Longitudinal	Support documentation over the life course of the patient: attainment of developmental milestones (even outside typical norms); physical growth (growth charts); and serial immunizations (eg, DTaP vaccine No. 2).
Preventive	Support the attainment, documentation, and review of measures designed to maintain health: immunization schedules and screening tools and testing.
Age based	Document and review data based on patient age: screenings, testing, and measurements and anticipatory guidance.
Pediatric condition specific	Document and review data based on patient conditions: dedicated growth charts for patients with conditions affecting growth parameters (eg, Down syndrome, prematurity) and documentation templates that guide assessment of patients with specific conditions (eg, evaluation of asthma severity or control for patients with asthma).
Patient and family centered	Documentation supports the family unit and includes patient and family input: shared or linked mother-infant records to support perinatal care and documentation, shared family and social history documentation across family members, integrated patient- and family-generated data and/or information, supporting adolescent confidentiality, making information such as immunization records available to patients, families, and their providers regardless of the site of receipt.
Team based	Shared documentation tasks across health care provider types, primary care and specialty physicians, and health care settings (ambulatory, acute care, and long-term care).

DTaP, diphtheria, tetanus, and acellular pertussis.

relatively easy use and reuse for clinical decision support, quality measurement, research, or reporting to regulatory agencies.[2] For example, discrete data can be used to support clinical decision aids that are valuable to pediatric care providers, including health maintenance schedules that address vaccinations and screening on the basis of AAP preventive care guidelines.[21] However, free-text or narrative documentation provides its own benefits because it allows for nuanced documentation for individual patients, which is critical for patient-centered care.

The need or desire for discrete data entry can have negative impacts on the relevance and clarity of clinical documentation and may increase documentation burden for health care providers.[20] Furthermore, the required components for some structured data entry for clinical information can result in an inability to record data that do not fit neatly into the structured syntactic organization or that are partially incomplete or unknown. For instance, some EHRs may limit the recording of immunization receipt or current medications if the exact immunization date is unknown or the patient or caregiver does not remember the name of a medication. This information, although incomplete, still may be clinically relevant, and the flexibility should be present to allow for inclusion of these data alongside other discrete data in that category, so important information is not missed.

Examples of discrete data of importance to pediatric care providers include vital signs, growth parameters, immunizations, screening tests (eg, hearing tests, visual acuity testing, and developmental and mental health questionnaires) and validated scoring and screening tools (eg, Apgar score, Pediatric Early Warning Score, Pediatric Quality of Life Inventory).[11,14,17] The discrete nature of the documentation of some of these items also makes them suitable for device integration and for machine-readable technology that streamline documentation and data entry. For example, the use of barcoding for vaccine administration eliminates the need to manually document the lot number and expiration date for every vaccine. Alternative technologies such as these can both serve to reduce documentation burden and reduce documentation errors.[22]

Data Display and Standards

Documentation should only have to be entered once for these key metrics, but retrieval and display of this information also requires careful consideration and build. Data display should be sensitive to both pediatric providers' needs and patients' conditions. As examples, immunizations should be displayed by vaccine components rather than by brand names or combinations, and vital signs should be displayed with their corresponding age-, sex-, height-, and/or weight-based percentiles.

Data elements should also be displayed on the basis of patient-specific conditions, such as growth charts for prematurity and Down syndrome. Other examples include immunization displays, the ability to document new vaccines for patients who have not responded to the original vaccine series, and patients who have received a stem cell transplant. In addition, there is a need for these displays to rapidly evolve with evidence-based updates, such as the recommendation to use the World Health Organization growth charts for children 0 to 2 years of age rather than those of the Centers for Disease Control and Prevention[23] and new guidelines for the management of hypertension.[24] Delays in updates may lead to the persistence of suboptimal or out-of-date care. However, even if optimal and current care is provided, any out-of-date

information populated in the documentation could be misinterpreted. For example, the provider made a clinical decision using the new hypertension management guidelines and blood pressure percentiles, but the old percentiles and/or guideline information still populate into the note.

Importantly, the value of discrete data is enhanced if the data can be used across health care institutions and organizations. For example, if patients' immunization records were shared seamlessly across EHRs and vaccine registries, the data at every location could be more robust and accurate. In addition, the task of documenting immunization histories into separate systems would be eliminated. For this reason, the AAP and other volunteer organizations should continue to support the creation and alignment of clinical data standards.[25,26] The integration of these standards within various EHRs would increase the likelihood that individual organizations would adopt these standards and would promote technical interoperability.

Note Structure

Given the evolution of electronic charting and regulatory requirements of documentation, note structure and the elements that should be included in various clinical note types (eg, ambulatory visit note, inpatient progress note, and operative report) need to be constantly reviewed. The increasing length and limited use of notes argue for a more streamlined structure in which the most important clinical information is more readily found.[27] A solution framework to address this pervasive issue is a modified subjective, objective, assessment, plan (SOAP) note (Fig 1), which retains the original SOAP note structure from the paper-based era[28] but mitigates known concerns of electronic note systems (M.J Curren, MD, and V.K. Reddy, MD, personal communication, 2017).

Managing Information Overload

The rapidly expanding volume of clinical documentation and its accessibility potentially across a patient's lifetime regardless of the location of care has important clinical benefits, but it has also introduced a new problem in clinical care: information overload. The concern is that the large volume of clinical information can lead to the inability of a clinical care provider to quickly retrieve appropriate diagnostic and therapeutic information when needed and may lead to a clinical care provider overlooking important clinical information. Technological solutions are likely necessary to mitigate this problem and maintain clinical care efficiency and value, including integrating graphs, tabular data, knowledge management tools, smart search engines, links to Web-based resources, and customized menus.[29] Functionalities that promote a more hierarchal display of data and promote the value of the synthesis of these data into information are needed to achieve this goal and mitigate information overload. For example, as the number of notes per patient continues to increase, standard naming convention, filtering, and semantic searching functions may help providers access necessary information in a timely manner.

Whenever possible, usability and information design should be an essential part of the EHR certification process. There should be a focus on graphical visualization of numerical data. Custom development of patient summaries for various provider types and care settings requires effort but can be valuable.

DOCUMENTATION FOR ADDITIONAL STAKEHOLDERS

Electronic clinical documentation also serves important functions for other stakeholders and plays important roles in supporting regulatory requirements, legal protections, medical research, quality improvement, and medical education. Although important, the needs of these additional stakeholders often add to the complexity and amount of information captured and contained within EHR systems.

Regulatory Requirements

Developing and implementing clinical templates, customized electronic forms, and computer-assisted coding for patient encounters may result in more complete evaluation and management (E&M) coding. There is evidence that the use of EHRs may have contributed to increased use of higher-level *Current Procedural Terminology* (CPT) codes, particularly in the emergency department setting.[30] Although it is important for EHR documentation tools to guide and facilitate providers in documenting pertinent information, the EHR should not promote the inclusion of extraneous or irrelevant information that then can be used to select a more complex CPT code.

The Office of the Inspector General holds individual physicians responsible for all professional coding in their name regardless of the EHR tools used or other coding support used to select the CPT code. For this reason, it may be useful for pediatric care providers to familiarize themselves with common CPT codes rather than relying solely on EHR tools for CPT selection guidance.[31] The Centers for Medicare and Medicaid Services (CMS) has begun the process of revising the E&M requirements in this new electronic era.[32]

In addition to E&M coding requirements, processes must be in place to ensure that the documentation for the health information used in care, research, and health management is accurate, complete, and timely because clinical

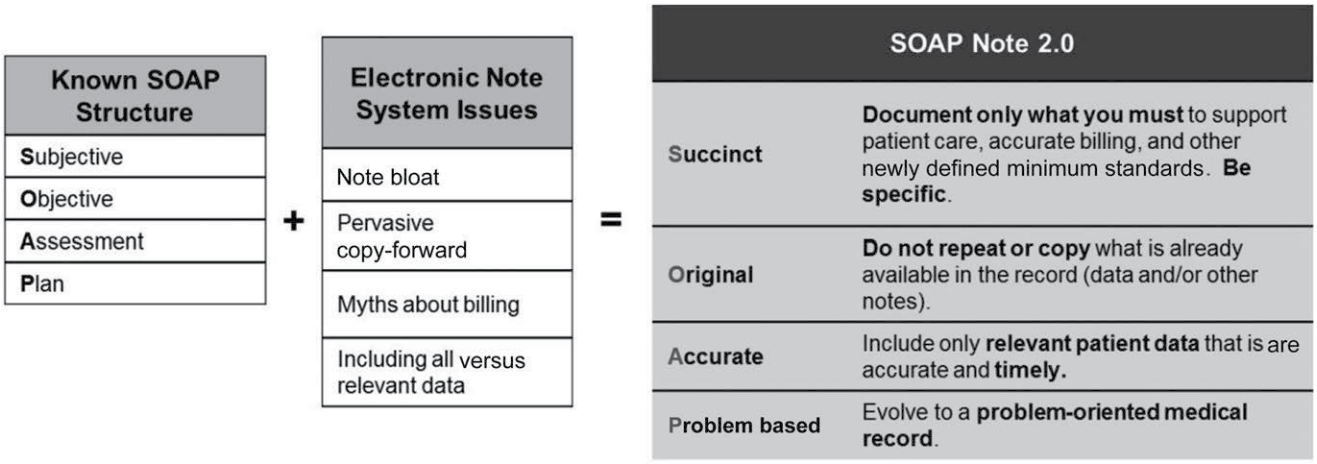


FIGURE 1
Evolution of SOAP Note 2.0 from known SOAP structure.

documentation serves as a key record to provide legal protection for providers and patients. Documentation standards should include recommendations regarding the use of electronic documentation functionalities, such as copy and paste, copy and forward, and automated insertion of data documented elsewhere in the EHR. Misuse of these functionalities can result in inaccurate, outdated, or irrelevant information, which may lead to significant quality of care and medical liability issues as well as the upcoding concerns noted previously. However, it is important to recognize that with proper use, these functionalities can save time and enhance documentation. After reviewing the literature on safety risks related to copying and pasting, the Partnership for Health IT Patient Safety made 4 recommendations that could improve the safety of its use: making copied and pasted text readily identifiable, referencing the text's origin, providing education on its safe use, and having practices in place to monitor its use.[7]

Clinical documentation is also an integral data source for reporting, quality improvement, and research. For example, electronic clinical quality measures are a set of quality objectives that have been developed for both ambulatory and inpatient hospital quality reporting programs and must be reported to the CMS.[33] A robust electronic documentation system also creates the platform for patient care–based research and quality improvement projects that are crucial for pediatric care providers to provide safer, higher-quality care.[34] The data used for these purposes often require more structured or specific data entry. Effective reporting, quality measurement, and medical research depend on accurate clinical documentation. In the development of new quality or research measures existing data should be used whenever possible and primary data entry should not be required explicitly for that measure, thereby avoiding additional documentation burden by providers. When making decisions about additional data elements required or requested from clinicians, we should take this fact into consideration and be judicious in implementation.

As electronic clinical documentation and documentation tools continue to evolve, it is key that clinicians, clinical informaticists, health information management professionals, and quality, regulatory reporting, research, and billing specialists work together on electronic documentation design, implementation, and improvement as well as the policies and procedures surrounding documentation and EHR use. The goal should be complying with billing, coding, and payer guidelines and providing data for quality reporting programs but also following best practices for electronic documentation.[35] In addition, it is crucial that the documentation burden placed on providers is not too high, and as much as possible, data solely necessary for other stakeholders should not disrupt the clinical narrative.

Documentation as a Vehicle for Medical Education

The steady shift of health care documentation from paper to electronic over the past 2 decades has had an impact on the learning process of medical students and pediatric residents and fellows. The EHR is an essential part of the daily work of medical students as they care for children and can also serve as an interactive learning tool by providing clinical decision support and ready access to the medical literature. Medical interns are estimated to spend 40% of their time dealing with EHR systems,[36] and in academic

medical centers, residents are a key source of clinical documentation.

Clinical documentation, itself, is an important learning objective of medical training, and close attention should be paid to trainees' understanding of the purpose of medical documentation and proper documentation technique in the electronic environment. In teaching institutions, trainees may be the primary documenters of clinical care because the CMS allows attending providers to verify both resident physician and medical student notes rather than redocumenting the work.[37] Trainees are often recipients of heavy workloads and may be more susceptible to some of the pitfalls of electronic documentation.[5] Medical school and residency programs should prioritize informatics resources to aid and assist in designing curriculums and providing instruction on the best practices for clinical documentation. Mentoring physicians should continue to provide feedback to their trainees regarding their documentation and proper mastery of the use of the EHR system.

In the 2013 Accreditation Council for Graduate Medical Education common program requirements, use of information technology is listed as one of the competencies under practice-based learning and improvement.[38] There are specific suggestions for EHR-related enhancements to core competencies, such as maintaining accurate problem and medication lists within the EHR to facilitate multispecialty care, which exemplifies the core competency of systems-based practice.[39]

Trainees are also in a unique position to advance health information technology. Trainees who are technically savvy and perhaps the heaviest users of the EHRs can provide important feedback on specific areas in which the EHR functionality can be improved. EHR and electronic documentation improvement efforts in teaching hospitals should include input of trainees.

UNIQUE STAKEHOLDERS FOR PEDIATRICS

Schools

Pediatricians have a unique relationship with school systems because children spend much of their time at the school and teachers and school nurses serve as important caregivers for children. Federal law, specifically the Individuals with Disabilities Act[40] and section 504 of the Rehabilitation Act of 1973,[41] ensures that all children, regardless of disability, have a right to free and public education that meets their needs. Schools are responsible for the care of any child's medical needs at school and are also important partners with pediatric care providers in ensuring that children with learning disabilities or developmental delays receive evaluations and appropriate education and therapies.

There is a vital need for school systems and child health providers to communicate and share relevant information in a bidirectional manner. Currently, much of the communication between schools and medical providers takes place via parents, who communicate between the 2 parties either with verbal information or by transporting paper school forms completed by educators and child health providers back and forth. This method leads to excessive work for parents and providers and presents multiple opportunities for error. In addition, the variability and constant changing of school forms required by private and public schools and child care centers causes great difficulty for health care providers and for the potential use of EHRs to aid form completion.

Communication between schools and health care providers could be facilitated by the streamlining and standardization of documentation essential for this process for schools and child care centers across the country. In addition, efforts should be made to enable sharing of this information electronically with parents and the school system and direct communication between health care and education providers. Privacy, consent, and security specifications would need to be defined for this information exchange.

Adolescents

Pediatric care providers need to document information regarding adolescent mental health, substance use, and reproductive health so that it can be used for their care and communicated with other providers. However, as discussed in an AAP policy statement,[10] this information is protected by federal and state laws. Although the adolescent is a minor, in some states, certain information cannot be shared with parents or guardians without the adolescent's permission unless there is a risk of harm.[10] Many EHR systems lack the technology to segment or filter confidential clinical data to prevent inadvertent disclosure to unauthorized parties, including the sharing of this protected information with parents in written form or electronically through a portal.[10,12] Unless a nationwide consensus on adolescent confidentiality issues is reached, there would also need to be flexibility in EHR settings regarding adolescents to account for state variations in laws.

NEW SHARED DOCUMENTATION PARADIGM

Shared Documentation With Patients and Families

Historically, the patient medical record, including clinical documentation, has been owned and held by medical providers and facilities, with access granted by request to patients as per regulations

in the Health Insurance Portability and Accountability Act.[42] Until more recently, most patient requests for medical records were handled in person and/or through a process of written request.

This paradigm is changing rapidly with improvements in patient portal technology and with the requirement to share information electronically with patients as part of the Promoting Interoperability Program requirements[43] and the 21st Century Cures Act.[44] In general, there is growing support that although the medical care establishment remains the steward of the data, patients should have more control over their clinical records. Although current meaningful use criteria do not explicitly require the sharing of specific clinical documentation, such as office visit notes, daily progress notes, or discharge summaries,[45] a few institutions have begun doing so and have found this sharing to be well received by patients. A study at 2 institutions in 3 geographic areas (OpenNotes) revealed improvements in patient-reported medication adherence, engagement, and satisfaction after the institutions began sharing provider notes electronically.[46]

The ease with which patients can now access their health records and information electronically could lead to a more shared model of EHRs and clinical documentation. Although concerns have been raised about the possibility of patient misunderstanding or worry regarding the information contained within the record,[47] the rates of this occurring, as reported by patients with access to clinical notes, were low.[46,48] Even so, providers should be educated on ways to document without using needless medical jargon, abbreviations, and judgmental language.[49] Guidelines on creating patient-centric notes without losing the documentation's role as a communication tool among providers and to substantiate billing are needed. In addition, because a significant portion of parents in America have basic or below-basic levels of health literacy,[50] their ability to make use of these notes to improve their child's care should be investigated.

It is also important to recognize that the sharing of clinical documentation between providers and patients could also reduce documentation burden for clinical providers. The plan section of notes and written patient instructions given to the patient (eg, after-visit summary and discharge instructions) often contain similar content but may be crafted separately. If one document could serve both purposes, it could eliminate redundancy and ensure that providers and patients communicate the medical plan effectively.

Patient-Generated Health Data

There is an opportunity in pediatrics to capitalize on patient-generated health data (PGHD), defined as "health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices, and other information—created, recorded, gathered, or inferred by or from patients or their designees (ie, care partners or those who assist them) to help address a health concern."[51,52] There is growing evidence that PGHD have value to both patients and providers.[52] The application of PGHD in pediatrics should continue to be explored and evaluated.

The value of PGHD includes the possibility of improving efficiency by the sharing of documentation tasks that would otherwise fall on providers and support staff or the time taken during the visits for patients and families to complete paper forms or questionnaires.[17] This value may only truly be reaped, however, if the data are safely and seamlessly integrated within clinical workflows and EHRs in a manner acceptable for patients and providers.

Another potential value of PGHD is the capture of important information that may otherwise be missed during a short visit and the empowerment of patients to have a significant voice in their own health care. Early-use cases in pediatrics include previsit surveys to tailor a clinical visit and questionnaires to assess and track development, quality of life, and indicators for various chronic medical conditions.[53]

Shared Provider Documentation

Communication among providers is an important function of clinical documentation. For example, to enable successful communication between a referring primary care provider and a medical subspecialist or surgical specialist, the reason for consultation and urgency should be clear and readily available. This information can then be reviewed by specialty providers and their support staff as the appointment is being scheduled and at the time of the visit. Similarly, the specialty assessment and plan should clearly delineate the plan, including which provider is responsible, and needs to be clearly communicated to the referring provider and the patient.[54]

Although primary care providers, medical subspecialists, surgical specialists, emergency physicians, and hospitalists may all provide care for the same medical problem for a given patient in the same EHR system, their documentation, including the assessment and plan, is usually housed in separate notes. Although distinct notes for each encounter are necessary for clearly documenting occurrences at a given visit or on a given day, models for shared documentation should be explored as a potential way to improve communication among providers.

Problem-Oriented Charting

Shared patient medical problem lists and problem-oriented charting could allow providers to view plans by all providers related to a particular medical problem. However, the use of problem-oriented charting has challenges, including problem list incompleteness and inaccuracies. An institution's use of problem-oriented charting or linkages between billing data and problem lists was associated with higher rates of problem list completeness.[55]

In addition, the success of maintaining accurate problem lists for patients, as well as problem-oriented documentation, is associated with a culture in which primary care physicians and medical subspecialists and surgical specialists share responsibility for the problem list.[56] However, actual completion of the problem list is difficult to both support and enforce, and that culture may not exist at every practice or institution. There is some evidence that primary care providers are responsible for the clear majority of problem list documentation, and although primary care providers believe medical subspecialists should contribute to the problem list, medical subspecialists believe it may be an incursion on the primary care provider's territory.[57,58] In addition, some medical subspecialists are likely to prefer documenting in a more systems-based format (eg, intensivists who care for more children with active multisystem issues). Providers may have differing needs for the information granularity level of any one given problem. Guidance and policies regarding how to effectively share problem lists and other shared documentation are necessary to support this new paradigm.

Although linking billing with problem lists is associated with more complete problems lists, basing a patient's problems on billable diagnosis codes (eg, the *International Statistical Classification of Diseases and Related Health Problems, 10th Revision*) can introduce additional issues. Diagnosis codes may be insufficient to reflect the clinical picture. For example, there are limited codes available for working diagnoses and for problems related to social determinants of health. In addition, multiple diagnosis codes or problems are often used for interrelated conditions, raising the concern that problem-oriented documentation does not help manage the patient as a whole individual.[59]

Medication Documentation and Management

Another example of shared documentation is medication lists. The idea behind shared medication documentation is to build on existing medication lists that multiple provider types across clinical settings contribute to rather than maintain separate lists, thereby reducing the harm caused by medication discrepancies during patient transitions.[60] However, similar to shared problem lists, not all providers believe they have ownership over the entire medication list. There is an inherent issue of medical subspecialists preferring to reconcile medications that are only relevant to their scope of care. Despite this, studies have revealed that a structured, systemwide intervention can be successful in achieving medication reconciliation compliance.[59]

One medication list may not be able to serve all purposes of medication documentation, however. For instance, there is a difference between prescribed medications and medications taken by the patient, and both are important information to maintain. In addition, many medication lists require structured entry of the medication name, concentration, dose, route, frequency, and dispense amount to prescribe medications and refills. There is also another layer of complexity when documenting medications in children, in that there may be multiple concentrations of the same liquid medication. However, even in the absence of knowing every detail, providers should be able to record partial medication information alongside all other active medications. Successful electronic medication documentation and management requires appropriate context, properly designed tools, and attention to implementation.[61,62]

EVOLVING CLINICAL DOCUMENTATION METHODS

The technologies and methodologies associated with electronic documentation continue to mature. New tools should be evaluated for their ability both to improve clinical care and to alleviate provider documentation burden. For instance, the scope of clinical documentation has expanded beyond textual rendition. Images (rashes and wound care), audio files (abnormal heart and breath sounds), and video files (seizures and endoscope findings) may be useful adjuncts in the EHR. These alternative media could prove more valuable to clinical care than text description of the findings and could reduce some documentation load. However, more information is needed about how clinicians can include these media in EHRs using existing or future technology in a way that complies with the Health Insurance Portability and Accountability Act. Another example is using alternative EHR data sources, such activity logs, to justify payment for services and eliminate the need for redundant documentation. The use of different types of media and EHR data sources as clinical documentation needs to be incorporated into E&M guidelines.

Speech Recognition

Speech (voice) recognition software is a growing technology that has the

potential to improve the efficiency of clinical documentation. As speech recognition software continues to improve, it may offer advantages over standard dictation and documentation by using a keyboard and mouse. However, further investigation is needed to assess its impact on documentation time and error rates.[63–65] The maturity and increasing use of artificial intelligence computing techniques has greatly improved speech recognition capabilities.

Scribes

In addition to technological solutions, the use of physician extenders or scribes has been considered as a possible solution to alleviate physicians' documentation burden. A scribe's core responsibility is to capture accurate and detailed documentation of the encounter in a timely manner. The general duties of a scribe may include assisting the provider in navigating the EHR, responding to various messages as directed by the provider, locating information for review, and entering information into the EHR. It is imperative that all entries regarding a patient's health information be completed in the presence of and at the direction of the provider. It is also important that authentication of each entry be completed in a timely manner as defined by a practice's policies and regulatory requirements.[66] Research in this area is limited and has shown discrepancies in whether scribes have led to improvements in provider efficiency and satisfaction.[67,68]

Technology to Enhance Data Reuse

New technologies could reduce documentation tasks by eliminating the need to document discrete information by enabling the reuse of text for research, quality metrics, and clinical decision support. Effective use of natural language-understanding tools, in which unstructured narrative information is converted into a structured form, could increase the amount of data usable for other purposes without increasing documentation burden on providers or favoring heavily structured notes over clinical narratives.[69] For example, natural language-understanding tools can enable the use of free-text information to drive clinical decision support.[70]

CONCLUSIONS

Electronic documentation is now the norm for the care of children in most industrialized countries. However, there are still struggles to fulfill the many roles of electronic documentation. Strategies to meet these multiple, often competing needs have shifted from replicating paper documentation to exploring different models that may better suit these requirements and achieve maximum value for pediatric providers and for the care of children. Examples include shared documentation and medication management. Documentation improvement is a multidisciplinary venture that should include input from clinical, research, regulatory, and education stakeholders.

LEAD AUTHORS

Heather C. O'Donnell, MD, MSc, FAAP
Srinivasan Suresh, MD, MBA, FAAP

COUNCIL ON CLINICAL INFORMATION TECHNOLOGY EXECUTIVE COMMITTEE, 2018–2019

Emily Chui Webber, MD, FAAP
Gregg M. Alexander, DO
Sandy Lee Chung, MD, FAAP
Alexander M. Hamling, MD, MBA, FAAP
Eric S. Kirkendall, MD, MBI, FAAP
Ann M. Mann, MD, FAAP
Heather C. O'Donnell, MD, MSc, FAAP
Reza Sadeghian, MD, MBA, MSc, FAAP
Eric Shelov, MD, MBI, FAAP
Srinivasan Suresh, MD, MBA, FAAP
Andrew M. Wiesenthal, MD, SM, FAAP

LIAISONS

Dale C. Alverson, MD, FAAP – *Section on Telehealth Care*
Francis Dick-Wai Chan, MD, FAAP – *Section on Advances in Therapeutics and Technology*
Melissa S. Van Cain, MD, FAAP – *Section on Pediatric Trainees*

STAFF

Lisa Krams, MAHS

ABBREVIATIONS

AAP: American Academy of Pediatrics
CMS: Centers for Medicare and Medicaid Services
CPT: *Current Procedural Terminology*
E&M: evaluation and management
EHR: electronic health record
PGHD: patient-generated health data
SOAP: subjective, objective, assessment, plan

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. The Free Dictionary by Farlex. Medical dictionary. Available at: http://medical-dictionary.thefreedictionary.com. Accessed August 20, 2018
2. Kuhn T, Basch P, Barr M, Yackel T; Medical Informatics Committee of the American College of Physicians. Clinical documentation in the 21st century: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med*. 2015;162(4):301–303
3. Ho YX, Gadd CS, Kohorst KL, Rosenbloom ST. A qualitative analysis evaluating the purposes and practices of clinical documentation. *Appl Clin Inform*. 2014;5(1):153–168
4. Office of the National Coordinator for Health Information Technology. Strategy on reducing regulatory and administrative burden relating to the use of health IT and EHRs. Available at: https://www.healthit.gov/sites/default/files/webform/reducing_burden_report/draft-strategy-on-reducing-regulatory-and-administrative-burden-relating—rkb-comments.pdf. Accessed June 4, 2019
5. O'Donnell HC, Kaushal R, Barrón Y, Callahan MA, Adelman RD, Siegler EL. Physicians' attitudes towards copy and pasting in electronic note writing. *J Gen Intern Med*. 2009;24(1):63–68
6. Hirschtick RE. A piece of my mind. Copy-and-paste. *JAMA*. 2006;295(20):2335–2336
7. Tsou AY, Lehmann CU, Michel J, Solomon R, Possanza L, Gandhi T. Safe practices for copy and paste in the EHR. Systematic review, recommendations, and novel model for Health IT collaboration. *Appl Clin Inform*. 2017;8(1):12–34
8. Gerstle RS; American Academy of Pediatrics Council on Clinical Information Technology. Electronic prescribing systems in pediatrics: the rationale and functionality requirements. *Pediatrics*. 2007;119(6):1229–1231
9. Council on Clinical Information Technology. Health information technology and the medical home. *Pediatrics*. 2011;127(5):978–982
10. Blythe MJ, Del Beccaro MA; Committee on Adolescence; Council on Clinical and Information Technology. Standards for health information technology to ensure adolescent privacy. *Pediatrics*. 2012;130(5):987–990
11. Lehmann CU; Council on Clinical Information Technology. Pediatric aspects of inpatient health information technology systems. *Pediatrics*. 2015;135(3). Available at: www.pediatrics.org/cgi/content/full/135/3/e756
12. Webber EC, Brick D, Scibilia JP, Dehnel P; Council on Clinical Information Technology; Committee on Medical Liability and Risk Management; Section on Telehealth Care. Electronic communication of the health record and information with pediatric patients and their guardians. *Pediatrics*. 2019;144(1):e20191359
13. O'Donnell HC, Suresh S; Council on Clinical Information Technology. Electronic documentation in pediatrics: the rationale and functionality requirements. *Pediatrics*. 2019;146(1):e20201682
14. Gerstle RS, Lehmann CU; American Academy of Pediatrics Council on Clinical Information Technology. Electronic prescribing systems in pediatrics: the rationale and functionality requirements. *Pediatrics*. 2007;119(6).Available at: www.pediatrics.org/cgi/content/full/119/6/e1413
15. Dufendach KR, Eichenberger JA, McPheeters ML, et al. *Core Functionality in Pediatric Electronic Health Records*. Rockville, MD: Agency for Healthcare Research and Quality; 2015
16. Agency for Healthcare Research and Quality. Children's Electronic Health Record Format. Available at: https://ushik.ahrq.gov/mdr/portals/cehrf?system=cehrf. Accessed August 20, 2018
17. Wald JS, Haque SN, Rizk S, et al. Enhancing health IT functionality for children: The 2015 Children's EHR Format. *Pediatrics*. 2018;141(4):e20163894
18. Committee on Pediatric Workforce. Definition of a pediatrician. *Pediatrics*. 2015;135(4):780–781. Reaffirmed December 2019
19. Medical Home Initiatives for Children With Special Needs Project Advisory Committee, American Academy of Pediatrics. The medical home. *Pediatrics*. 2002;110(1 pt 1):184–186. Reaffirmed May 2008
20. Rosenbloom ST, Denny JC, Xu H, Lorenzi N, Stead WW, Johnson KB. Data from clinical notes: a perspective on the tension between structure and flexible documentation. *J Am Med Inform Assoc*. 2011;18(2):181–186
21. Bright Futures, American Academy of Pediatrics. Recommendations for preventive pediatric health care. Available at: https://www.aap.org/en-us/documents/periodicity_schedule.pdf. Accessed August 20, 2018
22. Daily A, Kennedy ED, Fierro LA, et al. Evaluation of scanning 2D barcoded vaccines to improve data accuracy of vaccines administered. *Vaccine*. 2016;34(47):5802–5807
23. Centers for Disease Control and Prevention. WHO growth chart standards are recommended for use in the U.S. for infants and children 0 to 2 years of age. Available at: https://www.cdc.gov/growthcharts/who_charts.htm. Accessed August 20, 2018
24. Flynn JT, Kaelber DC, Baker-Smith CM, et al; Subcommittee on Screening and Management of High Blood Pressure in Children. Clinical practice guideline for screening and management of high blood pressure in children and adolescents. *Pediatrics*. 2017;140(3):e20171904
25. Spooner SA, Classen DC. Data standards and improvement of quality and safety in child health care. *Pediatrics*. 2009;123(suppl 2):S74–S79
26. Lehmann C, Kim GR, Johnson KB, eds. *Pediatric Informatics: Computer Applications in Child Health*. New York, NY: Springer-Verlag; 2009
27. Venkat KK. Short and sweet: writing better consult notes in the era of the electronic medical record. *Cleve Clin J Med*. 2015;82(1):13–17
28. Weed LL. Medical records that guide and teach. *N Engl J Med*. 1968;278(11):593–600

29. Hall A, Walton G. Information overload within the health care system: a literature review. *Health Info Libr J.* 2004;21(2):102–108

30. Pitts SR. Higher-complexity ED billing codes–sicker patients, more intensive practice, or improper payments? *N Engl J Med.* 2012;367(26):2465–2467

31. American Medical Association. CPT. Available at: https://www.ama-assn.org/practice-management/cpt. Accessed August 20, 2018

32. Centers for Medicare and Medicaid Services. CMS-1676-P. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1676-P.html. Accessed August 20, 2018

33. Centers for Medicare and Medicaid Services. eCQM library. Available at: https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/ecqm_library.html. Accessed August 20, 2018

34. National Quality Registry Network. What is a clinical data registry? Available at: www.abms.org/media/1358/what-is-a-clinical-data-registry.pdf. Accessed August 20, 2018

35. American Health Information Management Association. Integrity of the healthcare record: best practices for EHR documentation (2013 update). Available at: http://library.ahima.org/doc?oid=300257. Accessed August 20, 2018

36. Block L, Habicht R, Wu AW, et al. In the wake of the 2003 and 2011 duty hours regulations, how do internal medicine interns spend their time? *J Gen Intern Med.* 2013;28(8):1042–1047

37. Centers for Medicare and Medicaid Services. E/M service documentation provided by students (manual update). Available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10412.pdf. Accessed August 20, 2018

38. Accreditation Council for Graduate Medical Education. Common program requirements. 2013. Available at: www.acgme.org/acgmeweb/Portals/0/PFAssets/ProgramRequirements/CPRs2013.pdf. Accessed August 20, 2018

39. Pageler NM, Friedman CP, Longhurst CA. Refocusing medical education in the EMR era. *JAMA.* 2013;310(21):2249–2250

40. Individuals with Disabilities Act, Pub L No. 94-142, 89 Stat 773 (1975). Available at: https://www.govinfo.gov/content/pkg/STATUTE-89/pdf/STATUTE-89-Pg773.pdf. Accessed June 4, 2020

41. Rehabilitation Act of 1973, Pub L No. 93-112, 87 Stat 394 (1973). Available at: https://www.govinfo.gov/content/pkg/STATUTE-87/pdf/STATUTE-87-Pg355.pdf#page=1. Accessed June 4, 2020

42. Health Insurance Portability and Accountability Act of 1996, Pub L No. 104-191, 100 Stat 2548 (1996). Available at: https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/content-detail.html. Accessed August 20, 2018

43. Centers for Medicare and Medicaid Services. Promoting interoperability Programs. Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRIncentiveprograms/. Accessed June 4, 2019

44. Federal Register. 21st Century Cures act: interoperability, information blocking, and the ONC health IT certification program. 2019. Available at: https://www.govinfo.gov/content/pkg/FR-2019-03-04/pdf/2019-02224.pdf. Accessed June 4, 2020

45. Federal Register. Centers for Medicare & Medicaid Services. Medicare and Medicaid programs; electronic health record incentive program–stage 3 and modifications to meaningful use in 2015 through 2017. Final rules with comment period. 2015. Available at: https://www.govinfo.gov/content/pkg/FR-2015-10-16/pdf/2015-25595.pdf. Accessed June 4, 2020

46. Delbanco T, Walker J, Bell SK, et al. Inviting patients to read their doctors' notes: a quasi-experimental study and a look ahead. *Ann Intern Med.* 2012;157(7):461–470

47. Walker J, Leveille SG, Ngo L, et al. Inviting patients to read their doctors' notes: patients and doctors look ahead: patient and physician surveys [published correction appears in *Ann Intern Med.* 2012;157(1):80]. *Ann Intern Med.* 2011;155(12):811–819

48. Nazi KM, Turvey CL, Klein DM, Hogan TP, Woods SS. VA OpenNotes: exploring the experiences of early patient adopters with access to clinical notes. *J Am Med Inform Assoc.* 2015;22(2):380–389

49. Agency for Healthcare Research and Quality. Patient access to medical notes in primary care: improving engagement and safety. Available at: https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/patient-family-engagement/pfeprimarycare/opennotes-1.pdf. Accessed August 20, 2018

50. Yin HS, Johnson M, Mendelsohn AL, Abrams MA, Sanders LM, Dreyer BP. The health literacy of parents in the United States: a nationally representative study. *Pediatrics.* 2009;124(suppl 3):S289–S298

51. Shapiro M, Johnston D, Wald J, Mon D. Patient-generated health data. 2012. Available at: www.rti.org/pubs/patientgeneratedhealthdata.pdf. Accessed August 20, 2018

52. Cohen DJ, Keller SR, Hayes GR, Dorr DA, Ash JS, Sittig DF. Integrating patient-generated health data into clinical care settings or clinical decision-making: lessons learned from Project HealthDesign. *JMIR Hum Factors.* 2016;3(2):e26

53. Bergman DA, Beck A, Rahm AK. The use of internet-based technology to tailor well-child care encounters. *Pediatrics.* 2009;124(1). Available at: www.pediatrics.org/cgi/content/full/124/1/e37

54. Newton J, Eccles M, Hutchinson A. Communication between general practitioners and consultants: what should their letters contain? *BMJ.* 1992;304(6830):821–824

55. Wright A, McCoy AB, Hickman TT, et al. Problem list completeness in electronic health records: a multi-site study and assessment of success factors. *Int J Med Inform.* 2015;84(10):784–790

56. Wright A, Feblowitz J, Maloney FL, Henkin S, Bates DW. Use of an electronic problem list by primary care providers and specialists. *J Gen Intern Med.* 2012;27(8):968–973

57. Holmes C, Brown M, Hilaire DS, Wright A. Healthcare provider attitudes towards the problem list in an

electronic health record: a mixed-methods qualitative study. *BMC Med Inform Decis Mak*. 2012;12:127

58. Huynh C, Wong IC, Tomlin S, et al. Medication discrepancies at transitions in pediatrics: a review of the literature. *Paediatr Drugs*. 2013;15(3):203–215
59. Chowdhry SM, Mishuris RG, Mann D. Problem-oriented charting: a review. *Int J Med Inform*. 2017;103:95–102
60. Rappaport DI, Collins B, Koster A, et al. Implementing medication reconciliation in outpatient pediatrics. *Pediatrics*. 2011;128(6). Available at: www.pediatrics.org/cgi/content/full/128/6/e1600
61. Marien S, Krug B, Spinewine A. Electronic tools to support medication reconciliation: a systematic review. *J Am Med Inform Assoc*. 2017;24(1):227–240
62. Centers for Medicare and Medicaid Services. Meaningful use core measures. Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_14_MedicationReconciliation.pdf. Accessed August 20, 2018
63. Hodgson T, Coiera E. Risks and benefits of speech recognition for clinical documentation: a systematic review. *J Am Med Inform Assoc*. 2016;23(e1):e169–e179
64. Hodgson T, Magrabi F, Coiera E. Efficiency and safety of speech recognition for documentation in the electronic health record. *J Am Med Inform Assoc*. 2017;24(6):1127–1133
65. Payne TH, Alonso WD, Markiel JA, Lybarger K, White AA. Using voice to create hospital progress notes: description of a mobile application and supporting system integrated with a commercial electronic health record. *J Biomed Inform*. 2018;77:91–96
66. American Health Information Management Association. Using medical scribes in a physician practice. Available at: http://library.ahima.org/doc?oid=106220. Accessed December 7, 2017
67. Gidwani R, Nguyen C, Kofoed A, et al. Impact of scribes on physician satisfaction, patient satisfaction, and charting efficiency: a randomized controlled trial. *Ann Fam Med*. 2017;15(5):427–433
68. Heaton HA, Nestler DM, Lohse CM, Sadosty AT. Impact of scribes on emergency department patient throughput one year after implementation. *Am J Emerg Med*. 2017;35(2):311–314
69. Griffon N, Charlet J, Darmoni SJ. Managing free text for secondary use of health data. *Yearb Med Inform*. 2014;9:167–169
70. Demner-Fushman D, Chapman WW, McDonald CJ. What can natural language processing do for clinical decision support? *J Biomed Inform*. 2009;42(5):760–772

Emerging Issues in Male Adolescent Sexual and Reproductive Health Care

• *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Emerging Issues in Male Adolescent Sexual and Reproductive Health Care

Laura K. Grubb, MD, MPH, FAAP,[a] Makia Powers, MD, MPH, MSc, FAAP,[b] COMMITTEE ON ADOLESCENCE

abstract

Pediatricians are encouraged to address male adolescent sexual and reproductive health on a regular basis, including taking a sexual history, discussing healthy sexuality, performing an appropriate physical examination, providing patient-centered and age-appropriate anticipatory guidance, and administering appropriate vaccinations. These services can be provided to male adolescent patients in a confidential and culturally appropriate manner, can promote healthy sexual relationships and responsibility, can and involve parents in age-appropriate discussions about sexual health.

INTRODUCTION

During adolescence, several transitions occur for boys, including the physical, psychological, and social changes associated with puberty, with most male adolescents reporting the initiation of sexual behavior.[1,2] Many emerging behaviors, including sexual initiation, are associated with preventable negative health consequences such as sexually transmitted infections (STIs), unintended pregnancies, and nonconsensual sexual activity.[2] During this developmental period, the number of health encounters typically declines, particularly among older male adolescents, and there is a shift from routine to more time-limited acute visits.[3] Pediatricians and other physicians who care for natal male adolescents (cisgender or transgender female adolescents) or those who identify as male (transgender male adolescents or gender nonconforming) have unique opportunities to incorporate anticipatory guidance around issues such as puberty and sexuality not only at any health maintenance visits but also at sick and/or injury visits with adolescents and their families. For the purposes of this report, the term "male" refers to cisgender adolescents and young adults, unless otherwise specified.[4]

Even after the release of the American Medical Association's *Guidelines for Adolescent Preventive Services (GAPS)*[5] and the American Academy of Pediatrics (AAP) *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*,[6] which recommend preventive health services for adolescents, there have been few improvements in the counseling of male

Departments of [a]Adolescent Medicine, Pediatrics, and Public Health and Community Medicine, Floating Hospital for Children at Tufts Medical Center, Boston, Massachusetts; and [b]Departments of Pediatrics and Public Health and Community Medicine, Morehouse School of Medicine and Children's Healthcare of Atlanta, Atlanta, Georgia

DOI: https://doi.org/10.1542/peds.2020-0627

Address correspondence to Laura K. Grubb, MD, MPH, FAAP. E-mail: lgrubb@tuftsmedicalcenter.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

To cite: Grubb LK, Powers M, AAP COMMITTEE ON ADOLESCENCE. Emerging Issues in Male Adolescent Sexual and Reproductive Health Care. *Pediatrics*. 2020;145(5):e20200627

teenagers regarding the prevention of STIs or HIV infection.[7,8] Furthermore, data from outpatient medical records reveal that pediatricians are 3 times more likely to take sexual health histories from female than male patients and twice as likely to counsel female patients on the use of barrier methods.[7,9] Thus, it is important for pediatricians to have an understanding of what sexual and reproductive health care means for the male adolescent. Although boys and young men comprise approximately half of the adolescent population in the United States, standards for addressing their reproductive and sexual health needs lag behind those for adolescent girls and young women, and male adolescents continue to be a particularly vulnerable patient population.[7,8] Pediatricians are encouraged to address male adolescent sexual and reproductive health on a routine basis, including boys and young men with developmental or physical disabilities,[10,11] by taking a sexual history, discussing healthy sexuality, performing an appropriate examination, providing patient-centered and age-appropriate anticipatory guidance, performing appropriate screening, and administering vaccinations.[12]

The 2011 AAP clinical report on male adolescent sexual and reproductive health care discusses specific issues related to male adolescents' sexual and reproductive health care in the context of primary care, including pubertal and sexual development, sexual behavior, masturbation, consequences of sexual behavior, and methods of preventing STIs (including HIV) and pregnancy.[13] This revision provides updated information and recommendations since the 2011 clinical report, including the following:

- updated information concerning male adolescent sexual behavior;
- emerging issues in health confidentiality;
- data on the patterns of social media use in male sexual health;
- discussion of consent for sexual acts among adolescents;
- recommendations for counseling of male adolescents on their roles in contraception decision-making;
- updated data on STIs and treatment among male patients aged 15 to 24 years with updates on STI screening and treatment;
- recommendations on human papillomavirus (HPV) vaccine for boys;
- information on sexual dysfunction among adolescent and young adult males and recommendations for addressing in practice; and
- updated sexual and reproductive health resources (Supplemental Table 2) for pediatricians specifically for male adolescent patients.

ADOLESCENT MALE SEXUAL BEHAVIOR

According to the 2017 Youth Risk Behavioral Surveillance System (YRBSS), 41% of male teenagers of high school age reported they had sexual intercourse, defined as opposite-sex vaginal-penile contact, by the 12th grade.[2] In another study, male adolescents were significantly more likely to engage in oral sex compared with sexual intercourse and more likely to have significantly greater numbers of oral sex partners than sexual intercourse partners and indicated that during oral sex, they had never used STI protection.[14] A substantial number of young men report engaging in concerning sexual behaviors, including an earlier age of sexual debut and having more sexual partners than female adolescents.[2] YRBSS data from 2017 indicated that among surveyed male high school students, 22% reported using alcohol or drugs before last sexual intercourse, 12% reported $\geq$4 lifetime partners, 39% did not use a condom at last sexual intercourse, and 5% reported initiating sex at 13 years or younger.[2]

Adolescents with intellectual disabilities (IDs) and physical disabilities are an overlooked group in terms of sexual behavior, but they have similar rates of sexual behaviors when compared with their peers without disabilities.[15] These youth receive limited sexual education from their parents and pediatricians, who may assume they will not engage in sexual behaviors.[15] Much of the research on IDs and sexuality among adolescents and young adults is focused on contraception choices and pregnancy prevention among females, with little focus on male adolescents. Jahoda and Pownall[16] evaluated sexual knowledge and social networks among adolescents with IDs compared with adolescents without IDs. Results revealed that male adolescents with IDs scored higher in knowledge of sexual topics compared with female adolescents with IDs and discussed sexual topics more frequently in their social networks compared with female adolescents; however, male adolescents with IDs were less likely to have received information about sex from their pediatricians when compared with their peers without IDs.[16] Current research is now being focused on the importance of sexuality counseling with these adolescents and young adults so that they develop healthy sexual behaviors.[10] The AAP clinical report "Sexuality of Children and Adolescents With Developmental Disabilities" provides additional guidance and information.[11]

As the national dialogue shifts toward openness and acceptance of lesbian, gay, bisexual, transgender, and questioning (LGBTQ) individuals, adolescents are increasingly expressing sexual fluidity and flexibility. Discordance between

sexual attraction and orientation and behavior is also possible because one's sexual attraction and sexual identity do not always predict sexual behavior.[17–19] In the 2017 YRBSS, youth were asked questions to ascertain sexual identity and gender of sexual contacts. Among male students, 92% identified as heterosexual or straight, 2% identified as gay, 3% identified as bisexual, and 3% identified as not sure. Of male youth who ever had sexual intercourse, 80% reported having sexual contact with the opposite sex only and 76% reported having sexual contact with the same sex only or both sexes. Fifty-nine percent of high school students denied any history of sexual contact.[2]

Although most LGBTQ youth are resilient and emerge from adolescence as healthy adults, the effects of homophobia and heterosexism can contribute to concerning health issues for sexual minority youth (those who identify as gay, lesbian, or bisexual; those who are not sure about their sexual identity; or those who have sexual contact with only the same sex or with both sexes). Sexual minority youth, in comparison with heterosexual adolescents, have higher rates of depression and suicidal ideation, higher rates of substance abuse, and riskier sexual behaviors.[20] Sexual minority boys and young men reported significantly higher rates of violence-related behaviors, including being forced to have sex, school bullying, and being victims of physical and/or sexual dating violence.[21] Sexual minority boys and young men also reported higher rates of earlier sexual debut, ≥4 sexual partners, less barrier-method use, less contraceptive use when engaged in intercourse with female partners, and higher use of drugs or alcohol before sexual intercourse compared with their non–sexual minority counterparts.[21]

Pediatricians rarely discuss high-risk sexual behaviors during routine adolescent visits, and they discuss same-sex sexual behaviors even less frequently. Studies have revealed that pediatricians often do not discuss sensitive topics, such as sexual orientation, sexual identity, gender identity, violence prevention, or sexual or physical abuse, as part of their routine practice.[7,9,22–24] These studies reveal that pediatricians who care for adolescents are not routinely asking about sexual practices and the sexual orientation of their patients, preventing them from adequately addressing sexual health concerns and sexual risk. LGBTQ teenagers and young adults are an underserved population, many of whom struggle with acceptance of their sexuality while they are managing the other rigors of adolescence. It is important that pediatricians and other physicians obtain the skills needed to provide culturally effective, developmentally appropriate care for sexual minority youth. The 2013 AAP policy statement "Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth" provides additional guidance.[20]

EMERGING ISSUES IN HEALTH CONFIDENTIALITY

Adolescents' right to consent and confidentiality and health care are intertwined. Providing confidentiality supports adolescents in their development of autonomy and plays a significant role in their willingness to access necessary health care or disclose important information to pediatricians. There is no federal law that explicitly protects adolescents' right to confidential health care. There are individual state laws, and numerous international and national organizations have outlined the importance of confidentiality protections, including the United Nations, American Public Health Association, AAP, Society for Adolescent Health and Medicine, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists.[25–29] The 2017 AAP clinical report "Sexual and Reproductive Health Care Services in the Pediatric Setting" provides specific guidance on the provision of confidential sexual health services.[12] The Guttmacher Institute provides updated summaries of states' consent and confidentiality laws for minors on its Web site.[30]

The expansion of electronic health records and the increased coverage of young adults (up to age 26) through their parents' insurance plans have presented additional challenges to confidentiality. Although the Health Insurance Portability and Accountability Act of 1996[31] provides protection of private health information from some disclosures, it also allows disclosure of information for the purpose of treatment, payment, or health care operations with consent.[32] Adolescents are at risk for confidentiality breaches when insurers send explanations of benefits or denials of claims to policyholders after anyone covered under their policy obtains care. These insurance documents may identify the individual who received care, the health care provider, and the type of care obtained. In 2014, the AAP, American College of Obstetricians and Gynecologists, and Society for Adolescent Health and Medicine released a policy statement on the importance of confidentiality protections in the insurance billing process.[33] The AAP also recommended confidentiality protections in its 2012 policy statement "Standards for Health Information Technology to Ensure Adolescent Privacy."[34] This guidance provides pediatricians with a framework to provide confidentiality while delivering important adolescent services.

USE OF MEDIA AND SOCIAL MEDIA

Adolescents use a variety of media to socialize and learn about and engage in sexual activity. Media uses include television, video games, social media, texting, smart phone applications, Web sites, and online pornography. Boys are more likely than girls to make online friends and communicate with them online rather than in person.[35] Recent studies of adolescents revealed that male participants were statistically more likely to receive sexually explicit texts and be sexually active and that sexual minority male youth were more likely to send sexually explicit texts than female adolescents.[36,37] In a recent study examining "sextortion" (the threatened dissemination of explicit, intimate, or embarrassing images of a sexual nature without consent, usually for the purpose of procuring additional images, sexual acts, money, or something else) of US middle and high school students, researchers found that boys and sexual minority youth were more likely to be targeted and that boys were more likely to target other youth.[38]

Of concern to pediatricians is frequent adolescent exposure to pornography. In one study, more than half of male youth Internet users 14 to 15 years of age had been exposed to either unwanted or wanted online pornography in the past year, as had more than two-thirds of those 16 to 17 years of age. Thirty-eight percent of male Internet users aged 16 to 17 intentionally visited pornographic sites in the past year.[39] There are conflicting data concerning the effects of pornography. Some studies reveal that users report positive effects on sexual health whereas others report negative effects, and there is no conclusive information concerning sexual function or dysfunction. Pornography frequently portrays male and female inequalities, specific body types (thin women with surgically enhanced breasts), normalization of aggressive or violent sexual acts and violence, and a lack of emotional intimacy between actors.[40] During the social history, pediatricians can screen for social media use, pornography viewing, patients' perceptions of such material, and any adverse effects and provide guidance on safe and sensible Internet and social media use to parents and patients. The AAP provides policies, information, advice, and resources about families' and children's interactions with various forms of media on its Web site.[41,42]

SEXUAL ASSAULT AND CONSENT FOR SEXUAL ACTIVITY

Sexual assault is a prevalent issue that can affect many adolescents, regardless of gender. Until 2012, published US Federal Bureau of Investigation annual crime data defined "forcible rape" as "the carnal knowledge of a female forcibly and against her will."[43] As a result of this definition, there are limited data concerning sexual assault of male victims and even less information for male adolescents.[44] In the 2017 YRBSS report, 3.5% of male high school students disclosed ever being physically forced to have sexual intercourse, of whom 3% identified themselves as heterosexual, 16% as LGBTQ, and 12% as unsure of their sexual orientation. Male victims who experienced sexual violence reported the sex of their sexual contacts as the following: 4% opposite sex only, 26% same sex only or both sexes, and 1% no sexual contact. In the same report, 4.3% of male high school students reported experiencing any sexual violence.[2]

For male victims of sexual assault, there are significant stigmas to reporting the assault, including the misperceptions that males in noninstitutionalized settings are rarely sexually assaulted, that male victims are responsible for their assaults, that male sexual assault victims experience less trauma than their female counterparts, and that ejaculation is an indicator of a positive experience. As a result of these misbeliefs, there is an underreporting of sexual assaults by male victims, a lack of appropriate services for male victims, and less legal redress for male sexual assault victims. By comparison, male sexual assault victims have fewer resources and greater stigma than do female sexual assault victims.[45] Pediatricians are encouraged to ask male patients about exposure to sexual assault (and other types of victimization) during the social history of routine health supervision visits. When exploring alcohol or substance use, it is important to discuss the link between impairment and vulnerability to sexual assault. It is advised that adolescents who disclose a previous assault be asked about the dynamics of their relationships (eg, exploitative, controlling, nonconsensual). The 2017 AAP clinical report "Care of the Adolescent After an Acute Sexual Assault" provides additional guidance.[46] In addition to being victims of sexual assault, there have been many high-profile founded and unfounded cases of sexual assault by boys and young men resulting in significant disruption in the victims and alleged perpetrators' lives and futures. In the United States, of people arrested or convicted of sexual assault, 96% to 99% are male. Overall, an estimated 9% of the victims of rape and sexual assault were cisgender male. Nearly 99% of the offenders described in single-victim incidents were male. In the United States, per capita rates of rape/sexual assault were found to be highest among residents aged 16 to 19 years, demonstrating tha youth are particularly vulnerable.[47]

Each state has its own statutes regarding consent, rape, and sex

crimes, and each college or institution may have its own set of policies concerning sexual consent.[48] The US Department of Justice provides the following definitions: "Rape - Forced sexual intercourse including both psychological coercion as well as physical force. Forced sexual intercourse means penetration by the offender(s). Includes attempted rapes, male as well as female victims, and both heterosexual and same sex rape. Attempted rape includes verbal threats of rape. Sexual assault - A wide range of victimizations, separate from rape or attempted rape. These crimes include attacks or attempted attacks generally involving unwanted sexual contact between victim and offender. Sexual assaults may or may not involve force and include such things as grabbing or fondling. It also includes verbal threats."[49] There is no standard definition of consent, and many institutions have attempted to define and implement policies concerning sexual consent. The Department of Justice of the Government of Canada defines sexual consent for the purposes of sexual assault offenses as "the voluntary agreement of the complainant to engage in the sexual activity in question. Conduct short of a voluntary agreement to engage in sexual activity does not constitute consent as a matter of law."[50]

When discussing sexuality, pediatricians can address issues of consent during anticipatory guidance if sexual screening warrants concern. Additionally, pediatricians can encourage patients to communicate with partners concerning sexual activity before engagement by respecting verbal and nonverbal boundaries and cues, emphasizing that consent should occur with each activity every time and that parties may change their minds. Pediatricians can educate male youth that the following situations do not involve consent: refusing to acknowledge "no"; assuming that wearing certain clothes, flirting, or kissing is an invitation for anything more; someone being younger than the legal age of consent (as defined by the state); someone being incapacitated because of drugs or alcohol; pressuring someone into sexual activity by using fear or intimidation; and assuming permission to engage in a sexual act because it has occurred in the past. Pediatricians are encouraged to include discussions of definitions and understandings of sexual consent, dispel myths concerning consent, and provide anticipatory guidance concerning consensual sexual activity to facilitate safe and healthy relationships between male adolescents and their partners.

PREGNANCY PREVENTION AND CONTRACEPTION COUNSELING

According to the 2011–2015 National Survey of Family Growth, 84% of sexually experienced cisgender male teenagers reported using contraception at first sexual intercourse.[1] These rates varied by the age of the male at first sex: boys who were 14 years and younger had lower rates of contraception use at first sex than did males who were 17 to 19 years of age (71% and 95%, respectively).[1] Ninety percent of male teenagers used some method of contraception, including withdrawal at last sex, with 61% reporting using condoms at last sex, 19% reporting some contraceptive pill use, and 35% reporting a dual method (hormonal and barriers).[2]

The male adolescent can play an important role in the couple's contraception decision-making. In many cases, male adolescents prefer their partners to involve them in discussions of contraception methods.[51] Over the past decade, there has been a growing body of evidence regarding young men's knowledge of various forms of contraception and the association with shared decision-making.[52] Richards et al[52] recruited 93 ethnically diverse adolescent men to study their knowledge of emergency contraception (EC). Their findings revealed that fewer than half of the young men had ever heard of EC. Those who were aware of EC were more likely to be older (median 19.7 years), have knowledge of other contraceptive methods, and participate in shared contraceptive decision-making with their partners. The most recent literature review regarding EC-related knowledge, attitudes, and behaviors among men revealed that male adolescents have lower knowledge of EC than their adult male counterparts and are less likely to have had a partner use this form of contraception.[53] This study reveals the importance of counseling young men on all contraceptive methods to promote increased usage.

Once it is determined that an adolescent is at risk for pregnancy, the pediatrician may take the opportunity to provide counseling regarding all forms of contraception and each method's effectiveness in pregnancy prevention. If there is not time during a routine or sick appointment, the pediatrician can schedule follow-up appointments specifically to discuss pregnancy prevention and contraception options. Contraception counseling is relevant for heterosexual and sexual minority youth because LGBTQ youth are at a higher risk for unintended pregnancies than their heterosexual peers.[54] Transgender men or transmasculine people can themselves be at risk for pregnancy (and require contraceptive counseling if appropriate), and transgender women or transfeminine people may have male genitalia and require appropriate counseling about their risk of causing pregnancy.

Male adolescents can play a vital role in pregnancy prevention and

contraceptive decision-making in their female partners. Pediatricians can encourage male adolescents to attend contraceptive visits with their partners. During these visits, there is a great opportunity to elicit pregnancy desires and/or intentions of the couple and to educate them on a variety of contraceptive methods and the importance of shared decision-making. Additionally, the provider can encourage the male partner to commit to consistent condom use as a way to have personal control over unplanned pregnancy. If the male adolescent becomes a father, either through intended or unintended pregnancy with his partner, he will require unique social supports during the journey of fatherhood. These needs are the focus of the AAP clinical report "Care of Adolescent Parents and Their Children."[55]

STIS, SCREENING, AND TREATMENT RESISTANCE

Adolescents continue to face the greatest risk of acquiring STIs and not receiving appropriate care for STIs because of insufficient screening, confidentiality concerns, lack of access to health care, and multiple sexual partners. Most cases continue to go undiagnosed and untreated, putting individuals at risk for severe and often irreversible health consequences, including infertility, chronic pain, and increased risk for HIV as well as the propagation of STIs in the population. Youth aged 15 to 24 years comprise 27% of the sexually active population in the United States but account for more than 50% of new cases of STIs each year.[56] According to the Centers for Disease Control and Prevention (CDC), youth account for the majority of new cases of gonorrhea, chlamydia, HPV, and genital herpes and nearly one-quarter of new cases of HIV and syphilis annually. In this section, CDC data refer to cisgender male patients, unless otherwise stated.

From 2016 to 2017, the CDC reported substantially large increases for syphilis, gonorrhea, and chlamydia for both men and boys aged 15 to 24 years.[56]

In 2017, males aged 13 to 24 years accounted for 17.5% of all new HIV diagnoses in the United States and 87% of all diagnoses among young people aged 13 to 24 years. Most of those new HIV diagnoses among youth (81%) were attributed to male-to-male sexual contact.[57] Young people (aged 13–24 years) accounted for an estimated 21% of all new HIV diagnoses in the United States in 2017, totaling 8164 people, of which 87% were in natal males and 13% were in natal females.[2] Also, the study revealed that 25% of transgender women were living with HIV, and the percentage of transgender people who received a new HIV diagnosis was more than 3 times the national average in 2015.[58] In 2017, 1122 youth received a diagnosis of AIDS, representing 8% of total AIDS diagnoses that year.[2]

There has been an increase in the incidence of *Neisseria gonorrhoeae* infections among male adolescents, particularly among males who have sex with other males.[59] During 2013 to 2017, the rate of *N gonorrhoeae* infection among male patients increased 86.3%, compared with the rate increase among female patients of 39.4%.[59] The 2016 Gonococcal Isolate Surveillance Project revealed significant antibiotic resistance to gonococcal infections, and isolates from males who have sex with males are more likely to exhibit antimicrobial resistance than isolates from males who have sex with females.[60] With increasing cephalosporin-resistant gonorrhea, the CDC recommended in 2012 exclusive parental high-dose ceftriaxone treatment (250 mg, intramuscular) and a second antibiotic (azithromycin, 1 g) for uncomplicated gonococcal infections.[61]

There continues to remain significant underscreening of youth for STIs in the pediatric setting.[62,63] This underscores the need for pediatricians to offer screening based on risk assessment, appropriate treatment, and review strategies for prevention of transmission to reduce STI incidence and morbidity among all adolescents. The CDC recommends that clinicians consider screening for chlamydia in clinical settings serving populations of young male patients with a high prevalence of chlamydia (eg, adolescent clinics, correctional facilities, and STI clinics). The CDC does not recommend the routine screening of adolescents who are asymptomatic for certain STIs (eg, syphilis, trichomoniasis, bacterial vaginosis, herpes simplex virus, HPV, hepatitis A, and hepatitis B) but does recommend screening for syphilis in males who have sex with males.[61] The US Preventive Services Task Force concludes that the current evidence is insufficient to assess the balance of benefits and harms of routine screening for chlamydia and gonorrhea in boys and men.[64] For males who have had sex with males, the CDC recommends at least annual screening for HIV, syphilis, gonorrhea at all sites of contact (by using urine, rectal, and pharyngeal sampling), and chlamydia on urine and rectal sampling (testing for chlamydia pharyngeal infection is not recommended) regardless of barrier-method use. More frequent STI screening (ie, for syphilis, gonorrhea, and chlamydia) at 3- to 6-month intervals is indicated for males who have sex with males if risk behaviors persist or if they or their sexual partners have multiple partners.[61] Given the significant increases in all STIs among male patients in the past 5 years, it is reasonable for pediatricians to maintain a high index of suspicion for STIs and consider testing for male patients who are

Bright Futures Medical Screening Reference Table
Adolescence Visits (11 Through 21 Years)

Bright Futures

Selective Screening	Medical History Risk Factors[c]	Risk Assessment[d]	Action if Risk Assessment Is Positive
STIs	**Chlamydia** The US Preventive Services Task Force strongly recommends that clinicians routinely screen all sexually active females ≤25 years and other asymptomatic females at increased risk for infection for chlamydial infection. The AAP recommends that sexually active males who have sex with females may be considered for annual screening in settings with high prevalence rates. • Jails or juvenile corrections facilities • National job training programs • STI clinics • High school–based clinics • Adolescent clinics for patients who have a history of multiple partners Sexually active males who have sex with males (known as MSM) should be screened annually for rectal and urethral chlamydia. Males who have sex with males at high risk should be screened every 3 to 6 months. • Multiple or anonymous sex partners • Sex in conjunction with illicit drug use • Sex with partners who participate in these activities	***At the 11 through 14 Year (Older Child/Younger Adolescent) Visits,*** *ask the parent* • Adolescents who are sexually active are at risk of acquiring STIs. Are you concerned that your older child or young adolescent might be at risk? ***At the 11 through 14 Year (Early Adolescence) Visits, 15 through 17 Year (Middle Adolescence) Visits, and 18 through 21 Year (Late Adolescence) Visits,*** *ask the adolescent or young adult* • Have you ever had sex (including intercourse or oral sex)? ○ If no, skip to the next section. • Are you having unprotected sex? • Are you having sex with multiple partners or anonymous partners? • Are you or any of your past or current sexual partners bisexual? • Have you ever been treated for an STI? • Have any of your past or current sex partners been infected with HIV or used injection drugs? • Do you trade sex for money or drugs or have sex partners who do? • **For males:** Have you ever had sex with other males?	Chlamydia test
	Gonorrhea The US Preventive Services Task Force recommends that clinicians screen all sexually active females, including those who are pregnant, for gonorrheal infection if they are at increased risk for infection (ie, they are young or have other individual or population risk factors). The AAP recommends that sexually active males who have sex with females (known as MSF) may be considered for annual screening on the basis of individual and population risk factors, such as disparities by race and neighborhood. Sexually active males who have sex with males should be screened annually for rectal and urethral gonorrhea. Males who have sex with males at high risk should be screened every 3 to 6 months. • Multiple or anonymous sex partners • Sex in conjunction with illicit drug use • Sex with partners who participate in these activities		Gonorrhea test
	Syphilis • Males who have sex with males and engage in high-risk sexual behavior • Persons living with HIV • Commercial sex workers • Persons who exchange sex for drugs • Those in adult correctional facilities		Syphilis test

FIGURE 1
Bright Futures medical screening reference table: adolescence visits (11 through 21 years). (Reprinted with permission from American Academy of Pediatrics. Bright Futures medical screening reference table: adolescence visits [11 through 21 years]. Available at: https://brightfutures.aap.org/Bright%20Futures%20Documents/MSRTable_AdolVisits_BF4.pdf. Accessed June 9, 2019.)

sexually active. *Bright Futures* provides a risk assessment to assist with screening decisions (Fig 1).[65]

Only 10% of high school students have been tested for HIV, and among male students who have had sexual contact with other males, only 21% have ever been tested.[57] The AAP, in *Bright Futures*,[7] the *Red Book*,[66] and a policy statement,[67] recommends that routine screening be offered to all adolescents at least once by 16 to 18 years of age in health care settings when the prevalence of HIV in the patient population is more than 0.1%. In areas of lower community HIV prevalence, routine HIV testing is encouraged for all sexually active adolescents and those with other risk factors for HIV.[68] Additionally, the CDC recommends routine HIV screening for all patients seeking treatment of STIs, including all patients attending STI clinics, during each visit for a new complaint regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection.[69] For individuals at increased risk for HIV acquisition (sexually active males who have had sex with males, individuals with an HIV-positive partner, individuals participating in anal intercourse, individuals having frequent sex without a condom, and individuals with a high number of sexual partners), the CDC recommends preexposure prophylaxis (PrEP) to reduce HIV acquisition and transmission.[69] As of this publication, the US Food and Drug Administration has approved 2 medications, emtricitabine (200 mg)/tenofovir disoproxil fumarate (300 mg) and emtricitabine (200 mg)/tenofovir alafenamide (25 mg), for PrEP in adolescents and adolescents who weigh at least 35 kg.[70,71] The CDC Web site provides an HIV risk behavior assessment, PrEP clinical practice guidelines, patient and provider education, and tool kits.[72]

The CDC publishes treatment guidelines for STIs, including recommendations for special populations such as adolescents, people in correctional facilities, males who have sex with males, and transgender men and women.[57] Effective clinical management of patients with treatable STIs includes treatment of the patients' current sex partners to prevent reinfection and reduce further transmission. Expedited partner therapy (EPT) can be a particularly useful option to facilitate partner management for adolescents who are diagnosed with chlamydia or gonorrhea. The CDC's Web site provides guidance, a provider tool kit, and a summary of states' EPT laws.[73]

HPV AND VACCINE RECOMMENDATIONS

HPV is the most common STI in the United States, with almost every person acquiring an HPV infection at some time in their life.[74] The most common clinical manifestation of HPV is warts, and the most prevalent high-risk (oncogenic) types are HPV-16 and HPV-18. Persistent infections with high-risk HPV types can cause cervical, vaginal, and vulvar cancers in natal women, penile cancers in natal men, and oropharyngeal and anal cancers in both men and women.[75] Approximately 9100 US men each year receive a diagnosis of oropharyngeal cancer caused by HPV infection.[75] During 2013 to 2014, oral and genital HPV prevalence among adults 18 to 59 years of age was significantly higher for men than women. There are no data currently available for boys younger than 18 years. Males who have sex with males are at particularly high risk for HPV-mediated anal cancers.[76]

In 2006, the CDC Advisory Committee on Immunization Practices first recommended the HPV vaccine in the United States.[77] Beginning in December 2014, after US Food and Drug Administration approval of the 9-valent HPV vaccine (which provides additional protection against HPV-31, HPV-33, HPV-45, HPV-52, and HPV-58), use of the quadrivalent HPV vaccine has been slowly phased out.[78] In October 2016, the Advisory Committee on Immunization Practices updated its recommended dosing schedule for routine HPV vaccination to a 2-dose series for adolescents initiating vaccination before their 15th birthday on the basis of available immunogenicity evidence indicating that a 2-dose schedule (0 and 6–12 months) has an efficacy equivalent to a 3-dose schedule (0, 1–2, and 6 months) if the HPV vaccination series is initiated before 15 years of age.[78] In a 2-dose schedule of the HPV vaccine, the minimum interval between the first and second doses is 5 months.[78] In clinical trials for male subjects, the most common adverse events were injection-site reactions (most of which were mild or moderate in intensity), headache, and fever. Still, male adolescent HPV vaccination rates continue to be low compared with other adolescent vaccination rates or female HPV vaccination rates. In the United States, male HPV vaccination coverage with at least 1 dose was 63%, and 53% of boys ages 13 to 17 years were up to date with the recommended HPV vaccination series.[79] The modified schedule for younger adolescents may improve rates, and pediatricians are uniquely situated to address the lag in HPV vaccination rates among adolescent boys and young men.

SEXUAL DYSFUNCTION

Healthy sexual function has an important role in the well-being and development of adolescents and young adults.[80,81] A 2016 study of sexually active males aged 16 to 21 years revealed that 79% reported a sexual problem, using the validated surveys the International Index of Erectile Function and the Premature Ejaculation Diagnostic Tool. On the International Index of Erectile Function, respondents indicate agreement with 15 items used to assess erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction.[82] These problems are more prevalent than previously believed and cause significant distress to young men. The most common sexual problems among young men include premature ejaculation (PE) (20%) and erectile disorder (ED) (45%). Other common problems included low sexual satisfaction (48%) and low desire (46%).[80,81]

PE is a persistent or recurrent pattern of ejaculation occurring during partnered sexual activity within approximately 1 minute after penetration and before the person wishes it.[83] In a Swiss study of men aged 18 to 25 years, 11% reported PE.[84] This and another study revealed an association between PE and poor physical health, alcohol consumption, illegal drug use, tobacco use, and less sexual experience.[84,85]

ED is marked difficulty in obtaining an erection during sexual activity, marked difficulty in maintaining an erection until the completion of a sexual activity, or marked decrease in erectile rigidity.[83] ED prevalence among young men 18 to 25 years old approaches 30%.[84] Poor mental health, depression, and consumption of medication without prescription were predictive factors for ED. ED persistence was also associated with having multiple sexual partners.[85]

When pediatricians identify health issues such as mental health problems, physical inactivity, substance use, or multiple sexual partners, they may consider these an indication to screen for sexual dysfunction. Pediatricians

TABLE 1 Sexual Dysfunction Among Male Adolescents

System	Medical Condition
Cardiovascular	Moderate to mild valvular disease
	Uncontrolled hypertension
Endocrine	Addison disease
	Diabetes mellitus
	Hyperprolactinemia
	Hyperthyroidism
	Hypothyroidism
	Klinefelter syndrome
	Low testosterone level
Genitourinary	Congenital hypospadias
	Epispadias
	Pelvic trauma
	Priapism
Hematologic	Sickle cell disease
Infections	Prostatitis
	STIs
Neurologic	Back injury
	Brain injuries, lesions, or tumors
	Craniopharyngioma
	Epilepsy
	Multiple sclerosis
	Peripheral neuropathy
	Spinal cord injury
	Stroke
Other medical conditions	Chemotherapy
	Chronic infections
	Chronic medical diseases
	Eating disorders
	Excessive wt loss or gain
	Major or general surgery
	Malnutrition
	Obesity
	Obstructive sleep apnea
	Radiation
	Restless legs syndrome
Other conditions	
Psychological and mental health	Abuse: sexual, physical, emotional
	Environmental: lack of privacy, timing
	Fatigue
	Guilt or shame
	Mood disorders: anxiety, depression, bipolar
	Misconceptions about normal functioning
	Partner anxiety or sexual dysfunction
	Performance anxiety
	Relationship problems
	Sexuality concerns, gender dysphoria
	Substance use: illicit drugs, alcohol
	Trauma
	Unrealistic expectations
Substances and medications	Alcohol
	Amphetamines
	Antiandrogens (spironolactone)

have an opportunity to screen for problems with sexual functioning, to offer reassurance or treatment, or to appropriately assess for an underlying medical condition. Young patients often will not spontaneously discuss these topics because of embarrassment, pride, or masculinity or confidentiality concerns, so the onus is on the pediatrician to screen for sexual problems.[85,86] In screening for sexual problems, pediatricians may want to explore whether male patients have unrealistic expectations or misinformation concerning sex and sexual activity. When discussing medications with patients, pediatricians should discuss sexual dysfunction as an adverse effect and screen for sexual dysfunction in patients taking medications routinely or on a long-term basis. Conversely, identification of sexual dysfunction is an indicator to screen for other health problems (Table 1).

Even when patients do not initiate this conversation, they may still be receptive to screening from their pediatricians, who may use standardized tools such as the International Index of Erectile Function 5 and the Premature Ejaculation Diagnostic Tool, which were validated to screen men 18 years and older.[87,88] When male patients are identified as having sexual dysfunction, a complete medical and psychosocial history and physical examination, including genital examination with sexual maturity rating, are essential to evaluation to assess for any medical issues that can be worked up and addressed (Table 1).[89,90] Pediatricians may also screen patients concerning illicit use of any medications or supplements (prescription as well as over the counter), including pharmacologic agents for ED and performance-enhancing substances (ie, 3,4-methylenedioxymethamphetamine or supplements) because unmonitored

TABLE 1 Continued

System	Medical Condition
	Antidepressants, particularly selective serotonin reuptake inhibitors
	Anti-hypertensives:β-blockers, clonidine, guanethidine, methyldopa
	Antipsychotics
	Cimetidine
	Illicit substances
	Ketoconazole
	Opioids
	Prescription medication misuse
	Steroids
	Thiazides, particularly chlorthalidone

Adapted from Rew KT, Heidelbaugh JJ. Erectile dysfunction. *Am Fam Physician.* 2016;94(10):822.

use may pose health risks and has been associated with increased risky sexual behavior.[91]

Several studies in men older than 18 years revealed statistically significant improved self-esteem, mood, sexual function, sexual relationship health, orgasmic function, sexual desire, and intercourse satisfaction among those, including young men, who received short-term (maximum 8 attempts with medication) pharmacotherapy for ED.[80,92,93] In treating sexual dysfunction, having an established and ongoing provider-patient relationship and addressing mental health concerns, including substance use, may be crucial therapeutic measures. Follow-up therapy may need to include mental health services, relaxation techniques, and a discussion of the skills needed to assist the adolescent in achieving some degree of voluntary control of sexual function.

It is important that pediatricians familiarize themselves with available counseling services within their communities for adolescents and young adults. This clinical report does not contain explicit recommendations for mental health services, but pediatricians can consult AAP resources for more direction, such as the Key Resources of the Mental Health Initiative (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Mental-Health/Pages/Key-Resources.aspx).

CONCLUSIONS

Pediatricians are in the best position to deliver high-quality sexual and reproductive health care services to male adolescents and can view even follow-up, acute care, and immunization visits as opportunities to address these health issues. Although time constraints at most adolescent visits may preclude a full exploration of many issues surrounding sexuality in adolescents, additional visits can be scheduled to address identified issues.

Pediatricians can also use "clinical hooks," such as preparticipation physical evaluations or acne follow-up, to keep male adolescents engaged in care and to deliver sexual and reproductive health care services. Staying informed on different issues of sexuality and sexual behaviors, initiating these conversations with male patients, and being prepared to provide appropriate anticipatory guidance are best practices when taking care of male adolescents.[12] The AAP publications "Sexual and Reproductive Health Care Services in the Pediatric Setting" and "Targeted Reforms in Health Care Financing to Improve the Care of Adolescents and Young Adults"[94] provide a framework to assist pediatricians in incorporating various aspects of sexual and reproductive health care into their practices and to provide guidance on overcoming barriers to providing this care routinely while maximizing opportunities for confidential health services delivery in their office.[5] The AAP has issued a policy statement on refusal to provide information or treatment on the basis of conscience. According to the policy, pediatricians have a duty to inform their patients about relevant, legally available treatment options to which they object, and they have a moral obligation to refer patients to other physicians who will provide and educate about those services. Failure to inform and educate about availability and access to these services violates this duty to their adolescent and young adult patients.[95]

GUIDANCE FOR PEDIATRICIANS

1. Discuss sex and sexuality with all male adolescents during routine visits and more frequently, as appropriate, and screen for sexual activity and high-risk sexual activity at routine visits and other appropriate opportunities;
2. screen adolescents for social media use (especially sexually explicit material), pornography viewing, perceptions of such material, and any adverse effects and provide guidance on safe and sensible Internet and social media use to parents and patients during the social history of well visits;
3. screen for nonconsensual sexual activity and discuss principles of sexual consent and nonconsent during well visits as well as other visits, as appropriate;
4. coach male adolescents on how to talk with their partners about sex and family planning, encourage joint decision-making between partners about sexual and

reproductive health matters, and encourage use of both contraception and barrier methods, as appropriate;

5. provide routine STI risk assessment screening for all male patients and appropriate testing for STIs, including HIV, syphilis, chlamydia, and gonorrhea, when warranted and on request and provide appropriate STI treatment, including prevention therapy and EPT;
6. consider HPV vaccination for boys starting at age 9 years, provide routine vaccination for all adolescent boys at age 11 years, and aim for complete HPV vaccination for all male patients, and emphasize the importance of complete HPV vaccination for male patients who participate in high-risk behaviors; and
7. provide screening for sexual problems with all sexually active male patients as part of the well visit sexual history and at other appropriate visits, consider the use of standardized screening tools for sexual dysfunction, investigate further for other health or mental health issues in male patients with sexual dysfunction, screen male patients with health and mental health issues for sexual problems, and follow-up with patients who report sexual problems and consider therapies such as counseling or pharmacotherapy, as appropriate.

LEAD AUTHORS

Laura K. Grubb, MD, MPH, FAAP
Makia E. Powers, MD, MPH, FAAP

COMMITTEE ON ADOLESCENCE, 2019–2020

Elizabeth M. Alderman, MD, FSAHM, FAAP, Chairperson
Richard J. Chung, MD, FAAP
Laura K. Grubb, MD, MPH, FAAP
Janet Lee, MD, FAAP
Makia E. Powers, MD, MPH, FAAP
Krishna K. Upadhya, MD, FAAP
Stephenie B. Wallace, MD, MSPH, FAAP

PAST COMMITTEE MEMBERS

Cora C. Breuner, MD, MPH, FAAP, Former Chairperson
Laurie L. Hornberger, MD, FAAP

LIAISONS

Liwei L. Hua, MD, PhD - American Academy of Child and Adolescent Psychiatry
Ellie Vyver, MD - Canadian Pediatric Society
Geri Hewitt, MD - American College of Obstetricians and Gynecologists
Seema Menon, MD - North American Society of Pediatric and Adolescent Gynecology
Lauren B. Zapata, PhD, MSPH - Centers for Disease Control and Prevention

STAFF

Karen Smith
James Baumberger, MPP

ABBREVIATIONS

AAP: American Academy of Pediatrics
CDC: Centers for Disease Control and Prevention
EC: emergency contraception
ED: erectile disorder
EPT: expedited partner therapy
HPV: human papillomavirus
ID: intellectual disability
LGBTQ: lesbian, gay, bisexual, transgender, and questioning
PE: premature ejaculation
PrEP: preexposure prophylaxis
STI: sexually transmitted infection
YRBSS: Youth Risk Behavioral Surveillance System

Drs Grubb and Powers, along with the Committee on Adolescence, researched, conceived, designed, analyzed and interpreted data for, drafted, and revised this clinical report; and all authors approved the final manuscript as submitted.This document is copyrighted and is property of the American Academy of Pediatrics and its Board of Directors. All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors. The American Academy of Pediatrics has neither solicited nor accepted any commercial involvement in the development of the content of this publication.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Abma JC, Martinez GM. Sexual activity and contraceptive use among teenagers in the United States, 2011–2015. *Natl Health Stat Rep*. 2017;(104):1–23
2. Kann L, McManus T, Harris WA, et al. Youth Risk Behavior Surveillance - United States, 2017. *MMWR Surveill Summ*. 2018;67(8):1–114
3. Rand CM, Shone LP, Albertin C, Auinger P, Klein JD, Szilagyi PG. National health care visit patterns of adolescents: implications for delivery of new adolescent vaccines. *Arch Pediatr Adolesc Med*. 2007;161(3):252–259
4. Rafferty J; Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4):e20182162
5. Elster AB, Kuznets NJ. *AMA Guidelines for Adolescent Preventive Services (GAPS): Recommendations and Rationale*. Baltimore, MD: Williams & Wilkins; 1994
6. Hagan JF Jr, Shaw JS, Duncan PM, eds. *Bright Futures: Guidelines for Health Supervision of Infants, Children, and*

Adolescents. 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017

7. Marcell AV, Gibbs SE, Pilgrim NA, et al. Sexual and reproductive health care receipt among young males aged 15-24. *J Adolesc Health*. 2018;62(4):382–389
8. Adams SH, Husting S, Zahnd E, Ozer EM. Adolescent preventive services: rates and disparities in preventive health topics covered during routine medical care in a California sample. *J Adolesc Health*. 2009;44(6):536–545
9. Marcell AV, Pilgrim N, Jennings JM, et al. Young men's overall perceived quality of care: role of sexual and reproductive health and patient-centered care [abstract]. *J Adolesc Health*. 2017;60(2 suppl 1):S37
10. Walters FP, Gray SH. Addressing sexual and reproductive health in adolescents and young adults with intellectual and developmental disabilities. *Curr Opin Pediatr*. 2018;30(4):451–458
11. Murphy NA, Elias ER. Sexuality of children and adolescents with developmental disabilities. *Pediatrics*. 2006;118(1):398–403
12. Marcell AV, Burstein GR; Committee on Adolescence. Sexual and reproductive health care services in the pediatric setting. *Pediatrics*. 2017;140(5): e20172858
13. Marcell AV, Wibbelsman C, Seigel WM; Committee on Adolescence. Male adolescent sexual and reproductive health care. *Pediatrics*. 2011;128(6). Available at: www.pediatrics.org/cgi/content/full/128/6/e1658
14. Lindberg LD, Jones R, Santelli JS. Noncoital sexual activities among adolescents. *J Adolesc Health*. 2008; 43(3):231–238
15. Holland-Hall C, Quint EH. Sexuality and disability in adolescents. *Pediatr Clin North Am*. 2017;64(2):435–449
16. Jahoda A, Pownall J. Sexual understanding, sources of information and social networks; the reports of young people with intellectual disabilities and their non-disabled peers. *J Intellect Disabil Res*. 2014; 58(5):430–441
17. Chandra A, Mosher WD, Copen C, Sionean C. Sexual behavior, sexual attraction, and sexual identity in the United States: data from the 2006-2008 National Survey of Family Growth. *Natl Health Stat Report*. 2011;(36):1–36
18. McCabe J, Brewster KL, Tillman KH. Patterns and correlates of same-sex sexual activity among U.S. teenagers and young adults. *Perspect Sex Reprod Health*. 2011;43(3):142–150
19. Pathela P, Hajat A, Schillinger J, Blank S, Sell R, Mostashari F. Discordance between sexual behavior and self-reported sexual identity: a population-based survey of New York City men [published correction appears in *Ann Intern Med*. 2006;145(12):936]. *Ann Intern Med*. 2006;145(6):416–425
20. Committee on Adolescence. Office-based care for lesbian, gay, bisexual, transgender, and questioning youth. *Pediatrics*. 2013;132(1):198–203
21. Kann L, Olsen EO, McManus T, et al. Sexual identity, sex of sexual contacts, and health-related behaviors among students in grades 9-12 - United States and selected sites, 2015. *MMWR Surveill Summ*. 2016;65(9):1–202
22. Henry-Reid LM, O'Connor KG, Klein JD, Cooper E, Flynn P, Futterman DC. Current pediatrician practices in identifying high-risk behaviors of adolescents. *Pediatrics*. 2010;125(4). Available at: www.pediatrics.org/cgi/content/full/125/4/e741
23. Hill LL, Hovell M, Blumberg E, et al. Gaps between adolescent risk behaviors and disclosure during outpatient visits. *Int J Family Med*. 2013;2013:718568
24. Meckler GD, Elliott MN, Kanouse DE, Beals KP, Schuster MA. Nondisclosure of sexual orientation to a physician among a sample of gay, lesbian, and bisexual youth. *Arch Pediatr Adolesc Med*. 2006; 160(12):1248–1254
25. Center for Reproductive Rights; United Nations Population Fund. *Briefing Paper: The Rights to Contraceptive Information and Services for Women and Adolescents*. New York, NY: Center for Reproductive Rights; 2010. Available at: https://www.unfpa.org/sites/default/files/resource-pdf/Contraception.pdf. Accessed June 9, 2019
26. American Public Health Association. Universal access to contraception. 2015. Available at: https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2015/12/17/09/14/universal-access-to-contraception. Accessed June 15, 2018
27. Ott MA, Sucato GS; Committee on Adolescence. Contraception for adolescents. *Pediatrics*. 2014;134(4). Available at: www.pediatrics.org/cgi/content/full/134/4/e1257
28. Ford C, English A, Sigman G. Confidential health care for adolescents: position paper for the Society for Adolescent Medicine. *J Adolesc Health*. 2004;35(2):160–167
29. American Academy of Family Physicians. Adolescent health care, confidentiality. Available at: https://www.aafp.org/about/policies/all/adolescent-confidentiality.html. Accessed June 9, 2019
30. Guttmacher Institute. United States teens. Available at: https://www.guttmacher.org/united-states/teens. Accessed June 9, 2019
31. Health Insurance Portability and Accountability Act of 1996, Pub L No. 104-191, 100 Stat 2548 (1996)
32. US Department of Health and Human Services. Your rights under HIPAA. Available at: https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html. Accessed June 9, 2019
33. Committee opinion No. 599: adolescent confidentiality and electronic health records. *Obstet Gynecol*. 2014;123(5): 1148–1150
34. Blythe MJ, Del Beccaro MA; Committee on Adolescence; Council on Clinical and Information Technology. Standards for health information technology to ensure adolescent privacy. *Pediatrics*. 2012;130(5):987–990
35. Lenhart A. *Teens, Technology and Friendships*. Washington, DC: Pew Research Center; 2015. Available at: www.pewinternet.org/2015/08/06/teens-technology-and-friendships/. Accessed June 9, 2019
36. Rice E, Gibbs J, Winetrobe H, et al. Sexting and sexual behavior among middle school students. *Pediatrics*. 2014;134(1). Available at: www.pediatrics.org/cgi/content/full/134/1/e21

37. Houck CD, Barker D, Rizzo C, Hancock E, Norton A, Brown LK. Sexting and sexual behavior in at-risk adolescents. *Pediatrics*. 2014;133(2). Available at: www.pediatrics.org/cgi/content/full/133/2/e276

38. Patchin JW, Hinduja S. Sextortion among adolescents: results from a national survey of U.S. youth. *Sex Abuse*. 2020;32(1):30–54

39. Wolak J, Mitchell K, Finkelhor D. Unwanted and wanted exposure to online pornography in a national sample of youth Internet users. *Pediatrics*. 2007;119(2):247–257

40. Klaassen MJ, Peter J. Gender (in) equality in Internet pornography: a content analysis of popular pornographic Internet videos. *J Sex Res*. 2015;52(7):721–735

41. American Academy of Pediatrics. Media and children communication toolkit. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Pages/Media-and-Children.aspx. Accessed June 9, 2019

42. Reid Chassiakos YL, Radesky J, Christakis D, Moreno MA, Cross C; Council on Communications and Media. Children and adolescents and digital media. *Pediatrics*. 2016;138(5):e20162593

43. Federal Bureau of Investigation. Crime in the United States 2013: rape. 2013. Available at: https://ucr.fbi.gov/crime-in-the-u.s/2013/crime-in-the-u.s.-2013/violent-crime/rape. Accessed June 9, 2019

44. Stemple L, Meyer IH. The sexual victimization of men in America: new data challenge old assumptions. *Am J Public Health*. 2014;104(6):e19–e26

45. Bullock CM, Beckson M. Male victims of sexual assault: phenomenology, psychology, physiology. *J Am Acad Psychiatry Law*. 2011;39(2):197–205

46. Crawford-Jakubiak JE, Alderman EM, Leventhal JM; Committee on Child Abuse and Neglect; Committee on Adolescence. Care of the adolescent after an acute sexual assault [published correction appears in *Pediatrics*. 2017;139(6): e20170958]. *Pediatrics*. 2017;139(3):e20164243

47. Greenfeld LA. An analysis of data on rape and sexual assault: sex offenses and offenders. 1997. Available at: https://bjs.gov/content/pub/pdf/soo.pdf. Accessed June 9, 2019

48. Rape, Abuse, and Incest National Network. State law database. Available at: https://apps.rainn.org/policy/. Accessed June 9, 2019

49. Bureau of Justice Statistics. Rape and sexual assault. Available at: https://www.bjs.gov/index.cfm?ty=tp&tid=317. Accessed June 9, 2019

50. Government of Canada, Department of Justice. A definition of consent to sexual activity. Available at: https://www.justice.gc.ca/eng/cj-jp/victims-victimes/def.html. Accessed June 9, 2019

51. Brown S. 'They think it's all up to the girls': gender, risk and responsibility for contraception. *Cult Health Sex*. 2015;17(3):312–325

52. Richards MJ, Peters M, Sheeder J, Kaul P. Contraception and adolescent males: an opportunity for providers. *J Adolesc Health*. 2016;58(3):366–368

53. Marcell AV, Waks AB, Rutkow L, McKenna R, Rompalo A, Hogan MT. What do we know about males and emergency contraception? A synthesis of the literature. *Perspect Sex Reprod Health*. 2012;44(3):184–193

54. Lindley LL, Walsemann KM. Sexual orientation and risk of pregnancy among New York city high-school students. *Am J Public Health*. 2015;105(7):1379–1386

55. Pinzon JL, Jones VF; Committee on Adolescence; Committee on Early Childhood. Care of adolescent parents and their children. *Pediatrics*. 2012;130(6). Available at: www.pediatrics.org/cgi/content/full/130/6/e1743. Reaffirmed July 2016

56. Centers for Disease Control and Prevention. Sexually transmitted disease surveillance 2017. Available at: https://www.cdc.gov/std/life-stages-populations/adolescents-youngadults.htm. Accessed March 21, 2019

57. Centers for Disease Control and Prevention. HIV and youth. Available at: https://www.cdc.gov/hiv/pdf/group/age/youth/cdc-hiv-youth.pdf. Accessed March 21, 2019

58. Clark H, Babu AS, Wiewel EW, Opoku J, Crepaz N. Diagnosed HIV infection in transgender adults and adolescents: results from the National HIV Surveillance System, 2009-2014. *AIDS Behav*. 2017;21(9):2774–2783

59. Centers for Disease Control and Prevention. Sexually transmitted disease surveillance 2017: gonorrhea. Available at: https://www.cdc.gov/std/stats17/gonorrhea.htm. Accessed June 9, 2019

60. Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2016: Gonococcal Isolate Surveillance Project (GISP) Supplement and Profiles*. Atlanta, GA: Centers for Disease Control and Prevention, US Department of Health and Human Services; 2018

61. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015 [published correction appears in *MMWR Recomm Rep*. 2015;64(33):924]. *MMWR Recomm Rep*. 2015;64(RR-03):1–137

62. National Committee for Quality Assurance. *The State of Health Care Quality Report 2015*. Washington, DC: National Committee for Quality Assurance; 2015

63. Cuffe KM, Newton-Levinson A, Gift TL, McFarlane M, Leichliter JS. Sexually transmitted infection testing among adolescents and young adults in the United States. *J Adolesc Health*. 2016;58(5):512–519

64. US Preventive Services Task Force. Final recommendation statement: chlamydia and gonorrhea: screening. 2014. Available at: https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/chlamydia-and-gonorrhea-screening. Accessed June 9, 2019

65. American Academy of Pediatrics. Bright Futures medical screening reference table: adolescence visits (11 through 21 years). Available at: https://brightfutures.aap.org/Bright%20Futures%20Documents/MSRTable_AdolVisits_BF4.pdf. Accessed June 9, 2019

66. Committee on Infectious Diseases, American Academy of Pediatrics. Human Immunodeficiency Virus

Infection. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018–2021 Report of the Committee on Infectious Diseases*, 31st ed. Itasca, IL: American Academy of Pediatrics; 2018: 459–476

67. Emmanuel PJ, Martinez J; Committee on Pediatric AIDS. Adolescents and HIV infection: the pediatrician's role in promoting routine testing. *Pediatrics*. 2011;128(5):1023–1029. Reaffirmed September 2015
68. Branson BM, Handsfield HH, Lampe MA, et al; Centers for Disease Control and Prevention (CDC). Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Recomm Rep*. 2006;55(RR):1–17; quiz CE1–CE4
69. Centers for Disease Control and Prevention. US Public Health Service: preexposure prophylaxis for the prevention of HIV infection in the United States—2017 update: a clinical practice guideline. 2018. Available at: https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Accessed June 9, 2019
70. US Food and Drug Administration. Highlights for prescribing information. 2018. Available at:https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021752s055lbl.pdf. Accessed June 9, 2019
71. US Food and Drug Administration. FDA approves second drug to prevent HIV infection as part of ongoing efforts to end the HIV epidemic [press release]. October 3, 2019. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-second-drug-prevent-hiv-infection-part-ongoing-efforts-end-hiv-epidemic. Accessed March 20, 2020
72. Centers for Disease Control and Prevention. Pre-exposure prophylaxis (PrEP). 2018. Available at: https://www.cdc.gov/hiv/risk/prep/index.html. Accessed June 9, 2019
73. Centers for Disease Control and Prevention. Expedited partner therapy. 2018. Available at: https://www.cdc.gov/std/ept/default.htm. Accessed June 9, 2019
74. McQuillan G, Kruszon-Moran D, Markowitz LE, Unger ER, Paulose-Ram R. Prevalence of HPV in adults aged 18–69: United States, 2011–2014. *NCHS Data Brief*. 2017;(280):1–8
75. Centers for Disease Control and Prevention. HPV vaccine information for clinicians. 2016. Available at: https://www.cdc.gov/cancer/hpv/statistics/cases.htm. Accessed June 9, 2019
76. Sadlier C, Rowley D, Morley D, et al. Prevalence of human papillomavirus in men who have sex with men in the era of an effective vaccine; a call to act. *HIV Med*. 2014;15(8):499–504
77. Centers for Disease Control and Prevention (CDC). Recommendations on the use of quadrivalent human papillomavirus vaccine in males–Advisory Committee on Immunization Practices (ACIP), 2011. *MMWR Morb Mortal Wkly Rep*. 2011; 60(50):1705–1708
78. Meites E, Kempe A, Markowitz LE. Use of a 2-dose schedule for human papillomavirus vaccination - updated recommendations of the Advisory Committee on Immunization Practices. *MMWR Morb Mortal Wkly Rep*. 2016; 65(49):1405–1408
79. Walker TY, Elam-Evans LD, Yankey D, et al. National, regional, state, and selected local area vaccination coverage among adolescents aged 13-17 years - United States, 2017 [published correction appears in *MMWR Morb Mortal Wkly Rep*. 2018; 67(41):1164]. *MMWR Morb Mortal Wkly Rep*. 2018;67(33):909–917
80. Rosen RC, Seidman SN, Menza MA, et al. Quality of life, mood, and sexual function: a path analytic model of treatment effects in men with erectile dysfunction and depressive symptoms. *Int J Impot Res*. 2004;16(4): 334–340
81. Goldstein I, Mulhall JP, Bushmakin AG, Cappelleri JC, Hvidsten K, Symonds T. The erection hardness score and its relationship to successful sexual intercourse. *J Sex Med*. 2008;5(10): 2374–2380
82. O'Sullivan LF, Byers ES, Brotto LA, Majerovich JA, Fletcher J. A longitudinal study of problems in sexual functioning and related sexual distress among middle to late adolescents. *J Adolesc Health*. 2016; 59(3):318–324
83. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*, 5th ed. Washington, DC: American Psychiatric Association Publishing; 2013
84. Mialon A, Berchtold A, Michaud PA, Gmel G, Suris JC. Sexual dysfunctions among young men: prevalence and associated factors. *J Adolesc Health*. 2012;51(1): 25–31
85. Akre C, Berchtold A, Gmel G, Suris JC. The evolution of sexual dysfunction in young men aged 18-25 years. *J Adolesc Health*. 2014;55(6):736–743
86. Akre C, Michaud PA, Suris JC. "I'll look it up on the Web first": barriers and overcoming barriers to consult for sexual dysfunction among young men. *Swiss Med Wkly*. 2010;140(23–24): 348–353
87. Rosen RC, Cappelleri JC, Smith MD, Lipsky J, Peña BM. Development and evaluation of an abridged, 5-item version of the International Index of Erectile Function (IIEF-5) as a diagnostic tool for erectile dysfunction. *Int J Impot Res*. 1999; 11(6):319–326
88. Symonds T, Perelman MA, Althof S, et al. Development and validation of a premature ejaculation diagnostic tool. *Eur Urol*. 2007;52(2):565–573
89. Farrow JA. An approach to the management of sexual dysfunction in the adolescent male. *J Adolesc Health Care*. 1985;6(5):397–400
90. Rew KT, Heidelbaugh JJ. Erectile dysfunction. *Am Fam Physician*. 2016; 94(10):820–827
91. Harte CB, Meston CM. Recreational use of erectile dysfunction medications in undergraduate men in the United States: characteristics and associated risk factors. *Arch Sex Behav*. 2011;40(3): 597–606
92. Moncada I, Martínez-Jabaloyas JM, Rodriguez-Vela L, et al. Emotional changes in men treated with sildenafil citrate for erectile dysfunction: a double-blind, placebo-controlled clinical trial. *J Sex Med*. 2009;6(12): 3469–3477

93. Olsson AM, Speakman MJ, Dinsmore WW, et al; Sildenafil Multicentre Study Group. Sildenafil citrate (Viagra) is effective and well tolerated for treating erectile dysfunction of psychogenic or mixed aetiology. *Int J Clin Pract*. 2000; 54(9):561–566

94. Marcell AV, Breuner CC, Hammer L, Hudak ML; Committee on Adolescence; Committee on Child Health Financing. Targeted reforms in health care financing to improve the care of adolescents and young adults. *Pediatrics*. 2018;142(6):e20182998

95. Committee on Bioethics. Policy statement–physician refusal to provide information or treatment on the basis of claims of conscience. *Pediatrics*. 2009;124(6):1689–1693. Reaffirmed June 2018

Evaluation and Management of the Infant Exposed to HIV in the United States

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Evaluation and Management of the Infant Exposed to HIV in the United States

Ellen Gould Chadwick, MD, FAAP,[a] Echezona Edozie Ezeanolue, MD, MPH, FAAP,[b,c] COMMITTEE ON PEDIATRIC AIDS

Pediatricians play a crucial role in optimizing the prevention of perinatal transmission of HIV infection. Pediatricians provide antiretroviral prophylaxis to infants born to women with HIV type 1 (HIV) infection during pregnancy and to those whose mother's status was first identified during labor or delivery. Infants whose mothers have an undetermined HIV status should be tested for HIV infection within the boundaries of state laws and receive presumptive HIV therapy if the results are positive. Pediatricians promote avoidance of postnatal HIV transmission by advising mothers with HIV not to breastfeed. Pediatricians test the infant exposed to HIV for determination of HIV infection and monitor possible short- and long-term toxicity from antiretroviral exposure. Finally, pediatricians support families living with HIV by providing counseling to parents or caregivers as an important component of care.

INTRODUCTION

Each year approximately 8500 women with HIV infection give birth in the United States.[1] Through the implementation of effective, cost-saving[2] preventive strategies during pregnancy, the rate of perinatal transmission of HIV has remained low at <1% to 2%.[1] These preventive strategies include (1) the provision of universal opt-out HIV testing for all pregnant women and for those who have HIV infection, administration of combination antiretroviral therapy (ART) during pregnancy and labor; (2) planned cesarean delivery before the onset of labor and rupture of membranes for pregnant women with an HIV viral load of >1000 copies per mL before delivery; (3) provision of antiretroviral prophylaxis to the infant exposed to HIV for 4 to 6 weeks; and (4) complete avoidance of breastfeeding. Perinatal transmission occurs mostly when there is failure of implementation of these strategies, outlined in a separate 2008 American Academy of Pediatrics (AAP) policy statement titled "HIV Testing and Prophylaxis to Prevent Mother-to-Child Transmission in the United States."[3,4] This clinical report offers guidance on the evaluation and

abstract

[a]*Department of Pediatrics, Feinberg School of Medicine, Northwestern University and Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Illinois;* [b]*HealthySunrise Foundation, Las Vegas, Nevada; and* [c]*Department of Pediatrics, College of Medicine, University of Nigeria, Nsukka, Nigeria*

DOI: https://doi.org/10.1542/peds.2020-029058

Address correspondence to Ellen Gould Chadwick, MD.
E-mail: EGChadwick@luriechildrens.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Chadwick EG, AAP COMMITTEE ON PEDIATRIC AIDS. Evaluation and Management of the Infant Exposed to HIV in the United States. *Pediatrics.* 2020;146(5):e2020029058

management of infants born to women with HIV infection.

In addition to standard clinical care for the newborn infant, it is important that appropriate steps are taken for early detection of HIV infection, appropriate vaccines are administered, and adequate counseling is provided to families living with HIV infection. The management of infants in whom HIV infection is diagnosed should be undertaken in consultation with a pediatric HIV specialist. This report updates previous AAP recommendations.[5]

IDENTIFICATION OF MATERNAL HIV INFECTION

Although there has been a dramatic decrease in the number of new HIV infections in infants in the United States since 1994, when antiretroviral prophylaxis was first documented to prevent perinatal transmission, transmission continues to occur, albeit rarely.[1] Documented cases of perinatal transmission declined rapidly after the adoption of the recommendation by the Centers for Disease Control and Prevention (CDC), the AAP, and the American College of Obstetricians and Gynecologists for routine HIV testing for all pregnant women in the United States. HIV testing is now part of routine prenatal care in most states unless the patient declines, which is also known as "opt-out" consent or "right of refusal."[6,7] A second HIV test during the third trimester, preferably before 36 weeks' gestation, has been found to be cost-effective even in low-prevalence areas and should be considered for all pregnant women.[2] In particular, pregnant women at high risk for incident HIV infection (eg, those who are incarcerated, reside in communities with an HIV incidence greater than 1 per 1000 per year, inject drugs, exchange sex for money or drugs, are sex partners of individuals living with HIV, or have had a new or more than 1 sex partner during the current pregnancy) should have HIV testing repeated in the third trimester.[8] A plasma HIV RNA test is recommended in addition to routine antigen/antibody immunoassay testing when the possibility of acute retroviral syndrome is suspected in a pregnant woman.[9]

TESTING OF THE INFANT WHEN THE MOTHER'S HIV INFECTION STATUS IS UNKNOWN

When the HIV status of the mother is unknown, expedited HIV testing should be performed on the infant after consent procedures consistent with state and local law. Expedited HIV antigen/antibody testing allows timely identification of HIV infection in women whose HIV status is unknown late in pregnancy, during labor, or in the immediate postpartum period and is generally available on a 24-hour basis at all facilities with maternity services and/or a neonatal care unit. Positive HIV antigen/antibody test results should be urgently reported to health care providers so that presumptive HIV therapy can be initiated in the infant as soon after birth as possible and ideally within 6 to 12 hours of life. In addition, breastfeeding should be postponed, and the infant should be given formula feedings. If supplemental test results are negative, antiretroviral drugs should be stopped, and breastfeeding may be reinstated.[8]

STRATEGIES FOR PREVENTION OF PERINATAL HIV TRANSMISSION

Maternal Treatment During Pregnancy

Most women with HIV infection in the United States have access to free prenatal care, which allows for the initiation of effective ART in women in whom HIV is newly diagnosed or continuation of treatment in those who are currently receiving ART.[10] The determination of the appropriate mode of delivery and the decision not to breastfeed is also made during the prenatal period. The current US Department of Health and Human Services (HHS) Panel on Treatment of Pregnant Women With HIV Infection and Prevention of Perinatal Transmission (Perinatal Guidelines Panel) recommends the use of a combination of at least 3 antiretroviral drugs during pregnancy and labor for all pregnant women with HIV infection regardless of the plasma HIV RNA viral load or $CD4^+$ T-lymphocyte count.[11]

Interventions During Labor and at Delivery

Pregnant women with HIV infection generally continue the routine dosing schedule of their ART regimen during labor if possible. Intravenous zidovudine (ZDV), also known as azidothymidine (AZT), is added for pregnant women with HIV RNA >1000 copies per mL close to delivery and may be considered for RNA levels between 50 and 999 copies per mL, but it is no longer recommended for pregnant women with documented HIV RNA levels <50 copies per mL near delivery.[12] Planned cesarean delivery before labor and the rupture of membranes at 38 weeks' gestation is recommended for all pregnant women with HIV RNA levels of ≥ 1000 copies per mL near the time of delivery regardless of maternal HIV treatment.[13] Cesarean delivery solely for the prevention of transmission is not recommended for pregnant women with HIV RNA levels <1000 copies per mL because of the low risk of perinatal transmission of HIV in this group and the increased risk of complications with a major surgical procedure.[13]

Women who present in labor with unknown HIV status should receive expedited HIV testing with a combined HIV antigen/antibody test. If the screening result is positive, supplemental testing with an HIV-1/HIV-2 antibody differentiation

immunoassay and HIV RNA testing should be performed urgently, and intravenous ZDV should be initiated pending the result of the supplemental test.[12] Prompt initiation of intravenous ZDV, followed by infant antiretroviral prophylaxis, may decrease the risk of perinatal transmission of HIV in these settings.[14] Cesarean delivery before rupture of membranes, if feasible, may also be considered, but there is insufficient evidence to determine if cesarean delivery during labor reduces perinatal transmission.[13] If the supplemental results are negative, maternal and infant antiretroviral prophylaxis should be stopped.

Antiretroviral Management for the Infant Exposed to HIV

Postnatal antiretroviral drugs should be provided to all infants exposed to HIV to reduce the risk of perinatal HIV transmission. Antiretroviral prophylaxis is defined as the administration of 1 or more antiretroviral drug(s) to a newborn infant without confirmed HIV infection to reduce the risk of HIV acquisition, whereas presumptive HIV therapy consists of the administration of a 3-drug combination antiretroviral regimen to newborn infants at highest risk of HIV acquisition. Presumptive HIV therapy is intended to be preliminary treatment of a newborn infant who is later confirmed to have HIV infection but also serves as prophylaxis against perinatal transmission. Prophylaxis has historically been achieved by giving a 6-week neonatal ZDV chemoprophylaxis regimen. However, term infants born to women who received ART during pregnancy with documented viral suppression can be given a 4-week course.[15] In higher-risk cases, experts on the Perinatal Guidelines Panel recommend combining a 6-week infant ZDV prophylaxis regimen with 2 additional antiretroviral drugs including lamivudine (also known as "3TC") and either nevirapine (NVP) or raltegravir (RAL) to construct a presumptive HIV therapy regimen (see tables in ref 15).[15] This 3-drug combination antiretroviral drug regimen is recommended for infants born to mothers who (1) received prenatal antiretroviral drugs but had suboptimal viral suppression at delivery, (2) received only intrapartum antiretroviral drugs, (3) received no antepartum or intrapartum antiretroviral drugs, or (4) have known drug-resistant virus. Decisions about using a combination antiretroviral regimen over ZDV monotherapy can be made after balancing the benefits of enhanced prevention of perinatal transmission of HIV infection over possible toxicity from multiple drugs. The most information about the use of antiretroviral combinations in neonates is available for older regimens such as ZDV in combination with either single-dose nevirapine[16–19] or 3 doses of nevirapine in the first week of life[20] or the dual combination of ZDV and lamivudine.[21–24]

When making decisions to use combination antiretroviral drugs, consultation with a pediatrician experienced in the care of children with HIV infection or the National Clinician Consultation Center (https://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/) is beneficial. Monitoring for hematologic toxicity is necessary for any combination of ZDV and lamivudine compared to ZDV alone. Long-lasting resistance is possible if the infant is already infected when prophylaxis is given; this was most evident when nevirapine was used as a single agent for prophylaxis.[25] The HHS Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission[15] and Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV[26] each publish an extensive discussion of considerations for infant antiretroviral prophylaxis regimens for different clinical scenarios and provide specific neonatal antiretroviral dosing recommendations.

The administration of ZDV (possibly with other antiretroviral agents) to the infant should be initiated as soon as possible after birth and certainly within 6 to 12 hours after delivery.[27] If the infant's HIV exposure is first recognized between 12 and 48 hours after delivery, presumptive HIV therapy should be initiated in that time period.[15] Data from animal studies indicate that the longer the delay in institution of prophylaxis, the less likely that infection will be prevented. In most animal studies, antiretroviral prophylaxis initiated 24 to 36 hours after exposure is not as effective for preventing infection.[28–30]

The full course of drug supply needed for the entire 4 to 6 weeks should be supplied to the infant before discharge from the hospital irrespective of availability of out-of-pocket payment or insurance coverage because pediatric antiretroviral formulations are not widely available in commercial pharmacies.[15]

Avoidance of Postnatal HIV Infection

Postnatal transmission of HIV through ingestion of human milk from a mother with HIV infection is well documented, and prolonged breastfeeding from untreated mothers has resulted in rates as high as 9% to 15%.[31] However, studies in low-resource countries have revealed that maternal and/or infant antiretroviral drug administration during lactation reduces the risk of HIV transmission to the infant via human milk.[32,33] Because the risk of infant mortality from infectious diseases and malnutrition is low in the United States and effective alternative sources of feeding are readily available, women with HIV infection, including those receiving ART, should be counseled not to

breastfeed their infants or donate their milk.[34] Although maternal ART has been shown to reduce the concentration of cell-free HIV in human milk, it does not affect the amount of cell-associated virus in human milk.[35] In addition, discordance between the viral load in plasma and human milk has been observed. There is also differential penetration of antiretroviral drugs into human milk, with some antiretroviral drugs having concentrations in human milk that are higher than in maternal plasma, and others have lower or undetectable human milk concentrations.[36] These factors raise concerns about infant drug toxicity and the potential for selection of drug-resistant virus within human milk. Therefore, in the United States, where safe alternatives to breastfeeding are available, all women with HIV infection should avoid breastfeeding.[37]

Cultural differences require that counseling the mother about the avoidance of breastfeeding should be conducted in a sensitive manner. For some women, not being able to breastfeed may be the hardest component of their effort to protect their newborn infant from acquiring HIV infection.[37] Other mothers, particularly those who have emigrated from parts of the world where breastfeeding is nearly universal, may feel that formula feeding their infant discloses their own HIV infection to family or friends. As a result, recommendations to prevent perinatal transmission may not always be followed. Open, nonjudgmental communication about feeding practices facilitates appropriate follow-up and testing of all infants, including those whose mothers choose to breastfeed after appropriate counseling.[34] Education covering appropriate formula feeding and the cost of formula can be provided to women. Referrals, including enrollment in the Special Supplemental Nutrition Program for Women, Infants, and Children, are helpful in many cases. Evaluation of infant feeding practices with suggestions for safer feeding options and advice against premastication (the practice of prechewing solid food before feeding it to another), which is a potential risk factor for HIV transmission, are indicated.[38]

Framework for the Total Elimination of Perinatal Transmission of HIV

Several strategies have been documented that could potentially lead to the elimination of perinatal transmission of HIV. Early detection of HIV infection in the mother and evaluation and management of infants exposed to HIV remain the key to preventing perinatal transmission. This involves coordination of clinical care and social services, long-term follow-up of infants exposed to HIV, and ongoing HIV surveillance.[39] In many cases, early detection is not achieved because of social issues such as lack of access to mental, preventive, and general health care or substance use.[40,41] Interventions targeted to at-risk populations can minimize missed opportunities for the prevention of perinatal transmission of HIV. To be most effective, these efforts should be sustained and involve integrated clinical management and social services.[39]

CARE OF THE INFANT EXPOSED TO HIV

Testing to Determine the Infant's HIV Infection Status

Identification of the infant born to a mother with HIV infection and early determination of the presence or absence of HIV infection in the infant are critical to allow early initiation of prophylaxis or presumptive HIV therapy and provision of needed care. Appropriate HIV diagnostic testing for infants and children younger than 18 months differs from that for older children, adolescents, and adults. Passively transferred maternal HIV antibodies may be detectable in an exposed but uninfected infant's bloodstream until approximately 18 months of age. Therefore, routine serological testing of infants exposed to HIV and children before the age of 18 months is generally only informative if the test result is negative.

Polymerase chain reaction (PCR) assays that directly detect HIV DNA or RNA (generically referred to as HIV nucleic acid amplification tests [NAATs]) represent the gold standard for diagnostic testing of infants and young children younger than 18 months. With such testing, the diagnosis or the presumptive exclusion of HIV infection can be established within the first several weeks of life among nonbreastfed infants. Although neonatal antiretroviral drugs may decrease the concentration of HIV RNA in infant plasma in the first 6 weeks of life,[42] HIV DNA PCR results generally remain positive in most individuals taking ART who have undetectable plasma HIV RNA. The sensitivity of both DNA and RNA PCR testing is high,[43,44] so either can be used for the diagnosis of HIV infection in infancy.[45] False-positive results with low-level viral copy numbers have been described when using HIV RNA assays,[42,46,47] reinforcing the importance of repeating any positive assay result to confirm the diagnosis of HIV infection in infancy. False-negative results occur rarely, and retesting could be considered (perhaps by using a different test) if clinical findings suggest the presence of HIV infection.

Detection of Non–Subtype B HIV and HIV-2

For infants born to women known or suspected to have infection with non-B subtypes of HIV, use of HIV RNA assays may be preferable to the use of HIV DNA assays for diagnostic testing. Women who acquire HIV infection in

North America are most commonly infected with HIV subtype B.[48] Women who acquire HIV outside of North America are often infected with other HIV subtypes. Subtypes C and D predominate in southern and eastern Africa, subtype C predominates on the Indian subcontinent, and subtype E predominates in much of Southeast Asia.[48] HIV DNA PCR assays may be less sensitive in the detection of non-B subtype HIV, and false-negative HIV DNA PCR assay results have been reported in infants infected with non-B subtype HIV.[49,50] Some of the currently available HIV RNA assays have improved sensitivity for detection of non-B subtype HIV infection, although even these assays may not detect all non-B subtypes, such as the uncommon group O HIV strain. When testing infants suspected of infection with non-B subtype HIV, consultation with a pediatrician experienced in the care of infants and children with HIV infection is recommended.

HIV-2 is a retrovirus similar to HIV and is found most commonly in western Africa. It is less virulent, with a slower rate of progression of clinical disease and lower rates of perinatal transmission.[51] However, NAATs for HIV will not identify HIV-2, so if infection with HIV-2 is suspected, consultation with the CDC via the state department of health may be sought to help arrange specific HIV-2 testing.

Timing of Diagnostic Testing in Infants With Known Perinatal Exposure to HIV

For infants with known perinatal exposure, it is recommended that diagnostic testing with HIV DNA or RNA assays be performed at 14 to 21 days of age, and if results are negative, they should be repeated at 1 to 2 months of age and again at 4 to 6 months of age (Table 1).[52] For infants at a higher risk of perinatal HIV transmission who receive multiple antiretroviral drugs, additional virological diagnostic testing at birth as well as 2 to 4 weeks after cessation of antiretroviral prophylaxis should be considered.[12]

An HIV NAAT should be performed at birth or in the first few days of life for infants at highest risk of infection, including those whose mothers received no antiretroviral drugs during pregnancy, when maternal prophylaxis was started late in pregnancy or during labor, or if the mother had primary HIV infection during pregnancy. In the absence of maternal ART, as many as 30% to 40% of infants with HIV infection can be identified by 48 hours of age.[53,54] Infants with a positive NAAT result at or before 48 hours of age are considered to have in utero infection with HIV, whereas infants who have a negative NAAT result during the first week of life and a subsequent positive test result are considered to have intrapartum infection.[55] Cord blood specimens are not used for HIV RNA or DNA testing because they are associated with an unacceptably high rate of false-positive test results.

When a mother's HIV status is unknown at delivery or after birth, expedited HIV testing (preferably a combined test for HIV antigen and antibody) for mother and/or infant should be performed. In the event of a positive initial test result, presumptive HIV therapy is initiated in the infant as soon as possible pending the result of a supplemental test.[15] Treatment should be stopped if results of supplemental testing with HIV antibody and a NAAT are negative.

TABLE 1 Evaluation and Treatment of the Infant Exposed to HIV-1 (Birth to 18 Months of Age), in Addition to Routine Pediatric Care and Immunizations

Action[a]	Infant Age						
	Birth	14 d	4 wk	6 wk	8 wk	4 mo	12–18 mo
Antiretroviral prophylaxis or presumptive HIV therapy[b]	X	X	X	X	—	—	—
Recommend against breastfeeding and premastication	X	X	X	X	X	X	X
Hemoglobin or complete blood cell count	X	—	X[c]	—	X[c]	—	—
HIV-1 DNA or RNA PCR assay[d]	[e]	X[f]	X	—	[g]	X	—
Initiate PCP prophylaxis[h]	—	—	—	X	—	—	—
Antibody to HIV-1[i]	—	—	—	—	—	—	X

X, indication to conduct the specified action; —, not applicable.

[a] See the text for detailed discussion of each action. If during this period, HIV infection is diagnosed in the infant, laboratory monitoring and immunizations should follow guidelines for treatment of pediatric HIV infection.[52]

[b] Antiretroviral prophylaxis or presumptive HIV therapy, depending on the infant's risk of acquiring HIV (see text) is initiated as soon as possible after birth but certainly within 6–12 hours. ZDV prophylaxis is continued for 4–6 weeks, at which time it is stopped.

[c] Checked at 4 weeks by some experts and rechecked at 8 weeks if the week 4 hemoglobin level was significantly low.

[d] All infants exposed to HIV-1 should undergo virological testing for HIV-1 with HIV-1 DNA or RNA PCR assays at 14 to 21 days of age and, if results are negative, they should be repeated at 1 to 2 and 4 to 6 months of age to identify or exclude HIV-1 infection as early as possible. Any positive test result at any age is promptly repeated to confirm the diagnosis of HIV-1 infection.

[e] HIV-1 DNA or RNA PCR assay testing in the first few days of life allows identification of in utero infection and should be considered if maternal antiretroviral agents were not administered during pregnancy or in other high-risk situations. A negative test result at this age requires repeat testing to exclude HIV-1 infection.

[f] A negative test result at this age requires repeat testing to exclude HIV-1 infection. Presumptive uninfected indicates a negative NAAT result at ≥14 days and ≥4 weeks (1 month) of age; definitive uninfected indicates a negative NAAT result at ≥1 and ≥4 months of age (see text for complete details).

[g] For higher-risk infants, additional virological diagnostic testing should be considered 2 to 4 weeks after cessation of antiretroviral prophylaxis (ie, at 8–10 weeks of life).

[h] Infants with indeterminate HIV-1 infection status should receive prophylaxis starting at 4–6 weeks of age until they are deemed to be presumptively or definitively uninfected with HIV-1. Prophylaxis is not recommended for infants who meet criteria for presumptive or definitive lack of HIV-1 infection; therefore, a NAAT at 2 and 4–6 weeks of age allows for avoidance of PCP prophylaxis if both results are negative.

[i] Many experts confirm the absence of HIV-1 infection with a negative HIV-1 antibody assay result at 12–18 months of age.

If an HIV NAAT for the newborn infant was not performed shortly after birth, or if such test results were negative, diagnostic testing with an HIV NAAT is performed at 14 to 21 days of age because the diagnostic sensitivity of virological assays increases rapidly by 2 weeks of age.[53] This change in assay sensitivity reflects the biology of perinatal transmission, such that when HIV is acquired at the time of delivery, it may take up to 2 weeks for a NAAT to be able to detect the virus.[55] Therefore, negative results of HIV DNA PCR or RNA tests performed before 14 days of age are less helpful in excluding HIV infection acquired at the time of birth than are results of tests performed at or after 14 days of age.

Management if an HIV Virological Test Result Is Positive

If any of the HIV NAAT results are positive, an immediate repeat HIV NAAT is recommended to confirm the diagnosis of HIV infection. A diagnosis of HIV infection can be made on the basis of 2 separate blood samples, each of which is positive for HIV DNA or RNA. If infection is confirmed, a pediatric HIV specialist should be consulted for advice regarding ART and care. HIV disease can progress rapidly in infants with HIV infection, and neither $CD4^+$ T-lymphocyte count nor HIV RNA copy number is a reliable predictor of the risk of disease progression in infants.[53]

Interpretation of Negative HIV Test Results

On the basis of analysis of HIV DNA or RNA assay results from multiple studies, the CDC has revised the case definition for exclusion of HIV infection in infants for surveillance purposes.[56] The definitions supplied here are based on the CDC surveillance definitions and are appropriate for the management of children born to women with HIV infection. These definitions of exclusion of HIV infection are only for use in infants who do not meet the criteria for HIV infection noted above.[52]

In nonbreastfeeding infants younger than 18 months with no positive HIV NAAT results, presumptive exclusion of HIV infection is based on the following:

- two negative HIV RNA or DNA NAAT results, from separate specimens, both of which were obtained at ≥2 weeks of age and 1 of which was obtained at ≥4 weeks of age; or
- one negative HIV RNA or DNA NAAT result from a specimen obtained at ≥8 weeks of age; or
- one negative HIV antibody test result obtained at ≥6 months of age.

Definitive exclusion of HIV infection in a nonbreastfed infant is based on the following:

- two or more negative HIV RNA or DNA NAAT results, with 1 negative result at age ≥1 month and 1 negative result at age ≥4 months; or
- two negative HIV antibody test results from separate specimens obtained at age ≥6 months.

In the unusual case of an infant with a positive HIV NAAT result followed by a negative NAAT result, an expert in the care of children with HIV infection can be consulted for further testing recommendations.

Many experts confirm the absence of HIV infection with a negative HIV antibody assay result at 12 to 18 months of age (see next section). For both presumptive and definitive exclusion of infection, the child should have no other laboratory (eg, no positive NAAT results) or clinical (eg, no AIDS-defining conditions) evidence of HIV infection. For infants who have been breastfed, a similar testing algorithm can be followed, with additional testing every 3 months during breastfeeding followed by monitoring at 4 to 6 weeks, 3 months, and 6 months after breastfeeding cessation.[52]

Role of HIV Antibody Testing in Infants Exposed to HIV

In infants exposed to HIV who are not infected with HIV, maternal HIV antibodies transferred in utero may persist through 18 months of age. Loss of HIV antibody in an infant with previously negative HIV NAAT results (seroreversion) definitively confirms that the infant is not infected with HIV. Many infants exposed to HIV serorevert to HIV antibody negativity by 12 months of age.[57] Many experts confirm the absence of HIV infection with a negative HIV antibody assay result at 12 to 18 months of age. If an infant exposed to HIV who is not known to be infected is tested at 12 months of age and is still antibody-positive, then testing should be repeated at 18 to 24 months of age. Performing the first antibody test at 18 months of age to confirm seroreversion may avoid the cost and pain of performing 2 tests. Positive HIV antibodies at 24 months of age or older may indicate HIV infection and should be confirmed with an HIV virological test.[26] A confirmed NAAT result at or beyond 24 months of age in an infant with infection previously excluded as outlined above suggests that the infant was infected after infancy, such as through breastfeeding, premastication of solid food by a caregiver with HIV infection,[34] or sexual abuse.

Prevention of *Pneumocystis jirovecii* Pneumonia

The most common severe opportunistic infection in infants and children with HIV infection is *Pneumocystis jirovecii* pneumonia (PCP). PCP incidence in untreated infants with HIV is highest during the first year of life, with cases peaking at 3 to 6 months of age.[58,59] Chemoprophylaxis is highly effective in the prevention of PCP and should be administered to infants in whom HIV infection is diagnosed from 4 to

6 weeks of age until their first birthday. Thereafter, the need for prophylaxis is based on age-specific $CD4^+$ T-lymphocyte counts and/or percentages.[60] Trimethoprim-sulfamethoxazole is the most common drug used for prophylaxis because of its high efficacy, relative safety, low cost, and broad antimicrobial spectrum[60] (for further discussion, see ref 60).

PCP prophylaxis is not recommended for infants with presumptive lack of HIV infection (see previous section) but should be initiated for infants with indeterminate HIV infection status starting at 4 to 6 weeks of age.[60] Thus, for infants with negative HIV NAAT results at 2 and 4 to 6 weeks of age (presumptively not infected with HIV), PCP prophylaxis can be avoided completely. For an infant exposed to HIV with indeterminate HIV infection status who initiated prophylaxis at 4 to 6 weeks of age and subsequently meets criteria for presumptive or definitive lack of HIV infection, PCP prophylaxis can be stopped.

Prevention of Tuberculosis

Increased risk of tuberculosis (TB) among adults living with HIV infection is well documented. Because infants and children with TB infection and disease are usually infected by an adult with whom they live and have daily contact, TB infection status information should be obtained about the mother and all other household contacts of infants born to mothers with HIV. Bacille Calmette-Guerin immunization is not recommended for infants born to women with HIV infection in the United States and should not be administered to infants and children with known HIV infection because of its potential to cause disseminated disease.[61]

If an infant is exposed to anyone with active TB, the infant should be evaluated for TB disease and managed according to published guidelines.[61] If the infant's mother or any other person in the family receives a diagnosis of acid-fast bacillus smear-positive TB, the infant should be separated from that person until the TB infection has been treated with anti-TB medications and a physician has determined that the person is no longer contagious. In the event that a pregnant woman has documented TB that can be spread by the hematogenous route, the infant should be evaluated for congenital TB by a pediatric infectious disease expert.

Immunizations

Each year, the CDC publishes immunization schedules for children and adolescents 0 to 18 years of age[62] as well as for children with HIV infection.[63] All routine infant immunizations should be given to infants exposed to HIV. If HIV infection is confirmed in an infant exposed to HIV, then guidelines for the child with HIV infection should be followed.[62,63]

Monitoring for Toxicity From In Utero and Neonatal Antiretroviral Drug Exposure

Monitoring for and Management of Short-term Toxicity During Infant Antiretroviral Prophylaxis

Because exposure to maternal antiretroviral drugs taken during pregnancy can cause small but apparent variations of hemoglobin and neutrophil counts, a baseline complete blood cell and differential count has been recommended for the newborn infant.[64] The risk of anemia and neutropenia is greater in infants whose mothers received ART during pregnancy, but mild anemia was also observed commonly in infants whose mothers received ZDV monotherapy compared with infants whose mothers received no antiretroviral drugs during pregnancy.[65] Nonetheless, the advantages of maternal ART for prevention of perinatal transmission are far greater than hematologic toxicity in the newborn infant.[66,67]

The 6-week ZDV regimen in infants can cause anemia, which largely remains clinically insignificant and generally resolves after termination of ZDV prophylaxis. If anemia persists even after stopping the ZDV regimen, alternative etiologies are likely responsible. Anemia can be severe in infants taking ZDV who were born prematurely or with other medical problems. Also, administration of ZDV in combination with other antiretroviral drugs can cause hematologic toxicity.[68] The timing of monitoring of hematologic toxicity from ZDV prophylaxis depends on many factors such as baseline hematologic values, gestational age at birth, clinical condition of the child, receipt of concomitant medications, and maternal antepartum therapy. Hemoglobin and neutrophil counts should be measured in infants who have taken ZDV- and/or lamivudine-containing antiretroviral regimens for 4 or more weeks.

The decision of whether to discontinue antiretroviral prophylaxis early because of identification of hematologic abnormalities is made on the basis of factors such as severity of the laboratory abnormality, associated clinical symptoms, duration of infant prophylaxis already received, the magnitude of the risk of HIV infection in the infant (as assessed by maternal receipt of ART, maternal viral load near delivery, and mode of delivery), and availability of alternative interventions (eg, red blood cell transfusion) in consultation with a pediatric HIV specialist.

Routine measurement of serum lactate concentration in asymptomatic neonates to screen for possible mitochondrial toxicity related to ZDV prophylaxis is not recommended because the clinical relevance of increased lactate concentrations in the absence of symptoms is unknown, transient elevations return to normal, and there is poor predictive value for later appearance of symptomatic

toxicity.[69,70] However, if severe clinical symptoms, particularly neurologic symptoms, develop in the infant, a serum lactate concentration should be obtained. If the serum lactate concentration is significantly elevated in an infant with compatible clinical symptoms, a pediatric HIV expert can help determine if antiretroviral prophylaxis should be terminated. In general, prophylaxis should continue unless there is a compelling reason to stop.

Long-term Toxicity

Research has not revealed significant risk of neoplasia or organ-system toxicities from in utero exposure to ZDV or other antiretroviral drugs.[71] The issue of mitochondrial dysfunction from the use of ART has been unsubstantiated[69] but remains under investigation. However, in children exposed to HIV with severe clinical symptoms, neurologic or cardiac in particular, mitochondrial dysfunction is part of the differential diagnosis in HIV infection.[70,72–77]

Information regarding in utero and/or neonatal antiretroviral exposure is an important part of a permanent record, particularly in uninfected children. Uninfected children perinatally exposed to HIV have been found to have a higher rate of childhood infections in the first year of life than unexposed children and benefit from regular medical care.[78,79] Yearly follow-up into adulthood to monitor for long-term toxicity such as cancer or neurodevelopmental or metabolic disorders is appropriate.[71]

Testing Family Members

HIV screening should be recommended and offered to all immediate family members with unknown HIV infection status; this should be performed with the mother's consent to include the infant's father and/or mother's sexual partners. All siblings of the infant exposed to HIV, regardless of age of the siblings, should be tested because it is possible, albeit unusual, for perinatally infected children to remain asymptomatic into adolescence.[80,81]

Counseling and Support

An HIV diagnosis can have a significant impact on an individual and his or her family. When counseling the mother of an infant exposed to HIV, exploring whether HIV infection was recently diagnosed in the mother during or after pregnancy and whether she needs a referral for her own care may contribute to care of the whole family. Additionally, some families may require support related to an HIV-associated illness or death in other family members.

Increased need for social and psychological support services may result from factors including economic hardship, substance use, depression, social isolation, lack of health care, unemployment, difficulty in finding housing, or domestic violence. In addition, fear of loss of existing supports and services, such as loss of support from a partner or loss of employment, insurance, or health care coverage are important considerations.[82–84] Particularly vulnerable are pregnant adolescents with HIV infection.[85]

Additional factors may be present for women who have emigrated from other countries, in particular factors related to culture and concerns about immigration status. This population may have been subject to or know of stigmatization and discrimination against people with HIV infection. In addition, distrust or misunderstanding of the US medical system may complicate care and follow-up of the infant.

An outline of plans for medical care for the infant will help new parents, foster parents, or other caregivers optimally care for their infant exposed to HIV. Important topics include adherence to medications to prevent perinatal transmission of HIV and prompt assessment of illness in the infant exposed to HIV as well as the schedule of follow-up visits for assessment and laboratory assays (both for diagnosis of HIV infection and to check for any adverse effects of antiretroviral exposure). Breastfeeding is not recommended even if mothers are receiving ART for their own HIV disease.[37]

Counseling should include education about the risks of HIV transmission, including the lack of transmission risk in family activities such as eating, bathing, or sleeping together. Planning regarding future reproductive plans for the family, likely in collaboration with the family's adult HIV and gynecologic and obstetric providers, can minimize the risk of HIV acquisition for sexual partners and perinatal transmission in future pregnancies.

Confidentiality should be maintained at all times. In some cases, one or more family members may not be aware of the HIV infection status of the mother, which warrants extra caution in the labor and delivery unit and when discussing the postpartum management of the infant or in the pediatric office when discussing care of the child.

HIV Exposure and Infection Status Reporting

Name-based HIV reporting to state health departments is required in all states and territories for surveillance purposes.[86] In addition, many states require reporting pregnancy in women living with HIV and the infection status of their infants. To facilitate the required reporting, even when reporting is delegated to another party, the pediatrician should collect the maternal antiretroviral treatment history, maternal demographics, labor and delivery record, and newborn records at the time of birth.

SUMMARY (SEE TABLE 1)

1. Whenever possible, maternal HIV infection should be identified before or during pregnancy, which allows earlier initiation of care for the woman and for more effective interventions to prevent perinatal transmission. The AAP recommends documented, routine HIV testing for all pregnant women in the United States after notifying the patient that testing will be performed, unless the patient declines HIV testing (opt-out consent or right of refusal). All HIV testing, including during the third trimester, should be performed in a manner consistent with state and local laws.
2. If the mother's HIV serostatus is unknown at the time of labor or birth, the newborn infant's health care provider should perform expedited HIV antibody testing on the mother or the newborn infant or antigen/antibody testing on the mother, with appropriate consent consistent with state and local laws. The results should be reported to health care providers quickly enough to allow effective antiretroviral prophylaxis to be administered to the infant as soon as possible after birth and certainly within 6 to 12 hours after birth.
3. Intravenous ZDV for the mother and presumptive HIV therapy for the newborn infant should be administered promptly on the basis of a positive rapid antibody or antigen/antibody test result without waiting for the results of supplemental HIV testing, and breastfeeding should not be initiated. If the rapid test result is positive, supplemental testing should be performed, and if supplemental test results are negative (indicating that the infant was not truly exposed to HIV), then antiretroviral drugs should be stopped and breastfeeding can be initiated.
4. Avoidance of breastfeeding has been and continues to be a standard, strong recommendation for women living with HIV in the United States because maternal ART dramatically reduces but does not eliminate breast milk transmission, and safe infant feeding alternatives are readily available in the United States.
5. Pediatricians should provide counseling to parents and caregivers of infants exposed to HIV about HIV infection, including routine care of the infant, diagnostic tests, and potential drug toxicities.
6. All infants exposed to HIV should undergo virological testing with HIV DNA, RNA, or total nucleic acid assays at 14 to 21 days of age. If results are negative, these tests should be repeated at 1 to 2 and 4 to 6 months of age to identify or exclude HIV infection as early as possible. If any test result is positive, the test should be repeated immediately for confirmation.
7. Initial testing in the first few days of life allows identification of in utero infection and should be considered if maternal antiretroviral drugs were not administered during pregnancy or in other high-risk situations (see text). If an HIV NAAT for the newborn infant was not performed shortly after birth, or if such test results were negative, diagnostic testing with an HIV NAAT is performed at 14 to 21 days of age because the diagnostic sensitivity of virological assays increases rapidly by 2 weeks of age.
8. For nonbreastfeeding infants and children younger than 18 months with no positive HIV virological test results, presumptive exclusion of HIV infection is based on 2 negative HIV RNA or DNA NAAT results from separate specimens, both of which were obtained at $\geq$2 weeks of age and 1 of which was obtained at $\geq$4 weeks of age, 1 negative HIV RNA or DNA NAAT result obtained at $\geq$8 weeks of age, or 1 negative HIV antibody test result obtained at $\geq$6 months of age.
9. Definitive exclusion of HIV infection in a nonbreastfed infant is based on 2 or more negative HIV RNA or DNA test results, with 1 negative result at age $\geq$1 month and 1 negative result at age $\geq$4 months, or 2 negative HIV antibody test results from separate specimens obtained at age $\geq$6 months.
10. Many experts confirm the absence of HIV infection with a negative HIV antibody assay result at 12 to 24 months of age. These laboratory tests can only be used to exclude HIV infection if there is no other laboratory or clinical evidence of HIV infection (ie, no subsequent positive results from NAATs if tests were performed and no AIDS-defining condition for which there is no other underlying condition of immunosuppression) and the child is not receiving antiretroviral drugs.
11. PCP prophylaxis is not recommended for infants who are presumptively or definitively not infected with HIV (see recommendations 9 and 10). Infants with indeterminate HIV infection status after 6 weeks of age should receive prophylaxis until they are determined presumptively or definitively not to be infected with HIV.
12. All infants exposed to antiretroviral agents in utero or

as newborn infants should be monitored for short- and long-term drug toxicity.

13. Immunizations and TB screening should be provided for infants exposed to HIV in accordance with published guidelines. A BCG vaccine should not be administered to infants in whom HIV infection is diagnosed.
14. HIV testing should be offered and recommended to immediate family members of infants exposed to HIV.
15. The practitioner providing care for an infant with HIV infection should consult with a pediatric HIV specialist. An alternative service for advice on prevention of perinatal HIV transmission or HIV management is the National Clinician Consultation Center (https://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/). If the infant's mother is an adolescent, consultation with a practitioner familiar with the care of adolescents is advised.

LEAD AUTHORS

Ellen Gould Chadwick, MD, FAAP
Echezona Edozie Ezeanolue, MD, MPH, FAAP

COMMITTEE ON PEDIATRIC AIDS, 2018–2019

Ellen Gould Chadwick, MD, FAAP, Chairperson
Echezona Edozie Ezeanolue, MD, MPH, FAAP
Katherine Kai-Chi Hsu, MD, MPH, FAAP
Athena P. Kourtis, MD, PhD, MPH, FAAP
Ayesha Mirza, MD, FAAP
Rosemary M. Olivero, MD, FAAP
Natella Yurievna Rakhmanina, MD, PhD, FAAP
Carina Rodriguez, MD, FAAP

PREVIOUS COMMITTEE ON PEDIATRIC AIDS MEMBER

Elizabeth Montgomery Collins, MD, MPH, FAAP

CONSULTANT

Athena P. Kourtis, MD, PhD, MPH, FAAP

LIAISONS

Steve Nesheim, MD – *Centers for Disease Control and Prevention*
George Siberry, MD, MPH, FAAP – *United States Agency for International Development (USAID)*
Bill G. Kapogiannis, MD – *Eunice Kennedy Shriver National Institute for Child Health and Human Development*

STAFF

Anjie Emanuel, MPH

ABBREVIATIONS

AAP: American Academy of Pediatrics
ART: antiretroviral therapy
CDC: Centers for Disease Control and Prevention
HHS: US Department of Health and Human Services
NAAT: nucleic acid amplification test
PCP: *Pneumocystis jirovecii* pneumonia
PCR: polymerase chain reaction
TB: tuberculosis
ZDV: zidovudine

FINANCIAL DISCLOSURE: Dr Chadwick disclosed a financial relationship in which her spouse owns stock in pharmaceutical companies that manufacture drugs used to treat HIV/AIDS; and Dr Ezeanolue has indicated he has no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Dr Chadwick disclosed a financial relationship in which her spouse owns stock in pharmaceutical companies that manufacture drugs used to treat HIV/AIDS; and Dr Ezeanolue has indicated he has no potential conflicts of interest to disclose.

REFERENCES

1. Nesheim SR, Wiener J, Fitz Harris LF, Lampe MA, Weidle PJ. Brief report: estimated incidence of perinatally acquired HIV infection in the United States, 1978-2013. *J Acquir Immune Defic Syndr*. 2017;76(5):461–464
2. Bert F, Gualano MR, Biancone P, et al. HIV screening in pregnant women: a systematic review of cost-effectiveness studies. *Int J Health Plann Manage*. 2018;33(1):31–50
3. Camacho-Gonzalez AF, Kingbo M-H, Boylan A, Eckard AR, Chahroudi A, Chakraborty R. Missed opportunities for prevention of mother-to-child transmission in the United States. *AIDS*. 2015;29(12):1511–1515
4. American Academy of Pediatrics Committee on Pediatric AIDS. HIV testing and prophylaxis to prevent mother-to-child transmission in the United States. *Pediatrics*. 2008;122(5):1127–1134
5. Havens PL, Mofenson LM; American Academy of Pediatrics Committee on Pediatric AIDS. Evaluation and management of the infant exposed to HIV-1 in the United States. [published correction appears in Pediatrics. 2012;130(6):1183–1184]. *Pediatrics*. 2009;123(1):175–187
6. Mofensen LM; Centers for Disease Control and Prevention, U.S. Public Health Service Task Force. U.S. Public Health Service Task Force recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission in the United States. *MMWR Recomm Rep*. 2002;51(RR):1–38–4
7. Committee on Obstetric Practice; HIV Expert Work Group. ACOG Committee Opinion No. 752: prenatal and perinatal human immunodeficiency virus testing. *Obstet Gynecol*. 2018;132(3):e138–e142

8. Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at: https://clinicalinfo.hiv.gov/en/guidelines/perinatal/maternal-hiv-testing-and-identification-perinatal-hiv-exposure. Accessed September 23, 2020

9. Centers for Disease Control and Prevention; Association of Public Health Laboratories. *Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations*. Atlanta, GA: Centers for Disease Control and Prevention; 2014. Available at: http://stacks.cdc.gov/view/cdc/23447. Accessed January 8, 2020

10. American Pregnancy Association. Medicaid for pregnant women. Available at: https://americanpregnancy.org/first-year-of-life/medicaid-for-pregnant-women/. Accessed January 8, 2020

11. Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal/overview-2?view=full. Accessed September 23, 2020

12. Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at: https://clinicalinfo.hiv.gov/en/guidelines/perinatal/intrapartum-antiretroviral-therapyprophylaxis?view=full Accessed September 23, 2020

13. Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at: https://clinicalinfo.hiv.gov/en/guidelines/perinatal/transmission-and-mode-delivery?view=full Accessed September 23, 2020

14. Wade NA, Zielinski MA, Butsashvili M, et al. Decline in perinatal HIV transmission in New York State (1997-2000). *J Acquir Immune Defic Syndr*. 2004;36(5):1075–1082

15. Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at: https://clinicalinfo.hiv.gov/en/guidelines/perinatal/antiretroviral-management-newborns-perinatal-hiv-exposure-or-hiv-infection?view=full Accessed September 23, 2020

16. Dabis F, Bequet L, Ekouevi DK, et al.; ANRS 1201/1202 DITRAME PLUS Study Group. Field efficacy of zidovudine, lamivudine and single-dose nevirapine to prevent peripartum HIV transmission. *AIDS*. 2005;19(3):309–318

17. Lallemant M, Jourdain G, Le Coeur S, et al.; Perinatal HIV Prevention Trial (Thailand) Investigators. Single-dose perinatal nevirapine plus standard zidovudine to prevent mother-to-child transmission of HIV-1 in Thailand. *N Engl J Med*. 2004;351(3):217–228

18. Taha TE, Kumwenda NI, Hoover DR, et al. Nevirapine and zidovudine at birth to reduce perinatal transmission of HIV in an African setting: a randomized controlled trial. *JAMA*. 2004;292(2):202–209

19. Mirochnick M, Fenton T, Gagnier P, et al.; Pediatric AIDS Clinical Trials Group Protocol 250 Team. Pharmacokinetics of nevirapine in human immunodeficiency virus type 1-infected pregnant women and their neonates. *J Infect Dis*. 1998;178(2):368–374

20. Nielsen-Saines K, Watts DH, Veloso VG, et al.; NICHD HPTN 040/PACTG 1043 Protocol Team. Three postpartum antiretroviral regimens to prevent intrapartum HIV infection. *N Engl J Med*. 2012;366(25):2368–2379

21. Mandelbrot L, Landreau-Mascaro A, Rekacewicz C, et al.; Agence Nationale de Recherches sur le SIDA (ANRS) 075 Study Group. Lamivudine-zidovudine combination for prevention of maternal-infant transmission of HIV-1. *JAMA*. 2001;285(16):2083–2093

22. Moodley D, Moodley J, Coovadia H, et al.; South African Intrapartum Nevirapine Trial (SAINT) Investigators. A multicenter randomized controlled trial of nevirapine versus a combination of zidovudine and lamivudine to reduce intrapartum and early postpartum mother-to-child transmission of human immunodeficiency virus type 1. *J Infect Dis*. 2003;187(5):725–735

23. Moodley D, Pillay K, Naidoo K, et al. Pharmacokinetics of zidovudine and lamivudine in neonates following coadministration of oral doses every 12 hours. *J Clin Pharmacol*. 2001;41(7):732–741

24. Moodley J, Moodley D, Pillay K, et al. Pharmacokinetics and antiretroviral activity of lamivudine alone or when coadministered with zidovudine in human immunodeficiency virus type 1-infected pregnant women and their offspring. *J Infect Dis*. 1998;178(5):1327–1333

25. McIntyre JA, Hopley M, Moodley D, et al. Efficacy of short-course AZT plus 3TC to reduce nevirapine resistance in the prevention of mother-to-child HIV transmission: a randomized clinical trial. *PLoS Med*. 2009;6(10):e1000172

26. Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Available at: https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/antiretroviral-management-newborns-perinatal-hiv-exposure-or-hiv-infection?view=full. Accessed September 23, 2020

27. Wade NA, Birkhead GS, Warren BL, et al. Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. *N Engl J Med*. 1998;339(20):1409–1414

28. Van Rompay KKA, Otsyula MG, Marthas ML, Miller CJ, McChesney MB, Pedersen NC. Immediate zidovudine treatment protects simian immunodeficiency virus-infected newborn macaques against rapid onset of AIDS. *Antimicrob Agents Chemother*. 1995;39(1):125–131

29. Tsai CC, Follis KE, Sabo A, et al. Prevention of SIV infection in macaques by (R)-9-(2-phosphonylmethoxypropyl) adenine. *Science*. 1995;270(5239): 1197–1199

30. Böttiger D, Johansson NG, Samuelsson B, et al. Prevention of simian immunodeficiency virus, SIVsm, or HIV-2 infection in cynomolgus monkeys by pre- and postexposure administration of BEA-005. *AIDS*. 1997;11(2):157–162

31. Read JS; American Academy of Pediatrics Committee on Pediatric AIDS. Human milk, breastfeeding, and transmission of human immunodeficiency virus type 1 in the United States. *Pediatrics*. 2003;112(5): 1196–1205. Reaffirmed January 2007

32. Shapiro RL, Hughes MD, Ogwu A, et al. Antiretroviral regimens in pregnancy and breast-feeding in Botswana. *N Engl J Med*. 2010;362(24):2282–2294

33. Hudgens MG, Taha TE, Omer SB, et al. Pooled individual data analysis of 5 randomized trials of infant nevirapine prophylaxis to prevent breast-milk HIV-1 transmission. *Clin Infect Dis*. 2013;56(1): 131–139

34. Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States. Available at: https://clinicalinfo.hiv.gov/en/guidelines/perinatal/counseling-and-managing-women-living-hiv-united-states-who-desire-breastfeed?view=full Accessed September 23, 2020

35. Shapiro RL, Ndung'u T, Lockman S, et al. Highly active antiretroviral therapy started during pregnancy or postpartum suppresses HIV-1 RNA, but not DNA, in breast milk. *J Infect Dis*. 2005;192(5):713–719

36. Shapiro RL, Holland DT, Capparelli E, et al. Antiretroviral concentrations in breast-feeding infants of women in Botswana receiving antiretroviral treatment. *J Infect Dis*. 2005;192(5): 720–727

37. Committee on Pediatric Aids. Infant feeding and transmission of human immunodeficiency virus in the United States. *Pediatrics*. 2013;131(2):391–396

38. Ivy W III, Dominguez KL, Rakhmanina NY, et al. Premastication as a route of pediatric HIV transmission: case-control and cross-sectional investigations. *J Acquir Immune Defic Syndr*. 2012; 59(2):207–212

39. Nesheim S, Taylor A, Lampe MA, et al. A framework for elimination of perinatal transmission of HIV in the United States. *Pediatrics*. 2012;130(4):738–744

40. Katz IT, Leister E, Kacanek D, et al. Factors associated with lack of viral suppression at delivery among highly active antiretroviral therapy-naive women with HIV: a cohort study. *Ann Intern Med*. 2015;162(2):90–99

41. Birkhead GS, Pulver WP, Warren BL, et al. Progress in prevention of mother-to-child transmission of HIV in New York State: 1988-2008. *J Public Health Manag Pract*. 2010;16(6):481–491

42. Nesheim S, Palumbo P, Sullivan K, et al. Quantitative RNA testing for diagnosis of HIV-infected infants. *J Acquir Immune Defic Syndr*. 2003;32(2):192–195

43. Lambert JS, Harris DR, Stiehm ER, et al. Performance characteristics of HIV-1 culture and HIV-1 DNA and RNA amplification assays for early diagnosis of perinatal HIV-1 infection. *J Acquir Immune Defic Syndr*. 2003;34(5): 512–519

44. Delamare C, Burgard M, Mayaux MJ, et al.; The French Pediatric HIV Infection Study Group. HIV-1 RNA detection in plasma for the diagnosis of infection in neonates. *J Acquir Immune Defic Syndr Hum Retrovirol*. 1997;15(2):121–125

45. Read JS; Committee on Pediatric AIDS, American Academy of Pediatrics. Diagnosis of HIV-1 infection in children younger than 18 months in the United States. *Pediatrics*. 2007;120(6). Available at: www.pediatrics.org/cgi/content/full/120/6/e1547

46. Rouet F, Montcho C, Rouzioux C, et al.; Abidjan DITRAME Study Group (ANRS 049 clinical trial). Early diagnosis of paediatric HIV-1 infection among African breast-fed children using a quantitative plasma HIV RNA assay. *AIDS*. 2001;15(14):1849–1856

47. Cunningham CK, Charbonneau TT, Song K, et al. Comparison of human immunodeficiency virus 1 DNA polymerase chain reaction and qualitative and quantitative RNA polymerase chain reaction in human immunodeficiency virus 1-exposed infants. *Pediatr Infect Dis J*. 1999;18(1): 30–35

48. Geretti AM. HIV-1 subtypes: epidemiology and significance for HIV management. *Curr Opin Infect Dis*. 2006; 19(1):1–7

49. Kline NE, Schwarzwald H, Kline MW. False negative DNA polymerase chain reaction in an infant with subtype C human immunodeficiency virus 1 infection. *Pediatr Infect Dis J*. 2002; 21(9):885–886

50. Obaro SK, Losikoff P, Harwell J, Pugatch D. Failure of serial human immunodeficiency virus type 1 DNA polymerase chain reactions to identify human immunodeficiency virus type 1 clade A/G. *Pediatr Infect Dis J*. 2005; 24(2):183–184

51. O'Donovan D, Ariyoshi K, Milligan P, et al.; MRC/Gambia Government/University College London Medical School working group on mother-child transmission of HIV. Maternal plasma viral RNA levels determine marked differences in mother-to-child transmission rates of HIV-1 and HIV-2 in the Gambia. *AIDS*. 2000;14(4):441–448

52. Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Available at: https://clinicalinfo.hiv.gov/en/guidelines/pediatric-arv/diagnosis-hiv-infection-infants-and-children?view=full Accessed September 23, 2020

53. Dunn DT, Brandt CD, Krivine A, et al. The sensitivity of HIV-1 DNA polymerase chain reaction in the neonatal period and the relative contributions of intra-uterine and intra-partum transmission. *AIDS*. 1995;9(9):F7–F11

54. Bremer JW, Lew JF, Cooper E, et al. Diagnosis of infection with human immunodeficiency virus type 1 by a DNA polymerase chain reaction assay among infants enrolled in the Women and Infants' Transmission Study. *J Pediatr*. 1996;129(2):198–207

55. Bryson YJ, Luzuriaga K, Sullivan JL, Wara DW. Proposed definitions for in utero versus intrapartum transmission

of HIV-1. *N Engl J Med*. 1992;327(17): 1246–1247

56. Selik RM, Mokotoff ED, Branson B, Owen SM, Whitmore S, Hall HI; Centers for Disease Control and Prevention (CDC). Revised surveillance case definition for HIV infection–United States, 2014. *MMWR Recomm Rep*. 2014;63(RR):1–10
57. Moodley D, Bobat RA, Coutsoudis A, Coovadia HM. Predicting perinatal human immunodeficiency virus infection by antibody patterns. *Pediatr Infect Dis J*. 1995;14(10):850–852
58. Simonds RJ, Oxtoby MJ, Caldwell MB, Gwinn ML, Rogers MF. Pneumocystis carinii pneumonia among US children with perinatally acquired HIV infection. *JAMA*. 1993;270(4):470–473
59. Gibb DM, Davison CF, Holland FJ, Walters S, Novelli V, Mok J. Pneumocystis carinii pneumonia in vertically acquired HIV infection in the British Isles. *Arch Dis Child*. 1994;70(3):241–244
60. Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children.Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at: https://clinicalinfo.hiv.gov/en/guidelines/pediatric-opportunistic-infection/pneumocystis-jirovecii-pneumonia?view=full Accessed September 23, 2020
61. Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children.Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at: https://clinicalinfo.hiv.gov/en/guidelines/pediatric-opportunistic-infection/mycobacterium-tuberculosis?view=full Accessed September 23, 2020
62. Centers for Disease Control and Prevention. Recommended immunization schedule for children and adolescents aged 18 years or younger, United States, 2020. Available at: https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html. Accessed September 23, 2020
63. Panel on Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. Department of Health and Human Services. Available at: https://clinicalinfo.hiv.gov/en/guidelines/pediatric-opportunistic-infection/preventing-vaccine-preventable-diseases-children-and?view=full Accessed September 23, 2020
64. Pacheco SE, McIntosh K, Lu M, et al.; Women and Infants Transmission Study. Effect of perinatal antiretroviral drug exposure on hematologic values in HIV-uninfected children: an analysis of the Women and Infants Transmission study. *J Infect Dis*. 2006;194(8):1089–1097
65. Feiterna-Sperling C, Weizsaecker K, Bührer C, et al. Hematologic effects of maternal antiretroviral therapy and transmission prophylaxis in HIV-1-exposed uninfected newborn infants. *J Acquir Immune Defic Syndr*. 2007; 45(1):43–51
66. Mofenson LM, Munderi P. Safety of antiretroviral prophylaxis of perinatal transmission for HIV-infected pregnant women and their infants. *J Acquir Immune Defic Syndr*. 2002;30(2): 200–215
67. Thorne C, Newell M-L. Safety of agents used to prevent mother-to-child transmission of HIV: is there any cause for concern? *Drug Saf*. 2007;30(3): 203–213
68. Lambert JS, Nogueira SA, Abreu T, et al. A pilot study to evaluate the safety and feasibility of the administration of AZT/3TC fixed dose combination to HIV infected pregnant women and their infants in Rio de Janeiro, Brazil. *Sex Transm Infect*. 2003;79(6):448–452
69. Noguera A, Fortuny C, Muñoz-Almagro C, et al. Hyperlactatemia in human immunodeficiency virus-uninfected infants who are exposed to antiretrovirals. *Pediatrics*. 2004;114(5). Available at: www.pediatrics.org/cgi/content/full/114/5/e598
70. Dominguez K, Bertolli J, Fowler M, et al.; PSD Consortium. Perinatal Safety Review Working Group. Lack of definitive severe mitochondrial signs and symptoms among deceased HIV-uninfected and HIV-indeterminate children < or = 5 years of age, Pediatric Spectrum of HIV Disease Project (PSD), USA. *Ann N Y Acad Sci*. 2000;918:236–246
71. Van Dyke RB, Chadwick EG, Hazra R, Williams PL, Seage GR III. The PHACS SMARTT Study: assessment of the safety of in utero exposure to antiretroviral drugs. *Front Immunol*. 2016;7:199
72. Blanche S, Tardieu M, Rustin P, et al. Persistent mitochondrial dysfunction and perinatal exposure to antiretroviral nucleoside analogues. *Lancet*. 1999; 354(9184):1084–1089
73. European Collaborative Study. Exposure to antiretroviral therapy in utero or early life: the health of uninfected children born to HIV-infected women. *J Acquir Immune Defic Syndr*. 2003; 32(4):380–387
74. Spector SA, Saitoh A. Mitochondrial dysfunction: prevention of HIV-1 mother-to-infant transmission outweighs fear. *AIDS*. 2006;20(13):1777–1778
75. Blanche S, Tardieu M, Benhammou V, Warszawski J, Rustin P. Mitochondrial dysfunction following perinatal exposure to nucleoside analogues. *AIDS*. 2006;20(13):1685–1690
76. Brogly SB, Ylitalo N, Mofenson LM, et al. In utero nucleoside reverse transcriptase inhibitor exposure and signs of possible mitochondrial dysfunction in HIV-uninfected children. *AIDS*. 2007;21(8):929–938
77. Barret B, Tardieu M, Rustin P, et al.; French Perinatal Cohort Study Group. Persistent mitochondrial dysfunction in HIV-1-exposed but uninfected infants: clinical screening in a large prospective cohort. *AIDS*. 2003;17(12): 1769–1785
78. Adler C, Haelterman E, Barlow P, Marchant A, Levy J, Goetghebuer T. Severe infections in HIV-exposed uninfected infants born in a European country. *PLoS One*. 2015;10(8):e0135375
79. Ruck C, Reikie BA, Marchant A, Kollmann TR, Kakkar F. Linking susceptibility to infectious diseases to immune system abnormalities among HIV-exposed uninfected infants. *Front Immunol*. 2016;7:310
80. Warszawski J, Lechenadec J, Faye A, et al. Long-term nonprogression of HIV infection in children: evaluation of the ANRS prospective French Pediatric

Cohort. *Clin Infect Dis*. 2007;45(6):785–794

81. Ofori-Mante JA, Kaul A, Rigaud M, et al. Natural history of HIV infected pediatric long-term or slow progressor population after the first decade of life. *Pediatr Infect Dis J*. 2007;26(3):217–220
82. Mellins CA, Ehrhardt AA. Families affected by pediatric acquired immunodeficiency syndrome: sources of stress and coping. *J Dev Behav Pediatr*. 1994;15(suppl 3):S54–S60
83. Reidy M, Taggart ME, Asselin L. Psychosocial needs expressed by the natural caregivers of HIV infected children. *AIDS Care*. 1991;3(3):331–343
84. Giannattasio A, Officioso A, Continisio GI, et al. Psychosocial issues in children and adolescents with HIV infection evaluated with a World Health Organization age-specific descriptor system. *J Dev Behav Pediatr*. 2011;32(1):52–55
85. Callahan T, Modi S, Swanson J, Ng'eno B, Broyles LN. Pregnant adolescents living with HIV: what we know, what we need to know, where we need to go. *J Int AIDS Soc*. 2017;20(1):21858
86. Centers for Disease Control and Prevention. HIV. Surveillance overview. Available at: https://www.cdc.gov/hiv/statistics/surveillance/index.html. Accessed January 8, 2020

Executive Summary: Identification, Evaluation, and Management of Children With Autism Spectrum Disorder

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Executive Summary: Identification, Evaluation, and Management of Children With Autism Spectrum Disorder

Susan L. Hyman, MD, FAAP,[a] Susan E. Levy, MD, MPH, FAAP,[b] Scott M. Myers, MD, FAAP,[c] COUNCIL ON CHILDREN WITH DISABILITIES, SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS

INTRODUCTION

Autism spectrum disorder (ASD) is a common neurodevelopmental disorder with reported prevalence in the United States of 1 in 59 children (approximately 1.7%). ASD significantly influences the lives of affected children and families because they may need extensive behavioral, educational, health, and other services. Primary care providers play a critical role in identifying, diagnosing, and managing ASD in children and providing support for their families. This document provides a summary of the clinical report "Identification, Evaluation, and Management of Children with Autism Spectrum Disorder," published concurrently in the online version of *Pediatrics*. In the years since 2007, when the American Academy of Pediatrics published the clinical reports "Identification and Diagnosis of Children with Autism Spectrum Disorders" and "Management of Children with Autism Spectrum Disorders," reported prevalence rates of children with ASD have increased, understanding of potential risk factors has expanded, awareness of co-occurring medical and behavioral conditions and genetic contribution to etiology has improved, and the body of research supporting evidence-based interventions has grown substantially. The updated document discusses evaluation and treatment as a continuum in 1 publication with a table of contents to help the reader identify topic areas within the report. ASD is more commonly diagnosed than in the past, and the significant health, educational, and social needs of individuals with ASD and their families constitute an area of critical need for resources, research, and professional education.

[a]Golisano Children's Hospital, University of Rochester, Rochester, New York; [b]Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; and [c]Geisinger Autism & Developmental Medicine Institute, Danville, Pennsylvania

Drs Hyman and Myers participated in the planning for this manuscript and writing and editing the manuscript; Dr Levy participated in writing and editing the manuscript; and all authors approved the final manuscript as submitted.

Clinical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, clinical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2019-3448

(Continued)

To cite: Hyman SL, Levy SE, Myers SM, AAP COUNCIL ON CHILDREN WITH DISABILITIES, SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS. Executive Summary: Identification, Evaluation, and Management of Children With Autism Spectrum Disorder. *Pediatrics*. 2020;145(1): e20193448

1. TIMELY DIAGNOSIS, EARLY IDENTIFICATION, AND EVIDENCE-BASED INTERVENTION

- *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5) diagnosis: With the publication of the DSM-5 in 2013, there is a single category of ASD, replacing the subtypes of autistic disorder, Asperger syndrome, and pervasive developmental disorder not otherwise specified in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*. Core deficits are identified in 2 domains: social communication and interaction and restrictive, repetitive patterns of behavior. The DSM-5 recognizes that other co-occurring conditions like intellectual disability, language disorders, and behavioral health conditions such as attention-deficit/hyperactivity disorder and anxiety disorders may also be diagnosed in individuals with ASD. A diagnosis of ASD is made by a clinical evaluation that supports the DSM-5 criteria, including history and observation of characteristic behaviors, preferably using standardized approaches. Independent of age, a child who is evaluated for ASD should have standardized assessment of psychoeducational, adaptive, and language abilities, including pragmatic or social language.
- Early identification: General developmental screening using a validated tool continues to be recommended at 9, 18, and 30 months of age. ASD is common, can be diagnosed as young as 18 months of age, and has evidence-based interventions. Research into newer tools has promise to extend the age of diagnosis lower. Therefore, ongoing developmental and behavioral surveillance in addition to screening for ASD at 18 and 24 months of age continues to be recommended in primary care. Screening or surveillance may take place in other settings, with communication of findings to the primary care provider. More accurate and culturally sensitive screening approaches are needed. Ongoing developmental surveillance through school age is important. Children with typical intellectual abilities may not be diagnosed until their social differences become evident with the increased demands of the school environment. Clinicians need to recognize that some children will be at increased risk for ASD because they have a sibling with ASD, were born preterm, were exposed to teratogens (eg, valproic acid), or have other risk factors.
- Timely diagnosis: Toddlers and children should be referred for diagnostic evaluation when increased risk for developmental disorders (including ASD) is identified through screening and/or surveillance. Most children with ASD will have other developmental issues. Standard of care requires evaluation of multiple streams of development, including cognitive, communication, motor, and adaptive skills. In many settings, this evaluation may be best accomplished by team evaluations, including, for example, psychology, speech and language, occupational therapy, physical therapy, and special education. This type of evaluation may occur through an early intervention program, school system, or appropriate insurance-funded evaluator(s) whenever ASD, with or without other delays, is suspected. Children should be referred for intervention for all identified developmental delays at the time of identification and not wait for an ASD diagnostic evaluation to take place. The referral should be to a clinician experienced in diagnosis, which might be a developmental-behavioral or neurodevelopmental pediatrician, neurologist, psychiatrist, psychologist, or primary care provider with requisite training. Clinicians should be particularly aware of the potential for delayed diagnosis in children from underserved groups and whose families speak languages other than English.
- Early and effective intervention: Clinicians should respond appropriately to family or clinical concerns and results of screening to avoid delays in diagnosis and treatment. Intervention for the communicative, adaptive, and behavioral deficits associated with ASD should take place as soon as the need becomes evident. Intervention is most effective if it is early, intense, and involves the family. Research has demonstrated that interventions using principles of behavioral intervention are associated with skill acquisition and improved outcome. There is evidence that training parents to support developmental skill building is helpful. Primary care providers should help families learn to interpret evidence about interventions so they can make informed decisions about their child's care. Many interventions, including many nutritional interventions, do not have evidence to support their use at this time. Families should be referred to community support resources and be included in the shared decision-making process.
- Etiologic evaluation: The pediatric provider needs to consider genetic and neurologic disorders that are associated with ASD. Knowledge of the etiology of the child's condition can help guide monitoring for co-occurring conditions, potentially influence therapy choices, help families understand recurrence risk estimates, and help therapists provide individualized behavioral, educational, motor, and communication intervention plans.

Families should be offered genetic evaluation, including chromosomal microarray and fragile X testing, with consideration of other cytogenetic and molecular testing, as indicated. Consultation with a pediatric geneticist may be warranted. Metabolic testing, EEG, neuroimaging, and additional workup of medical symptoms are guided by history and physical examination.

- Medical management of co-occurring conditions: The value of routine primary care visits and anticipatory guidance for children with chronic conditions is stressed. The primary care provider should be aware of common co-occurring conditions and include surveillance for and management of these conditions in the context of routine care with subspecialty referral, as appropriate. Examples of common co-occurring conditions are disorders of sleep, feeding problems, gastrointestinal symptoms, obesity, seizures, attention-deficit/hyperactivity disorder, anxiety, wandering or elopement, and others.

High-quality pediatric care calls for the development of systems to promote accurate and early identification, cost-effective and timely diagnosis, prompt implementation of evidence-based interventions, involvement of the patient and family in shared decision-making, and steps toward elimination of disparities in access to care for all children and youth with ASD. Care within a medical home, using a chronic care model in which health and community systems interact with informed patients and families to ensure more-satisfactory outcomes, is recommended for children with ASD.

2. COLLABORATION OF SYSTEMS OF CARE

- Evidence-based interventions*:* Children and youth with ASD should be provided evidence-based interventions to address the core social communication and interaction and restricted and repetitive behavior symptoms as well as associated impairments. Attention to social skills development should be addressed in school, community, behavioral health, and family settings. The primary care provider should be aware of the recommendation for educational services in the least-restrictive environment and the hierarchy of educational interventions based on a student's needs in school rather than a medical diagnosis of ASD.
- Common co-occurring conditions: Although ASD is a neurodevelopmental disorder characterized by symptoms related to social interaction and repetitive behaviors, there is increasing awareness that physical, behavioral, and mental symptoms affect the care of children and youth with ASD. Children and youth with ASD should have anticipatory guidance for common co-occurring conditions in the context of well-child care, referral as necessary for specialty care, and ongoing management as possible in the medical home.
- Behavioral health interventions*:* Providers should be aware of the common behavioral challenges faced by children and youth with ASD and be prepared to provide parent counseling and initial management of sleep problems, food refusal, and disruptive behaviors, with referral to appropriate specialty and mental health care if needed. It is important to evaluate the medical and behavioral causes for behavior change. Pain and discomfort from medical conditions and behavioral modifications should be addressed. Medication may be a useful addition for management of attention, hyperactivity, anxiety, and disruptive behaviors as part of an overall treatment strategy.
- Community services*:* The primary care provider needs to know where to refer families for information about community services, such as respite and leisure activities for individuals with ASD and other developmental disabilities. To promote wellness, communities should provide opportunities for individuals with ASD to participate in inclusive and appropriate active leisure activities. Clinicians should educate families about managing ASD as a chronic condition.

3. PLANNING FOR ADOLESCENCE AND TRANSITION TO ADULT SYSTEMS OF CARE

- Communities should build services to promote social skills appropriate for work and postsecondary education, access to appropriate medical and behavioral health services, job skills development, and community leisure opportunities. The medical home provider should support the family and youth to advocate for appropriate postsecondary work or schooling, residential supports, and activities to maintain a healthy lifestyle. The family needs to plan for the needs of the child in adulthood by making the necessary preparations for public programs (such as Supplemental Security Income) and personal financial planning.
- Pediatricians need to engage with families and youth to plan a transition to adult medical and behavioral health care.

4. PROMOTING SHARED DECISION-MAKING WITH INDIVIDUALS WITH ASD AND THEIR FAMILIES

Shared decision-making calls for the health care provider to engage in respectful, reciprocal dialogue to plan and monitor choices in care. The pediatrician can help educate youth

with ASD and their families about how to evaluate the evidence for interventions, advocate for participation in clinical research when appropriate, refer families to support organizations, include the patient in decision-making, and prepare families to navigate transitions.

5. ONGOING EDUCATION OF PEDIATRIC PROVIDERS TO SUPPORT AN INFORMED MEDICAL HOME FOR CHILDREN AND YOUTH WITH ASD

All children and youth with ASD should have a medical home, a source of care that is accessible, collaborative, culturally sensitive, knowledgeable, and cost-effective. To best serve patients and families affected by ASD, the clinician caring for children and youth with ASD should be familiar with issues related to diagnosis, co-occurring medical and behavioral conditions, and the impact of ASD on the family to provide a medical home for these patients. Actively addressing capacity building to care for children and youth with ASD requires initiatives directed at provider education and practice quality improvement and public health, educational, and social programs to support families in their journey from diagnosis to service provision to the transition to adult care.

6. SUPPORT FOR A NATIONAL AGENDA FOR BASIC, CLINICAL, AND HEALTH SERVICES RESEARCH ABOUT ASD

The American Academy of Pediatrics supports the current approach taken by the Interagency Autism Coordinating Committee of the National Institutes of Health of including representative stakeholders in planning a meaningful research agenda. Stakeholders include families and affected individuals, scientists, clinicians, and public health agencies. This committee's 2009 strategic plan, updated in 2017, identified 7 areas for research funding: (1) early detection, (2) underlying biology, (3) genetic and environmental risk factors, (4) treatments and interventions, (5) services and implementation science, (6) life span services and supports, and (7) epidemiological surveillance and infrastructure. It is important that multiple levels of inquiry be pursued simultaneously to inform evidence-based clinical care. These include the following:

- o basic and translational science in the areas of genetics and epigenetics, neurobiology, environmental risk factors, and psychopharmacology to understand the typical and atypical brain development and function to develop ASD-specific behavioral and pharmacologic therapies;
- o clinical trials to test focused interventions informed by translational studies to provide the evidence necessary for community implementation;
- o epidemiological surveillance to gather data important for planning for current and future needs, including screening, diagnosis, and life span health and mental health services, with special attention to underserved populations; and
- o health services research to provide guidance for comprehensive, accessible, and culturally appropriate medical, educational, and behavioral care for children, youth, adults, and families affected by ASD.

Research in all of these areas is critical to move forward with early diagnosis, effective treatment, and evidence-based interventions at each age. To provide appropriate care to all children and families affected by ASD, organizations responsible for health, education, social services, and public health need to collaborate and build integrated and adequately funded and staffed systems. The pediatric health care provider plays a critical role in identifying young children at risk for ASD; shepherding these children through diagnosis and into effective interventions; supporting the families, including siblings; anticipating and managing co-occurring health and behavioral disorders; and preparing the youth and family for transition to adult services. The updated clinical report provides the health care provider with information and resources to support the care of the child and family affected by ASD.

LEAD AUTHORS

Susan L. Hyman, MD, FAAP
Susan E. Levy, MD, MPH, FAAP
Scott M. Myers, MD, FAAP

CONTRIBUTORS

Paul H. Lipkin, MD, FAAP
Michelle M. Macias, MD, FAAP

EDITOR

Anne B. Rodgers

COUNCIL ON CHILDREN WITH DISABILITIES EXECUTIVE COMMITTEE, 2019–2020

Dennis Kuo, MD, MHS, FAAP, Chairperson
Susan Apkon, MD, FAAP
Lynn F. Davidson, MD, FAAP
Kathryn A. Ellerbeck, MD, FAAP
Jessica E.A. Foster, MD, MPH, FAAP
Susan L. Hyman, MD, FAAP
Garey H. Noritz, MD, FAAP
Mary O'Connor Leppert, MD, FAAP
Barbara S. Saunders, DO, FAAP
Christopher Stille, MD, MPH, FAAP
Larry Yin, MD, MSPH, FAAP

PAST COUNCIL ON CHILDREN WITH DISABILITIES EXECUTIVE COMMITTEE MEMBERS

Timothy Brei, MD, FAAP
Beth Ellen Davis, MD, MPH, FAAP
Susan E. Levy, MD, MPH, FAAP
Paul H Lipkin, MD, FAAP
Scott M. Myers, MD, FAAP
Kenneth Norwood, Jr, MD, FAAP, Immediate Past Chairperson

LIAISONS

Cara Coleman, MPH, JD – *Family Voices*
Marie Mann, MD, MPH – *Maternal and Child Health Bureau*

ABBREVIATIONS

ASD: autism spectrum disorder
DSM-5: *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*

Address correspondence to Susan L. Hyman, MD. E-mail: susan_hyman@RMC.Rochester.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: MeMix LLC is a company that makes an app (for phones). Dr Levy is on the advisory board for the app's development. This app is being developed to assist in nutritional and dietary management of children with autism. Dr Levy has not received any money yet from this company. This app is the focus of a National Institutes of Health R21 grant, for which Dr Levy is funded for ∼2% of her salary. Once it is studied and marketed (if appropriate), Dr Levy will (possibly in the future) earn some money. Dr Levy has worked with MeMix LLC from 2015 to the present. Dr Hyman is the site principal investigator of a clinical trial of a novel agent being tested to promote social function in patients with autism. The University of Rochester (Dr Hyman's institution) was 1 of >40 sites and had 2 study participants in 2018. University of Rochester will be leaving the trial in 2019 (withdrawal submitted) because of staffing, and that reimbursement for staff time does not cover the cost of participation. Funding was for the staff to complete the assessments required for the clinical trial. Dr Hyman got no personal reimbursement from the company; the funding was for staff time for recruitment and assessment and clinical research center support for the trial. Dr Myers has indicated he has no potential conflicts of interest to disclose.

Fertility Preservation for Pediatric and Adolescent Patients With Cancer: Medical and Ethical Considerations

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Fertility Preservation for Pediatric and Adolescent Patients With Cancer: Medical and Ethical Considerations

Sigal Klipstein, MD, FACOG,[a,b] Mary E. Fallat, MD, FAAP,[c] Stephanie Savelli, MD, FAAP,[d] COMMITTEE ON BIOETHICS, SECTION ON HEMATOLOGY/ONCOLOGY, SECTION ON SURGERY

Many cancers presenting in children and adolescents are curable with surgery, chemotherapy, and/or radiotherapy. Potential adverse consequences of treatment include sterility, infertility, or subfertility as a result of gonad removal, damage to germ cells as a result of adjuvant therapy, or damage to the pituitary and hypothalamus or uterus as a result of irradiation. In recent years, treatment of solid tumors and hematologic malignancies has been modified in an attempt to reduce damage to the gonadal axis. Simultaneously, advances in assisted reproductive technology have led to new possibilities for the prevention and treatment of infertility. This clinical report reviews the medical aspects and ethical considerations that arise when considering fertility preservation in pediatric and adolescent patients with cancer.

INTRODUCTION

Childhood cancer affects 1 of every 285 children younger than 20 years in the United States. Because of advances in treatment, survival has steadily increased since the 1970s. With increasing survival rates, there are currently more than 375 000 survivors of childhood cancer in the United States, with 70% of them being 20 years or older.[1,2] Improvements in prognosis and survival have been observed for many childhood cancers, including hematologic malignancies, Wilms tumor, malignant bone tumors, and rhabdomyosarcomas. The relative 5-year survival rate for all childhood cancers combined is 83.8%.[2]

With the improved survival rate of children affected by childhood cancer has come a growing population of adult survivors of childhood cancer who are or will be interested in having children. Past and contemporary treatments for childhood cancer, including chemotherapy, radiotherapy, and hematopoietic stem cell transplant, can affect future fertility. In the current era, many children and adolescents who present with a new cancer diagnosis can benefit from fertility-preserving modalities initiated

abstract

[a]Department of Obstetrics and Gynecology, Pritzker School of Medicine, University of Chicago, Chicago, Illinois; [b]InVia Fertility Specialists, Chicago, Illinois; [c]Division of Pediatric Surgery, Hiram C. Polk Jr MD Department of Surgery, University of Louisville, Louisville, Kentucky; and [d]Division of Pediatric Hematology/Oncology, Akron Children's Hospital, Akron, Ohio

Dr Fallat conceptualized the initial manuscript and drafted, reviewed, and revised the updated manuscript; Drs Klipstein and Savelli drafted, reviewed, and revised the updated manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work. This document is copyrighted and is property of the American Academy of Pediatrics and its Board of Directors. All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors. The American Academy of Pediatrics has neither solicited nor accepted any commercial involvement in the development of the content of this publication.

DOI: https://doi.org/10.1542/peds.2019-3994

To cite: Klipstein S, Fallat ME, Savelli S, AAP COMMITTEE ON BIOETHICS, AAP SECTION ON HEMATOLOGY/ONCOLOGY, AAP SECTION ON SURGERY. Fertility Preservation for Pediatric and Adolescent Patients With Cancer: Medical and Ethical Considerations. *Pediatrics.* 2020;145(3):e20193994

before cancer treatment. Individuals whose previous treatment of childhood cancer led to infertility or sterility can often benefit from fertility treatment options such as egg and sperm donation and gestational surrogacy.

Although not specifically addressed in this report, the same strategies of fertility preservation apply to children facing gonadotoxic therapies for treatment of nonmalignant diseases such as juvenile idiopathic arthritis and Fanconi anemia. Infertility resulting from the treatment of differences of sexual development and as a result of hormonal or surgical gender-affirming therapies for transgender individuals are beyond the scope of this document.

Although this document focuses on adolescents and young adults under the age of 18 years, many individuals who received a cancer diagnosis in childhood continue to be seen by their pediatric providers well into adulthood. As such, these guidelines are generalizable beyond the age of majority and apply to decision-making for adult survivors of childhood cancers as well. Complex ethical considerations arise when counseling families confronting a cancer diagnosis regarding fertility preservation options. The difficulty of such decision-making is often compounded by the frequently limited time available to make decisions that can affect fertility. The differences between male and female reproductive physiology affect the range of options available to boys and girls. Options in adolescents who have undergone puberty are broader than those in prepubertal children. The ideal time to consider fertility preservation is before the initiation of therapies that may decrease fertility or cause sterility, but this sometimes is not possible.

It is important for physicians who care for children who develop cancer or other diseases requiring treatment with gonadotoxic therapies to understand the potential deleterious effects of the various treatments on male and female fertility and to be familiar with the American Society of Clinical Oncology (ASCO) guidelines for fertility preservation in children. Recognizing the risks associated with both radiation and chemotherapy, the ASCO recommends that oncologists (1) use established methods of fertility preservation (semen cryopreservation and oocyte cryopreservation) for postpubertal minor children, with patient assent as appropriate, and parent or guardian consent; (2) present information on additional methods that are available for children but are still investigational; and (3) refer for experimental protocols when available.[3] Establishing relationships with centers and physicians who have expertise in counseling and treating children who may benefit from fertility preservation will help oncologists better streamline care for their patients who are interested in fertility preservation. Oncologists can refer families for consultation to discuss both the effects of therapy and potential fertility preservation options in a timely manner, as long as any delay will not negatively affect the success of their treatment. In so doing, they will prevent missed opportunities for information and interventions related to fertility care.

Recognizing that older adolescents and even young adults may develop cancers that fall under the umbrella of childhood malignancies, this clinical report will include options that may be more appropriate for the patient who is older than 18 years but is still being cared for in a children's hospital.

BACKGROUND

Infertility is defined as the inability to achieve or sustain a successful pregnancy after 12 months or more of regular unprotected intercourse. Earlier evaluation and treatment may be justified on the basis of medical history, such as anovulation or erectile dysfunction. For women 35 years and older, a fertility evaluation is recommended after 6 months of unsuccessful attempts at conception.[4] Although fertility declines with age for both men and women, this decline is much more profound in women. At age 40, half of women will have trouble conceiving. If in vitro fertilization (IVF) is required, the chance of pregnancy per cycle is only 13.9% in women at age 40 and under and 4% in women older than 42 years.[5] For men at age 45, the chance of achieving a pregnancy is much higher, and for these older men, the age of their female partner is the most significant determinant of outcome.[6] The risk of infertility after cancer treatment depends on the type of malignancy and its specific treatment as well as the age of the individual both at the time of diagnosis and at the time that they wish to initiate a pregnancy.[7] In men, treatments can lead to a complete absence of spermatogenesis, a decreased sperm count, or sexual dysfunction. In women, there can be a complete depletion of viable egg production or diminished ovarian reserve, leading to subfertility and a shortened fertile window. A hysterectomy or insult to the uterus may lead to the inability to gestate a pregnancy.

NORMAL PHYSIOLOGY AND FERTILITY POTENTIAL

Differences in the male and female reproductive systems influence available options for fertility after cancer treatment.[8,9] In general, there is a lack of proven options for preservation of fertility in prepubertal boys and girls. The process of spermatogenesis begins in the prepubertal boy, but the production of mature sperm and

steroidogenesis are functions of the adult testes.[10] Spermarche (the release of spermatozoa) is an early- to midpubertal event that precedes the ability to produce an ejaculate and is associated with age-appropriate gonadotropin production.[11,12] There is a large variation in the stage of maturity among 13- to 18-year-old males with respect to sperm production. Once sperm are present, sperm quality in young boys, as determined by a semen analysis, does not seem to be affected by patient age. At this point, sperm can be collected via masturbation, electrostimulation, or surgical sperm extraction, and sperm can then be cryopreserved for future use. It is important to note that not all pediatric centers have electroejaculation equipment available, and surgical extraction requires the expertise of a urologist experienced in this technique. Many boys will, therefore, require referral to a reproductive urologist for these services.[13,14]

In girls, oocyte production peaks in the fetus during midgestation, at which time approximately 6 to 7 million oogonia are present within the ovary. This number decreases to 2 million at birth and to approximately 300 000 at puberty.[15,16] Once menarche has been initiated, mature oocytes develop, and monthly ovulation occurs. At this point, fertility treatments can stimulate multiple eggs, which can be retrieved from the ovary and cryopreserved for later use.

RISK OF INFERTILITY AFTER TREATMENT

Most children treated for cancer can expect to be cured, although the specific chance of cure depends on risk factors at the time of diagnosis, including cancer type, stage, and grade. Although permanent infertility or sterility may occur after cancer treatment, individuals may experience temporary but reversible infertility, a shortened reproductive window, or no compromise in fertility. Many survivors of childhood cancer with intact fertility worry about the potential effects of previous cancer treatment on the health of their offspring.[17] Reassuringly, decades of cumulative experience have shown that naturally conceived biological children of survivors have no increased incidence of congenital malformations,[18–22] genetic or chromosomal anomalies,[23–25] or cancer compared with sibling controls and general population data.[26–33]

Risk of Infertility in the Male Patient After Cancer Treatment

Male fertility can be affected by impairment of spermatogenesis as a result of gonadotoxic chemotherapy, gonadotropin deficiency from central nervous system–directed therapy, or functional abnormalities of genitourinary organs caused by spinal or pelvic surgery and/or radiotherapy. Deleterious effects on testicular function have been observed with alkylating agents, such as cyclophosphamide, as evidenced by increased follicle-stimulating and luteinizing hormone concentrations, indicating decreasing gonadal function.[34–36]

In a large cohort study, the St Jude Lifetime Cohort Study, testicular function was evaluated by using a semen analysis. The investigators performed a semen analysis on 214 adult male survivors of childhood cancer, all of whom had received alkylating agents without radiotherapy. Azoospermia was noted in 25%, oligospermia was noted in 28%, and normospermia was noted in 48%. Importantly, there was no identified threshold dose below which azoospermia did not occur or one above which azoospermia was uniformly present.[37]

Several large studies, including the Childhood Cancer Survivor Study (CCSS),[38,39] have evaluated the fertility outcome of survivors of childhood cancer. The most recent cohort study included almost 11 000 survivors not exposed to gonadal or cranial radiotherapy and more than 3900 sibling controls. On the basis of self-reported data, it was found that male survivors had a decreased likelihood of fathering a pregnancy compared with a sibling control group.[40] This finding confirmed results from an earlier CCSS study showing that among male patients, risk factors for impaired fertility included increasing alkylating-agent exposures and higher testicular radiation doses (Tables 1 and 2). These studies are important in counseling because although increasing chemotherapy and radiation doses are associated with a higher chance of infertility, there is no dose so low as to guarantee the maintenance of fertility and no dose so high that infertility is certain to occur.

Risk of Infertility in the Female Patient After Cancer Treatment

Chemotherapy and tradiotherapy can destroy ovarian follicles and

TABLE 1 Alkylating Agents With Infertility Risk

Alkylating Agents
Classic alkylating agents
Busulfan
Carmustine (BCNU)
Chlorambucil
Cyclophosphamide
Ifosfamide
Lomustine (CCNU)
Mechlorethamine
Melphalan
Procarbazine
Thiotepa
Heavy metals
Cisplatinum
Carboplatinum
Nonclassical alkylators
Dacarbazine (DTIC)
Temozolomide

Adapted from Children's Oncology Group. *Long-Term Follow-Up Guidelines for Survivors of Childhood, Adolescent, and Young Adult Cancers. Version 5.0.* Monrovia, CA: Children's Oncology Group; 2018:12–14. Available at: http://www.survivorshipguidelines.org/pdf/2018/COG_LTFU_Guidelines_v5.pdf. Accessed April 26, 2019.

TABLE 2 Childhood Cancer Therapy Affecting Reproductive Tissues

	Reproductive Effect	Predisposing Therapy	Modifying Factors
Sex			
Both	Altered pubertal timing (precocious, early, rapid tempo), delayed puberty, gonadotropin insufficiency or deficiency	Hypothalamic-pituitary radiation	Altered pubertal timing more common after low-dose radiation at 18–24 Gy, gonadotropin insufficiency more common after radiation at more than 30 Gy
Female	Acute ovarian failure (ovarian failure within 5 y of diagnosis), premature menopause (cessation of menses before age 40 y)	Alkylating-agent chemotherapy, radiation affecting the female reproductive system (whole abdomen, pelvis, lumbosacral spine, total body), oophorectomy	Older age at treatment due at higher risk
	Uterine vascular insufficiency, uterine growth impairment	Radiation affecting the uterus (whole abdomen, pelvis, lumbosacral spine, total body)	History of Wilms tumor and associated Müllerian anomalies
	Vaginal fibrosis or stenosis	Radiation affecting the vagina	History of hypogonadism (estrogen insufficiency), history of chronic graft-versus-host disease
	Sexual dysfunction, dyspareunia	Pelvic surgery, hysterectomy, radiation affecting the uterus or vagina	History of hypogonadism (estrogen insufficiency)
	Spontaneous abortion, neonatal death, premature labor, neonate with low birth wt, fetal malposition	Radiation affecting the uterus (whole abdomen, pelvis, lumbosacral spine, total body)	History of Wilms tumor and associated Müllerian anomalies
Male	Azoospermia oligospermia	Alkylating-agent chemotherapy, radiation affecting the male reproductive system (pelvic, testicular, total body), orchiectomy (bilateral)	Prepubertal status at treatment does not reduce risk
	Retrograde ejaculation, anejaculation erectile dysfunction	Pelvic surgery (retroperitoneal node or tumor dissection, cystectomy, radical prostatectomy), radiation to pelvis, bladder, or spine	History of hypogonadism (androgen insufficiency)

See www.survivorshipguidelines.org for health risks to other organs and tissues resulting from treatment of childhood cancer. Adapted, with permission from Elsevier, from Hudson MM. Survivors of childhood cancer: coming of age. *Hematol Oncol Clin North Am.* 2008;22(2):218.

predispose female patients to diminished ovarian reserve and premature ovarian failure. Premature ovarian failure is defined as premature menopause occurring before age 40. This differs from diminished ovarian reserve, which can lead to increased difficulty in achieving a pregnancy or to a shortened reproductive window despite regular menstrual periods. The deleterious effects of chemotherapy are dependent on the age of the patient at the time of therapy, the specific agents used, and cumulative dosing.[41] Oocytes do not regenerate after birth, as opposed to spermatogenesis, which continues to occur from progenitor stem cells throughout a man's life. Premature ovarian failure is rare in survivors of childhood cancer and was found to have an incidence of 6% to 9% in CCSS cohorts.[42] Many women who do not have overt ovarian failure will have diminished ovarian reserve.[43] Several studies have used anti-Müllerian hormone (AMH) concentrations to estimate ovarian reserve.[44,45] Survivors of childhood cancer often have lower AMH concentrations compared with a control group.[46,47] Low AMH concentrations can predispose to diminished ovarian reserve and, therefore, a higher risk of infertility as well as earlier menopause. When evaluated by treatment exposure (alkylators only, alkylators and subdiaphragmatic radiation, or high-dose alkylating therapy), all survivor groups had diminished ovarian surface area and AMH concentrations. Ovarian reserve was worse when survivors received a high dose versus a conventional dose of alkylating therapy.

Radiation has an effect on both the brain and the end organs. When the brain is the target of irradiation, infertility can present as hypothalamic amenorrhea. High-dose cranial radiotherapy (35–40 Gy) can cause infertility via hypogonadism through its effects on the hypothalamic-pituitary axis. Such infertility can be treated medically with stimulation of the ovaries or testes with gonadotropins to induce the maturation and release of gametes. Radiation can affect the uterus and vagina, and women undergoing radiation to the uterus are less likely to both conceive a pregnancy and carry it to term.[48] Direct pelvic radiotherapy, abdominal or spinal radiation, or scatter radiation can all affect the ovaries. The oocyte median lethal dose for radiotherapy is less than 2 Gy.[49]

Several studies have been focused on infertility and achievement of pregnancy in female survivors of cancer. One CCSS cohort study found that the risk of nonsurgical premature menopause was increased for survivors of childhood cancer.[42] Survivors also had an increased risk of clinical infertility when compared with sibling

controls. This risk was most pronounced in the early reproductive years (≤24 years), when fertility is high in a general population. Increasing doses of uterine radiation and alkylators were most strongly associated with infertility. Promisingly, almost two-thirds of survivors with clinical infertility reported a pregnancy during the study period, which included both those achieving pregnancy spontaneously and those who underwent fertility treatment.[50] Another CCSS cohort study analyzed only survivors who had not received gonadal or cranial radiotherapy to evaluate the effect of chemotherapeutic agents on pregnancy. Just as with male survivors, female survivors had a decreased likelihood of pregnancy and live birth compared with sibling controls. If a pregnancy was not achieved by age 30, the likelihood of ever becoming pregnant by age 45 was further reduced compared with siblings. As with previous studies, the most deleterious chemotherapeutic agents were the alkylating agents, including lomustine and cyclophosphamide.[40]

OPTIONS FOR FERTILITY PRESERVATION

The options, burdens, and costs of fertility preservation differ for boys and girls. The availability of options also differs depending on whether the child facing cancer treatment is prepubertal or postpubertal and on the urgency with which treatment must be initiated. Some treatments are well established and have known efficacy and outcomes data, and others are still experimental. It is important to differentiate between clinically accepted and experimental treatments when counseling patients and families regarding their fertility-preserving options.

PRESERVATION OF FERTILITY BEFORE TREATMENT IN THE PREPUBERTAL CHILD

Fertility preservation in the prepubertal child is challenging. The majority of proposed treatment modalities are thus far experimental in nature and without proven efficacy. The one exception is gonadal shielding or moving the gonads out of the radiation field.[51] Familiarity with these options and the data surrounding them can assist physicians in treating and counseling their patients with cancer. Furthermore, patients who wish to undergo prepubertal fertility preservation attempts may be best served under an institutional review board (IRB)–approved clinical trial so that they can be carefully monitored and their experience used to determine if such therapies should continue to be offered in the future.

Boys

Before puberty, methods available for gonadal and gamete preservation in the male patient are primarily theoretical at the present time, with the exception of shielding the testes or moving them out of the radiation field.[52,53] Most methods involve hormonal and other manipulations to protect the testes from injury during cancer treatment or involve preserving a testicular tissue sample. Primordial sperm cells are susceptible to toxicity at all stages of life. Gonad shielding can be used during radiotherapy but is only possible with selected radiation fields and anatomy and may increase the risk of harboring malignant cells.[3] The gonad(s) can also be temporarily relocated outside of the radiation field to either the thigh or the anterior abdominal wall.[54,55]

To date, no effective pharmacologic intervention has been identified. Gonadal protection through hormone manipulation has been evaluated only in small studies in patients with cancer and is uniformly ineffective in either preserving fertility or speeding the recovery of spermatogenesis.[3] Animal studies suggest that testicular tissue cryopreservation, autotransplantation, xenotransplantation, and in vitro maturation may be successful methods of fertility preservation, but most have yet to be tested in humans.[56] Human spermatocytes have been matured in vitro to mature spermatids, resulting in at least 1 pregnancy.[57] Testicular tissue cryopreservation has been reported, and ongoing clinical trials are being conducted to address prepubertal fertility preservation in boys.[58,59] Oncologists can help their male patients and their families by sharing with them information and options regarding clinical trials to address prepubertal fertility preservation. Once testicular tissue has been cryopreserved, future options for its use may include in vitro maturation or germ cell transplant, which at this time are theoretical in nature.

Girls

Similar to prepubertal boys, most fertility preservation modalities in prepubertal girls are experimental in nature and are without adequate long-term outcomes data. The exception is gonadal shielding and oophoropexy. Shielding of the ovaries during radiotherapy and oophoropexy to remove the ovaries from the radiation field are strategies to preserve ovarian function during treatment, although radiation scatter is a concern despite best efforts to avoid radiation exposure.[60–62] Although ovarian transposition is relatively effective for preserving the endocrine function of the ovary (in 60% of cases), only approximately 15% of patients treated with transposition and wishing to become pregnant ever achieve this goal.[60] Of note, the benefit of gonadal shielding is less effective if adjuvant chemotherapy with gonadotoxic agents is required as part of the treatment regimen.

There are also potential means for preserving ovarian function in selected cases of reproductive tract malignancy, including more conservative surgery for certain early-stage tumors and choosing chemotherapeutic agents that have less gonadal toxicity.[60,63,64]

In prepubescent girls, the ovaries cannot be stimulated to produce mature eggs. Ovarian tissue cryopreservation has been proposed as a method to preserve fertility in this cohort of girls. In contrast to oocyte cryopreservation, ovarian tissue cryopreservation (via removal of a portion of the ovary or unilateral oophorectomy) is a process in which normal, functioning ovarian tissue is excised from the ovary and cryogenically stored.[65–70] Currently, this technique is only available in certain parts of the United States as an open clinical trial to assess its efficacy and safety as a potential option for preservation of fertility in prepubertal girls.[71,72] Within this context, it is the only method that can be offered to prepubertal girls.[73] This technique has been performed in children as young as 2.7 years of age, and the chance of later restoring fertility should theoretically be higher because the ovarian cortex contains more primordial and primary follicles in younger children.[73] Ideally, the stored ovarian tissue is thawed and autotransplanted into the donor once her treatment has been completed.[74] There are no data yet available regarding whether cryopreservation of ovarian tissue in prepubertal girls can lead to pregnancy and delivery. Given the potentially limited viability of the autotransplanted tissue, this procedure is more likely to restore reproductive endocrine function rather than result in preserving fertility, unless the oocytes are retrieved relatively soon after the transplant. Studies using flow cytometric evaluation have confirmed the presence of contaminating leukemia cells in histologically normal pretreatment ovarian tissue specimens removed from patients with leukemia and lymphoma before initiation of treatment, leading to the theoretical concern for reseeding the body with tumor cells after the autotransplant.[75,76] In adults, more than 70 live births have been reported in women who cryopreserved ovarian tissue, but only when the tissue was harvested postpubertally.[77–82] A potential confounder in the various case series in which live births were reported is that in the majority of cases, some native ovarian tissue was present in addition to the autotransplanted ovarian tissue. It is possible that pregnancies occurred from oocytes obtained from the native ovarian tissue and not from the transplanted material.[83]

Until recently, all of the reports of successful births after autografts of cryopreserved ovarian tissue in the pediatric population were obtained from adolescents who had already begun the pubertal transition. There has now been at least 1 published report of a live birth after an autograft of cryopreserved ovarian tissue in a prepubertal girl, who was 9 years old at the time that her ovarian tissue was cryopreserved.[84] Before this, the youngest age at the time of ovarian tissue cryopreservation was 14 years, in a girl preparing to undergo a myeloablative conditioning regimen as part of a hematopoietic stem cell transplant performed for homozygous sickle cell anemia. Although she had not yet achieved menarche, there was evidence that she had already started the pubertal transition on the basis of existence of breast development.[85] Given the unknown efficacy of this technique, ovarian tissue cryopreservation in prepubertal girls is best performed under an IRB protocol.

PRESERVATION OF FERTILITY BEFORE TREATMENT IN THE POSTPUBERTAL ADOLESCENT

Once a male adolescent is able to produce mature sperm or a female adolescent is able to be stimulated to provide mature oocytes, fertility preservation options become more viable. The options for germ cell preservation before treatment differ depending on sex.

Male Adolescents

Sperm cryopreservation after masturbation is the most established and effective method of fertility preservation in male adolescents.[71] Whenever possible, sperm should be collected before initiation of cancer therapy to prevent the risk that sperm DNA integrity or sample quality will be compromised. Sperm can be collected at infertility centers or andrology laboratories and stored either at these sites or at long-term storage facilities. Patients may be shy or embarrassed at the prospect of masturbation, such that a discussion of the available options is best conducted with the patient and his legal guardian(s) in a comfortable and accepting manner. It may be helpful to provide a space for the patient to speak privately with a medical team member in the absence of the parent or guardian to allow the adolescent to ask questions and address concerns. Physicians may be instrumental in guiding parents regarding approaches to effectively discuss sperm cryopreservation with their adolescent sons.[86] One study suggested that adolescent boys may be more successful at masturbation if a parent does not accompany them to the appointment.[87] Underlying sperm quality may be poor in certain cancer types, including testicular cancer, leukemia, and Hodgkin's disease.[88,89] Nevertheless, recent progress in andrology laboratories and with assisted reproductive technology (ART) allows for successful freezing and future use of even a limited

number of sperm and even when the sperm quality is diminished.[90]

Alternative methods of obtaining sperm besides masturbation include testicular aspiration or extraction, electroejaculation under sedation or anesthesia,[91] or retrieval from a postmasturbation urine sample.[87] Although fresh sperm samples may result in higher success rates than frozen sperm, the success rate depends more on the sperm parameters at the time of production than on whether the sample was used fresh or was previously cryopreserved.[92,93] With fair-quality frozen sperm samples, IVF is often recommended to achieve pregnancy rather than intrauterine insemination because cycle success rates are much higher and sperm are a limited resource. In cases in which only a few sperm are present, fertilization and pregnancy can be achieved by performing IVF with intracytoplasmic sperm injection (ICSI).

Female Adolescents

Although postpubertal female adolescents historically had few available options, this has changed over the past decade with improvements in oocyte cryopreservation. Oocyte cryopreservation remains generally more invasive and expensive than sperm harvesting. In October 2012, the American Society for Reproductive Medicine released a statement describing oocyte cryopreservation as no longer experimental and recommending that it be offered to adult patients facing the risk of infertility resulting from chemotherapy and other gonadotoxic therapies.[94] Embryology laboratories are increasingly able to cryopreserve, thaw, and fertilize mature oocytes, with success rates approaching or equaling those achieved with more traditional embryo freezing.[94] This opens up a viable option for the postmenarcheal pediatric patient with cancer.[95,96] Successful pregnancy rates by using previously cryopreserved oocytes have been reported to be as high as 50% in adult women cryopreserving their oocytes but would be expected to be even better in young women and adolescents.[97] Such rates have been obtained at fertility centers that are experienced with egg freezing, and patients should be encouraged to freeze oocytes at centers with ample experience using this technology. The number of infants born from frozen oocytes is increasing. Information on the health outcomes of children born via this specific technique for fertility preservation is limited but has overall been reassuring. No increases in chromosomal abnormalities, birth defects, or developmental deficits have been noted in the children born from cryopreserved oocytes as compared with other standard ART procedures, such as IVF, and with natural conception[98–101]; however, these data are not from patients who cryopreserved their oocytes after a cancer diagnosis. To date, it is not known whether success rates in this situation will mirror those achieved after oocyte cryopreservation for other indications. Nevertheless, given the reassuring outcomes data for egg freezing in other contexts and the lack of other options for many women facing gonadotoxic therapies, the American Society for Reproductive Medicine and the American College of Obstetricians and Gynecologists support the use of oocyte cryopreservation for women at risk for losing ovarian reserve because of gonadotoxic exposures.[102] This technique requires controlled ovarian hyperstimulation with approximately 10 days of subcutaneous gonadotropin hormone injections. Eggs are then retrieved from the ovaries with transvaginal ultrasonography-guided needle aspiration performed under intravenous sedation. As mentioned previously, although medically viable, this technique has limitations in the adolescent age group because of the invasive nature of the process. Although oocyte cryopreservation is a medically viable option beginning around the time of menarche, it is less clear whether it should be routinely offered to young adolescents or to any minor. The process of oocyte cryopreservation requires approximately 10 days of monitoring with transvaginal ultrasonography and blood tests, followed by a transvaginal oocyte retrieval performed under anesthesia. In some clinical situations, a delay of a week or more before initiating cancer treatment may not be possible or may compromise care such that oocyte cryopreservation may not be a viable option. For many adolescents and their parents or guardians, the invasive nature of the ovarian stimulation process and retrieval may prevent its acceptance on psychological and emotional grounds.

Women with hormonally sensitive tumors who are interested in oocyte or embryo cryopreservation present specific challenges because standard protocols for ovarian stimulation are associated with significant (albeit temporary) elevations in estradiol concentrations. Such elevations may theoretically increase the risk of tumor progression and spread.[103] There has been a growing experience with the use of selective estrogen receptor modulators and aromatase inhibitors during the stimulation portion of the cycle. Use of these agents has been shown to significantly reduce peak estradiol levels during ovarian stimulation to those more typical of a spontaneous ovulation during a normal menstrual period, thus theoretically decreasing the risk of stimulating hormonally sensitive tumors. Fortunately, this blunting of the hormones does not have a negative effect on egg quality or cycle outcome. The lower estradiol concentrations in cycles using selective estrogen receptor modulators and aromatase inhibitors do not appear to decrease the chance

of achieving a pregnancy when the resultant embryos are ultimately transferred to the uterus.[104,105]

Cryopreservation of embryos, in which oocytes are fertilized with sperm from the woman's male partner or with anonymous donor sperm, was historically the only option available to postpubertal girls and young women wishing to preserve their fertility. As compared with oocyte cryopreservation, embryo cryopreservation is more socially, emotionally, and ethically complex because the patient needs the maturity to fully comprehend all aspects of the procedure, including the fact that the eggs will be fertilized with (usually anonymous) donor sperm.[67] Given the success rate with oocyte cryopreservation, there is little need to consider fertilizing the eggs before cryopreserving them, and embryo cryopreservation should only be used in rare circumstances, for example, when an older adolescent is married or in a long-term committed relationship. Even then, cryopreserving oocytes opens up more future options than cryopreserving embryos and should be encouraged when available and when the patient is of an appropriate age and maturity level to undergo an ovarian stimulation procedure.

For women who have previously undergone pelvic irradiation, there may be scarring or other postradiation effects to the uterus and vagina that preclude conception or the ability to maintain a pregnancy. For girls who will be receiving pelvic irradiation and their families, discussion of the future use of a gestational surrogate may be warranted. If the ovaries remain functional after irradiation, it will be possible to retrieve eggs from them, fertilize them through IVF, and transfer them into a gestational carrier. When premature ovarian failure has occurred, women with uterine or vaginal compromise who wish to consider parenting options outside of adoption will require both donation from a known or anonymous egg donor and the services of a gestational carrier. There are significant costs associated with this mode of reproduction. Also, gestational surrogacy laws are complex, differ among states, and evolve over time.

There has been speculation that concomitant treatment with gonadotropin-releasing hormone (GnRH) analogs may prevent ovarian failure induced by cancer therapy by protecting against chemotherapy-induced follicle depletion. The studies looking at this option to date were performed on adult women with breast cancer, and it is not clear whether these data are applicable to children. In adults, most studies evaluating GnRH analogs to prevent ovarian failure have not demonstrated benefits,[106–108] although 1 recent randomized trial revealed a significant reduction in ovarian failure and an increased fertility rate in women receiving GnRH analogs.[109] These findings cannot be applied to prepubertal girls, in whom the hypothalamic-pituitary-ovarian axis is still quiescent.[71] The 2018 ASCO guidelines acknowledge that there is conflicting evidence regarding the use of GnRH analogs to protect fertility but suggest that in situations in which proven fertility preservation methods are not feasible, GnRH analogs may be offered to patients, with the hope of reducing chemotherapy-induced ovarian insufficiency.[3]

COSTS OF FERTILITY PRESERVATION

The costs of fertility preservation are often not covered by insurance,[110] especially given that insurance usually does not cover experimental therapies, thus compounding the psychological distress with the economic impact of infertility.[111,112] Some states have comprehensive fertility coverage because of mandates on insurance, and some have recently begun mandating coverage of fertility preservation.[113,114] The later use of stored gametes may be covered under such fertility mandates.[115] Legislative efforts are underway in a number of states to address this issue.[116] Because the cost burden on patients or families can be expected to change over time and by geographic area, good counseling will require familiarity with current regional data.[117] Some patients may benefit from fertility preservation under experimental protocols, and these should be considered when applicable and after appropriate counseling has been provided.

Sperm cryopreservation is a technique that has been used for many years and has associated benefits and a record of success that supports its widespread use in the postadolescent male patient. The cost of sperm cryopreservation after masturbation can total hundreds of dollars a year, with additional costs incurred if alternative methods, such as surgical sperm extraction, are needed to obtain sperm or for prolonged storage.[3] When ready to be used for reproduction, IVF and often ICSI may be needed to achieve pregnancy, especially given the often-limited quantities of sperm available. The relevant costs of IVF are discussed later in this section.

In postmenarcheal female adolescents, controlled ovarian hyperstimulation for the purpose of retrieving and cryopreserving oocytes is often not covered by insurance. The various components of such cycles include (1) stimulating the ovaries with daily subcutaneous injections over the course of 8 to 21 days and monitoring of the ovarian response with approximately 5 blood tests and ultrasonographic examinations over the course of the stimulation; (2) the cost of gonadotropins to stimulate the ovaries, medications to prevent early

ovulation, and medications to blunt the estrogen response in cases of hormonally sensitive malignancies; (3) egg retrieval under anesthesia; (4) embryology and laboratory fees; and (5) cryopreservation of the oocytes. A typical oocyte cryopreservation cycle can cost between $7000 and $14 000.[118–121] Medications per egg retrieval cycle can cost between $2000 and $7000, although currently, some pharmacies and pharmaceutical companies provide these medications at a discount or at no cost to patients with a cancer diagnosis. Storage fees for cryopreserved oocytes are approximately $350 to $600 per year.[3] When cryopreserved eggs are ready to be used for reproduction, there are additional costs associated with thawing the eggs and fertilizing them with sperm as well as transferring the embryos back to the uterus.

Women requiring an egg donor because of ovarian failure or diminished ovarian reserve may incur additional costs, particularly if they need to use eggs from an anonymous egg donor, who is reimbursed for her contribution. Women who require a gestational surrogate because of an inability to carry a pregnancy will incur costs of both IVF and gestational surrogacy, which often total in the tens of thousands of dollars.

Experimental fertility preservation options may be covered under a research protocol in some cases such that there may be no or minimal costs to the patient. The therapies themselves can be expensive. Once they are no longer considered experimental, the cost will be borne by the families of children using them in the future to the extent that insurance does not provide coverage.

For prepubertal boys, testicular tissue cryopreservation is a potentially costly option that has not yet proven to result in offspring in humans but has been successful in primates.[122] If successful, the tissue would either need to be retransplanted into the testes or some extratesticular location, and/or sperm would need to be extracted from the tissue after sperm maturation. If sperm were to be extracted, then IVF and ICSI would need to be used in the future to obtain viable embryos.

For prepubertal girls, the costs of ovarian tissue preservation can be separated into 3 parts: (1) the procedure to retrieve the tissue, generally laparoscopy and attendant anesthesia[123]; (2) ovarian tissue pathologic evaluation and freezing; and (3) the annual cost of ovarian tissue storage. Laparoscopic procedures, even in children, often can be performed on an outpatient basis, precluding an inpatient hospitalization cost.[74] The cost of ovarian tissue freezing alone might be similar to that of freezing testicular sperm after testicular dissection (see previous discussion), incurring an annual cost for ovarian tissue storage of several hundred dollars a year or greater. Assuming recovery of the patient after treatment, the costs will include tissue thawing and the procedure for autotransplantation, subsequent medications, and laboratory testing. Ovarian tissue preservation remains experimental and is best performed at a specialized center and under IRB approval. In some cases, enrollment in such studies does not incur a cost to the participants.

Counseling Families Regarding Options for Fertility Preservation

Counseling regarding fertility preservation options is the first step in assisting families in navigating options for fertility preservation. This counseling is best undertaken as early as feasible after a cancer diagnosis is made and before the initiation of any cancer treatment, if possible. For preadolescents, it is appropriate for one or both parents or guardians to be present for such conversations. Adolescents may benefit from the opportunity to speak one on one with their physician and/or child psychologist or reproductive specialty surgeon in the absence of their parents. For adolescent girls who may benefit from oocyte cryopreservation, a frank discussion regarding their experience with tampon use and intercourse should be undertaken because the monitoring that is required before retrieving the oocytes requires multiple transvaginal ultrasonographic examinations. For adolescent boys, a discussion of sexual experience and comfort with masturbation should occur. Recognizing that fertility preservation may create both burdens and opportunities for patients and their families, discussions regarding reproductive potential have, as their goal, the maximization of the child's future options and well-being.

Most often, a child will initially present to the general pediatrician and then be referred to a pediatric hematologist oncologist. Physicians involved in cancer treatment should be familiar with the ASCO guidelines for fertility preservation[3] and be able to provide referral for consultation and treatment to patients and families who wish to seek these out. When possible, a child should be referred to a multidisciplinary team for a comprehensive approach to the evaluation of options for fertility preservation for his or her specific circumstances. This team can provide counseling regarding appropriate treatments, their timing, and their scope. The team may consist of the patient's primary care physician, pediatric hematologist and oncologist, radiation oncologist, reproductive endocrinologist, urologist specializing in male infertility, surgeon (if surgery is part of the treatment), child-life or other integrative health specialist, and mental health professionals. Ethics consultants may be helpful when conflicts arise between medical

professionals and the patient and family.[124] Such a team approach allows families to obtain the information they require to make decisions regarding fertility preservation and allows those who decide to pursue fertility preservation options to do so in an efficient manner and maximizes the chance that fertility preservation options are initiated before starting cancer therapy. For prepubertal children, consultation with and/or referral to a center performing testicular and ovarian cryopreservation under an IRB protocol is appropriate. The type, stage, and severity of the cancer affect the time frame during which decisions surrounding fertility preservation must be made. In some cases, these decisions must be made emergently, whereas in other cases, the window for action is urgent but not emergent. In some circumstances, lifesaving treatment will need to start immediately and fertility preservation options will not be available. Even when fertility preservation is not possible because of the need for treatment or other determinants, counseling regarding the risks to fertility inherent in the various treatment options will allow patients and their families to cope with the effects of cancer treatment.

Counseling Regarding Expected Outcomes After Fertility Preservation

Physicians have an important role in counseling children and their caregivers regarding their future reproductive options when faced with a cancer diagnosis. The option of fertility preservation may be of great comfort for patients and their families and may assist them in managing the emotional trauma of the cancer diagnosis,[60] although the offer may also result in unrealistic expectations.[125] Most younger patients with cancer have historically been left with significant anxieties and insufficient information about reproductive issues.[126] Appropriate counseling of parents and patients (as appropriate for age) in developmentally appropriate language will help patients and their families understand the likelihood that cancer treatment will permanently affect fertility. Reproductive endocrinologists and urologists can be instrumental in explaining the pre- and posttreatment options and may help alleviate these anxieties.[3] The downstream options of adoption, egg and sperm donation, and gestational surrogacy can be discussed as well as the success rates, costs, surgical risks, and experimental nature of specific ART options and the acceptability of the option to decline the intervention.[125,127] As part of this discussion, families and children (as appropriate for age) should be made aware that cancer treatments do not guarantee a loss of reproductive potential and that pregnancy can occur in sexually active postpubertal adolescents and young adults. The complexity and impact of the various fertility preservation options may be overwhelming to children and their families. Whenever possible, the information should be conveyed incrementally over multiple visits. This will allow families the time to internalize the various treatment options and determine the optimal course of action for their particular situation. However, some clinical diagnoses do not allow for the luxury of time between identification of the cancer and implementation of treatment, and fertility preservation decisions must be made urgently.

Dispositional Control of Cryopreserved Reproductive Tissue

The fertility specialist can play an important role in discussing the issue of dispositional control of reproductive tissue in the event of the patient's death or incapacity. Such discussions best occur before the collection of any reproductive tissue. Posthumous use of reproductive tissue is defined as the use of gametes or embryos in an attempt to create offspring after the death of the individual who provided the reproductive tissue. Posthumous reproduction from gametes procured in childhood should not occur if the child does not survive beyond the age of majority. This is further discussed below in the section on ethics. Consent forms should designate that the disposition of reproductive tissue will be delayed until the child reaches the age of majority or discarded if the child does not survive to the age of majority. Once the child becomes an adult, he or she can make changes to the disposition of the reproductive tissue, including provisions for its posthumous use. Legal review of the institutional consent process and associated documentation can be considered to preclude future misunderstanding or a misinterpretation of tissue or specimen disposition or disposal. Because case law has evolved in the area of disposition of previously collected embryos and gametes, which has not always strictly enforced documentation in a consent form, periodic review of the program's written consents by an institutional attorney may be helpful. For this reason, involving an attorney as part of the team can be beneficial to families and medical personnel. Once the child reaches the age of majority, he or she should issue new documentation regarding his or her wishes for future storage of previously collected reproductive material.

It should also be disclosed that success rates are not guaranteed. Even with successful collection and freezing of eggs, sperm, and/or embryos, success rates will never be 100%; some children who go through the process of fertility preservation will not ultimately be successful in using their cryopreserved reproductive tissue. Additionally, there are no guarantees that stored embryos and gametes will be viable when ready for reproductive use or

be free of neoplasia. Also, unexpected catastrophes, both natural and man-made, can lead to unintended damage to or destruction of reproductive tissue.

Barriers to Receiving Counseling

Survey results of adult male and female survivors of cancer of reproductive age and studies evaluating oncology practice patterns for discussing infertility have suggested that a conversation with patients with cancer regarding the potential consequences of their treatment on future fertility was lacking in more than half of cases.[3] Pediatric oncologists admit that, despite their motivation to preserve fertility in their patients and their belief that all pubertal patients with cancer could benefit from a fertility consultation, they do not use the ASCO fertility preservation guidelines[3] and instead refer their patients to fertility specialists only a minority of the time.[128] Oncologists provide many different explanations for not referring patients for fertility preservation, including not recognizing the importance of this issue, assuming that patients cannot afford fertility preservation procedures, feeling emotionally uncomfortable discussing the topic, or choosing not to refer the patient because of a poor prognosis.[73] Additional barriers include beliefs that such discussions will add additional stress to an overwhelmed family or will violate provider or family cultural taboos on issues of sexuality. Even when counseling does occur, family satisfaction with the process is often lacking; in one study, only 30% of parents were satisfied with the fertility preservation counseling they received regarding their children.[129] In a survey study identifying reproductive concerns of adolescent girls with cancer and their parents, the concerns of the respective groups were not congruent. Parents incorrectly expected their daughters to be satisfied with only survivorship and less concerned about reproductive potential.[130] In another study in which families were to recall discussions they had regarding fertility expectations after surviving cancer, only about half of parents recalled receiving information on the topic and nearly one-third expected normal fertility.[131]

Patients themselves are generally asking for this information and have identified preservation of fertility as extremely important.[17] Most men taking one survey responded that they believed having experienced cancer increased the value they placed on family closeness and would make them better parents.[132] For men who desire children in the future, lack of timely information is the most common reason for not banking sperm. A survey of adolescent patients with cancer revealed that 81% would want to undergo investigational or research-based procedures to attempt to maintain their fertility.[133] Additional data suggest that the process of fertility preservation, in and of itself, may be therapeutic; for example, young male survivors demonstrated lower distress and enhanced coping with cancer treatment simply from the knowledge that they had stored sperm.[134,135] In addition, the long-term morbidity associated with infertility and interrupted childbearing is not minor and persists well into adulthood.[136] In addition to fertility preservation options, strategies to help survivors of cancer identify and deal with unresolved grief about cancer-related infertility are important health care interventions.

Despite its perceived importance, the process is not easy for patients and families. Making an appointment with the andrology laboratory usually is the responsibility of the patient and family. Chemotherapy induction may need to proceed expeditiously and may not allow the luxury of time for needed consultations and decision-making or may preclude the ability of the patient to provide more than 1 or 2 samples.[87] Facilitating the andrology laboratory visit and delaying the initiation of chemotherapy, if possible, are 2 approaches that might be used in appropriate cases to increase fertility options of survivors of cancer. Some situations are true medical emergencies (eg, respiratory compromise from a mediastinal lymphoma) or are significantly urgent to preclude even the short delay required for an andrology laboratory visit.

Currently available fertility preservation options are not believed to compromise the success of cancer therapy or adversely affect a survivor's health.[3] Other than hereditary genetic syndromes, large registry studies have failed to demonstrate an increased risk of genetic abnormalities,[19,23] congenital malformations,[20–22] or cancers in the children of survivors of cancer.[26–30,32,33] Disclosing this information to patients and families will provide reassurance of the potential value of fertility preservation.[137] For families with hereditary conditions that are risk factors for developing malignancies, the development of preimplantation genetic testing of embryos allows couples to undergo IVF and screen their embryos for the hereditary cancer syndrome for which their offspring is at risk. By electing not to transfer affected embryos, the risk of transmitting cancer genes to their offspring is dramatically reduced. This approach is supported by the American Academy of Pediatrics as well as by the Ethics Committee of the American Society for Reproductive Medicine for couples who wish to avoid having children with high-risk cancers.[138]

One difficulty in counseling either sex regarding risks to future fertility is that there are few absolutes, and the

discussion should be focused on a risk assessment. Some treatments have a high risk of infertility, diminished ovarian reserve, sterility, and/or premature ovarian failure. Other treatments are less likely to lead to the inability to have children. The level of concern over the potential loss of fertility should be addressed, and the spectrum of fertility options that are available to an individual should be presented.

ETHICAL CONSIDERATIONS

Fertility preservation raises several ethical issues, including the dilemma of counseling someone who has not yet reached adulthood, obtaining appropriate consent and/or assent,[125,139] managing disagreements between desires of the patient and his or her family, and later use and disposition of reproductive tissue that was acquired before the age of assent.

A central ethical concern for children facing a cancer diagnosis whose treatment may limit future fertility is that of supporting the right to an open future.[140] This encompasses a set of moral rights children possess that are derived from the autonomy rights of adults. These rights protect children from having important decisions made by others before they have had the ability to make them for themselves. The right to an open future encompasses strategies that may safeguard a child's future fertility.[141]

Of critical concern is the extent to which the minor child should be involved in decisions surrounding his or her care. Guidance on patient participation in decision-making and assent should comply with recommendations in the American Academy of Pediatrics policy statement "Informed Consent in Decision-making in Pediatric Practice."[142]

The patient's family and physicians should work together to help provide an open future for the child. At times, there may be disagreements between a parent and child or between the family and the physicians regarding fertility preservation. Reasons for this include the cultural or religious beliefs of the family or discomfort surrounding discussions of an intimate nature with a child who has not yet or only just recently reached sexual maturity. Parents should be cognizant of their biases and work to maximize options for their children. Although they may not feel completely comfortable with fertility preservation, it is important to consider that the child will become an adult who will make reproductive decisions regarding their fertility.

When possible, after the child has become an adult, he or she should have the broadest possible options from which to choose given the medical circumstances of his or her cancer diagnosis. The opportunity to parent a biologically related child is an important option to attempt to preserve for the child. Recognizing the limits of safety and current technology, medical providers should strive to discuss these options and help provide access to them. Special circumstances might be posed by specific religious beliefs or cultural values that preclude either discussing or allowing ART or that prohibit masturbation.[110] The parent(s) or guardian(s) will most likely be transferring their beliefs to the clinical situation, and these beliefs may or may not represent those of the child at the present time or in the future. Individuals who will later wish to have biologically related children may be adversely affected by decisions that are made for them by their parents or guardians. In some cultures, a person's status in their community may be culturally dependent on their ability to reproduce. It may be helpful, when such options are presented to an adolescent who is mature enough to provide assent, to discuss them without a legal guardian present to help elucidate the adolescent's feelings regarding such decisions. Such discussions should take place regardless of the child's sexual orientation because reproductive considerations remain the same as for any child. When conflicts between patient and family desires arise, involving mental health professionals and/or an ethics consultant to work through the contrasting desires is often helpful and should be considered.

Issues may arise with disposition of gametes (sperm, oocytes, embryos, or gonadal tissue) whether the child lives or dies.[110,143,144] Any procedure performed has as its aim the preservation of a child's reproductive future, and this should be discussed as part of the consent and/or assent process. If the child survives, decisions surrounding disposition of the gametes should be delayed until after the child has reached the age of majority. This stands in contrast to organ donation, in which parents do have control over donation decisions. The contrast between gamete and organ donation stems from the capacity of gametes to propagate the genome of the deceased. Posthumous gamete use in adults is ethically complex. In minors who have not survived to the age of majority, use of cryopreserved gametes is ethically impermissible. It is unethical for parents or legal guardians to arrange for gametes to be fertilized for the purpose of reproduction. The only individual ethically able to consent to the use of their gametes for reproduction is the child who has reached the age of majority. Organs and other tissues are donated for the purpose of saving a life or improving the health of another. Posthumous gamete donation does not serve either of these purposes. These issues are not unique, have precedent in case law, and need to be addressed by any person agreeing to the preservation of tissue or gametes.[144]

Eggs, sperm, and testicular and ovarian tissue obtained from a child who does not survive into adulthood should be discarded. Because a child or an adolescent who lacks capacity cannot give consent to have donated gametes used for procreation and to avoid the risks inherent in the creation of a "commemorative child," parents would not have discretion over the biological material of a child who has died, and the gametes should be destroyed. This is consistent with recommendations made by the American Society for Reproductive Medicine and the European Society of Human Reproduction and Embryology.[145,146]

GUIDANCE FOR COUNSELING OF PARENTS AND PATIENTS ABOUT PRESERVATION OF FERTILITY OPTIONS IN CHILDREN AND ADOLESCENTS WITH CANCER

1. Physicians providing cancer treatment to children should be able to counsel patients and their families regarding the risk of infertility and fertility preservation options. Although there will be cases in which cancer treatment must be initiated emergently and fertility preservation will not be an option, the impact of the treatment on fertility should be discussed.
2. When medically effective fertility preservation options exist, patients and their families should be offered timely referral to centers and providers offering these options. This may include delaying treatment to allow for fertility preservation to occur, as long as the delay does not compromise the success of the cancer therapy.
3. Physicians who provide cancer treatment should be aware that fertility preservation options are limited in prepubertal children and that most treatments in this age group are experimental at the present time.
4. When counseling families regarding fertility preservation, physicians should be clear as to whether the treatments have proven efficacy or are experimental in nature. Experimental therapies should only be undertaken under IRB approval.
5. Evaluation for candidacy for fertility preservation should be guided by an institutional policy. Such policies should be informed by a team of specialists that may include a pediatric oncologist, a specialist in reproductive medicine, a urologist with expertise in male fertility, a radiation oncologist, an ethics consultant, an expert in reproductive law, and a mental health professional.
6. Cryopreservation of sperm and oocytes should be offered whenever possible to postpubertal patients or families of adolescents, dependent on the predicted gonadotoxicity of the prescribed treatment.
7. Given the success that has been achieved with cryopreservation of oocytes, embryo cryopreservation should not be considered in children. Experience with oocyte cryopreservation is variable, and patients should be referred to fertility centers with significant experience and success with this technique.
8. The option of ovarian tissue cryopreservation for female children and adolescents and of testicular tissue in male children and adolescents is still considered experimental and should be offered only in selected institutions in the setting of a research protocol.
9. In considering actions to preserve a child's fertility, parents should consider a child's assent, the details of the procedure involved, and whether such procedures are of proven utility or are experimental in nature.
10. Instructions concerning disposition of stored gametes or gonadal tissue in the event of the patient's death, unavailability, or other contingency should be formally recorded at the center where the gametes or tissue will be stored and should include the patient if possible before collection of the tissue and/or germ cells. There should be another discussion between the patient and the physicians at the center where the reproductive tissue is stored about disposition of gametes after the child reaches the age of majority. Eggs, sperm, and testicular and ovarian tissue obtained from a child who does not survive into adulthood should be discarded by the center preserving the reproductive tissue as per the consents signed at the time of cryopreservation.
11. When conflicts arise between the parent and child regarding fertility preservation, all possible attempts should be made to support an open future for the child while respecting the family's wishes.

LEAD AUTHORS

Sigal Klipstein, MD, FACOG
Mary E. Fallat, MD, FAAP
Stephanie Savelli, MD, FAAP

COMMITTEE ON BIOETHICS, 2018–2019

Mary E. Fallat, MD, FAAP, Chairperson
Aviva L. Katz, MD, FAAP
Robert C. Macauley, MD, FAAP
Mark R. Mercurio, MD, FAAP
Margaret R. Moon, MD, FAAP
Alexander L. Okun, MD, FAAP
Kathryn L. Weise, MD, FAAP

ACKNOWLEDGMENTS

We acknowledge Dr Aviva Katz for her insight and assistance throughout the process of drafting this article. We also thank Dr Sarah Friebert and Dr Daniel M. Green for their drafting of the original document on which the current statement is based.

ABBREVIATIONS

AMH: anti-Müllerian hormone
ART: assisted reproductive technology
ASCO: American Society of Clinical Oncology
CCSS: Childhood Cancer Survivor Study
GnRH: gonadotropin-releasing hormone
ICSI: intracytoplasmic sperm injection
IRB: institutional review board
IVF: in vitro fertilization

Address correspondence to Sigal Klipstein, MD. E-mail: sklipstein@inviafertility.com

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Volerman A. Primary care of the childhood cancer survivor. *Med Clin North Am*. 2015;99(5):1059–1073
2. Howlader N, Noone AM, Krapcho M, et al. *SEER Cancer Statistics Review, 1975-2013*. Bethesda, MD: National Cancer Institute; 2016. Available at: http://seer.cancer.gov/csr/1975_2013/. Accessed April 29, 2019
3. Oktay K, Harvey BE, Partridge AH, et al. Fertility preservation in patients with cancer: ASCO clinical practice guideline update. *J Clin Oncol*. 2018; 36(19):1994–2001
4. Practice Committee of American Society for Reproductive Medicine. Definitions of infertility and recurrent pregnancy loss: a committee opinion. *Fertil Steril*. 2013;99(1):63
5. Klipstein S, Regan M, Ryley DA, Goldman MB, Alper MM, Reindollar RH. One last chance for pregnancy: a review of 2,705 in vitro fertilization cycles initiated in women age 40 years and above. *Fertil Steril*. 2005;84(2): 435–445
6. Hassan MA, Killick SR. Effect of male age on fertility: evidence for the decline in male fertility with increasing age. *Fertil Steril*. 2003; 79(suppl 3):1520–1527
7. Centers for Disease Control and Prevention; National Center for Health Statistics. Infertility. 2007. Available at: https://www.cdc.gov/nchs/fastats/infertility.htm. Accessed April 29, 2019
8. Mariotto AB, Rowland JH, Yabroff KR, et al. Long-term survivors of childhood cancers in the United States. *Cancer Epidemiol Biomarkers Prev*. 2009; 18(4):1033–1040
9. Wallace WH, Walker DA. Conference consensus statement: ethical and research dilemmas for fertility preservation in children treated for cancer. *Hum Fertil (Camb)*. 2001;4(2): 69–76
10. Nistal M, Paniagua R. Occurrence of primary spermatocytes in the infant and child testis. *Andrologia*. 1984;16(6): 532–536

11. Kulin HE, Frontera MA, Demers LM, Bartholomew MJ, Lloyd TA. The onset of sperm production in pubertal boys. Relationship to gonadotropin excretion. *Am J Dis Child*. 1989;143(2):190–193
12. Nielsen CT, Skakkebaek NE, Richardson DW, et al. Onset of the release of spermatozoa (spermarche) in boys in relation to age, testicular growth, pubic hair, and height. *J Clin Endocrinol Metab*. 1986;62(3):532–535
13. Richardson DW, Short RV. Time of onset of sperm production in boys. *J Biosoc Sci Suppl*. 1978;(5):15–25
14. Hirsch M, Lunenfeld B, Modan M, Ovadia J, Shemesh J. Spermarche–the age of onset of sperm emission. *J Adolesc Health Care*. 1985;6(1):35–39
15. Peters H, Himelstein-Braw R, Faber M. The normal development of the ovary in childhood. *Acta Endocrinol (Copenh)*. 1976;82(3):617–630
16. Jahnukainen K, Ehmcke J, Söder O, Schlatt S. Clinical potential and putative risks of fertility preservation in children utilizing gonadal tissue or germline stem cells. *Pediatr Res*. 2006; 59(4, pt 2):40R–47R
17. Schover LR. Patient attitudes toward fertility preservation. *Pediatr Blood Cancer*. 2009;53(2):281–284
18. Seppänen VI, Artama MS, Malila NK, et al. Risk for congenital anomalies in offspring of childhood, adolescent and young adult cancer survivors. *Int J Cancer*. 2016;139(8):1721–1730
19. Signorello LB, Mulvihill JJ, Green DM, et al. Congenital anomalies in the children of cancer survivors: a report from the childhood cancer survivor study. *J Clin Oncol*. 2012;30(3):239–245
20. Winther JF, Boice JD Jr., Frederiksen K, et al. Radiotherapy for childhood cancer and risk for congenital malformations in offspring: a population-based cohort study. *Clin Genet*. 2009;75(1):50–56
21. Dodds L, Marrett LD, Tomkins DJ, Green B, Sherman G. Case-control study of congenital anomalies in children of cancer patients. *BMJ*. 1993;307(6897): 164–168
22. Green DM, Zevon MA, Lowrie G, Seigelstein N, Hall B. Congenital anomalies in children of patients who received chemotherapy for cancer in childhood and adolescence. *N Engl J Med*. 1991;325(3):141–146
23. Winther JF, Boice JD Jr., Mulvihill JJ, et al. Chromosomal abnormalities among offspring of childhood-cancer survivors in Denmark: a population-based study. *Am J Hum Genet*. 2004; 74(6):1282–1285
24. Winther JF, Olsen JH, Wu H, et al. Genetic disease in the children of Danish survivors of childhood and adolescent cancer. *J Clin Oncol*. 2012; 30(1):27–33
25. Byrne J, Rasmussen SA, Steinhorn SC, et al. Genetic disease in offspring of long-term survivors of childhood and adolescent cancer. *Am J Hum Genet*. 1998;62(1):45–52
26. Chow EJ, Kamineni A, Daling JR, et al. Reproductive outcomes in male childhood cancer survivors: a linked cancer-birth registry analysis. *Arch Pediatr Adolesc Med*. 2009;163(10): 887–894
27. Mueller BA, Chow EJ, Kamineni A, et al. Pregnancy outcomes in female childhood and adolescent cancer survivors: a linked cancer-birth registry analysis. *Arch Pediatr Adolesc Med*. 2009;163(10):879–886
28. Green DM, Peabody EM, Nan B, Peterson S, Kalapurakal JA, Breslow NE. Pregnancy outcome after treatment for Wilms tumor: a report from the National Wilms Tumor Study Group. *J Clin Oncol*. 2002;20(10):2506–2513
29. Green DM, Lange JM, Peabody EM, et al. Pregnancy outcome after treatment for Wilms tumor: a report from the national Wilms tumor long-term follow-up study. *J Clin Oncol*. 2010;28(17): 2824–2830
30. Green DM, Fine WE, Li FP. Offspring of patients treated for unilateral Wilms' tumor in childhood. *Cancer*. 1982; 49(11):2285–2288
31. Li FP, Fine W, Jaffe N, Holmes GE, Holmes FF. Offspring of patients treated for cancer in childhood. *J Natl Cancer Inst*. 1979;62(5):1193–1197
32. Li FP, Gimbrere K, Gelber RD, et al. Outcome of pregnancy in survivors of Wilms' tumor. *JAMA*. 1987;257(2): 216–219
33. Madanat-Harjuoja LM, Malila N, Lähteenmäki P, et al. Risk of cancer among children of cancer patients - a nationwide study in Finland. *Int J Cancer*. 2010;126(5):1196–1205
34. Servitzoglou M, De Vathaire F, Oberlin O, Patte C, Thomas-Teinturier C. Dose-effect relationship of alkylating agents on testicular function in male survivors of childhood lymphoma. *Pediatr Hematol Oncol*. 2015;32(8):613–623
35. Howell S, Shalet S. Gonadal damage from chemotherapy and radiotherapy. *Endocrinol Metab Clin North Am*. 1998; 27(4):927–943
36. Jaffe N, Sullivan MP, Ried H, et al. Male reproductive function in long-term survivors of childhood cancer. *Med Pediatr Oncol*. 1988;16(4):241–247
37. Green DM, Liu W, Kutteh WH, et al. Cumulative alkylating agent exposure and semen parameters in adult survivors of childhood cancer: a report from the St Jude Lifetime Cohort Study. *Lancet Oncol*. 2014;15(11):1215–1223
38. Green DM, Kawashima T, Stovall M, et al. Fertility of female survivors of childhood cancer: a report from the childhood cancer survivor study. *J Clin Oncol*. 2009;27(16):2677–2685
39. Green DM, Kawashima T, Stovall M, et al. Fertility of male survivors of childhood cancer: a report from the Childhood Cancer Survivor Study. *J Clin Oncol*. 2010;28(2):332–339
40. Chow EJ, Stratton KL, Leisenring WM, et al. Pregnancy after chemotherapy in male and female survivors of childhood cancer treated between 1970 and 1999: a report from the Childhood Cancer Survivor Study cohort. *Lancet Oncol*. 2016;17(5):567–576
41. Trudgen K, Ayensu-Coker L. Fertility preservation and reproductive health in the pediatric, adolescent, and young adult female cancer patient. *Curr Opin Obstet Gynecol*. 2014;26(5):372–380
42. Levine JM, Whitton JA, Ginsberg JP, et al. Nonsurgical premature menopause and reproductive implications in survivors of childhood cancer: a report from the Childhood Cancer Survivor Study. *Cancer*. 2018; 124(5):1044–1052
43. Chemaitilly W, Li Z, Krasin MJ, et al. Premature ovarian insufficiency in

childhood cancer survivors: a report from the St. Jude Lifetime Cohort. *J Clin Endocrinol Metab*. 2017;102(7): 2242–2250

44. George SA, Williamson Lewis R, Schirmer DA, et al. Early detection of ovarian dysfunction by anti-Mullerian hormone in adolescent and young adult-aged survivors of childhood cancer. *J Adolesc Young Adult Oncol*. 2019;8(1):18–25
45. van den Berg MH, Overbeek A, Lambalk CB, et al; DCOG LATER-VEVO Study Group. Long-term effects of childhood cancer treatment on hormonal and ultrasound markers of ovarian reserve. *Hum Reprod*. 2018;33(8):1474–1488
46. Lie Fong S, Laven JS, Hakvoort-Cammel FG, et al. Assessment of ovarian reserve in adult childhood cancer survivors using anti-Müllerian hormone. *Hum Reprod*. 2009;24(4):982–990
47. Lunsford AJ, Whelan K, McCormick K, McLaren JF. Antimüllerian hormone as a measure of reproductive function in female childhood cancer survivors. *Fertil Steril*. 2014;101(1):227–231
48. Hudson MM. Reproductive outcomes for survivors of childhood cancer. *Obstet Gynecol*. 2010;116(5):1171–1183
49. Wallace WH, Thomson AB, Kelsey TW. The radiosensitivity of the human oocyte. *Hum Reprod*. 2003;18(1):117–121
50. Barton SE, Najita JS, Ginsburg ES, et al. Infertility, infertility treatment, and achievement of pregnancy in female survivors of childhood cancer: a report from the Childhood Cancer Survivor Study cohort. *Lancet Oncol*. 2013;14(9): 873–881
51. Levine JM. Preserving fertility in children and adolescents with cancer. *Children (Basel)*. 2014;1(2):166–185
52. Singhal MK, Kapoor A, Singh D, et al. Scattered radiation to gonads: role of testicular shielding for para-aortic and homolateral illiac nodal radiotherapy. *J Egypt Natl Canc Inst*. 2014;26(2): 99–101
53. Sayan M, Cassidy RJ, Butker EE, et al. Gonadal shielding technique to preserve fertility in male pediatric patients treated with total body irradiation for stem cell transplantation. *Bone Marrow Transplant*. 2016;51(7):997–998
54. Acosta JM, Tiao G, Stein JE, Mahour GH. Temporary relocation of testes to the anterior abdominal wall before radiation therapy of the pelvis or perineum. *J Pediatr Surg*. 2002;37(8): 1232–1233
55. D'Angio GJ, Exelby PR, Ghavimi F, Cham WC, Tefft M. Protection of certain structures from high doses of irradiation. *Am J Roentgenol Radium Ther Nucl Med*. 1974;122(1):103–108
56. Wyns C, Curaba M, Vanabelle B, Van Langendonckt A, Donnez J. Options for fertility preservation in prepubertal boys. *Hum Reprod Update*. 2010;16(3): 312–328
57. Tesarik J, Bahceci M, Ozcan C, Greco E, Mendoza C. Restoration of fertility by in-vitro spermatogenesis. *Lancet*. 1999; 353(9152):555–556
58. Bahadur G, Chatterjee R, Ralph D. Testicular tissue cryopreservation in boys. Ethical and legal issues: case report. *Hum Reprod*. 2000;15(6): 1416–1420
59. Pietzak EJ III, Tasian GE, Tasian SK, et al. Histology of testicular biopsies obtained for experimental fertility preservation protocol in boys with cancer. *J Urol*. 2015;194(5):1420–1424
60. Aubard Y, Piver P, Pech JC, Galinat S, Teissier MP. Ovarian tissue cryopreservation and gynecologic oncology: a review. *Eur J Obstet Gynecol Reprod Biol*. 2001;97(1):5–14
61. Kuohung W, Ram K, Cheng DM, Marcus KJ, Diller LR, Laufer MR. Laparoscopic oophoropexy prior to radiation for pediatric brain tumor and subsequent ovarian function. *Hum Reprod*. 2008; 23(1):117–121
62. Tulandi T, Al-Shahrani AA. Laparoscopic fertility preservation. *Obstet Gynecol Clin North Am*. 2004;31(3):611–618, x
63. Farthing A. Conserving fertility in the management of gynaecological cancers. *BJOG*. 2006;113(2):129–134
64. Plante M. Fertility preservation in the management of gynecologic cancers. *Curr Opin Oncol*. 2000;12(5):497–507
65. Armstrong AG, Kimler BF, Smith BM, Woodruff TK, Pavone ME, Duncan FE. Ovarian tissue cryopreservation in young females through the Oncofertility Consortium's National Physicians Cooperative. *Future Oncol*. 2018;14(4): 363–378
66. Duncan FE, Pavone ME, Gunn AH, et al. Pediatric and teen ovarian tissue removed for cryopreservation contains follicles irrespective of age, disease diagnosis, treatment history, and specimen processing methods. *J Adolesc Young Adult Oncol*. 2015;4(4): 174–183
67. Roberts JE, Oktay K. Fertility preservation: a comprehensive approach to the young woman with cancer. *J Natl Cancer Inst Monogr*. 2005; (34):57–59
68. Wallace WH, Anderson RA, Irvine DS. Fertility preservation for young patients with cancer: who is at risk and what can be offered? *Lancet Oncol*. 2005;6(4): 209–218
69. Siebzehnrübl E, Kohl J, Dittrich R, Wildt L. Freezing of human ovarian tissue–not the oocytes but the granulosa is the problem. *Mol Cell Endocrinol*. 2000; 169(1–2):109–111
70. Wallace WH, Anderson RA. Cancer survivors and infertility: where do we go from here? *J Support Oncol*. 2006; 4(4):183–184
71. Oehninger S. Strategies for fertility preservation in female and male cancer survivors. *J Soc Gynecol Investig*. 2005;12(4):222–231
72. Nugent D, Hamilton M, Murdoch A; BFS Committee. BFS recommendations for good practice on the storage of ovarian and prepubertal testicular tissue. *Hum Fertil (Camb)*. 2000;3(1):5–8
73. Poirot C, Vacher-Lavenu MC, Helardot P, Guibert J, Brugières L, Jouannet P. Human ovarian tissue cryopreservation: indications and feasibility. *Hum Reprod*. 2002;17(6): 1447–1452
74. Oktay K. Fertility preservation: an emerging discipline in the care of young patients with cancer. *Lancet Oncol*. 2005;6(4):192–193
75. Dolmans MM, Marinescu C, Saussoy P, Van Langendonckt A, Amorim C, Donnez J. Reimplantation of cryopreserved ovarian tissue from patients with acute lymphoblastic leukemia is potentially unsafe. *Blood*. 2010;116(16):2908–2914

76. Rosendahl M, Andersen MT, Ralfkiær E, Kjeldsen L, Andersen MK, Andersen CY. Evidence of residual disease in cryopreserved ovarian cortex from female patients with leukemia. *Fertil Steril*. 2010;94(6):2186–2190

77. Hovatta O. Cryopreservation and culture of human primordial and primary ovarian follicles. *Mol Cell Endocrinol*. 2000;169(1–2):95–97

78. Oktay K, Karlikaya G. Ovarian function after transplantation of frozen, banked autologous ovarian tissue. *N Engl J Med*. 2000;342(25):1919

79. Donnez J, Dolmans MM, Demylle D, et al. Livebirth after orthotopic transplantation of cryopreserved ovarian tissue. *Lancet*. 2004;364(9443): 1405–1410

80. Meirow D, Levron J, Eldar-Geva T, et al. Pregnancy after transplantation of cryopreserved ovarian tissue in a patient with ovarian failure after chemotherapy. *N Engl J Med*. 2005; 353(3):318–321

81. Silber S. Ovarian tissue cryopreservation and transplantation: scientific implications. *J Assist Reprod Genet*. 2016;33(12):1595–1603

82. Dunlop CE, Brady BM, McLaughlin M, et al. Re-implantation of cryopreserved ovarian cortex resulting in restoration of ovarian function, natural conception and successful pregnancy after haematopoietic stem cell transplantation for Wilms tumour. *J Assist Reprod Genet*. 2016;33(12): 1615–1620

83. Practice Committee of American Society for Reproductive Medicine. Ovarian tissue cryopreservation: a committee opinion. *Fertil Steril*. 2014;101(5): 1237–1243

84. Matthews SJ, Picton H, Ernst E, Andersen CY. Successful pregnancy in a woman previously suffering from β-thalassemia following transplantation of ovarian tissue cryopreserved before puberty. *Minerva Ginecol*. 2018;70(4):432–435

85. Demeestere I, Simon P, Dedeken L, et al. Live birth after autograft of ovarian tissue cryopreserved during childhood. *Hum Reprod*. 2015;30(9):2107–2109

86. Hayden RP, Kashanian JA. Facing a cancer diagnosis: empowering parents to speak with adolescents about sperm banking. *Fertil Steril*. 2017;108(6):957–958

87. Opsahl MS, Fugger EF, Sherins RJ, Schulman JD. Preservation of reproductive function before therapy for cancer: new options involving sperm and ovary cryopreservation. *Cancer J Sci Am*. 1997;3(4):189–191

88. Magelssen H, Brydøy M, Fosså SD. The effects of cancer and cancer treatments on male reproductive function. *Nat Clin Pract Urol*. 2006;3(6): 312–322

89. Hallak J, Kolettis PN, Sekhon VS, Thomas AJ Jr., Agarwal A. Cryopreservation of sperm from patients with leukemia: is it worth the effort? *Cancer*. 1999;85(9): 1973–1978

90. Bahadur G, Ling KL, Hart R, et al. Semen production in adolescent cancer patients. *Hum Reprod*. 2002;17(10): 2654–2656

91. Schmiegelow ML, Sommer P, Carlsen E, Sønksen JO, Schmiegelow K, Müller JR. Penile vibratory stimulation and electroejaculation before anticancer therapy in two pubertal boys. *J Pediatr Hematol Oncol*. 1998;20(5):429–430

92. Balet R, Thornhill AR, Handyside A, lammarrone E, Shaw L, Grudzinskas G. Day surgery sperm retrieval using pesa or tese with elective freezing: a retrospective review of 6 years experience and 292 cases [abstract]. *Fertil Steril*. 2008;90(suppl):S466

93. Habermann H, Seo R, Cieslak J, Niederberger C, Prins GS, Ross L. In vitro fertilization outcomes after intracytoplasmic sperm injection with fresh or frozen-thawed testicular spermatozoa. *Fertil Steril*. 2000;73(5): 955–960

94. Practice Committees of American Society for Reproductive Medicine; Society for Assisted Reproductive Technology. Mature oocyte cryopreservation: a guideline. *Fertil Steril*. 2013;99(1):37–43

95. Jain JK, Paulson RJ. Oocyte cryopreservation. *Fertil Steril*. 2006; 86(suppl 4):1037–1046

96. Smith GD, Serafini PC, Fioravanti J, et al. Prospective randomized comparison of human oocyte cryopreservation with slow-rate freezing or vitrification. *Fertil Steril*. 2010;94(6):2088–2095

97. Cobo A, García-Velasco JA, Coello A, Domingo J, Pellicer A, Remohí J. Oocyte vitrification as an efficient option for elective fertility preservation. *Fertil Steril*. 2016;105(3):755–764.e8

98. Noyes N, Porcu E, Borini A. Over 900 oocyte cryopreservation babies born with no apparent increase in congenital anomalies. *Reprod Biomed Online*. 2009; 18(6):769–776

99. Chian RC, Huang JY, Tan SL, et al. Obstetric and perinatal outcome in 200 infants conceived from vitrified oocytes. *Reprod Biomed Online*. 2008;16(5): 608–610

100. Cobo A, Bellver J, de los Santos MJ, Remohí J. Viral screening of spent culture media and liquid nitrogen samples of oocytes and embryos from hepatitis B, hepatitis C, and human immunodeficiency virus chronically infected women undergoing in vitro fertilization cycles. *Fertil Steril*. 2012; 97(1):74–78

101. Levi-Setti PE, Borini A, Patrizio P, et al. ART results with frozen oocytes: data from the Italian ART registry (2005-2013). *J Assist Reprod Genet*. 2016; 33(1):123–128

102. ACOG: committee opinion No. 584: oocyte cryopreservation. *Obstet Gynecol*. 2014;123(1):221–222

103. Maltaris T, Weigel M, Mueller A, et al. Cancer and fertility preservation: fertility preservation in breast cancer patients. *Breast Cancer Res*. 2008;10(2): 206

104. Oktem O, Oktay K. Fertility preservation for breast cancer patients. *Semin Reprod Med*. 2009;27(6):486–492

105. Rodriguez-Wallberg KA, Oktay K. Fertility preservation in women with breast cancer. *Clin Obstet Gynecol*. 2010;53(4): 753–762

106. Gerber B, von Minckwitz G, Stehle H, et al; German Breast Group Investigators. Effect of luteinizing hormone-releasing hormone agonist on ovarian function after modern adjuvant breast cancer chemotherapy: the GBG 37 ZORO study. *J Clin Oncol*. 2011;29(17): 2334–2341

107. Munster PN, Moore AP, Ismail-Khan R, et al. Randomized trial using gonadotropin-releasing hormone agonist triptorelin for the preservation of ovarian function during (neo) adjuvant chemotherapy for breast cancer. *J Clin Oncol*. 2012;30(5):533–538

108. Del Mastro L, Boni L, Michelotti A, et al. Effect of the gonadotropin-releasing hormone analogue triptorelin on the occurrence of chemotherapy-induced early menopause in premenopausal women with breast cancer: a randomized trial. *JAMA*. 2011;306(3): 269–276

109. Lambertini M, Falcone T, Unger JM, Phillips KA, Del Mastro L, Moore HC. Debated role of ovarian protection with gonadotropin-releasing hormone agonists during chemotherapy for preservation of ovarian function and fertility in women with cancer. *J Clin Oncol*. 2017;35(7):804–805

110. Rosoff PM, Katsur ML. Preserving fertility in young cancer patients: a medical, ethical and legal challenge. *J Philos Sci Law*. 2003;3:4–28

111. Greil AL. Infertility and psychological distress: a critical review of the literature. *Soc Sci Med*. 1997;45(11): 1679–1704

112. Schover LR. Psychosocial aspects of infertility and decisions about reproduction in young cancer survivors: a review. *Med Pediatr Oncol*. 1999;33(1):53–59

113. Cardozo ER, Huber WJ, Stuckey AR, Alvero RJ. Mandating coverage for fertility preservation - a step in the right direction. *N Engl J Med*. 2017; 377(17):1607–1609

114. Alliance for Fertility Preservation. Illinois becomes fifth state to enact law on fertility preservation coverage. Available at: https://www.allianceforfertilitypreservation.org/state-legislation/Illinois. Accessed April 26, 2019

115. Basco D, Campo-Engelstein L, Rodriguez S. Insuring against infertility: expanding state infertility mandates to include fertility preservation technology for cancer patients. *J Law Med Ethics*. 2010;38(4):832–839

116. California Legislative Information. SB-172 health care coverage: fertility preservation. Available at: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180SB172. Accessed April 26, 2019

117. Partridge AH. Ovarian suppression for prevention of premature menopause and infertility: empty promise or effective therapy? *J Clin Oncol*. 2012; 30(5):479–481

118. Carrns A. Meeting the cost of conceiving. *New York Times*. January 28, 2014. Available at: https://www.nytimes.com/2014/01/29/your-money/meeting-the-cost-of-conceiving.html. Accessed April 29, 2019

119. Gerson Uffalussy J. The cost of IVF: 4 things I learned while battling infertility. *Forbes*. February 6, 2014. Available at: https://www.forbes.com/sites/learnvest/2014/02/06/the-cost-of-ivf-4-things-i-learned-while-battling-infertility/#4876c4db24dd. Accessed April 26, 2019

120. Teoh PJ, Maheshwari A. Low-cost in vitro fertilization: current insights. *Int J Womens Health*. 2014;6:817–827

121. Katz P, Showstack J, Smith JF, et al. Costs of infertility treatment: results from an 18-month prospective cohort study. *Fertil Steril*. 2011;95(3):915–921

122. Fayomi AP, Peters K, Sukhwani M, et al. Autologous grafting of cryopreserved prepubertal rhesus testis produces sperm and offspring [published correction appears in *Science*. 2019; 364(6435):eaax4999]. *Science*. 2019; 363(6433):1314–1319

123. Meirow D, Fasouliotis SJ, Nugent D, Schenker JG, Gosden RG, Rutherford AJ. A laparoscopic technique for obtaining ovarian cortical biopsy specimens for fertility conservation in patients with cancer. *Fertil Steril*. 1999;71(5):948–951

124. American Academy of Pediatrics, Committee on Bioethics. Institutional ethics committees. *Pediatrics*. 2001; 107(1):205–209

125. Grundy R, Larcher V, Gosden RG, et al. Fertility preservation for children treated for cancer (2): ethics of consent for gamete storage and experimentation. *Arch Dis Child*. 2001; 84(4):360–362

126. Schover LR, Rybicki LA, Martin BA, Bringelsen KA. Having children after cancer. A pilot survey of survivors' attitudes and experiences. *Cancer*. 1999;86(4):697–709

127. Wallace WH, Thomson AB. Preservation of fertility in children treated for cancer. *Arch Dis Child*. 2003;88(6): 493–496

128. Köhler TS, Kondapalli LA, Shah A, Chan S, Woodruff TK, Brannigan RE. Results from the survey for preservation of adolescent reproduction (SPARE) study: gender disparity in delivery of fertility preservation message to adolescents with cancer. *J Assist Reprod Genet*. 2011;28(3):269–277

129. Oosterhuis BE, Goodwin T, Kiernan M, Hudson MM, Dahl GV. Concerns about infertility risks among pediatric oncology patients and their parents. *Pediatr Blood Cancer*. 2008;50(1):85–89

130. Quinn GP, Knapp C, Murphy D, Sawczyn K, Sender L. Congruence of reproductive concerns among adolescents with cancer and parents: pilot testing an adapted instrument. *Pediatrics*. 2012;129(4). Available at: www.pediatrics.org/cgi/content/full/129/4/e930

131. van den Berg H, Langeveld NE. Parental knowledge of fertility in male childhood cancer survivors. *Psychooncology*. 2008; 17(3):287–291

132. Schover LR, Brey K, Lichtin A, Lipshultz LI, Jeha S. Knowledge and experience regarding cancer, infertility, and sperm banking in younger male survivors. *J Clin Oncol*. 2002;20(7):1880–1889

133. Burns KC, Boudreau C, Panepinto JA. Attitudes regarding fertility preservation in female adolescent cancer patients. *J Pediatr Hematol Oncol*. 2006;28(6):350–354

134. Saito K, Suzuki K, Iwasaki A, Yumura Y, Kubota Y. Sperm cryopreservation before cancer chemotherapy helps in the emotional battle against cancer. *Cancer*. 2005;104(3):521–524

135. Ginsberg JP, Ogle SK, Tuchman LK, et al. Sperm banking for adolescent and young adult cancer patients: sperm quality, patient, and parent perspectives. *Pediatr Blood Cancer*. 2008;50(3):594–598

136. Canada AL, Schover LR. The psychosocial impact of interrupted childbearing in long-term female

cancer survivors. *Psychooncology*. 2012; 21(2):134–143

137. Levi Setti PE, Albani E, Morenghi E, et al. Comparative analysis of fetal and neonatal outcomes of pregnancies from fresh and cryopreserved/thawed oocytes in the same group of patients. *Fertil Steril*. 2013;100(2):396–401
138. Ethics Committee of the American Society for Reproductive Medicine. Fertility preservation and reproduction in cancer patients. *Fertil Steril*. 2005; 83(6):1622–1628
139. Grundy R, Gosden RG, Hewitt M, et al. Fertility preservation for children treated for cancer (1): scientific advances and research dilemmas. *Arch Dis Child*. 2001;84(4):355–359
140. Feinberg J. The Child's Right to an Open Future. In: Aiken W, LaFollette H, eds. *Whose Child? Children's Rights, Parental Authority, and State Power*. Totowa, NJ: Rowman & Littlefield; 1980: 124–153
141. Millum J. The foundation of the child's right to an open future. *J Soc Philos*. 2014;45(4):522–538
142. Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2): e20161484
143. Glaser A, Wilkey O, Greenberg M. Sperm and ova conservation: existing standards of practice in North America. *Med Pediatr Oncol*. 2000;35(2):114–118
144. Sugarman J, Rosoff PM. Ethical issues in gamete preservation for children undergoing treatment for cancer. *J Androl*. 2001;22(5):732–737
145. Ethics Committee of the American Society for Reproductive Medicine. Posthumous collection and use of reproductive tissue: a committee opinion. *Fertil Steril*. 2013;99(7): 1842–1845
146. Pennings G, de Wert G, Shenfield F, Cohen J, Devroey P, Tarlatzis B; ESHRE Task Force on Ethics and Law. ESHRE Task Force on Ethics and Law 11: posthumous assisted reproduction. *Hum Reprod*. 2006;21(12):3050–3053

Fluoride Use in Caries Prevention in the Primary Care Setting

- *Clinical Report*
  - *PPI: AAP Partnership for Policy Implementation*
    See Appendix 1 for more information.

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Fluoride Use in Caries Prevention in the Primary Care Setting

Melinda B. Clark, MD, FAAP,[a] Martha Ann Keels, DDS, PhD,[b,c] Rebecca L. Slayton, DDS, PhD,[d] SECTION ON ORAL HEALTH

Dental caries remains the most common chronic disease of childhood in the United States. Caries is a largely preventable condition, and fluoride has proven effectiveness in caries prevention. This clinical report aims to clarify the use of available fluoride modalities for caries prevention in the primary care setting and to assist pediatricians in using fluoride to achieve maximum protection against dental caries, while minimizing the likelihood of enamel fluorosis. Fluoride varnish application is now considered the standard of care in pediatric primary care. This report highlights administration, billing, and payment information regarding the fluoride varnish procedure.

Dental caries (ie, tooth decay) is an infectious disease caused by bacteria on the tooth surface metabolizing carbohydrates and producing acid, which dissolves tooth enamel. If unchecked, this process continues through the tooth and into the pulp, resulting in pain and tooth loss. This can further progress to local infections (ie, dental alveolar abscess or facial cellulitis), systemic infection, and, in rare cases, death. Dental caries in the United States is responsible for many of the 51 million school hours lost per year as a result of dental-related illness, which translates into lost work hours for the adult caregiver.[1] Early childhood caries is the single greatest risk factor for caries in the permanent dentition. Good oral health is a necessary part of overall health, and studies have demonstrated adverse effects of poor oral health on multiple chronic conditions, including diabetes control.[2] Therefore, failure to prevent caries has health, educational, and financial consequences at both the individual and societal levels.

Dental caries is the most common chronic disease of childhood,[1] with 59% of 12- to 19-year-olds having at least 1 documented cavity.[3] Caries is a "silent epidemic" that disproportionately affects poor, young, minority populations and children living below 100% of the poverty level.[1] In the United States, 25% of 2- to 5-year-old children from low socioeconomic and minority groups experience 80% of dental disease.[4] Among 3- to 5-year-olds, untreated dental decay was significantly greater for non-

abstract

[a]Department of Pediatrics, Albany Medical Center, Albany, New York; [b]Department of Surgery and Pediatrics, Duke University, Durham, North Carolina; [c]The Adams School of Dentistry, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; and [d]Department of Pediatric Dentistry, School of Dentistry, University of Washington, Seattle, Washington

Drs Clark, Keels, and Slayton participated in the concept and design of the manuscript, analysis and interpretation of data, and drafting and revising of the manuscript; and all authors approved the final manuscript as submitted.This document is copyrighted and is property of the American Academy of Pediatrics and its Board of Directors. All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors. The American Academy of Pediatrics has neither solicited nor accepted any commercial involvement in the development of the content of this publication.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-034637

Address correspondence to Melinda B. Clark, MD. Email: ClarkM@amc.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

To cite: Clark MB, Slayton RL, AAP SECTION ON ORAL HEALTH. Fluoride Use in Caries Prevention in the Primary Care Setting. *Pediatrics.* 2020;146(6):e2020034637

Hispanic Black and Hispanic children (19.3% and 19.8%, respectively) than for non-Hispanic white children (11.3%).[4] This disparity persisted among children 6 to 9 years and 13 to 15 years of age.[4] Dental caries is a global problem, with early childhood caries prevalence among socioeconomically disadvantaged groups reported to be as high as 70%.[5] It has been suggested that health beliefs, self-efficacy, access to care, and parents' attitudes and practices related to dietary and oral hygiene behaviors may contribute to this disparity.[6]

Children with special health care needs, including those with developmental delay, complex neurodevelopmental disabilities, or congenital heart disease are also affected disproportionately.[7,8] In a study of Head Start children, those with developmental delays had a caries prevalence ratio that was 1.26 times higher than classmates without developmental delays.[8] This difference may be attributable to challenges with home care routines such as toothbrushing and use of medications with high sugar content, among other factors.[8] Children with special health care needs are frequently considered as a group when determining caries risk. However, some diagnoses place children at greater risk for caries, whereas other children are at decreased or similar risk as children without special health care needs. In a retrospective longitudinal study of children with autism spectrum disorder, Down syndrome, congenital heart disease, and cerebral palsy, Frank et al[7] determined that the caries risk among the group of children with special health care needs was higher than among the control subjects but the risk differed significantly by diagnosis. The caries burden was greatest in children with congenital heart disease, followed by those with autism spectrum disorders.[7] For children with Down syndrome, the risk was close to that of controls and considerably lower than the other 3 groups of children with special health care needs.[7]

Unfortunately, dental caries prevalence in young children increased between the previous 2 national surveys, despite improvements among older children.[9] Many children do not receive dental care at young ages, and because the risk of dental caries is heavily influenced by parenting practices, pediatricians have a unique opportunity to participate in the primary prevention of dental caries. The 2007–2016 Medical Expenditure Panel Survey demonstrated that 88.8% of infants and 1-year-olds have office-based physician visits annually, compared with only 3.6% of infants and 1-year-olds having general dental visits (American Academy of Pediatrics [AAP], unpublished analysis of 2007–2016 Medical Expenditure Panel Survey, August 2019). Studies show that health care dollars are saved with simple home and primary care setting prevention measures.[10]

The development of dental caries requires 4 components: teeth, bacteria, carbohydrate exposure, and time. Once teeth emerge, they become colonized with cariogenic bacteria. The bacteria metabolize carbohydrates and create acid as a byproduct. The acid dissolves the mineral content of enamel (demineralization) and, over time, with repeated acid attacks, the enamel surface disintegrates and results in a cavity in the tooth. Protective factors that help to remineralize enamel include exposing the teeth to fluoride, limiting the frequency of carbohydrate consumption (to 3 meals and 2 healthy snacks per day), choosing less cariogenic foods (selecting cheese or raw carrots over candy or crackers; selecting fresh fruit over dried fruit or processed fruit snacks), practicing good oral hygiene (brushing twice a day for 2 minutes and flossing between all teeth that touch), and receiving regular dental assessments and care. If carious lesions are identified early, the process can be halted or reversed by modifying the patient's individual risk and protective factors. The AAP's publications "Maintaining and Improving the Oral Health of Young Children"[11] and *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*[12] discuss these concepts in greater depth and provide targeted anticipatory guidance. For primary prevention to be effective, it is imperative that pediatricians be knowledgeable about the process of dental caries, social determinants of oral health, prevention of the disease, and available interventions, including fluoride.

Fluoride is available from many sources, divided into 3 major categories: tap water (and foods and beverages processed with fluoridated water), home administered, and professionally applied. The widespread decline in dental caries in many developed countries, including the United States, has been largely attributable to the use of fluoride. Fluoride has 3 main mechanisms of action[13]:

1. Fluoride promotes enamel remineralization.
2. Fluoride reduces enamel demineralization.
3. Fluoride inhibits bacterial metabolism and acid production.

The mechanisms of fluoride are both topical and systemic, but the topical effect is the most important, especially over the life span.[14]

There has been substantial public and professional debate about fluoride, and a great deal of information is available, often with confusing or conflicting messages. Excess fluoride ingestion during tooth development can result in subsurface

hypomineralization and porosity between the developing enamel rods, termed enamel fluorosis.[15] Fluorosis of permanent teeth occurs when excessive fluoride is ingested during the time that tooth enamel is being mineralized; therefore, the risk is influenced by both dose and frequency of ingestion. Recent evidence also suggests a genetic susceptibility or resistance to the development of fluorosis.[16] Fluorosis develops in children younger than 8 years, with the most susceptible period for permanent maxillary incisor fluorosis (central teeth) between 15 and 30 months of age.[17–19] The vast majority of enamel fluorosis is mild or very mild and characterized by small white striations or opaque areas not readily noticeable to the casual observer and is of minimal clinical consequence. Moderate and severe forms of enamel fluorosis are uncommon in the United States but have both an aesthetic concern and, potentially, a structural concern with pitting, brittle incisal edges and weakened groove anatomy in the permanent 6-year molars.[20] After 8 years of age, there is no further risk of fluorosis except for the third molars because all other permanent tooth enamel is fully mineralized.

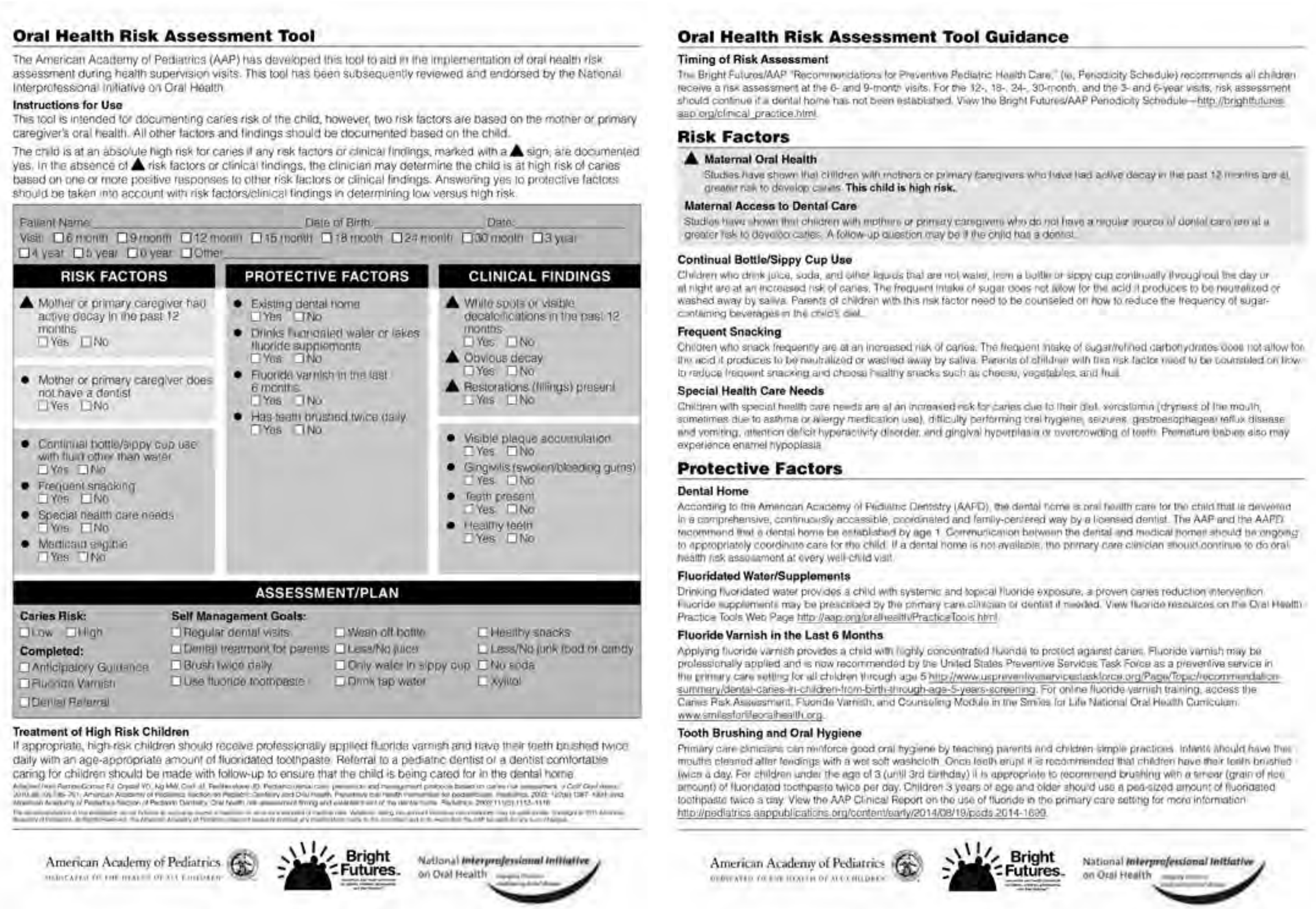
Dental and governmental organizations (the American Dental Association [ADA], American Academy of Pediatric Dentistry [AAPD], and Centers for Disease Control and Prevention [CDC]) have all published guidelines on the use of fluoride. In 2001, the AAP endorsed the CDC publication "Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States."[21]

The 2 intents of this clinical report are as follows:

1. to assist pediatricians in using fluoride to achieve maximum protection against dental caries, while minimizing the likelihood of enamel fluorosis; and
2. to clarify what advice should be given by pediatricians regarding fluoride in the primary care setting.

CURRENT INFORMATION REGARDING FLUORIDE USE IN CARIES PREVENTION

Sources of ingested fluoride include drinking water, infant formula, fluoride toothpaste, prescription fluoride supplements, fluoride mouth rinses, professionally applied topical



Oral Health Risk Assessment Tool

The American Academy of Pediatrics (AAP) has developed this tool to aid in the implementation of oral health risk assessment during health supervision visits. This tool has been subsequently reviewed and endorsed by the National Interprofessional Initiative on Oral Health.

Instructions for Use

This tool is intended for documenting caries risk of the child, however, two risk factors are based on the mother or primary caregiver's oral health. All other factors and findings should be documented based on the child.

The child is at an absolute high risk for caries if any risk factors or clinical findings, marked with a ▲ sign, are documented yes. In the absence of ▲ risk factors or clinical findings, the clinician may determine the child is at high risk of caries based on one or more positive responses to other risk factors or clinical findings. Answering yes to protective factors should be taken into account with risk factors/clinical findings in determining low versus high risk.

Patient Name: ______ Date of Birth: ______ Date: ______
Visit: ☐ 6 month ☐ 9 month ☐ 12 month ☐ 15 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 3 year ☐ 4 year ☐ 5 year ☐ 6 year ☐ Other ______

RISK FACTORS
- ▲ Mother or primary caregiver had active decay in the past 12 months ☐ Yes ☐ No
- ● Mother or primary caregiver does not have a dentist ☐ Yes ☐ No
- ● Continual bottle/sippy cup use with fluid other than water ☐ Yes ☐ No
- ● Frequent snacking ☐ Yes ☐ No
- ● Special health care needs ☐ Yes ☐ No
- ● Medicaid eligible ☐ Yes ☐ No

PROTECTIVE FACTORS
- ● Existing dental home ☐ Yes ☐ No
- ● Drinks fluoridated water or takes fluoride supplements ☐ Yes ☐ No
- ● Fluoride varnish in the last 6 months ☐ Yes ☐ No
- ● Has teeth brushed twice daily ☐ Yes ☐ No

CLINICAL FINDINGS
- ▲ White spots or visible decalcifications in the past 12 months ☐ Yes ☐ No
- ▲ Obvious decay ☐ Yes ☐ No
- ▲ Restorations (fillings) present ☐ Yes ☐ No
- ● Visible plaque accumulation ☐ Yes ☐ No
- ● Gingivitis (swollen/bleeding gums) ☐ Yes ☐ No
- ● Teeth present ☐ Yes ☐ No
- ● Healthy teeth ☐ Yes ☐ No

ASSESSMENT/PLAN

Caries Risk: ☐ Low ☐ High

Completed: ☐ Anticipatory Guidance ☐ Fluoride Varnish ☐ Dental Referral

Self Management Goals: ☐ Regular dental visits ☐ Dental treatment for parents ☐ Brush twice daily ☐ Use fluoride toothpaste ☐ Wean off bottle ☐ Less/No juice ☐ Only water in sippy cup ☐ Drink tap water ☐ Healthy snacks ☐ Less/No junk food or candy ☐ No soda ☐ Xylitol

Treatment of High Risk Children

If appropriate, high-risk children should receive professionally applied fluoride varnish and have their teeth brushed twice daily with an age-appropriate amount of fluoridated toothpaste. Referral to a pediatric dentist or a dentist comfortable caring for children should be made with follow-up to ensure that the child is being cared for in the dental home.

Oral Health Risk Assessment Tool Guidance

Timing of Risk Assessment

The Bright Futures/AAP "Recommendations for Preventive Pediatric Health Care," (ie, Periodicity Schedule) recommends all children receive a risk assessment at the 6- and 9-month visits. For the 12-, 18-, 24-, 30-month, and the 3- and 6-year visits, risk assessment should continue if a dental home has not been established. View the Bright Futures/AAP Periodicity Schedule—http://brightfutures.aap.org/clinical_practice.html.

Risk Factors

▲ **Maternal Oral Health**
Studies have shown that children with mothers or primary caregivers who have had active decay in the past 12 months are at greater risk to develop caries. **This child is high risk.**

Maternal Access to Dental Care
Studies have shown that children with mothers or primary caregivers who do not have a regular source of dental care are at a greater risk to develop caries. A follow-up question may be if the child has a dentist.

Continual Bottle/Sippy Cup Use
Children who drink juice, soda, and other liquids that are not water, from a bottle or sippy cup continually throughout the day or at night are at an increased risk of caries. The frequent intake of sugar does not allow for the acid it produces to be neutralized or washed away by saliva. Parents of children with this risk factor need to be counseled on how to reduce the frequency of sugar-containing beverages in the child's diet.

Frequent Snacking
Children who snack frequently are at an increased risk of caries. The frequent intake of sugar/refined carbohydrates does not allow for the acid it produces to be neutralized or washed away by saliva. Parents of children with this risk factor need to be counseled on how to reduce frequent snacking and choose healthy snacks such as cheese, vegetables, and fruit.

Special Health Care Needs
Children with special health care needs are at an increased risk for caries due to their diet, xerostomia (dryness of the mouth, sometimes due to asthma or allergy medication use), difficulty performing oral hygiene, seizures, gastroesophageal reflux disease and vomiting, attention deficit hyperactivity disorder, and gingival hyperplasia or overcrowding of teeth. Premature babies also may experience enamel hypoplasia.

Protective Factors

Dental Home
According to the American Academy of Pediatric Dentistry (AAPD), the dental home is oral health care for the child that is delivered in a comprehensive, continuously accessible, coordinated and family-centered way by a licensed dentist. The AAP and the AAPD recommend that a dental home be established by age 1. Communication between the dental and medical homes should be ongoing to appropriately coordinate care for the child. If a dental home is not available, the primary care clinician should continue to do oral health risk assessment at every well-child visit.

Fluoridated Water/Supplements
Drinking fluoridated water provides a child with systemic and topical fluoride exposure, a proven caries reduction intervention. Fluoride supplements may be prescribed by the primary care clinician or dentist if needed. View fluoride resources on the Oral Health Practice Tools Web Page http://aap.org/oralhealth/PracticeTools.html.

Fluoride Varnish in the Last 6 Months
Applying fluoride varnish provides a child with highly concentrated fluoride to protect against caries. Fluoride varnish may be professionally applied and is now recommended by the United States Preventive Services Task Force as a preventive service in the primary care setting for all children through age 5 http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/dental-caries-in-children-from-birth-through-age-5-years-screening. For online fluoride varnish training, access the Caries Risk Assessment, Fluoride Varnish, and Counseling Module in the Smiles for Life National Oral Health Curriculum: www.smilesforlifeoralhealth.org.

Tooth Brushing and Oral Hygiene
Primary care clinicians can reinforce good oral hygiene by teaching parents and children simple practices. Infants should have their mouths cleaned after feedings with a wet soft washcloth. Once teeth erupt it is recommended that children have their teeth brushed twice a day. For children under the age of 3 (until 3rd birthday) it is appropriate to recommend brushing with a smear (grain of rice amount) of fluoridated toothpaste twice per day. Children 3 years of age and older should use a pea-sized amount of fluoridated toothpaste twice a day. View the AAP Clinical Report on the use of fluoride in the primary care setting for more information http://pediatrics.aappublications.org/content/early/2014/08/19/peds.2014-1699.

American Academy of Pediatrics
Bright Futures.
National Interprofessional Initiative on Oral Health

FIGURE 1
AAP Oral Health Risk Assessment Tool.

fluoride, and some foods and beverages.[22] Preventive strategies for caries can be tailored by focusing on key risk factors for dental caries associated with diet, bacteria, saliva, and status of the teeth (both current and previous caries experience).[11] The AAP Oral Health Risk Assessment Tool (Fig 1) is recommended in *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents* and endorsed by the National Interprofessional Initiative on Oral Health. This tool can be found at www.aap.org/en-us/Documents/oralhealth_RiskAssessmentTool.pdf.

Table 1 provides condensed recommendations for use of fluoride modalities in patients at low and high risk of caries as described in the following sections.

Fluoride Toothpaste

Fluoride toothpaste has consistently been proven to provide a caries-preventive effect for individuals of all ages.[21,23] In the United States, the fluoride concentration of over-the-counter (OTC) toothpaste ranges from 1000 to 1100 ppm. This translates into 1 mg of fluoride in a 1-inch (1 g) strip of paste. A pea-sized amount of toothpaste is approximately one-quarter of an inch. Therefore, a pea-sized amount of toothpaste containing 1000 to 1100 ppm fluoride would have approximately 0.25 mg of fluoride. Most fluoride toothpastes in the United States contain sodium fluoride, sodium monofluorophosphate, or stannous fluoride as the active ingredient. Children younger than 6 years are more likely to ingest toothpaste and increase the risk of fluorosis. Fluorosis risk can be minimized by using the recommended amounts of toothpaste and storing toothpaste where young children cannot access it without parental help. Parents should supervise children younger than 8 years to ensure the proper amount of toothpaste and effective brushing technique.

Recommendations and Dosing

The use of fluoride toothpaste should begin with the eruption of the first tooth. For children younger than 3 years, the recommended amount is a smear or grain of rice size (approximately 0.1 mg of fluoride). Once the child has turned 3 years of age and is more able to consistently expectorate, a pea-sized amount of toothpaste (approximately 0.25 mg of fluoride) should be used.[24,25] It is preferable to spit, but not rinse, after brushing. Expectorating without rinsing reduces the amount of fluoride swallowed and leaves some fluoride available in the saliva for uptake by the dental plaque. Parents should be strongly advised to supervise their child's use of fluoride toothpaste to avoid overuse or ingestion, especially with children who have complex neurodevelopmental disabilities and cannot consistently expectorate.

High-concentration toothpaste (5000 ppm) is available by prescription only, and this decision is usually made by a dental health professional. The active ingredient in this toothpaste is sodium fluoride. This agent can be recommended for children 6 years and older and adolescents who are at high risk of caries and who are able to expectorate after brushing. Examples of children for whom high-concentration fluoride toothpaste might be indicated are those with history of dental caries and new lesions, children with xerostomia, and those with gastroesophageal reflux causing dental erosion. Dental health professionals may also prescribe this agent for adolescents who are undergoing orthodontic treatment because they are at increased risk of caries during this time.[26]

Fluoride Varnish

Fluoride varnish is a concentrated topical fluoride applied to the teeth that sets on contact with saliva. Advantages of this modality are that it is well tolerated by infants and young children, has a prolonged therapeutic effect, and can be applied by both dental and nondental health professionals in a variety of settings.[27] The concentration of fluoride varnish is 22 600 ppm (2.26% fluoride ion), and the active ingredient is sodium fluoride. The unit dose packaging from most manufacturers provides a specific measured amount (0.25 mL, providing 5 mg of fluoride ion). The application of fluoride varnish during an oral screening is of benefit to children, especially those with limited access to dental care. The current AAPD recommendation for children at high risk of caries is that fluoride varnish be applied to the teeth every 3 to 6 months.[28] The 2013 ADA

TABLE 1 Summary of Fluoride Modalities for Low- and High-Risk Patients

Fluoride Modality	Low Caries Risk	High Caries Risk
Toothpaste	Starting at tooth emergence (smear of paste until age 3, then pea-sized)	Starting at tooth emergence (smear of paste until age 3, then pea-sized)
Fluoride varnish	Every 3–6 mo starting at tooth emergence	Every 3 mo starting at tooth emergence
Mouth rinse OTC	Do not use	Starting at age 6 y if the child can reliably swish and spit
Community water fluoridation	Yes	Yes
Dietary fluoride supplements	Yes, if drinking water supply is not fluoridated	Yes, if drinking water supply is not fluoridated

guideline recommends application of fluoride varnish at least every 6 months to both primary and permanent teeth of those at elevated caries risk.[29] Medicaid pays both physicians and dentists for the application of fluoride varnish in all 50 states.

Under the Patient Protection and Affordable Care Act,[30] payers are required to cover, without cost-sharing, preventive services recommended by the US Preventive Services Task Force (USPSTF) and *Bright Futures* guidelines. The USPSTF recommended in 2014 that primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption (B recommendation).[31] All children 5 years and younger deserve to have application of fluoride varnish fully covered, as per USPSTF recommendations, as part of health maintenance and preventive care and for fluoride varnish application to be a covered benefit and separately paid service (ie, not considered incidental to the office visit). All practices should be paid separately and appropriately according to the definition of the *Current Procedural Terminology* (CPT) code, which defines fluoride application as a separately identifiable procedure. Fluoride varnish payment should not be bundled with routine preventive evaluation and management services because definitions of preventive care under those specific CPT codes do not include fluoride varnish application. Information regarding coding, billing, and payment for fluoride varnish application can be found on the AAP Web site (www.aap.org/oralhealth) and the Pew Center on the States Web site (www.pewstates.org/research/analysis/reimbursing-physicians-for-fluoride-varnish-85899377335). Many AAP Chapters have chapter oral health advocates who promote and advocate for pediatric oral health within their community. Contact information for these chapter oral health advocates can be found at www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Oral-Health/Pages/Chapter-Oral-Health-Advocates.aspx.

Indications for Use

In the primary care setting, fluoride varnish should be applied at least once every 6 months for all children and every 3 months for children at high risk for caries, starting when the first tooth erupts and until the establishment of a dental home. Medical and dental professionals are encouraged to work in collaboration to ensure that fluoride varnish is being applied.

Instructions for Use

Fluoride varnish must be applied by a dentist, dental auxiliary professional, physician, nurse, or other health care professional on the basis of individual state practice acts. It should not be dispensed to families to apply at home. Application of fluoride varnish is most commonly performed in the context of a well-child visit. Teeth are dried with a 2-inch gauze square, and then the varnish is painted onto all surfaces of the teeth with a brush. The dose recommended for young children is 0.25 mL, which is available in single-dose applicator kits. Children can eat and drink immediately after application and are instructed to eat soft foods and not to brush their teeth on the evening after the varnish application to maximize the contact time of varnish on the teeth. Children should resume brushing twice daily with fluoridated toothpaste the following morning.

OTC Fluoride Rinse

OTC fluoride rinse provides a lower concentration of sodium fluoride than toothpaste or varnish. The concentration is most commonly 230 ppm (0.05% sodium fluoride). Expert panels on this topic have concluded that OTC fluoride rinses should not be recommended for children younger than 6 years because of their limited ability to rinse and spit and increased risk of swallowing higher than recommended amounts of fluoride.[32] A teaspoon (5 mL) of OTC fluoride rinse contains approximately 1 mg of fluoride. For children older than 6 years, OTC rinses provide additional topical fluoride that may assist in the prevention of enamel demineralization. However, the evidence for an anticaries effect is limited, and decisions to recommend OTC fluoride rinses should be made in consultation with the child's dental health care provider.[33,34]

Dietary Fluoride Supplements

The USPSTF recommended in 2014 that primary care clinicians prescribe dietary fluoride supplements for children living in communities with nonfluoridated water or who drink well water that does not contain fluoride.[31] Because there are many sources of fluoride in water supplies and processed food and drinks, it is essential that all potential sources of fluoride be assessed before prescribing a dietary supplement, including consideration of differing environmental exposures (dual homes and child care). As a general guideline, if the source of drinking water in the primary home is fluoridated tap or well water, children will not require fluoride supplementation, even if they primarily drink bottled water because the teeth are exposed to fluoride through food preparation and brushing. The risk of fluorosis is high if fluoride supplements are given to a child consuming fluoridated water.[35] Information about the fluoridation levels in many community water systems can be found on the CDC Web site "My Water's Fluoride" (https://nccd.cdc.gov/doh_mwf/default/default.aspx). Not all communities report this information to the CDC, so it may be necessary to contact the local water department to determine the level of

fluoride in the community water. Well water must be tested for fluoride content before prescribing supplements, and this testing is available in most areas through the state or county public health laboratory. Challenges with dietary fluoride supplementation include determining the child's fluoride exposures and proper administration of the medication.

It is important to note that the USPSTF recommendations vary from the ADA and AAPD guidelines, which both recommend fluoride supplementation only be considered for children who drink fluoride-deficient water and are also at high risk for dental caries.[36,37] No caries risk assessment tool has been validated for pediatricians to use, but the AAP Oral Health Risk Assessment Tool was piloted through the Quality Improvement Innovation Network, and more than 80% of practices found the tool easy to implement because clinicians did not need to significantly alter current practice to incorporate risk assessment. Identification of high-risk patients for oral health referral increased from 11% to more than 87% with the use of this tool (Brightening Oral Health Workgroup and Quality Improvement Innovation Networks, AAP, Brightening Oral Health: Teaching and Implementing Oral Health Risk Assessments in Pediatric Care project, unpublished data, 2009).

Guidelines for Use

The CDC-recommended fluoride supplementation dosage schedule is provided in Table 2. Supplements can be prescribed in liquid, tablet, or lozenge form. Tablets are preferable for children who can chew because they gain an additional topical benefit to the teeth during the chewing process. Liquid supplements are recommended for younger children and should ideally be added to water or put directly into the child's mouth. Addition of the fluoride supplement to milk or formula is not recommended because absorption of fluoride is reduced in the presence of calcium.[38] The risk of fluorosis can be minimized by health care providers verifying that there are no other sources of fluoride exposure before prescribing systemic fluoride supplements.

TABLE 2 Fluoride Supplementation Schedule for Children

Age	Fluoride Ion Level in Drinking Water, ppm[a]		
	<0.3	0.3–0.6	>0.6
Birth to 6 mo	None	None	None
6 mo to 3 y	0.25 mg/d[b]	None	None
3–6 y	0.50 mg/d	0.25 mg/d	None
6–16 y	1.0 mg/d	0.50 mg/d	None

Source: Centers for Disease Control and Prevention.[21]
[a] 1.0 ppm = 1 mg/L.
[b] 2.2 mg of sodium fluoride contains 1 mg of fluoride ion.

Other Sources of Fluoride

Fluoride is present in processed foods and beverages and may be naturally occurring in some areas of the country. The presence of fluoride in juices and carbonated beverages does not counteract the cariogenic nature of these beverages.

Breastfeeding and Reconstitution of Infant Formula

The AAP recommends exclusive breastfeeding for the first 6 months of life, and there is no need during this period of time to supplement with fluoride or water that is fluoridated. A study of infant feeding practices revealed that 70% to 75% of mothers who fed their infants formula used tap water to reconstitute the powdered formula.[39] According to 2014 CDC data,[40] approximately 74% of US households using a community public water supply received optimally fluoridated water.[41] Before the emergence of the primary teeth, tap water can be used to reconstitute formula. There is a small risk of fluorosis in the permanent dentition if a fluoridated water source is used to reconstitute formula.[22] If families elect to purchase water, it is appropriate to buy water with no added fluoride before tooth emergence. After tooth emergence, formula should be mixed with optimally fluoridated tap water or nursery water with fluoride, or fluoride supplements should be prescribed. It should be noted that most bottled water has suboptimal concentrations of fluoride and that fluoride content is not listed unless fluoride is added by the manufacturer. Fluoride is often added to "nursery" water, and this must be declared on the packaging. Dietary fluoride supplements should not be prescribed for children drinking infant formula reconstituted with fluoridated water.

Community Water Fluoridation

Community water fluoridation is the practice of adding a small amount of fluoride to the water supply to achieve a fluoride concentration of 0.7 ppm. Community water fluoridation was heralded by the CDC as 1 of the top 10 public health achievements of the 20th century.[42] Community water fluoridation is a safe, efficient, and cost-effective way to prevent tooth decay and has been shown to reduce tooth decay by 25%.[43] It prevents tooth decay by providing both topical and systemic exposure of low levels of fluoride to the teeth over time. Although more than 210 million Americans live in communities with optimally fluoridated water, more than 70 million others do not have access to fluoridated water in their public water system.[41] The fluoridation status of a community water supply can be determined by contacting the local water department or accessing the CDC Web site "My Water's Fluoride" (https://nccd.cdc.gov/doh_mwf/default/default.aspx).

Recommended Concentration

Community water fluoridation was initiated in the United States in the 1940s. In 2015, the US Department of Health and Human Services finalized

a recommendation to lower the optimal fluoride concentration in drinking water to 0.7 mg/L.[44] This fluoride concentration replaced the previous recommendation, which was based on climate and ranged from 0.7 mg/L in warmest climates to 1.2 mg/L in coldest climates.[44] The change was recommended because recent studies revealed no variation in water consumption by young children on the basis of climate and to adjust for an overall increase in fluoride intake through foods and beverages processed with fluoridated water, fluoridated mouth rinses, and fluoride toothpastes.

Evidence Supporting Community Water Fluoridation

Despite overwhelming evidence supporting the safety and preventive benefits of fluoridated water, community water fluoridation continues to be a controversial and highly emotional issue. Opponents express a number of concerns that have been addressed or disproven by validated research. The only scientifically documented adverse effect of excess (nontoxic) exposure to fluoride is fluorosis. An increase in the incidence of mild enamel fluorosis among teenagers has been cited as a reason to discontinue fluoridation, although this is a cosmetic condition with no detrimental health outcomes. Recent opposition has sometimes centered on the question of who decides whether to fluoridate: elected and/or public officials or the voters. Some opponents believe fluoridation to be mass medication and call into question the ethics of community water fluoridation, but courts have consistently upheld that it is legal and appropriate for a community to adopt a fluoridation program.[45] Opponents express concern about the quality and source of fluoride, claiming that the additives (fluorosilicic acid, sodium fluoride, or sodium fluorosilicate), in their concentrated form, are highly toxic byproducts of the production of phosphate fertilizer and may include other contaminants, such as arsenic. The quality and safety of fluoride additives are ensured by Standard 60 of the National Sanitation Foundation/American National Standards Institute, a program commissioned by the US Environmental Protection Agency (EPA), and testing is conducted to confirm that the concentrations of arsenic or other substances are below those allowed by the EPA.[46] Finally, there have been many unsubstantiated or disproven claims that fluoride leads to kidney disease, bone cancer, and compromised IQ. More than 3000 studies or research articles have been published on the subject of fluoride or fluoridation.[47] Few topics have been as thoroughly researched as community water fluoridation, and the overwhelming weight of the evidence (along with over 75 years of experience) supports the safety and effectiveness of this public health practice.

Naturally Occurring Fluoride in Drinking Water

The optimal fluoride concentration in drinking water is 0.7 ppm, an amount proven beneficial in reducing tooth decay.[44] Naturally occurring fluoride may be below or above these levels in some areas. Under the Safe Drinking Water Act,[48] the EPA requires notification by the water supplier if the fluoride concentration exceeds 2 ppm. In areas where naturally occurring fluoride concentrations in drinking water exceed 2 ppm, people should consider an alternative water source or home water treatments to reduce the risk of fluorosis in young children.[49] Well water should be tested for the concentration of fluoride, and this testing is most commonly performed through the local health department.

Fluoride Toxicity

Toxic levels of fluoride are possible, particularly in children, resulting from ingesting large quantities of fluoride supplements, fluoridated toothpaste, or fluoride mouth rinse. The toxic dose of elemental fluoride is 5 to 10 mg of fluoride/kg of body weight.[50] Lethal doses in children have been calculated to be between 8 and 16 mg/kg. When prescribing sodium fluoride supplements, it is recommended to limit the quantity prescribed at one time to no more than a 4-month supply. Parents should be advised to keep fluoride products out of the reach of young children and to supervise their use.

Fluoride-Removal Systems

A number of water treatment systems are effective in removing fluoride from water,[51] including reverse osmosis and distillation. Parents should be counseled on the use of these and activated alumina filters in the home and, should they choose to use one that removes fluoride, the potential adverse effects on the family's oral health. Commonly used home carbon filters (eg, Brita or PUR) do not remove fluoride.[51] Families concerned about heavy metals or other impurities in their home water supply can use an activated carbon filter and still retain the benefits of fluoridated water.

Silver Diamine Fluoride

Silver diamine fluoride (SDF) is a minimally invasive, low-cost liquid solution that is painted on cavitated lesions. In young children, SDF provides a nonsurgical technique to manage carious lesions until the child can cope with traditional restorative dental care and, potentially, avoid sedation or a general anesthetic.[52] SDF has been used in Japan for more than 40 years and was cleared by the US Food and Drug Administration in 2014 to treat tooth sensitivity in adults.[53,54] Similar to fluoride varnish, SDF (38% solution) has been used off-label in children and adults to stabilize dental caries and reduce dental sensitivity. At present, the use

of SDF in the United States is largely limited to the dental profession because there are no formal professional guidelines for use outside of dentistry. SDF is indicated for the arrest of cavitated carious lesions in primary teeth as part of a comprehensive caries management program.[52] Information about SDF is included in this report in expectation of questions to pediatricians about this increasingly publicized intervention and increasing numbers of SDF-treated teeth seen in pediatric practices. The mechanism of SDF action is poorly understood, but silver ions are known to be antimicrobial, and the fluoride prevents further enamel demineralization. After SDF application, the lesions must be followed to assess their hardness state. Additional treatments can be applied to obtain sufficient hardness. The only known contraindication to SDF is silver allergy, but SDF is not indicated for carious lesions involving the pulp. The only significant adverse effect of SDF is that the carious lesion turns black (Figs 2 and 3), which can be esthetically problematic for some. SDF can also temporarily stain the skin black if it accidentally comes into contact with the epithelium, and SDF can cause mucosal irritation for approximately 48 hours after mucosal contact. Care must be taken when applying SDF to a cavitated lesion to avoid contact with the child's mucosa or skin. Details of SDF application technique for dental health professionals are delineated in the AAPD Chairside Guide.[54]

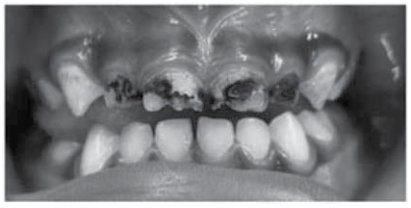


FIGURE 2
Permanent staining of carious lesions after SDF application. Photograph courtesy of Martha Ann Keels, DDS, PhD.

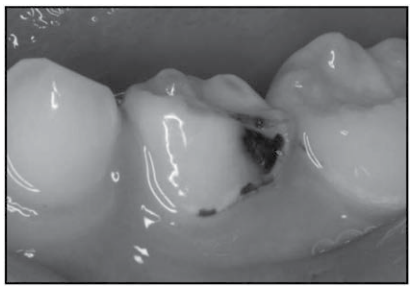


FIGURE 3
Three-year stabilization of a carious lesion on 1 primary molar after SDF application. Photograph courtesy of Martha Ann Keels, DDS, PhD.

SUGGESTIONS FOR PEDIATRICIANS

1. Know how to assess caries risk. As recommended by the AAP in "Maintaining and Improving the Oral Health of Young Children" and the fourth edition of Bright Futures, pediatricians should perform oral health risk assessments on all children at every routine well-child visit beginning at 6 months of age. The Oral Health Risk Assessment Tool has been developed by the AAP and Bright Futures and endorsed by the National Interprofessional Initiative on Oral Health. This tool can be accessed at www.aap.org/en-us/Documents/oralhealth_RiskAssessmentTool.pdf. The tool is a guide to help clinicians counsel patients about oral health and counsel in reducing risk.
2. Recommend use of fluoridated toothpaste starting at the eruption of the first tooth. A smear or grain of rice sized amount is recommended for children younger than 3 years, and a pea-sized amount of toothpaste is appropriate for most children starting at 3 years of age (see Fig 4).
3. Apply fluoride varnish according to the periodicity schedule and bill using the CPT code 99188. Fluoride varnish is a proven tool in early childhood caries prevention. Additional training on oral screenings, fluoride varnish indications and application, and office implementation can be found in the Smiles for Life Curriculum Course: Caries Risk Assessment, Fluoride Varnish and Counseling[55] at www.smilesforlifeoralhealth.org. Additionally, the AAP Children's oral health Web site is a resource for oral health practice tools at https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Oral-Health/Pages/Oral-Health-Practice-Tools.aspx.
4. Know how to determine the concentration of fluoride in a child's primary drinking water and determine the need for systemic supplements.[21]
5. Advocate for water fluoridation in your local community. Public water fluoridation is an effective and safe method of protecting the most vulnerable members of our population from dental caries. Pediatricians are encouraged to advocate on behalf of public water fluoridation in their communities and states. For additional information and water fluoridation facts and detailed questions and answers, see the following:
   - o http://www.ilikemyteeth.org;
   - o www.ada.org/en/public-programs/advocating-for-the-public/fluoride-and-fluoridation/fluoridation-facts; and

FIGURE 4
Diagram of smear versus pea-sized amount of fluoride toothpaste.

- o http://www.cdc.gov/fluoridation/.

6. Understand indications for SDF and be able to recognize the clinical appearance of SDF-treated teeth.

LEAD AUTHORS

Melinda B. Clark, MD, FAAP
Martha Ann Keels, DDS, PhD
Rebecca L. Slayton, DDS, PhD

SECTION ON ORAL HEALTH EXECUTIVE COMMITTEE, 2018–2019

Patricia A. Braun, MD, MPH, FAAP, Chairperson
Susan A. Fisher-Owens, MD, MPH, FAAP
Qadira Ali Huff, MD, MPH, FAAP
Jeffrey M. Karp, DMD
Anupama Rao Tate, DMD
John H. Unkel, DDS, MD, MPA, FAAP
David Krol, MD, MPH, FAAP, Immediate Past Chairperson

LIAISONS

Tooka Zokaie, MPH, CLSSGB – *American Dental Association*
Matt Crespin, MPH, RDH – *American Dental Hygienists' Association*
John Fales, DDS, MS – *American Academy of Pediatric Dentistry*

STAFF

Ngozi Onyema-Melton, MPH, CHES
Lauren Barone, MPH

ABBREVIATIONS

AAP: American Academy of Pediatrics
AAPD: American Academy of Pediatric Dentistry
ADA: American Dental Association
CDC: Centers for Disease Control and Prevention
CPT: *Current Procedural Terminology*
EPA: US Environmental Protection Agency
OTC: over-the-counter
SDF: silver diamine fluoride
USPSTF: US Preventive Services Task Force

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. US Department of Health and Human Services. *Oral Health in America: A Report of the Surgeon General*. Rockville, MD: National Institute of Dental and Craniofacial Research; 2000
2. Mealey BL. Periodontal disease and diabetes. A two-way street. [published correction appears in *J Am Dent Assoc*. 2008;139(3):252]. *J Am Dent Assoc*. 2006;137(suppl):26S–31S
3. Tomar SL, Reeves AF. Changes in the oral health of US children and adolescents and dental public health infrastructure since the release of the Healthy People 2010 Objectives. *Acad Pediatr*. 2009;9(6):388–395
4. Dye BA, Li X, Thorton-Evans G. Oral health disparities as determined by selected healthy people 2020 oral health objectives for the United States, 2009–2010. *NCHS Data Brief*. 2012;(104):1–8
5. Ramos-Gomez F, Kinsler J, Askaryar H. Understanding oral health disparities in children as a global public health issue: how dental health professionals can make a difference. *J Public Health Policy*. 2020;41(2):114–124
6. Tinanoff N, Baez RJ, Diaz Guillory C, et al. Early childhood caries epidemiology, aetiology, risk assessment, societal burden, management, education, and policy: global perspective. *Int J Paediatr Dent*. 2019;29(3):238–248
7. Frank M, Keels MA, Quiñonez R, Roberts M, Divaris K. Dental caries risk varies among subgroups of children with special health care needs. *Pediatr Dent*. 2019;41(5):378–384
8. Chi DL, Rossitch KC, Beeles EM. Developmental delays and dental caries in low-income preschoolers in the USA: a pilot cross-sectional study and preliminary explanatory model. *BMC Oral Health*. 2013;13:53
9. Dye BA, Thornton-Evans G. Trends in oral health by poverty status as measured by Healthy People 2010 objectives. *Public Health Rep*. 2010; 125(6):817–830
10. Stearns SC, Rozier RG, Kranz AM, Pahel BT, Quiñonez RB. Cost-effectiveness of preventive oral health care in medical offices for young Medicaid enrollees. *Arch Pediatr Adolesc Med*. 2012;166(10): 945–951
11. Section on Oral Health. Maintaining and improving the oral health of young children. *Pediatrics*. 2014;134(6): 1224–1229
12. Hagan JF, Shaw JS, Duncan PM, eds.. Promoting Oral Health. *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*, 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017:205–217
13. Lynch RJM, Navada R, Walia R. Low-levels of fluoride in plaque and saliva and their effects on the demineralisation and remineralisation of enamel; role of fluoride toothpastes. *Int Dent J*. 2004;54(5 suppl 1):304–309
14. Featherstone JD. Prevention and reversal of dental caries: role of low level fluoride. *Community Dent Oral Epidemiol*. 1999;27(1):31–40
15. Aoba T, Fejerskov O. Dental fluorosis: chemistry and biology. *Crit Rev Oral Biol Med*. 2002;13(2):155–170
16. Everett ET. Fluoride's effects on the formation of teeth and bones, and the influence of genetics. *J Dent Res*. 2011; 90(5):552–560
17. DenBesten PK. Biological mechanisms of dental fluorosis relevant to the use of fluoride supplements. *Community Dent Oral Epidemiol*. 1999;27(1):41–47
18. Ismail AI, Bandekar RR. Fluoride supplements and fluorosis: a meta-

analysis. *Community Dent Oral Epidemiol*. 1999;27(1):48–56

19. Levy SM, Broffitt B, Marshall TA, Eichenberger-Gilmore JM, Warren JJ. Associations between fluorosis of permanent incisors and fluoride intake from infant formula, other dietary sources and dentifrice during early childhood. *J Am Dent Assoc*. 2010; 141(10):1190–1201
20. National Center for Health Statistics; National Center for Chronic Disease Prevention and Health Promotion. Data quality evaluation of the dental fluorosis clinical assessment data from the National Health and Nutrition Examination Survey, 1999–2004 and 2011–2016. *Vital Health Stat*. 2019; 2(183):1–32
21. Centers for Disease Control and Prevention. Recommendations for using fluoride to prevent and control dental caries in the United States. *MMWR Recomm Rep*. 2001;50(rr):1–42
22. Berg J, Gerweck C, Hujoel PP, et al.; American Dental Association Council on Scientific Affairs Expert Panel on Fluoride Intake From Infant Formula and Fluorosis. Evidence-based clinical recommendations regarding fluoride intake from reconstituted infant formula and enamel fluorosis: a report of the American Dental Association Council on Scientific Affairs. *J Am Dent Assoc*. 2011;142(1):79–87
23. Wong MCM, Clarkson J, Glenny A-M, et al. Cochrane Reviews on the benefits/ risks of fluoride toothpastes. *J Dent Res*. 2011;90(5):573–579
24. Wright JT, Hanson N, Ristic H, Whall CW, Estrich CG, Zentz RR; American Dental Association, Council on Scientific Affairs. Fluoride toothpaste efficacy and safety in children younger than 6 years: a systematic review. *J Am Dent Assoc*. 2014;145(2):182–189
25. Scottish Intercollegiate Guidelines Network. *Prevention and Management of Dental Decay in the Pre-School Child. A National Guideline*. Edinburgh, Scotland: Scottish Intercollegiate Guidelines Network; 2005
26. Al-Mulla A, Karlsson L, Kharsa S, Kjellberg H, Birkhed D. Combination of high-fluoride toothpaste and no post-brushing water rinsing on enamel demineralization using an in-situ caries model with orthodontic bands. *Acta Odontol Scand*. 2010;68(6):323–328
27. American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: evidence-based clinical recommendations. *J Am Dent Assoc*. 2006;137(8):1151–1159
28. American Academy of Pediatric Dentistry. Fluoride therapy. In: *The Reference Manual of Pediatric Dentistry*. Chicago, IL: American Academy of Pediatric Dentistry; 2018: 262–265. Available at: www.aapd.org/media/Policies_Guidelines/G_fluoridetherapy.pdf. Accessed March 25, 2019
29. Weyant RJ, Tracy SL, Anselmo TT, et al; American Dental Association Council on Scientific Affairs Expert Panel on Topical Fluoride Caries Preventive Agents. Topical fluoride for caries prevention: executive summary of the updated clinical recommendations and supporting systematic review. [published correction appears in *J Am Dent Assoc*. 2013;144(12):1335]. *J Am Dent Assoc*. 2013;144(11):1279–1291
30. Patient Protection and Affordable Care Act, 42 USC §18001 (2010)
31. Moyer VA; US Prevention Services Task Force. Prevention of dental caries in children from birth through age 5 years: US Preventive Services Task Force recommendation statement. *Pediatrics*. 2014;133(6):1102–1111
32. Maternal and Child Health Bureau Expert Panel. Topical fluoride recommendations for high-risk children: development of decision support matrix. 2007. Available at: www.mchoralhealth.org/PDFs/TopicalFluorideRpt.pdf. Accessed March 25, 2019
33. Adair SM. Evidence-based use of fluoride in contemporary pediatric dental practice. *Pediatr Dent*. 2006; 28(2):133–142–198
34. Twetman S, Petersson L, Axelsson S, et al. Caries-preventive effect of sodium fluoride mouthrinses: a systematic review of controlled clinical trials. *Acta Odontol Scand*. 2004;62(4):223–230
35. Pendrys DG, Katz RV, Morse DE. Risk factors for enamel fluorosis in a fluoridated population. *Am J Epidemiol*. 1994;140(5):461–471
36. Rozier RG, Adair S, Graham F, et al. Evidence-based clinical recommendations on the prescription of dietary fluoride supplements for caries prevention: a report of the American Dental Association Council on Scientific Affairs. *J Am Dent Assoc*. 2010;141(12):1480–1489
37. American Academy of Pediatric Dentistry. Best practices: fluoride therapy. In: *The Reference Manual of Pediatric Dentistry*. Chicago, IL: American Academy of Pediatric Dentistry; 2018:262–265. Available at: https://www.aapd.org/research/oral-health-policies–recommendations/. Accessed March 25, 2019
38. Buzalaf MAR, Whitford GM. Fluoride metabolism. *Monogr Oral Sci*. 2011;22: 20–36
39. Fein SB, Grummer-Strawn LM, Raju TNK. Infant feeding and care practices in the United States: results from the Infant Feeding Practices Study II. *Pediatrics*. 2008;122(suppl 2):S25–S27
40. Centers for Disease Control and Prevention. 2014 fluoridation statistics. Available at: https://www.cdc.gov/fluoridation/statistics/2014stats.htm. Accessed October 14, 2020
41. Centers for Disease Control and Prevention. Water fluoridation data & statistics. Available at: www.cdc.gov/fluoridation/statistics/index.htm. Accessed March 25, 2019
42. Centers for Disease Control and Prevention. Ten great public health achievements–United States, 1900–1999. *MMWR Morb Mortal Wkly Rep*. 1999;48(12):241–243
43. US Department of Health and Human Services, Centers for Disease Control and Prevention. Statement on the evidence supporting the safety and effectiveness of community water fluoridation. Available at: www.cdc.gov/fluoridation/pdf/Scientific-Statement-on-Community-Water-Fluoridation-h.pdf. Accessed May 5, 2019
44. US Department of Health and Human Services Federal Panel on Community Water Fluoridation. US Public Health Service Recommendation for fluoride concentration in drinking water for the prevention of dental caries. *Public Health Rep*. 2015;130(4):318–331

45. Burt BA, Eklund S. *Dentistry, Dental Practice, and the Community*, 6th ed. St Louis, MO: Elsevier Saunders; 2005

46. Centers for Disease Control and Prevention. Water fluoridation additives. Available at: https://americanfluoridationsociety.org/wp-content/uploads/2017/05/f-Water-Fluoridation-Additives-Engineering-Fact-Sheet-CDC-2011.pdf. Accessed March 25, 2019

47. Cheng KK, Chalmers I, Sheldon TA. Adding fluoride to water supplies. *BMJ*. 2007;335(7622):699–702

48. Safe Water Drinking Act, 42 USC §300f (1974)

49. American Dental Association Division of Communications. For the dental patient: infants, formula and fluoride. *J Am Dent Assoc*. 2007;138(1):132

50. Shulman JD, Wells LM. Acute fluoride toxicity from ingesting home-use dental products in children, birth to 6 years of age. *J Public Health Dent*. 1997;57(3):150–158

51. Van Winkle S, Levy SM, Kiritsy MC, Heilman JR, Wefel JS, Marshall T. Water and formula fluoride concentrations: significance for infants fed formula. *Pediatr Dent*. 1995;17(4):305–310

52. Crystal YO, Marghalani AA, Ureles SD, et al. Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs. *Pediatr Dent*. 2017;39(5):135–145

53. American Academy of Pediatric Dentistry. *Policy on the Use of Silver Diamine Fluoride for Pediatric Dental Patients*. Chicago, IL: American Academy of Pediatric Dentistry; 2018. Available at: https://www.aapd.org/media/Policies_Guidelines/P_SilverDiamine.pdf. Accessed March 24, 2019

54. American Academy of Pediatric Dentistry. *Chairside Guide: Silver Diamine Fluoride in the Management of Dental Caries Lesions*. Chicago, IL: American Academy of Pediatric Dentistry; 2018. Available at: https://www.aapd.org/media/Policies_Guidelines/R_ChairsideGuide.pdf. Accessed March 24, 2019

55. Douglass AB, Clark MB, Maier R, et al. *Smiles for Life: A National Oral Health Curriculum*. 3rd ed. Leawood, KS: Society of Teachers of Family Medicine; 2010, Available at: www.smilesforlifeoralhealth.com. Accessed March 28, 2019

Health Care Supervision for Children With Williams Syndrome

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Health Care Supervision for Children With Williams Syndrome

Colleen A. Morris, MD,[a] Stephen R. Braddock, MD,[b] COUNCIL ON GENETICS

This set of recommendations is designed to assist the pediatrician in caring for children with Williams syndrome (WS) who were diagnosed by using clinical features and with chromosome 7 microdeletion confirmed by fluorescence in situ hybridization, chromosome microarray, or multiplex ligation-dependent probe amplification. The recommendations in this report reflect review of the current literature, including previously peer-reviewed and published management suggestions for WS, as well as the consensus of physicians and psychologists with expertise in the care of individuals with WS. These general recommendations for the syndrome do not replace individualized medical assessment and treatment.

Williams syndrome (WS), also known as Williams-Beuren syndrome, is caused by a deletion of part of chromosome 7 and is a multisystem disorder that was first identified as a distinct clinical entity in 1961.[1] It is present at birth with a prevalence of 1 in 7500[2] and affects boys and girls equally. Children with WS usually come to the attention of pediatricians during infancy or early childhood. WS is characterized by dysmorphic facies (100%), cardiovascular disease (80%; most commonly supravalvular aortic stenosis [SVAS]), intellectual disability (75%), a characteristic cognitive profile (90%), and idiopathic hypercalcemia (15% to 45%).[1,3–7]

The deleted portion of chromosome 7q11.23 seen in WS is 1.5 to 1.8 Mb and contains 26 to 28 genes.[3,4,8] It includes the *ELN* gene that codes for the structural protein elastin, which is an important component of the elastic fibers found in the connective tissue of many organs. The *ELN* deletion explains some of the characteristics of WS, such as some of the facial features, hoarse voice, inguinal hernia, bladder and bowel diverticula, cardiovascular disease, and orthopedic problems. The pathogenesis of other characteristics, such as intellectual disability, is likely attributable to deletion of contiguous genes in the region. Most deletions in the WS region are de novo. Affected individuals have a 50% chance of transmitting the deletion to offspring. A specific inversion

abstract

[a]*Department of Pediatrics, University of Nevada, Reno, Reno, Nevada; and* [b]*Division of Genetics and Genomic Medicine, Department of Pediatrics, School of Medicine, Saint Louis University, St Louis, Missouri*

Drs Morris and Braddock were equally responsible for writing and revising the manuscript and considering input from all reviewers and the board of directors; and both authors approved the final manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

Resources for parents include the following: the Williams Syndrome Association (570 Kirts Boulevard, Suite 223, Troy, MI 48084-4156; phone: 800-806-1871 [toll free] and 248-244-2229; fax: 248-244-2230; e-mail: info@williams-syndrome.org; Web site: www.williams-syndrome.org), the Canadian Association of Williams Syndrome (PO Box 26206, Richmond, British Columbia V6Y 3V3, Canada; phone: 604-214-0132; e-mail: cawbc@yahoo.com; Web site: caws.sasktelwebhosting.com), and the US National Library of Medicine Genetics Home Reference (Web site: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC385319/).

DOI: https://doi.org/10.1542/peds.2019-3761

To cite: Morris CA, Braddock SR, AAP COUNCIL ON GENETICS. Health Care Supervision for Children With Williams Syndrome. *Pediatrics.* 2020;145(2):e20193761

TABLE 1 Medical Problems in WS by Organ System and Age

Organ	System Prevalence, %	Age		
		Infancy	Childhood	Adult
Ocular and visual				
Esotropia	50	x	—	—
Hyperopia	50	—	x	x
Auditory				
Recurrent otitis media	50	x	x	—
Hypersensitivity to sound	90	x	x	x
Progressive sensorineural hearing loss	65	—	x	x
Dental				
Malocclusion	85	—	x	x
Microdontia	95	—	x	x
Cardiovascular				
Any abnormality (total)	80	x	x	x
SVAS	75	x	x	x
SVPS	25	x	x	x
PPS	50	x	—	—
Other arterial stenosis	20	—	x	x
VSD	10	x	—	—
Hypertension	50	—	x	x
Prolonged QTc	13	—	x	x
Genitourinary				
Structural anomaly	5	x	x	x
Enuresis	50	—	x	—
Nephrocalcinosis	<5	x	—	x
Bladder diverticula	50	—	x	x
Gastrointestinal				
Feeding difficulties	70	x	x	—
Constipation	50	x	x	x
Colon diverticula	30	—	x	x
Rectal prolapse	15	x	x	—
Integument				
Soft, lax skin	90	x	x	x
Inguinal hernia	40	x	—	—
Umbilical hernia	50	x	—	—
Prematurely gray hair	90	—	—	x
Musculoskeletal				
Joint hypermobility	90	x	x	—
Joint contractures	50	x	x	x
Radioulnar synostosis	20	x	x	x
Kyphosis	20	—	—	x
Scoliosis	18	—	x	x
Lordosis	40	—	x	x
Awkward gait	60	—	x	x
Calcium				
Hypercalcemia	15–40[a]	x	—	x
Hypercalciuria	30	x	x	x
Endocrine				
Hypothyroidism	5–10	x	x	x
Early puberty (but rarely true precocious puberty)	20	—	x	—
Diabetes mellitus	15	—	—	x
Obesity	30	—	x	x
Neurologic				
Hyperactive deep tendon reflexes	75	—	x	x
Chiari I malformation	10	x	x	x
Hypotonia (central)	80	x	x	—
Hypertonia (peripheral)	50	—	x	x
Cognitive				
Developmental delay	95	x	x	—
Intellectual disability	75	—	x	x
Normal intelligence	5	—	x	x
Impaired visuospatial constructive cognition	95	—	x	x
Behavioral				
ADHD	65	—	x	—
Anxiety disorder (specific phobia, generalized)	70	—	x	x
Sleep disorders	65	—	x	x

Percentages are based on the following: (1) review of rates of complications in several reports of series of patients with WS and (2) a database of 582 children and adults with WS evaluated by Colleen A. Morris, MD. PPS, peripheral pulmonary artery stenosis; SVPS, supravalvular pulmonic stenosis, VSD, ventricular septal defect; —, not applicable.

[a] Hypercalcemia prevalence was greater in those <2 y of age.

polymorphism in this area can be seen in 6% of the general population and in 25% of parents of individuals with WS, indicating that the presence of this inversion may increase the chance of having a child with WS.[9] When the deletion includes only the *ELN* gene, or if the *ELN* gene contains a mutation or pathogenic variant, the result is the autosomal, dominantly inherited condition SVAS. These individuals do not have WS. Currently, the majority of cases of WS are detected through a chromosomal microarray that is done for developmental disability. Some of these cases do not have the typical deletion seen in WS and have varying phenotypes that may lack some of the most defining features of WS. The term WS is reserved for the individuals who have typical deletions. A medical genetics evaluation is recommended to discuss the clinical manifestations, natural history, and recurrence risks for parents and other family members.

The pediatrician can use knowledge of the clinical manifestations (Table 1) and the natural history of WS to anticipate medical problems and educate the family. The characteristic facial features of WS are a broad forehead, bitemporal narrowness, periorbital fullness, a stellate and/or lacy iris pattern, a short nose with a bulbous nasal tip, a wide mouth, full lips, and mild micrognathia (Fig 1 A and B). Infants have epicanthal folds, full cheeks, and a flat facial profile, whereas older children and adults often have a narrow face and long neck. Young children typically have small, widely spaced teeth; dental malocclusion is common at all ages. Mild prenatal growth deficiency and a postnatal growth rate that is ~75% of what is normal are consistently observed. Microcephaly is present in one-third of affected individuals.[10] Growth parameters should be plotted on WS growth charts[11] (Fig 2A–2F). Children with WS typically have decreased fat stores,[12] but obesity may become a problem in teenagers and adults.[13,14] The recommendations in this report reflect review of the current literature, including previously peer-reviewed and published management suggestions for WS,[3,4,13,15] as well as the consensus of physicians and

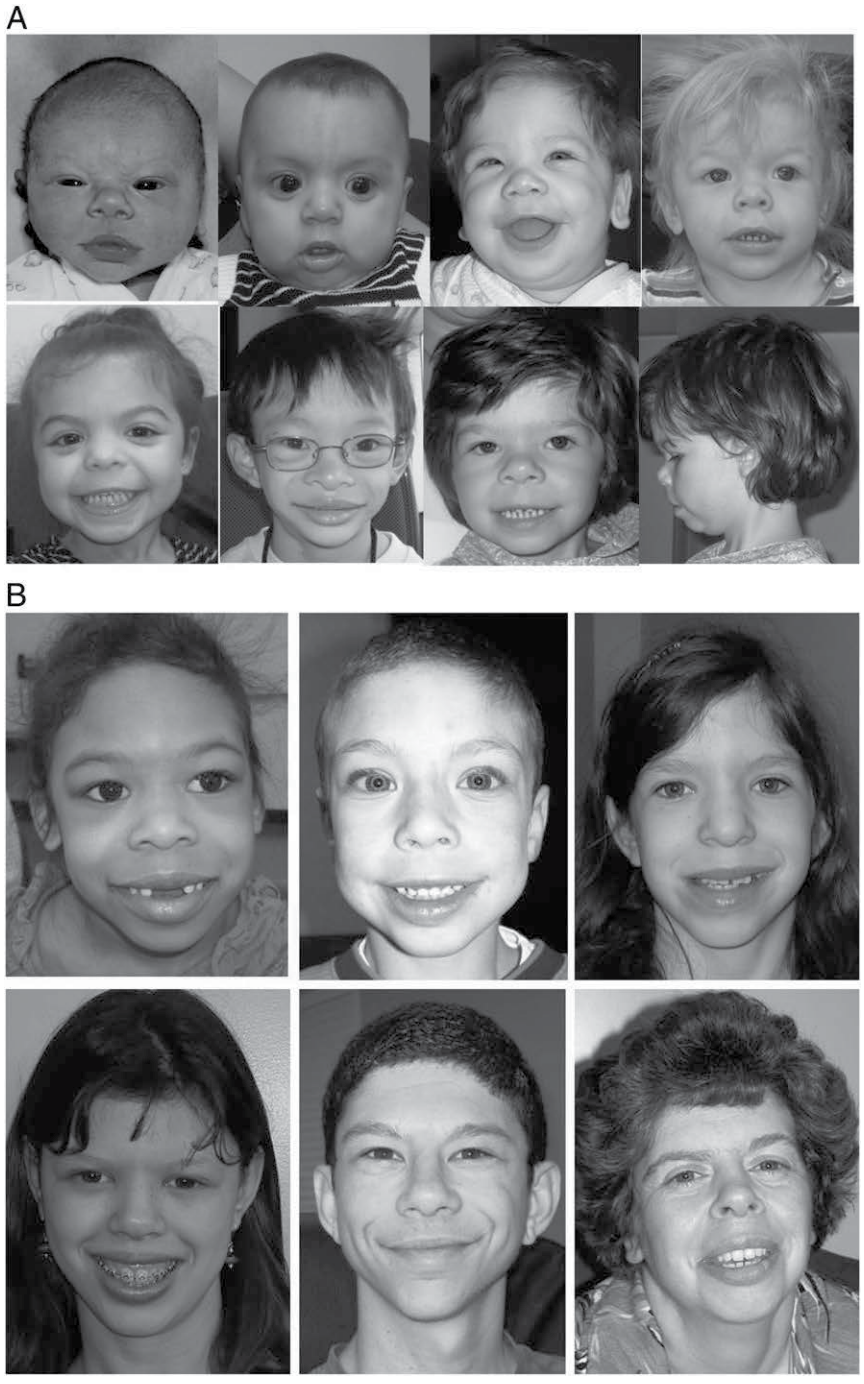


FIGURE 1

A, Infants and young children with WS. Top row (left to right) is as follows: newborn boy, 6-month-old boy, 9-month-old boy, and 1-year-old girl. Bottom row (left to right) is as follows: 2-year-old girl, 4-year-old boy, and 4-year-old girl (front view and profile). B, Children and adults with WS. Top row (left to right) is as follows: 5-year-old girl, 6-year-old boy, and 10-year-old-girl. Bottom row (left to right) is as follows: 14-year-old girl, 23-year-old man, and 34-year-old woman.

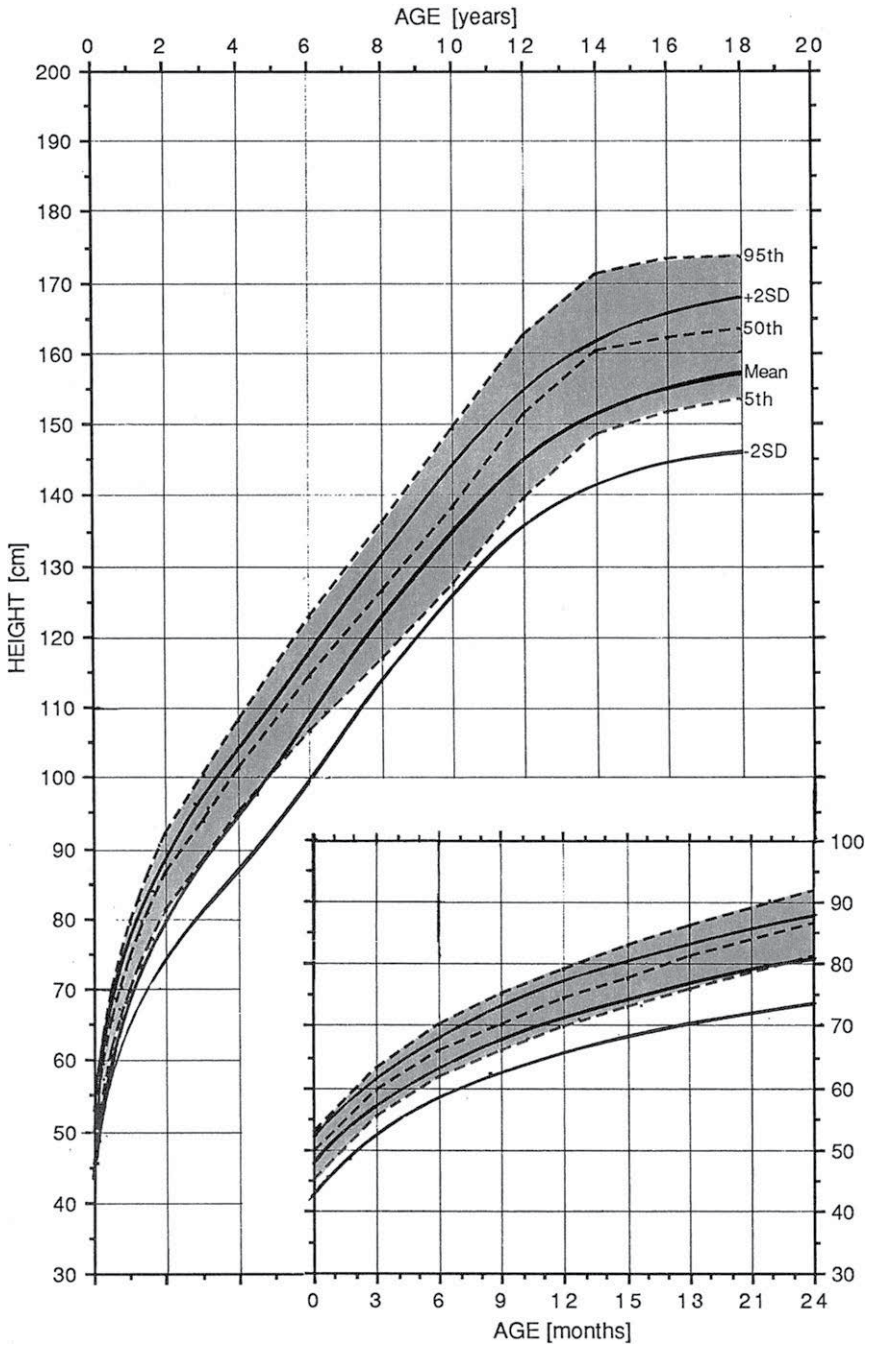


FIGURE 2A
Height for females with Williams syndrome. Normal curves = dashed lines; affected patients = solid lines. Reprinted with permission from: Saul RA, Geer JS, Seaver LH, Phelan MC, Sweet KM, Mills MS. *Growth References: Third Trimester* to Adulthood. Greenwood, SC: Greenwood Genetic Center; 1998.

psychologists with expertise in the care of individuals with WS.

CARDIOVASCULAR

The majority of children with WS have cardiovascular anomalies secondary to elastin arteriopathy, the major source of morbidity and mortality. Although any artery may be narrowed, the most common problem is SVAS, which may worsen over time, particularly in the first 5 years. Progression is more likely if the severity of the stenosis is moderate or severe and presents in infancy or early childhood.[16] SVAS is most commonly a discrete hourglass stenosis or may be a long segment stenosis (~15%).[17] Approximately 30% of children with SVAS will require surgical correction.[18] The mortality rate is 6% for cardiac surgery or catheterization.[19] Peripheral pulmonic stenosis is common in infancy but often improves over time when occurring in isolation. Mitral valve prolapse and aortic insufficiency may occur in adolescents or adults. QTc prolongation has been reported in 13% of individuals.[20]

Hypertension is present in 50% of people with WS, may occur at any age, and is occasionally associated with renal artery stenosis.[21–23] Increased vascular stiffness, which is a risk factor for stroke, is another manifestation of elastin arteriopathy found in both hypertensive and normotensive children and adults with WS.[23] Blood pressure measurement in both arms is recommended at well-child visits with use of a manual cuff at the end of the visit to minimize anxiety. Antihypertensive therapy successfully controls hypertension in most patients and also ameliorates vascular stiffness.[21,23] Consider cardiology or nephrology referral for hypertension (blood pressure >90th percentile for age and height).[24]

Patients with WS are at increased risk for myocardial ischemia, acute hemodynamic deterioration, and sudden death because of their cardiovascular anomalies, especially in the setting of sedation and anesthesia.[25] Individuals with biventricular outflow tract obstruction are at the greatest risk.[19,26] Sudden death in WS (1 per 1000 patient-years)[27] may be related to abnormalities of the coronary arteries (ostial or diffuse stenosis or dilatation)[28] or biventricular outflow

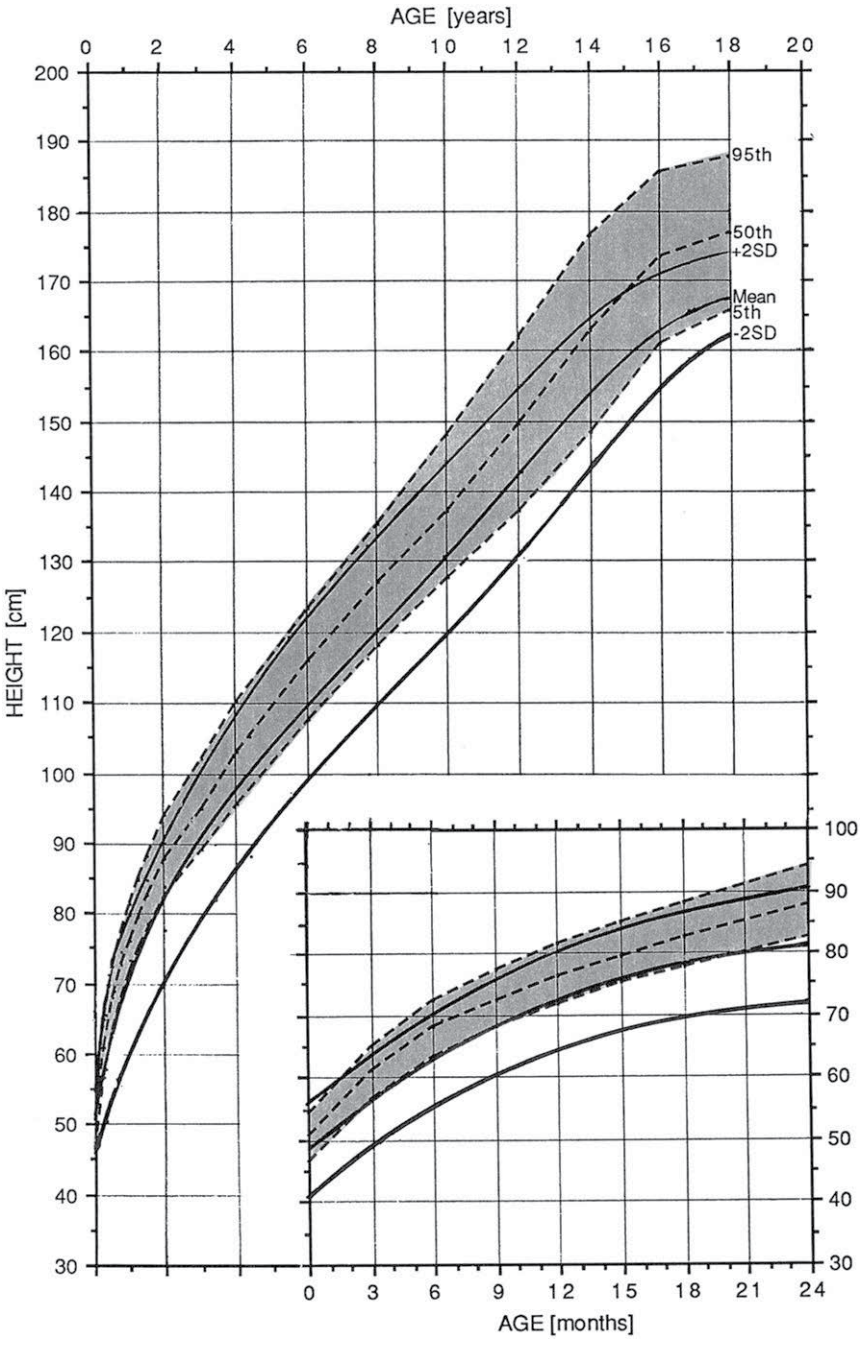


FIGURE 2B
Height for males with Williams syndrome. Normal curves = dashed lines; affected patients = solid lines. Reprinted with permission from: Saul RA, Geer JS, Seaver LH, Phelan MC, Sweet KM, Mills MS. *Growth References: Third Trimester to Adulthood.* Greenwood, SC: Greenwood Genetic Center; 1998.

tract obstruction. Because there is an increased risk of adverse events with sedation and aesthesia, recommendations have been developed for management of sedation and anesthesia in individuals with WS.[26,29,30]

Children with WS should be evaluated by a pediatric cardiologist with experience in treating WS when feasible. The initial evaluation should include 3 limb blood pressures (2 arms and 1 leg); echocardiogram, including Doppler flow studies; and electrocardiogram. Cardiology follow-up should occur frequently (every 3 months) in the first year of life and at least annually through middle childhood with subsequent intervals dictated by the nature and severity of cardiovascular disease. Children who have decreased pulses, bruits, and/or evidence of diffuse thoracic aortic stenosis will require additional cardiovascular imaging studies (computed tomography, magnetic resonance angiography, or cardiac catheterization) to define the anatomy. Because of the increased risk for serious cardiovascular complications surrounding procedures requiring anesthesia, careful perioperative planning, particularly of nonemergency procedures, is recommended with pediatric anesthesiologists who are familiar with WS and work in centers that can provide multidisciplinary support in the event of serious cardiac decompensation during sedation and anesthesia.[26,29,30]

HYPERCALCEMIA

Idiopathic infantile hypercalcemia may contribute to the presence of extreme irritability, vomiting, constipation, and muscle cramps associated with this condition.[6,31] Problems associated with hypercalcemia include dehydration, hypercalciuria, and nephrocalcinosis.[32] Symptomatic hypercalcemia is most common in the first 2 years and usually resolves during childhood,[3,33] but lifelong abnormalities of calcium and vitamin D metabolism may persist. Individuals with WS in all age groups have higher median calcium levels than controls.[32] There is increased calcium absorption from the gut; the cause of the abnormality in calcium metabolism is unknown.[14]

Serum calcium determination should be obtained every 4 to 6 months until 2 years of age, every 2 years thereafter, and when hypercalcemia is

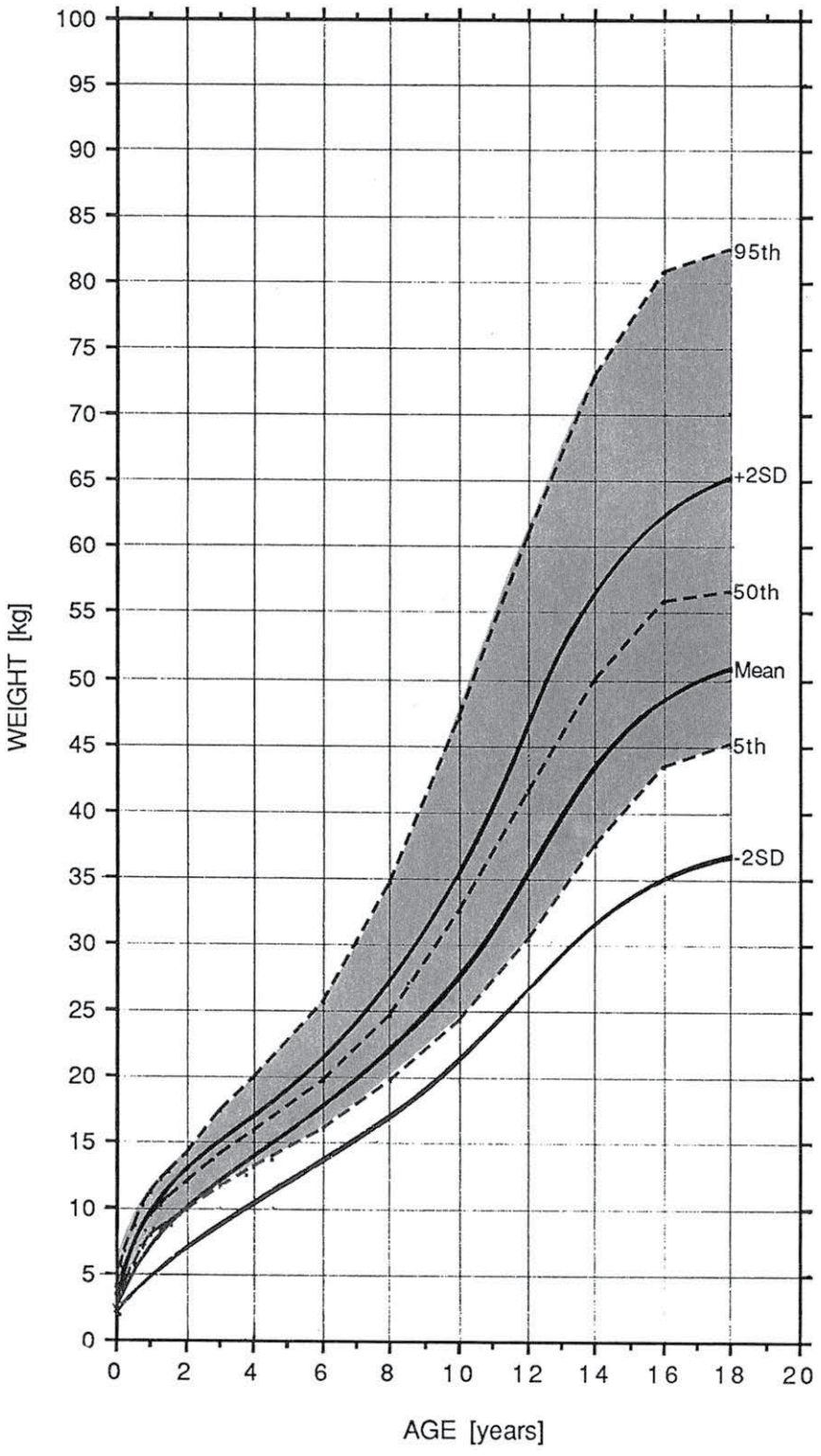


FIGURE 2C
Weight for females with Williams syndrome. Normal curves = dashed lines; affected patients = solid lines. Reprinted with permission from: Saul RA, Geer JS, Seaver LH, Phelan MC, Sweet KM, Mills MS. *Growth References: Third Trimester to Adulthood.* Greenwood, SC: Greenwood Genetic Center; 1998.

suspected clinically. Parents should be educated regarding the signs and symptoms of hypercalcemia. Children with WS and normocalcemia should have the reference daily intake of calcium,[34] and parents should be cautioned not to restrict calcium without medical supervision.[31] Infants with hypercalcemia are usually successfully treated with a low-calcium diet and increased water intake under medical and nutritional supervision, and they require more frequent surveillance of calcium concentrations. Serum blood urea nitrogen, creatinine, vitamin D concentrations (25-hydroxyvitamin D and 1,25-dihydroxyvitamin D), and intact parathyroid hormone should be checked if hypercalcemia is present.[35] The urine calcium/creatinine ratio in a random spot urine should be obtained at the time of diagnosis and if hypercalcemia is present (Table 2). If hypercalciuria is found, hydration status should be assessed, serum calcium concentration should be measured, dietary calcium intake should be assessed, and renal ultrasonography should be performed to evaluate for nephrocalcinosis. Referral to a pediatric nephrologist and/or pediatric endocrinologist should be considered for management of persistent hypercalcemia, hypercalciuria, or nephrocalcinosis.[32] Multivitamin preparations containing vitamin D should be avoided in early childhood, and vitamin D supplementation should be used with caution in older children and adults.[4] Approximately 50% of individuals with WS have impaired bone mineral status osteopenia or osteoporosis; the etiology is unknown.[1,14]

GASTROINTESTINAL

Infants and toddlers with WS often have difficulty feeding (eg, disordered suck and swallow and textural aversion) and may be brought for medical care because there are symptoms of gastroesophageal reflux,

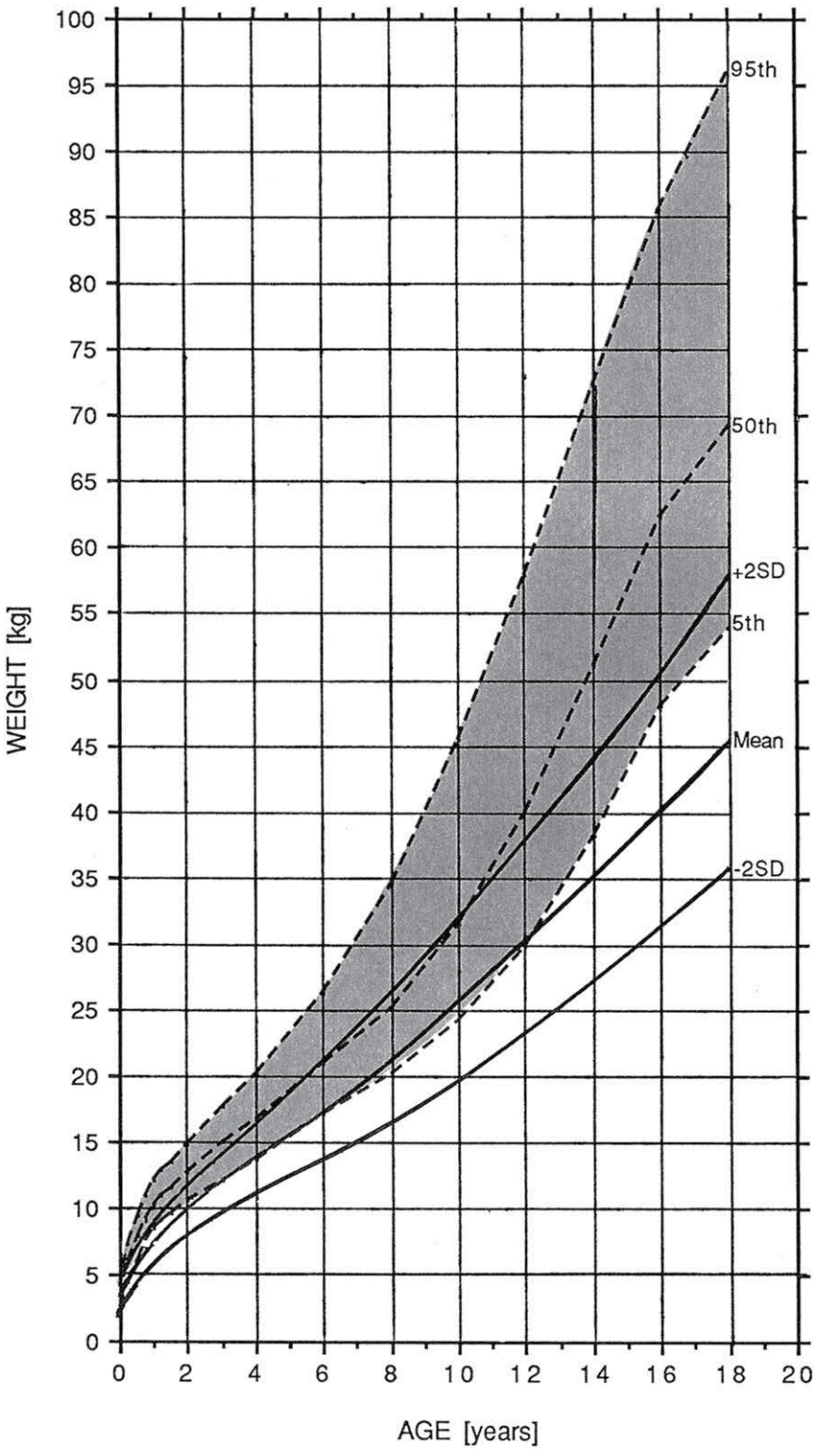


FIGURE 2D
Weight for males with Williams syndrome. Normal curves = dashed lines; affected patients = solid lines. Reprinted with permission from: Saul RA, Geer JS, Seaver LH, Phelan MC, Sweet KM, Mills MS. *Growth References: Third Trimester to Adulthood.* Greenwood, SC: Greenwood Genetic Center; 1998.

colic, or failure to achieve anticipated weight gain.[6] Feeding evaluation and therapy may be of benefit for infants having difficulty transitioning to solid foods, for assessment of aspiration risk and dysphagia, and for intervention for failure to gain weight appropriately according to WS growth curves. Feeding gastrostomy tubes are rarely necessary in WS. Obesity may become a problem for older children and adults.[13]

Chronic constipation is a common lifelong problem and must be aggressively treated. Typical interventions include increasing water and fiber in the diet followed by the addition of osmotic laxative treatment. Complications of constipation include rectal prolapse, hemorrhoids, and intestinal perforation. There is an increased incidence of diverticulitis occurring at a young age in adolescents and adults.[36] Abdominal pain is a frequent complaint in both children and adults; potential causes include gastroesophageal reflux, hiatal hernia, constipation, cholecystitis, diverticular disease, and discrete arterial stenosis causing ischemia.[37]

GENITOURINARY

Urinary tract malformations are present in 10% of children with WS,[38] bladder diverticula are present in 50%,[38,39] and a history of urinary tract infection is present in 25%.[40] Bladder capacity is reduced and detrusor overactivity is found in 60% of patients,[36] leading to urinary frequency in 69% and enuresis.[40] Daytime urinary continence is typically achieved by 4 years of age, and nocturnal continence is present in 50% at 10 years of age.[6] Children 4 to 12 years of age have a daytime urinary incontinence rate of 18% and nocturnal enuresis rate of 45%, whereas 2.7% of teenagers have daytime incontinence and 13.5% have nocturnal enuresis.[41]
Ultrasonography of the kidneys and

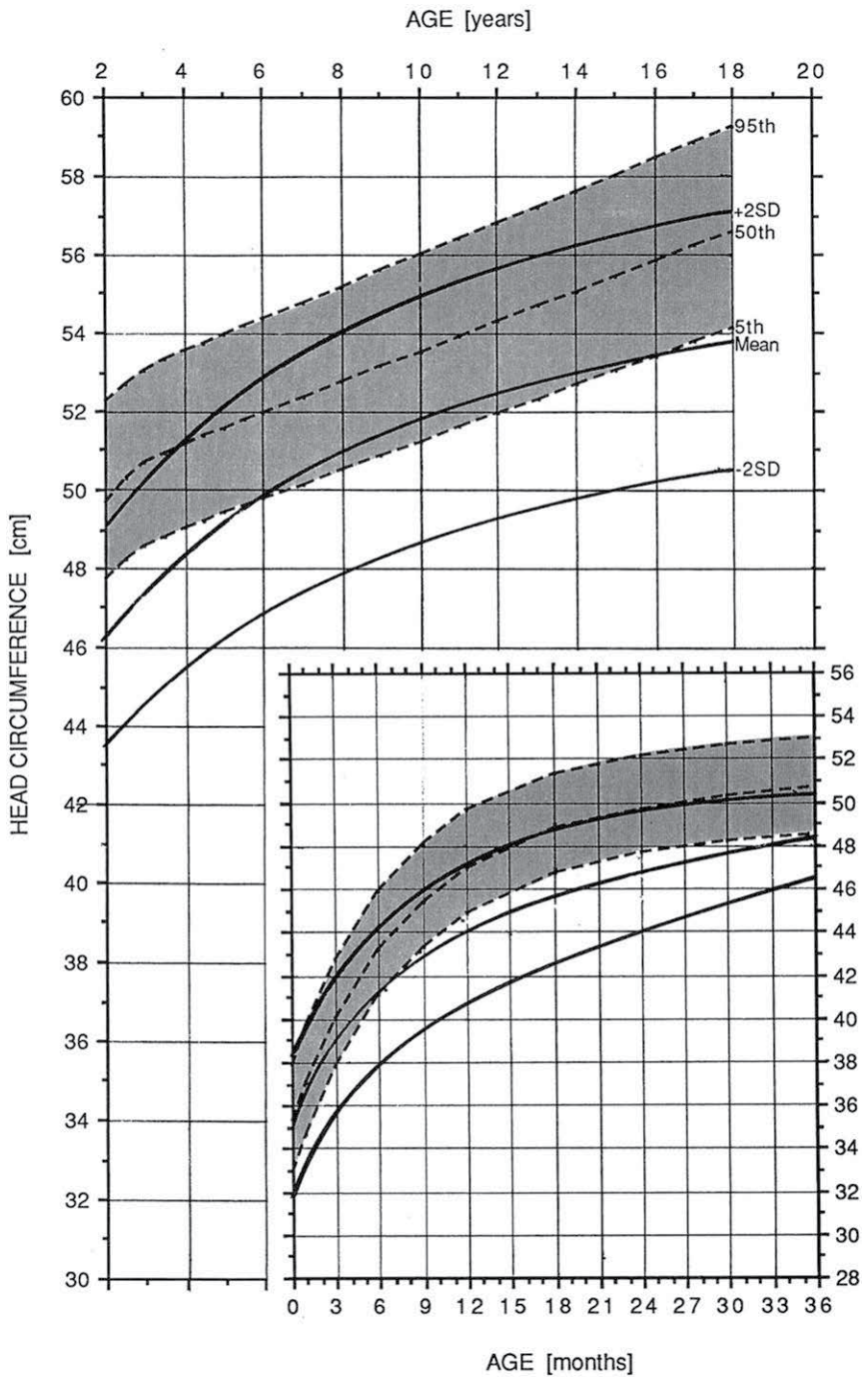


FIGURE 2E
Head circumference for females with Williams syndrome. Normal curves = dashed lines; affected patients = solid lines. Reprinted with permission from: Saul RA, Geer JS, Seaver LH, Phelan MC, Sweet KM, Mills MS. *Growth References: Third Trimester to Adulthood.* Greenwood, SC: Greenwood Genetic Center; 1998.

bladder should be completed at the time of diagnosis. Individuals with recurrent urinary tract infections may require additional urologic evaluation. The practitioner should maintain a low threshold for lower urinary tract imaging (voiding cystourethrography) for the evaluation of voiding dysfunction and/or urinary tract infection. Diverticula may lead to both of these symptoms and can be recurrent after surgical repair. Kidney function should be assessed at the time of diagnosis (serum urea nitrogen and creatinine concentrations and urinalysis).

NEUROLOGY, DEVELOPMENT, COGNITION, AND BEHAVIOR

Neurologic problems include axial hypotonia and peripheral hypertonia with increased deep tendon reflexes in the lower extremities. Signs of cerebellar dysfunction, such as ataxia and tremor, may increase with age.[42] Posterior fossa size is reduced in WS, although cerebellar volume is preserved and may contribute to Chiari I malformation in some individuals with WS.[43] Symptoms of headache, dizziness, and dysphagia should prompt the clinician to consider a pediatric neurology referral for evaluation for Chiari malformation. Developmental milestones are delayed,[6] and children should be referred to an early intervention program for physical, occupational, and speech therapy evaluation and treatment. Hippotherapy referral may be considered; hippotherapy uses equine movement during physical, occupational, and/or speech therapy and addresses problems of balance.[44] Although joint laxity is present in young children, joint contractures occur in older children and adults and lead to an awkward gait.[45] Nightly stretching range-of-motion exercises are often recommended. Radioulnar synostosis, found in 10% of affected children, does not respond to physiotherapy or surgical intervention.[46] Lordosis and kyphosis are common at all ages; 18% have scoliosis.[6,47]

Children with WS have a unique cognitive and behavioral profile.[7,48,49] Cognitive, motor, and language delay are universal, and in 75% of children, intellectual disability is ultimately diagnosed. Children demonstrate

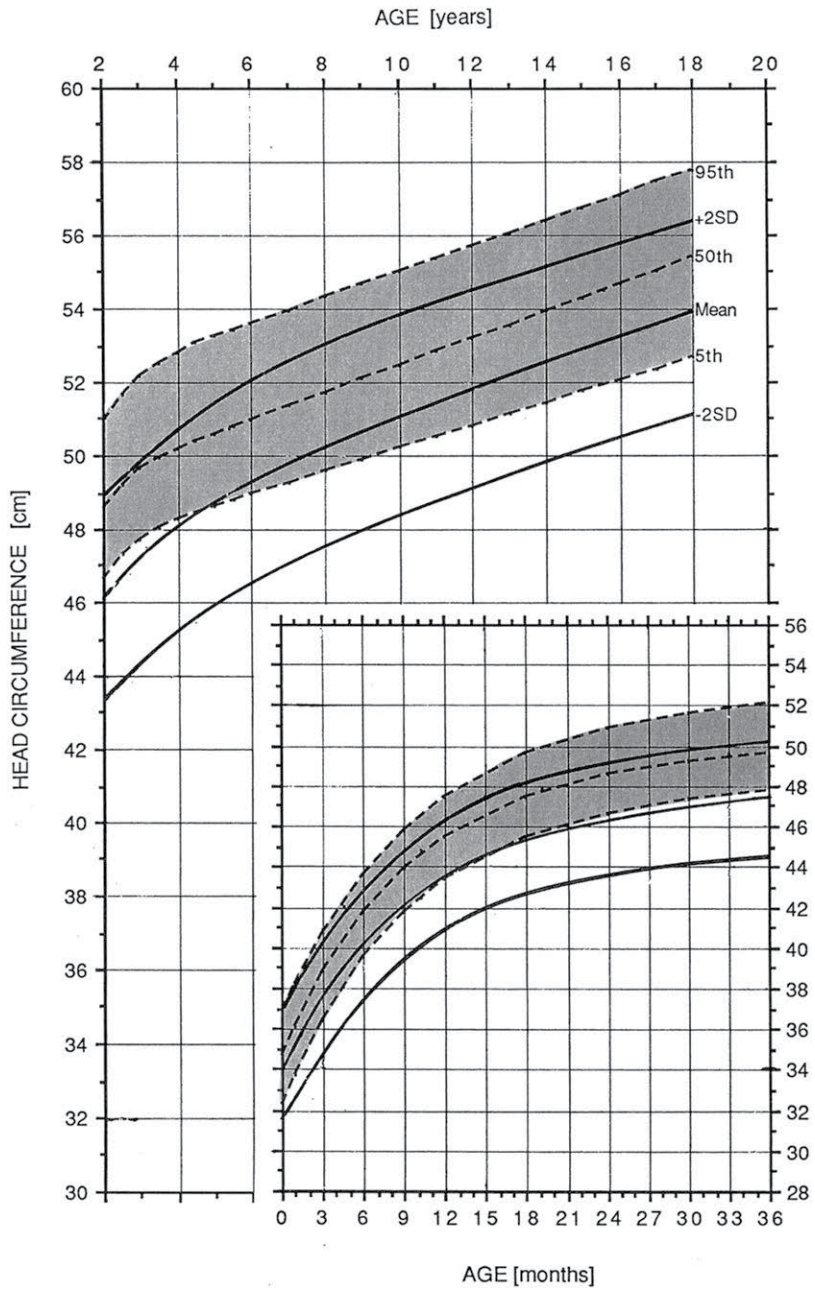


FIGURE 2F
Head circumference for males with Williams syndrome. Normal curves = dashed lines; affected patients = solid lines. Reprinted with permission from: Saul RA, Geer JS, Seaver LH, Phelan MC, Sweet KM, Mills MS. *Growth References: Third Trimester to Adulthood.* Greenwood, SC: Greenwood Genetic Center; 1998.

TABLE 2 Normal Values for Random Urinary Calcium/Creatinine Ratios

Age	Calcium/Creatinine Ratio (mg/mg; 95th Percentile for Age)
<7 mo	0.86
7–18 mo	0.6
19 mo–6 y	0.42
Adults	0.22

Adapted from Sargent JD, Stukel TA, Kresel J, Klein RZ. Normal values for random urinary calcium to creatinine ratios in infancy. *J Pediatr.* 1993;123(3):393–397

a relative strength in language and verbal short-term memory, with a significant weakness in visuospatial construction.[7] A detailed psychoeducational evaluation with information provided by the primary care pediatrician to the school regarding the unique cognitive and behavioral profile is important for school-aged children to develop an appropriate educational plan. A referral to a neuropsychologist may be of benefit. Speech and language, physical, and occupational therapies are important for school-aged children.

Behavioral problems may include hypersensitivity to sound, attention-deficit/hyperactivity disorder (ADHD), and nonsocial anxiety.[50] Approximately 50% of children with WS will require pharmacologic treatment of ADHD and/or anxiety. Although overfriendliness and an empathetic nature are commonly observed, many individuals have difficulty with emotional regulation.[51] In young children who have limited language, there may be symptom overlap with autism spectrum disorder, such as restricted interests and repetitive behaviors.[52] A referral for assessment for autism may be considered in those children. Behavioral interventions based on applied behavior analysis may be helpful, and older children benefit from social skills training and training to master daily living skills.[48] Adaptive behavior skills in both children and adults are often more impaired than would be expected for IQ.[53,54] Adults require vocational training and instruction in community living skills. Mental health problems, most commonly anxiety, are reported in 25% to 75% of adults.[13,55]

Sleep disorders are common (50% to 65%), including sleep onset delay, frequent awakenings, decreased sleep efficiency, and increased respiratory-related arousals.[56,57] An abnormal or absent melatonin peak may explain disturbance of circadian rhythm in some children.[58,59] The clinician

TABLE 3 Anticipatory Guidance in WS

Option	At Diagnosis	0–12 mo Old	1–5 y Old	6–12 y Old	13–18 y Old	Adult
Health maintenance physical examination	Yes	Each visit	Each visit	Yearly	Yearly	Yearly
Establish medical home	Yes	Yes	Yes	Yes	Yes	Yes
Plot growth parameters on WS growth charts	Yes	Each visit	Each visit	Each visit	Each visit	Monitor wt
Check blood pressure (both arms), auscultate for murmurs and bruits, check pulses	Yes	Each visit	Each visit	Each visit	Each visit	Each visit
Check for inguinal hernia	Yes	Each visit	Yearly	Yearly	Yearly	Yearly
Evaluate for neurologic abnormalities (hypotonia, hyperreflexia, cerebellar signs)	Yes	Each visit	Yearly	Yearly	Yearly	Yearly
Screen for musculoskeletal problems (joint laxity, joint contractures, kyphosis, scoliosis, lordosis)	Yes	Yearly	Yearly	Yearly	Yearly	Yearly
Review diagnosis and potential complications	Yes	PRN	PRN	PRN	PRN	PRN
Discuss feeding issues, nutrition	Yes	Yes	PRN	PRN	PRN	PRN
Counsel regarding symptoms of hypercalcemia; avoid multivitamins with vitamin D and advise calcium RDI	Yes	Yes	Yes	PRN	PRN	Yes
Discuss constipation, treat aggressively	Yes	Yes	Yearly	Yearly	Yearly	Yearly
Advise daily range-of-motion exercises	Yes	—	Yearly	Yearly	Yearly	Yearly
Inquire about sleep problems	Yes	Yes	Yearly	Yearly	Yearly	Yearly
Pediatric anesthesia consultation before procedures	Yes	Yes	Yes	Yes	Yes	—
Provide support group information	Yes	PRN	PRN	PRN	PRN	PRN
Ocular						
Vision screening for strabismus, refractive errors, cataracts (adults)	Yes	Yearly	Yearly	Yearly	Yearly	Yearly
Ophthalmologic evaluation	Yes	PRN	PRN	PRN	PRN	Yearly
Auditory						
Audiological evaluation	Yes	Yearly	Yearly	Yearly	Yearly	Yearly
Counsel regarding sensitivity to sound	Yes	PRN	PRN	PRN	PRN	PRN
Dental						
Dental cleaning	Yes	—	Every 6 mo	Every 6 mo	Every 4 mo	Every 4 mo
Refer to orthodontics for malocclusion	—	—	—	Yes	Yes	Yes
Calcium						
Serum concentration of calcium	Yes	Every 4 mo	Every 4–6 mo until age 2 y then every 2 y	Every 2 y	Every 2 y	Every 2 y
Spot random urine for urine calcium/creatinine ratio	Yes	PRN	PRN	PRN	PRN	PRN
Cardiovascular						
Pediatric cardiology evaluation to include 3 limb blood pressures and echocardiography, including Doppler flow studies; additional imaging studies (CT, MRA, catheterization) to be considered in the setting of severe SVAS, diminished femoral pulses, bruits, or suspicion of long segment aortic stenosis	Yes	Every 3 mo	Yearly	Every 2 y	Every 2 y	Every 2 y
Electrocardiogram	Yes	Yearly	Yearly	Yearly	Yearly	Yearly
Genitourinary						
Renal ultrasonography with Doppler and bladder ultrasonography evaluation for malformation, nephrocalcinosis, diverticulitis	Yes	—	—	Every 10 y	Every 10 y	Every 10 y
Serum BUN, creatinine	Yes	PRN	PRN	PRN	PRN	PRN
Urinalysis	Yes	Yearly	Yearly	Yearly	Yearly	Yearly
Refer to pediatric nephrologist and/or endocrinologist for persistent hypercalcemia, hypercalciuria, or nephrocalcinosis	Yes	Yes	PRN	PRN	PRN	PRN
Endocrine						
Thyroid function tests	Yes	Yearly	Yearly until age 3 y	Every 2 y	Every 2 y	Every 2 y
Consider treating early puberty	—	—	—	PRN	—	—
Fasting glucose level followed by oral glucose tolerance test if abnormal result	—	—	—	—	Yearly	Yearly
Development and cognition						
Multidisciplinary developmental evaluation	Yes	Yearly	Yearly	—	—	—
Neuropsychological evaluation	—	—	Yes at age 3 y	Every 3 y	Every 3 y	PRN
	Yes	Yes	Yes	Yes	Yes	Yes

TABLE 3 Continued

Option	At Diagnosis	0–12 mo Old	1–5 y Old	6–12 y Old	13–18 y Old	Adult
Refer for therapy (speech and language, physical and occupational), consider hippotherapy						
Feeding therapy if needed	Yes	PRN	PRN	—	—	—
Refer to early intervention program	Yes	Yes	—	—	—	—
Refer for special education	Yes	—	Yes	Yes	Yes	—
Behavior						
Assessment of behavior (attention, anxiety, adaptive skills)	Yes	—	Yearly	Yearly	Yearly	Yearly
Consider behavioral interventions based on applied behavior analysis	Yes	—	PRN	PRN	—	—
Treatment of mental health problems (ADHD, anxiety, depression)	Yes	—	PRN	PRN	PRN	PRN
Social skills training	Yes	—	Yes	Yes	Yes	Yes
Genetic counseling						
Medical genetics evaluation	Yes	PRN	PRN	PRN	PRN	PRN
Genetic counseling for family	Yes	—	—	—	—	—
Genetic counseling for individual	—	—	—	—	Yes	Yes
Transition						
Vocational training	—	—	—	—	Yes	Yes

BUN, blood urea nitrogen; CT, computed tomography; MRA, magnetic resonance angiography; PRN, as needed; RDI, Reference Daily Intake; —, not applicable.

should discuss appropriate sleep hygiene and consider a sleep study if obstructive sleep apnea is suspected.

OCULAR AND AUDITORY

Hyperopia, nasolacrimal duct obstruction, and strabismus are common in WS.[60] An ophthalmologic evaluation should be performed at the time of diagnosis with follow-up as necessary. Mild to moderate sensorineural hearing loss is present in 60% of children and 90% of adults.[61] Audiologic assessment should be performed between 6 and 12 months of age and repeated annually.[61] Recurrent otitis media is common. The use of noise-canceling headphones is helpful to children who have increased sensitivity to sound or specific phobia for loud noises. Earwax buildup is a common problem and may be treated with cerumen-softening drops.[13]

DENTAL

Dental problems include microdontia, missing teeth, and localized enamel hypoplasia.[62] Poor fine motor skills cause difficulty with maintenance of dental hygiene and increase the risk of dental caries. A dental home should be established by 1 year of age or within 6 months of the eruption of the first tooth. The dental recall interval should be based on caries risk; dental cleaning every 4 months has been recommended.[4] Caregivers should be instructed to assist with brushing and flossing. If dental procedures require anesthesia, WS-specific sedation and anesthesia recommendations should be followed.[29,30] Dental malocclusion is present in 85% of individuals with WS and responds to orthodontic treatment. An orthodontic assessment should be part of the evaluation in the dental home.

ENDOCRINE

Hypothyroidism is present in 5% to 10% of children[33] At a minimum, thyroid function should be assessed at the time of diagnosis, annually for the first 3 years, and every 2 years thereafter. Subclinical hypothyroidism (mild thyroid-stimulating hormone elevation with normal thyroxine [T4]) is present in 30%.[63] Puberty often occurs early (18% of girls), but true precocious puberty is rare.[64] A gonadotropin-releasing hormone agonist may be used to treat early puberty; treatment in girls successfully delays menarche and results in taller height compared with controls.[65] Abnormal glucose tolerance test results have been documented in 60% to 75% of adults with WS with an increased prevalence of type 2 diabetes mellitus.[66,67] An oral glucose tolerance test is recommended at 30 years of age and should be repeated every 5 years if results are normal.[13]

MEDICAL HOME AND TRANSITION

Establish a medical home with a clear emphasis on continuity of care and the role of the family members as partners in the ongoing management and care of the child. A summary of anticipatory guidance is provided in Table 3. Counsel the family regarding networks of support, such as extended family, friends, clergy, support groups, and community agencies that serve children and adults with disabilities. The diagnosis should be reviewed and discussed with the affected individual in adolescence with referral to support groups for the adolescent (see American Academy of Pediatrics policy statement "Transition of Care Provided for Adolescents With Special Needs").[68]

Assist in transition to adult care (especially for cardiology care). Many pediatricians feel comfortable continuing to provide primary care

well into young adulthood. Pediatricians can educate the adult and family regarding medical management for adults with WS.[37] Counseling should be provided regarding sexuality and reproductive issues, and genetic counseling should be provided. Vocational training and social skills training are essential for successful transition to independent functioning within the community for adults.

Address correspondence to Colleen A Morris, MD, FAAP. Email: cmorris@med.unr.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Williams JC, Barratt-Boyes BG, Lowe JB. Supravalvular aortic stenosis. *Circulation*. 1961;24:1311–1318
2. Strømme P, Bjørnstad PG, Ramstad K. Prevalence estimation of Williams syndrome. *J Child Neurol*. 2002;17(4):269–271
3. Morris CA. Williams Syndrome. In: Pagon RA, Adam MP, Ardinger HH, eds., et al *GeneReviews*. Seattle, WA: University of Washington, Seattle; 1999:1993–2014
4. Pober BR. Williams-Beuren syndrome. *N Engl J Med*. 2010;362(3):239–252
5. Beuren AJ. Supravalvular aortic stenosis: a complex syndrome with and without mental retardation. *Natl Found March Dimes Birth Defects Orig Art Ser*. 1972;8:45–56
6. Morris CA, Demsey SA, Leonard CO, Dilts C, Blackburn BL. Natural history of Williams syndrome: physical characteristics. *J Pediatr*. 1988;113(2):318–326
7. Mervis CB, Robinson BF, Bertrand J, Morris CA, Klein-Tasman BP, Armstrong SC. The Williams syndrome cognitive profile. *Brain Cogn*. 2000;44(3):604–628
8. Ewart AK, Morris CA, Atkinson D, et al. Hemizygosity at the elastin locus in a developmental disorder, Williams syndrome. *Nat Genet*. 1993;5(1):11–16
9. Hobart HH, Morris CA, Mervis CB, et al. Inversion of the Williams syndrome region is a common polymorphism found more frequently in parents of children with Williams syndrome. *Am J Med Genet C Semin Med Genet*. 2010;154C(2):220–228
10. Pankau R, Partsch CJ, Neblung A, Gosch A, Wessel A. Head circumference of children with Williams-Beuren syndrome. *Am J Med Genet*. 1994;52(3):285–290
11. Saul RA, Stevenson RE, Rogers RC, Skinner SA, Prouty LA, Flannery DB. Williams syndrome. In: Proceedings of the Greenwood Genetic Center. Greenwood, SC: Greenwood Genetic Center; 1988:204–209
12. Nogueira RJ, Zimmerman LF, Moreno YM, et al. Anthropometric and body-mass composition suggests an intrinsic feature in Williams-Beuren syndrome. *Rev Assoc Med Bras (1992)*. 2011;57(6):681–685
13. Cherniske EM, Carpenter TO, Klaiman C, et al. Multisystem study of 20 older

adults with Williams syndrome. *Am J Med Genet A*. 2004;131(3):255–264

14. Stagi S, Manoni C, Scalini P, et al. Bone mineral status and metabolism in patients with Williams-Beuren syndrome. *Hormones (Athens)*. 2016; 15(3):404–412
15. Committee on Genetics. American Academy of Pediatrics: health care supervision for children with Williams syndrome. [published correction appears in *Pediatrics*. 2002;109(2):329]. *Pediatrics*. 2001;107(5):1192–1204
16. Collins RT II, Kaplan P, Somes GW, Rome JJ. Long-term outcomes of patients with cardiovascular abnormalities and Williams syndrome. *Am J Cardiol*. 2010; 105(6):874–878
17. Collins RT II. Cardiovascular disease in Williams syndrome. *Circulation*. 2013; 127(21):2125–2134
18. Kececioglu D, Kotthoff S, Vogt J. Williams-Beuren syndrome: a 30-year follow-up of natural and postoperative course. *Eur Heart J*. 1993;14(11):1458–1464
19. Pham PP, Moller JH, Hills C, Larson V, Pyles L. Cardiac catheterization and operative outcomes from a multicenter consortium for children with Williams syndrome. *Pediatr Cardiol*. 2009;30(1): 9–14
20. Collins RT II, Aziz PF, Gleason MM, Kaplan PB, Shah MJ. Abnormalities of cardiac repolarization in Williams syndrome. *Am J Cardiol*. 2010;106(7):1029–1033
21. Bouchireb K, Boyer O, Bonnet D, et al. Clinical features and management of arterial hypertension in children with Williams-Beuren syndrome. *Nephrol Dial Transplant*. 2010;25(2):434–438
22. Del Campo M, Antonell A, Magano LF, et al. Hemizygosity at the NCF1 gene in patients with Williams-Beuren syndrome decreases their risk of hypertension. *Am J Hum Genet*. 2006;78(4):533–542
23. Kozel BA, Danback JR, Waxler JL, et al. Williams syndrome predisposes to vascular stiffness modified by antihypertensive use and copy number changes in NCF1. *Hypertension*. 2014; 63(1):74–79
24. National High Blood Pressure Education Program Working Group on High Blood Pressure in Children and Adolescents. The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. *Pediatrics*. 2004;114(2 ,suppl 4th report): 555–576
25. Bird LM, Billman GF, Lacro RV, et al. Sudden death in Williams syndrome: report of ten cases. *J Pediatr*. 1996; 129(6):926–931
26. Latham GJ, Ross FJ, Eisses MJ, Richards MJ, Geiduschek JM, Joffe DC. Perioperative morbidity in children with elastin arteriopathy. *Paediatr Anaesth*. 2016;26(9):926–935
27. Wessel A, Gravenhorst V, Buchhorn R, Gosch A, Partsch CJ, Pankau R. Risk of sudden death in the Williams-Beuren syndrome. *Am J Med Genet A*. 2004; 127A(3):234–237
28. Ergul Y, Nisli K, Kayserili H, et al. Evaluation of coronary artery abnormalities in Williams syndrome patients using myocardial perfusion scintigraphy and CT angiography. *Cardiol J*. 2012;19(3):301–308
29. Burch TM, McGowan FX Jr., Kussman BD, Powell AJ, DiNardo JA. Congenital supravalvular aortic stenosis and sudden death associated with anesthesia: what's the mystery? *Anesth Analg*. 2008;107(6):1848–1854
30. Matisoff AJ, Olivieri L, Schwartz JM, Deutsch N. Risk assessment and anesthetic management of patients with Williams syndrome: a comprehensive review. *Paediatr Anaesth*. 2015;25(12): 1207–1215
31. Martin ND, Snodgrass GJ, Cohen RD. Idiopathic infantile hypercalcaemia–a continuing enigma. *Arch Dis Child*. 1984; 59(7):605–613
32. Sindhar S, Lugo M, Levin MD, et al. Hypercalcemia in patients with Williams-Beuren syndrome. *J Pediatr*. 2016;178: 254–260.e4
33. Kim YM, Cho JH, Kang E, et al. Endocrine dysfunctions in children with Williams-Beuren syndrome. *Ann Pediatr Endocrinol Metab*. 2016;21(1):15–20
34. Ross AC, Taylor CL, Yaktine AL, Del Valle HB, eds. *Dietary Reference Intakes for Calcium and Vitamin D*. Washington, DC: National Academies Press; 2011
35. Lameris AL, Geesing CL, Hoenderop JG, Schreuder MF. Importance of dietary calcium and vitamin D in the treatment of hypercalcaemia in Williams-Beuren syndrome. *J Pediatr Endocrinol Metab*. 2014;27(7–8):757–761
36. Stagi S, Lapi E, Chiarelli F, de Martino M. Incidence of diverticular disease and complicated diverticular disease in young patients with Williams syndrome. *Pediatr Surg Int*. 2010;26(9):943–944
37. Pober BR, Morris CA. Diagnosis and management of medical problems in adults with Williams-Beuren syndrome. *Am J Med Genet C Semin Med Genet*. 2007;145C(3):280–290
38. Pankau R, Partsch CJ, Winter M, Gosch A, Wessel A. Incidence and spectrum of renal abnormalities in Williams-Beuren syndrome. *Am J Med Genet*. 1996;63(1): 301–304
39. Sammour ZM, de Bessa J Jr., Hisano M, et al. Lower urinary tract symptoms in children and adolescents with Williams-Beuren syndrome. *J Pediatr Urol*. 2017; 13(2):203.e1-203.e6
40. Sammour ZM, Gomes CM, Duarte RJ, Trigo-Rocha FE, Srougi M. Voiding dysfunction and the Williams-Beuren syndrome: a clinical and urodynamic investigation. *J Urol*. 2006;175(4): 1472–1476
41. von Gontard A, Niemczyk J, Borggrefe-Moussavian S, Wagner C, Curfs L, Equit M. Incontinence in children, adolescents and adults with Williams syndrome. *Neurourol Urodyn*. 2016;35(8):1000–1005
42. Chapman CA, du Plessis A, Pober BR. Neurologic findings in children and adults with Williams syndrome. *J Child Neurol*. 1996;11(1):63–65
43. Pober BR, Filiano JJ. Association of Chiari I malformation and Williams syndrome. *Pediatr Neurol*. 1995;12(1): 84–88
44. Giagazoglou P, Arabatzi F, Dipla K, Liga M, Kellis E. Effect of a hippotherapy intervention program on static balance and strength in adolescents with intellectual disabilities. *Res Dev Disabil*. 2012;33(6):2265–2270
45. Kaplan P, Kirschner M, Watters G, Costa MT. Contractures in patients with Williams syndrome. *Pediatrics*. 1989; 84(5):895–899
46. Morris CA, Carey JC. Three diagnostic signs in Williams syndrome. *Am J Med Genet Suppl*. 1990;6:100–101
47. Morris CA, Pani AM, Mervis CB, Rios CM, Kistler DJ, Gregg RG. Alpha 1 antitrypsin

deficiency alleles are associated with joint dislocation and scoliosis in Williams syndrome. *Am J Med Genet C Semin Med Genet*. 2010;154C(2):299–306

48. Mervis CB, John AE. Cognitive and behavioral characteristics of children with Williams syndrome: implications for intervention approaches. *Am J Med Genet C Semin Med Genet*. 2010;154C(2): 229–248
49. Leyfer OT, Woodruff-Borden J, Klein-Tasman BP, Fricke JS, Mervis CB. Prevalence of psychiatric disorders in 4 to 16-year-olds with Williams syndrome. *Am J Med Genet B Neuropsychiatr Genet*. 2006;141B(6):615–622
50. Woodruff-Borden J, Kistler DJ, Henderson DR, Crawford NA, Mervis CB. Longitudinal course of anxiety in children and adolescents with Williams syndrome. *Am J Med Genet C Semin Med Genet*. 2010;154C(2):277–290
51. Pitts CH, Klein-Tasman BP, Osborne JW, Mervis CB. Predictors of specific phobia in children with Williams syndrome. *J Intellect Disabil Res*. 2016;60(10): 1031–1042
52. Klein-Tasman BP, Phillips KD, Lord C, Mervis CB, Gallo FJ. Overlap with the autism spectrum in young children with Williams syndrome. *J Dev Behav Pediatr*. 2009;30(4):289–299
53. Mervis CB, Pitts CH. Children with Williams syndrome: developmental trajectories for intellectual abilities, vocabulary abilities, and adaptive behavior. *Am J Med Genet C Semin Med Genet*. 2015;169(2):158–171
54. Howlin P, Udwin O. Outcome in adult life for people with Williams syndrome–results from a survey of 239 families. *J Intellect Disabil Res*. 2006;50(pt 2): 151–160
55. Stinton C, Elison S, Howlin P. Mental health problems in adults with Williams syndrome. *Am J Intellect Dev Disabil*. 2010;115(1):3–18
56. Annaz D, Hill CM, Ashworth A, Holley S, Karmiloff-Smith A. Characterisation of sleep problems in children with Williams syndrome. *Res Dev Disabil*. 2011;32(1):164–169
57. Mason TB, Arens R, Sharman J, et al. Sleep in children with Williams syndrome. *Sleep Med*. 2011;12(9): 892–897
58. Santoro SD, Giacheti CM, Rossi NF, Campos LM, Pinato L. Correlations between behavior, memory, sleep-wake and melatonin in Williams-Beuren syndrome. *Physiol Behav*. 2016;159: 14–19
59. Sniecinska-Cooper AM, Iles RK, Butler SA, Jones H, Bayford R, Dimitriou D. Abnormal secretion of melatonin and cortisol in relation to sleep disturbances in children with Williams syndrome. *Sleep Med*. 2015;16(1):94–100
60. Winter M, Pankau R, Amm M, Gosch A, Wessel A. The spectrum of ocular features in the Williams-Beuren syndrome. *Clin Genet*. 1996;49(1):28–31
61. Marler JA, Sitcovsky JL, Mervis CB, Kistler DJ, Wightman FL. Auditory function and hearing loss in children and adults with Williams syndrome: cochlear impairment in individuals with otherwise normal hearing. *Am J Med Genet C Semin Med Genet*. 2010;154C(2): 249–265
62. Hertzberg J, Nakisbendi L, Needleman HL, Pober B. Williams syndrome–oral presentation of 45 cases. *Pediatr Dent*. 1994;16(4):262–267
63. Palacios-Verdú MG, Segura-Puimedon M, Borralleras C, et al. Metabolic abnormalities in Williams-Beuren syndrome. *J Med Genet*. 2015;52(4): 248–255
64. Partsch CJ, Japing I, Siebert R, et al. Central precocious puberty in girls with Williams syndrome. *J Pediatr*. 2002; 141(3):441–444
65. Spielmann S, Partsch CJ, Gosch A, Pankau R. Treatment of central precocious puberty and early puberty with GnRH analog in girls with Williams-Beuren syndrome. *J Pediatr Endocrinol Metab*. 2015;28(11–12):1363–1367
66. Pober BR, Wang E, Caprio S, et al. High prevalence of diabetes and pre-diabetes in adults with Williams syndrome. *Am J Med Genet C Semin Med Genet*. 2010; 154C(2):291–298
67. Masserini B, Bedeschi MF, Bianchi V, et al. Prevalence of diabetes and pre-diabetes in a cohort of Italian young adults with Williams syndrome. *Am J Med Genet A*. 2013;161A(4):817–821
68. American Academy of Pediatrics Committee on Children with Disabilities and Committee on Adolescence. Transition of care provided for adolescents with special health care needs. *Pediatrics*. 1996;98(6, pt 1): 1203–1206

Health Supervision for People With Achondroplasia

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Health Supervision for People With Achondroplasia

Julie Hoover-Fong, MD, PhD, FACMG,[a] Charles I. Scott, MD, FAAP,[b] Marilyn C. Jones, MD, FAAP,[c] COMMITTEE ON GENETICS

Achondroplasia is the most common short-stature skeletal dysplasia, additionally marked by rhizomelia, macrocephaly, midface hypoplasia, and normal cognition. Potential medical complications associated with achondroplasia include lower extremity long bone bowing, middle-ear dysfunction, obstructive sleep apnea, and, more rarely, cervicomedullary compression, hydrocephalus, thoracolumbar kyphosis, and central sleep apnea. This is the second revision to the original 1995 health supervision guidance from the American Academy of Pediatrics for caring for patients with achondroplasia. Although many of the previously published recommendations remain appropriate for contemporary medical care, this document highlights interval advancements in the clinical methods available to monitor for complications associated with achondroplasia. This document is intended to provide guidance for health care providers to help identify individual patients at high risk of developing serious sequelae and to enable intervention before complications develop.

The original "Health Supervision for Children with Achondroplasia" policy from the American Academy of Pediatrics (AAP) in 1995 provided useful management recommendations to pediatricians caring for children with achondroplasia from birth through early adulthood.[1] The first revision in 2005 expanded the scope of the document to include new information about the molecular genetics of achondroplasia and improvements in anticipatory guidance in terms of prevention and treatment of complications of the condition.[2] The majority of the information provided in those documents remains pertinent and accurate in the current care of patients with achondroplasia. This revision highlights additional interval advancements in the clinical methods available to monitor for complications associated with achondroplasia, including adult health complications that may be rooted in childhood and should, therefore, be monitored and managed from birth. This document also incorporates a few of the more recent treatment options for achondroplasia to provide an informational core from which the general pediatrician can explore

abstract

[a]Greenberg Center for Skeletal Dysplasias, McKusick-Nathans Department of Genetic Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland; [b]Nemours/Alfred I. duPont Hospital for Children and Sidney Kimmel Medical College, Thomas Jefferson University, Wilmington, Delaware; and [c]Department of Pediatrics, University of California, San Diego and Rady Children's Hospital, San Diego, California

Drs Hoover-Fong and Scott wrote new content and edited content from the previous AAP statement and responded to reviews; Dr Jones provided editorial and content review, shepherded the document through multiple stakeholders review, and addressed specific concerns; and all authors approved the final manuscript as submitted.

Clinical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, clinical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-1010

Address correspondence to Julie Hoover-Fong, MD, PhD. E-mail: jhoover2@jhmi.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Hoover-Fong J, Scott CI, Jones MC, AAP COMMITTEE ON GENETICS. Health Supervision for People With Achondroplasia. *Pediatrics.* 2020;145(6):e20201010

additional resources with patients. The authors recognize the audience for this document may have variable medical resources at their disposal to monitor and treat patients with achondroplasia. The intent of this consensus document is to provide guidance that may be adapted to each individual patient in his or her unique environment. Children and adolescents with achondroplasia should have care coordinated through a medical home; however, some of the surveillance and counseling suggested in this document will be provided by a number of specialists with expertise in the management of achondroplasia, if these individuals are available.

Achondroplasia is the most common condition associated with severe, disproportionate short stature, with an estimated birth incidence of 1 in 10 000 to 1 in 30 000.[3,4] There is no recognized ethnic or sex predisposition. The diagnosis can usually be made on the basis of clinical characteristics and specific features on radiographs, including a square shape of the pelvis with a small sacrosciatic notch, short pedicles of the vertebrae with interpedicular narrowing from the lower thoracic through lumbar region, rhizomelic (proximal) shortening of the long bones, proximal femoral radiolucency, and a characteristic chevron shape of the distal femoral epiphyses. Other clinical features include short stature, macrocephaly (absolute and relative), trident configuration of the hands, and long, near-normal-length trunk.

Achondroplasia is an autosomal dominant disorder, meaning a person with achondroplasia has a 50% chance of passing the condition on to each of his or her offspring regardless of the sex of the parent or child, provided the other parent is unaffected. Approximately 75% to 80% of patients with achondroplasia are born to average-stature parents, representing a new dominant mutation in the fibroblast growth factor receptor type 3 *(FGFR3)* gene in that affected individual.[3,5,6] Because virtually all of the causal mutations occur at exactly the same nucleotide within the gene,[6] genetic testing for achondroplasia is straightforward. It is not necessary to perform molecular testing in every child with a clinical diagnosis of achondroplasia. However, *FGFR3* testing should be considered when a confirmed achondroplasia diagnosis is needed. For example, infants or children with an atypical achondroplasia presentation may have a second genetic condition.[7] Such children also should be referred for clinical genetics evaluation. Different mutations in the *FGFR3* gene can also cause 2 other short stature dysplasias: hypochondroplasia and thanatophoric dysplasia. A child with hypochondroplasia has the same clinical features as one with achondroplasia, as listed above, but milder overall. Growth hormone therapy may be considered as a treatment option for those with hypochondroplasia, but it has not been shown to be effective in patients with achondroplasia.[8–11] Thanatophoric dysplasia usually can be distinguished from achondroplasia and hypochondroplasia because severe thoracic and lung hypoplasia are expected to be lethal in the pre- or early postnatal period in the former.[12] Rare exceptions of a patient with thanatophoric dysplasia surviving are reported but only with aggressive measures of resuscitation at delivery and significant respiratory support thereafter.[13,14] Age-specific recommendations pertaining to genetic counseling and testing are also included in each age category discussed later in this report.

A great deal is known about the natural history of achondroplasia that can be shared with the family.[4,15] The average adult height in achondroplasia is approximately 120 to 135 cm (4–4.5 ft) (Fig 1).[16] The most common complication, occurring in adulthood, is related to lumbosacral spinal stenosis with compression of the spinal cord or nerve roots.[17–19] This complication is usually treatable by surgical decompression, with less sequelae if treated at an early stage. Most children with achondroplasia do well. However, children affected with achondroplasia commonly have delayed motor milestones (Fig 2),[20–22] otitis media, and bowing of the lower legs.[23] Less commonly, infants and children may have serious health consequences related to craniocervical junction compression because of a relatively small foramen magnum, hydrocephalus, upper-airway obstruction, or thoracolumbar kyphosis. Although they are less common, anticipatory care should include identifying children at highest risk and intervening to prevent potentially serious sequelae. Most individuals with achondroplasia are of normal intelligence and are able to lead independent and productive lives.[24] Because of their disproportionate short stature, however, a number of psychosocial problems can arise.[25] Chronic pain, a problem that may begin in childhood and magnify into adulthood without intervention, may be playing a larger role in overall life satisfaction and coping than has been previously appreciated.[26] Further investigation is needed to better understand the temporal relationship among pain, function, and medical or surgical treatment to allow for the highest quality of life possible. Families can benefit from anticipatory guidance and the opportunity to learn from other families with children of disproportionate short stature. The consensus-based guidance in this report is designed to help the pediatrician care for children with achondroplasia and their families. Issues that need to be addressed at various ages are outlined in Table 1.

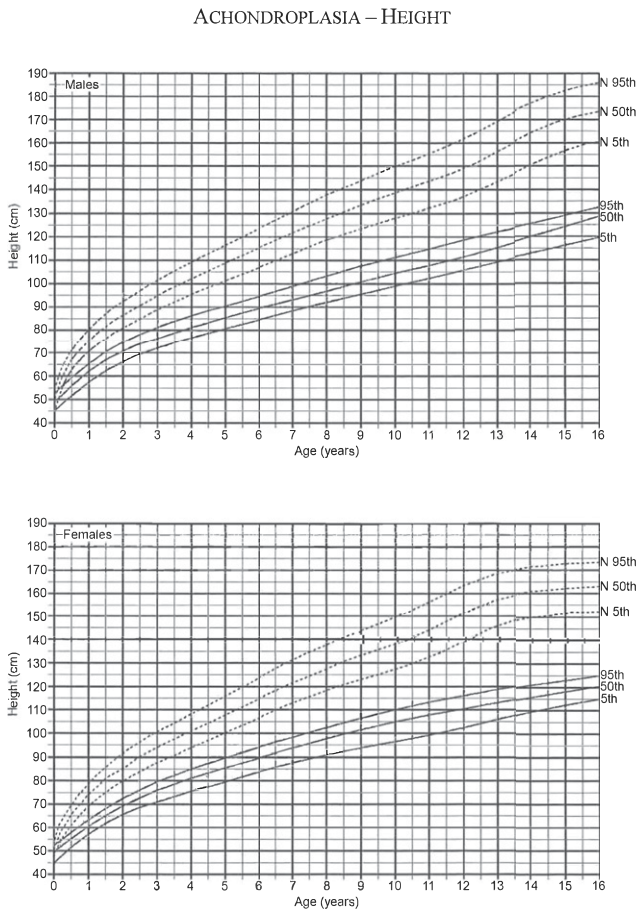


FIGURE 1

Fifth, 50th, and 95th percentiles for height for children with achondroplasia (solid lines) compared with height growth curves for the general population (dotted lines), based on 1955 observations from 162 boys and 131 girls with achondroplasia. Adapted from Hoover-Fong JE, Schulze KJ, McGready J, Barnes H, Scott CI. Age-appropriate body mass index in children with achondroplasia: interpretation in relation to indexes of height. *Am J Clin Nutr*. 2008;88(2):364–371. Curves for the US population are from Kuczmarski RJ, Ogden CL, Guo SS, et al. *2000 CDC Growth Charts for the United States: Methods and Development*. Hyattsville, MD: National Center for Health Statistics; 2002. Illustration is from *Growth References*. Third edition. 2011. Permission for use was granted by the Greenwood Genetic Center.

It should be noted that these suggestions are not appropriate for other skeletal dysplasia diagnoses because each type has its own natural history, complications, and specific management recommendations. The most recent nosology of genetic skeletal disorders includes 436 different disorders with primary bone manifestations, and more than half of these are considered to be skeletal dysplasias.[27] Because of the vast range of medical considerations for patients with these diagnoses, it is important that pediatricians and their patients partner with a physician with special experience and expertise concerning skeletal dysplasias, particularly achondroplasia, early in the child's life. This report provides generally applicable suggestions that must be tailored to a particular child's condition and needs. For reference, the American Board of Medical Genetics and Genomics has an online resource to search for a certified geneticist throughout the United States and in several countries around the world (http://www.abmg.org/pages/searchmem.shtml).[28]

Similarly, the Little People of America, Inc, the largest US patient support group for short-stature skeletal dysplasia patients and their families, may be a suitable resource for information for medical providers and families (http://www.lpaonline.org/).[29]

In addition to the age group–specific guidance presented in this report, 3 topics often arise in early discussions with families about potential treatment of achondroplasia: growth hormone therapy, surgical limb lengthening, and, more recently, drug trials for new medications to alter bone morphology and growth. The following is not meant to be an exhaustive review of these issues but rather a brief foundation on which further discussions can be built.

First, in reference to supplemental growth hormone treatment, there have been longitudinal studies of relatively small groups of patients with achondroplasia treated with growth hormone of various doses and durations.[8–11] A recent meta-analysis of 12 trials showed a clinically insignificant increase of –5 to –4 SD below the mean when children with achondroplasia were treated with growth hormone.[10] Some authors also suggest that the rapid (although unsustained) linear growth predisposes to worsening scoliosis and kyphosis in these patients.[10] In contrast, a few studies have shown a greater adult height in patients with hypochondroplasia treated with growth hormone therapy.[8] As noted previously, genetic testing would be useful to differentiate these 2 conditions before embarking on a long and expensive course of supplemental growth hormone treatment.

With respect to limb lengthening, there is a body of medical literature addressing different surgical methods of lengthening, complications of the procedures,[30] perspectives on lengthening the upper extremities,[31]

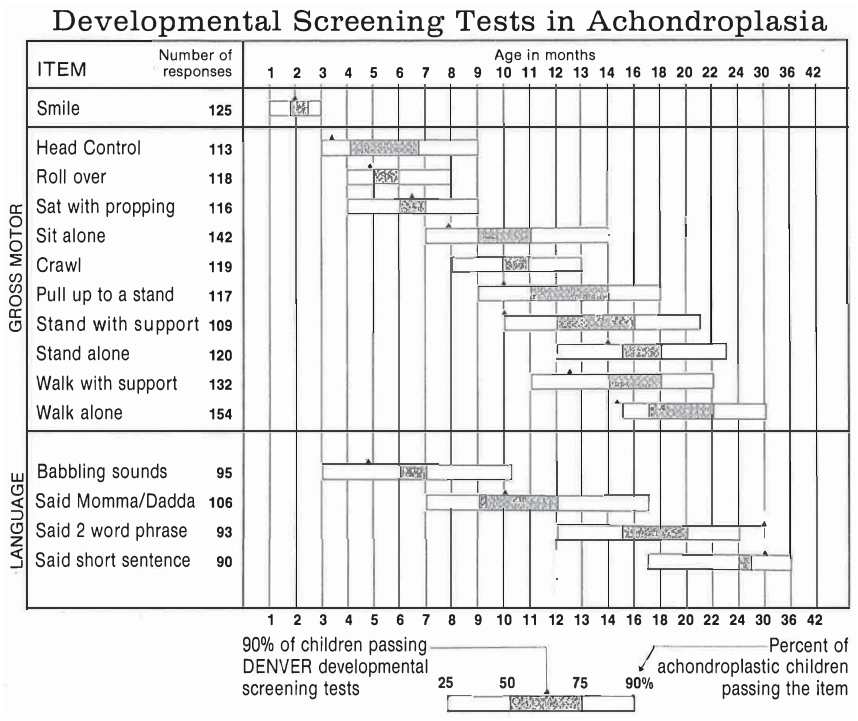


FIGURE 2

Developmental screening tests in achondroplasia, based on questionnaire information from 197 individuals. The bar scale reveals the percentage of children with achondroplasia passing the item. The black triangle on top of the bar reveals the age at which 90% of normal children pass the same item. Illustration is from *Growth References*. Third edition. 2011. Permission for use was granted by the Greenwood Genetic Center.

and reviews of the entire process.[32] Opinions about the use and success of surgical limb lengthening vary widely. Regardless of a patient or family's position, however, it is important for the pediatrician to be aware of a few key issues surrounding surgical limb lengthening. Limb lengthening is a long and costly process, associated with significant physical pain for the young patient. The age at which this procedure is recommended varies among surgeons, but implementation before epiphyseal closure is the norm, with many encouraging commencement at younger than 10 years. Medical decision-making in this age group rests with the parent or legal representative who could make a decision without involving the child in the discussion. Per AAP policy on informed consent,[33] it is highly desired that the child and parents engage in discussion about such elective procedures before a decision is made. Finally, this procedure is associated with complications. Therefore, it is critical that the surgical team is readily available to manage short- and long-term complications associated with limb lengthening.

The last novel issue to address is the pharmaceuticals under development to potentially increase long bone growth and/or ameliorate the skeletal complications of this condition. There are several compounds currently at various stages of development with different targets and mechanisms.[34,35] More information about these trials can be found online at https://clinicaltrials.gov. The trial process often takes several years, and final approval is required from the US Food and Drug Administration for a new drug to become available through a prescription. For families contemplating enrollment of their child with achondroplasia in one of these trials, it is important to know that a physician conducting a clinical trial should have sufficient experience with the condition to differentiate complications (or a response) to a research pharmaceutical from the natural history of that condition.

THE PRENATAL VISIT

Pediatricians may be asked to counsel expectant parents whose fetus has achondroplasia or is suspected to have achondroplasia because of recognition on ultrasonography of disproportionate small stature and relative large head size. In some situations, the pediatrician may be the primary resource for counseling the family. At other times, counseling may already have been provided to the family by a clinical geneticist, genetic counselor, or maternal-fetal medicine specialist. Because of a previous relationship with the family, however, the pediatrician could be called on to review this information and assist the family in the decision-making process.

The diagnosis of achondroplasia in the fetus is made most often with certainty when one or both biological parents have this condition. In this circumstance, the parents are usually (but not always) knowledgeable about the disorder, the inheritance, and the prognosis for the offspring. However, specific inquiry about the presence of a short stature diagnosis in both parents is recommended when only the mother is present for the clinical visit and may not spontaneously offer that her partner also has short stature. Additionally, it is important to establish clearly the specific short stature diagnosis in both parents. If both parents have achondroplasia, for example, review of the potential outcome of this and each future pregnancy (25% average stature, 50% achondroplasia, 25% homozygous or "double dominant" and, therefore, lethal) is

TABLE 1 Health Supervision for People With Achondroplasia

	Prepregnancy and Short-Stature Parents	Prenatal and Short- and Average-Stature Parents	Birth to 1 mo	1 mo to 1 y	1–5 y	5–13 y	13–21 y	Adult
Diagnosis								
Physical examination	X	X of fetus	X	X	—	—	—	—
Imaging	X radiographs	X ultrasonography of fetus	X	—	—	—	—	—
Molecular testing	X	X of fetus	X	—	—	—	—	X
Genetic counseling								
Review natural history	X of potential offspring	X	X	X	X	X	X	X
Recurrence risk and genetics	X	X	X	X	X	X	X	X
Delivery mode and location	X	X	—	—	—	—	—	X
Support group(s), family support	X	X	X	X	X	X	X	X
Desired pregnancy?	—	X	X	—	—	—	—	X
Medical evaluation								
Growth (height or length, weight, occipitofrontal circumference)	—	X	X	X	X	X	X	X
Physical examination	—	—	X	X	X	X	X	X
Neurologic examination	—	—	X	X	X	X	X	X
Development	—	—	X	X	X	X	—	—
Neuroimaging	—	—	X	X if new diagnosis	X as indicated	X as indicated	X as indicated	X as indicated
Polysomnography	—	—	X	X if new diagnosis	X as indicated	X as indicated	X as indicated	X as indicated
Hearing assessment	—	—	X	X	X	X	X	X
Radiography for kyphosis, genu varus, bowing	—	—	—	X	X as indicated	X as indicated	X as indicated	X as indicated
Anticipation or guidance								
Warning signs of severe complications	—	—	X	X	X	X	X	X
Car seats	—	X for hospital discharge	X	X	X	X	—	—
Achondroplasia-specific development	—	—	X	X	X	—	X	—
Jugular bulb dehiscence warning	—	—	—	X	X	X	X	X
Supplemental security income inclusion	—	—	—	X	X	X	X	X
Accommodations	—	—	—	—	X	X	X	X
Obesity, exercise, diet	—	—	—	—	X	X	X	X
Driving	—	—	—	—	—	—	X	X
College	—	—	—	—	—	—	X	X
Job training	—	—	—	—	—	—	X	X

straightforward. In the situation in which one parent has achondroplasia but the partner has a different dysplasia diagnosis, the recurrence risk discussion must be tailored to their specific diagnoses and associated inheritance. Often, there is little medical literature available to reference and anticipate the medical course of a compound heterozygous offspring. Ideally, such genetic counseling should be provided by genetic medicine professionals, such as genetic counselors and/or clinical geneticists.

Most often, the scenario presents when the diagnosis of achondroplasia is suspected late in gestation on the basis of long bone foreshortening incidentally discovered via ultrasonography in the fetus of an average-stature couple. It is rare for ultrasonographic features of achondroplasia to be noticeable before 26 weeks' gestation, although Boulet et al[36] reported a new prenatal ultrasonographic diagnostic sign for achondroplasia they named the "collar hoop" sign, which may be evident earlier. If long bone anomalies and/or disproportion are appreciated earlier in gestation, a skeletal dysplasia more severe than achondroplasia is likely.[37] Higher-level ultrasonography and examination for other diagnostic features are then required. Confirmation of diagnosis on the basis of ultrasonographic features

characteristic of achondroplasia can be provided by molecular testing (*FGFR3* mutational testing) of prenatal specimens (chorionic villus sampling at 11–13 weeks' gestation or amniocentesis after 15 weeks' gestation). Typically, this would be performed at a specialized prenatal center. If no such confirmation for achondroplasia (or any other dysplasia) has been completed, caution should be exercised when counseling the family.

Prenatal consultation involving a couple in which one or both carry a skeletal dysplasia diagnosis and are seeking genetic counseling and anticipatory guidance is best arranged before pregnancy.[38] Typically, this visit would be with a medical geneticist or genetic counselor. In this scenario, there is ample time to confirm the parental dysplasia diagnoses and evaluate the woman (if she is short stature) for neuraxial complications or previous surgical procedures, which could influence anesthesia options for delivery (ie, general versus spinal or epidural).

Depending on the prenatal situation, the pediatrician may consider the following steps as needed:

1. Review, confirm, and demonstrate laboratory or imaging studies leading to the diagnosis.
2. Explain the mechanisms for occurrence of achondroplasia in the fetus and the recurrence risk for the family, depending on the presence of a dysplasia in both, one, or neither of the parents.
3. Explain that up to 80% of patients with achondroplasia are born to average-stature parents. In these affected children, their achondroplasia occurred because of a spontaneous mutation in the *FGFR3* gene. In this situation, recurrence risk is empirically approximately 1% for future pregnancies for this specific couple because of the possibility of gonadal mosaicism.
4. Review the natural history and manifestations of achondroplasia, including variability.[4,15]
5. Discuss additional studies that could be performed in the newborn period to confirm the diagnosis (eg, blood test for mutation in *FGFR3,* radiographs to review for achondroplasia-specific features). If miscarriage, stillbirth, or termination occurs, confirmatory testing is important if the woman or family desires optimal genetic counseling. If specific molecular testing cannot be offered immediately, try to secure a blood or tissue sample for future testing.
6. Review currently available treatments and interventions, including efficacy, complications, adverse effects, costs, and other burdens of these treatments. Discuss possible future treatments and interventions. Please see the medical evaluation and anticipatory guidance discussions in the sections on health supervision for children ages 1 month to 1 year, 1 to 5 years, and 5 to 13 years.
7. Explore the options available to the family for the management and rearing of the child by using a nondirective approach. In cases of early prenatal diagnosis, these options may include discussion of pregnancy termination, continuation of pregnancy and rearing of the child at home, foster care, or adoption. If adoption is planned, the Little People of America, Inc, has adoption resources available (http://www.lpaonline.org/adoption).[39]
8. If the pregnant woman carries the diagnosis of achondroplasia, inform her that a cesarean delivery will be necessary because of the characteristic small pelvis and cephalopelvic disproportion (regardless of whether the fetus is average stature or has achondroplasia also and, therefore, macrocephaly). Prenatal consultation with a high-risk maternal or fetal medicine specialist is recommended to investigate whether general anesthesia or spinal or epidural anesthesia will be needed for delivery. In an average-stature pregnant woman carrying a fetus with achondroplasia, a cesarean delivery may also, but not always, be necessary because of fetal macrocephaly.
9. Establish where the infant with the suspected (or possible) skeletal dysplasia diagnosis will be delivered. Pediatric services to manage potential medical complications at or shortly after delivery may be necessary and are not available at all hospitals.
10. When both parents are of disproportionate short stature, assess the possibility of the fetus inheriting both conditions. Infants with homozygous achondroplasia usually are stillborn or die shortly after birth.[40]
11. Be aware that many of these discussions will be coordinated with the prenatal team, including a medical geneticist, genetic counselor, and/or maternal-fetal medicine specialist. The importance of a knowledgeable medical home for the expected infant should be reviewed.

HEALTH SUPERVISION FROM BIRTH TO 1 MONTH OF AGE: NEWBORN INFANTS

Diagnosis, Genetic Counseling

1. Confirm the diagnosis by radiographic studies in the newborn period. External physical

features may not be highly obvious for achondroplasia. Radiographs should include anteroposterior and lateral skull, anteroposterior and lateral cervical spine, anteroposterior and lateral chest and abdomen with pelvis and upper femurs, anteroposterior of each upper and lower extremity long bone, and anteroposterior of hands and feet separate from long bones. Molecular studies may be pursued if desired.

2. Discuss genetics of achondroplasia with the parents, including the following:
   a. Autosomal dominant inheritance: Any person with achondroplasia will have a 50% chance of passing this condition on to each offspring, regardless of the sex of the parent and child.
   b. Approximately 80% of children born with achondroplasia represent spontaneous new mutations in the *FGFR3* gene.
   c. Germ-line mosaicism (in which some germ cells are derived from a normal cell line and some are from a cell line with a mutation, also known as gonadal mosaicism) has been reported in families with achondroplasia. This means that 2 average-stature parents have had more than 1 child with achondroplasia attributable to gonadal mosaicism. The recurrence risk of achondroplasia in sporadic cases via gonadal mosaicism is approximately 1%.[41–43]
   d. Recurrence risk when both parents have a skeletal dysplasia diagnosis should also be reviewed.
3. Recognize the potential psychosocial implications for both parent and child related to short stature.
   a. Refer the family to a support group, such as Little People of America.[39]
   b. If parents do not wish to join a group, offer meeting individually with other affected individuals or parents.
   c. Discuss how they will tell their family and friends about their child's diagnosis.
   d. Refer to other support resources, such as clergy, social workers, and psychologists.
   e. Remind parents that most people with achondroplasia lead productive, independent lives.
   f. Supply the parents with educational books and pamphlets (http://www.lpaonline.org/).[29]
   g. Discuss the realistic functional difficulties for affected individuals.

Medical Evaluation

1. Measure and plot total body length, weight, and occipitofrontal circumference on achondroplasia-specific growth charts (Figs 1 and 3–5)[16,22,44] at birth and every health supervision visit. Review these growth parameters with both parents.
2. Use achondroplasia-specific developmental charts at every health supervision visit (Fig 2).[20,22]
3. Assess every infant with achondroplasia for craniocervical junction risks as soon as the diagnosis is recognized[45] via the following:
   a. Careful neurologic history and examination. This includes inquiry about feeding ability, choking or gagging with feeding, prolonged apnea while sleeping, cyanosis of lips or mouth with feeding or sleeping, symmetry of limb movements, and axial and appendicular tone.
   b. Polysomnography (overnight sleep study, evaluated by a pediatric pulmonologist, including end tidal carbon dioxide in addition to standard measures of apnea, hypopnea, saturation) to assess for unusual central apnea.
   c. Neuroimaging, provided it can be performed safely by appropriate medical personnel if sedation or anesthesia is required to obtain images. If abnormalities suggestive of craniocervical compromise are detected in the medical history, neurologic examination, or sleep study, then neuroimaging is indicated. Neuroimaging should not be used in isolation to determine when or whether surgery is indicated.
4. Consider the pros and cons of the neuroimaging options:
   a. Computed tomography with thin cuts and bone windows:
      i. Can compare foramen magnum size with published achondroplasia norms.[46,47]
      ii. May be possible without sedation.
      iii. Does not provide adequate images of brainstem and upper cervical cord to determine if there is neural compromise, signaling change.
   b. MRI:
      i. Provides direct assessment of the brainstem and upper cervical spinal cord, but no standards for estimation of foraminal size by MRI are currently available.
      ii. May require general anesthesia if fast MRI protocol is not used or available. General anesthesia should only be

performed in a clinical setting in which a pediatric anesthesiologist, nurse anesthetist, or other airway specialist is present to manage the procedure. Often, a newborn infant can be wrapped and scanned while asleep without sedation or anesthesia, particularly when a faster magnetic resonance scanner is available.

iii. Evidence that flexion or extension of the cervical spine during MRI may reveal dynamic cord compression and alteration of cerebrospinal fluid (CSF) flow in achondroplasia, which is a better indicator of the need for surgical intervention.[48,49]

5. Refer in a timely manner to experienced neurosurgical specialist if any of the following are detected during the aforementioned craniocervical junction assessment:
   a. Abnormal neurologic examination marked by hypotonia or "floppiness," weakness, sustained lower extremity clonus, asymmetric reflexes, or choking or gagging with eating.
   b. Poor weight gain on achondroplasia-specific growth charts, especially if caloric intake and/or infant feeding is sufficient.
   c. Sleep study showing hypoxemic episodes with oxygen saturation <85% and/or central apnea beyond that expected in an average-stature, healthy newborn infant.[50]
   d. Imaging showing marked smaller foramen magnum size, substantial deformation of the upper cervical spinal cord, or lack of CSF around the spinal cord.
6. Establish care with a pediatric orthopedist to monitor the spine.
7. Confirm newborn screening hearing result and follow-up failed screening results with formal audiology assessment.

Anticipatory Guidance

1. Discuss the following possible severe medical complications and methods of prevention:
   a. Unexpected infant death occurs in 2% to 5% of all infants with achondroplasia[50,51] if aggressive, early assessments are not pursued to detect central apnea resulting from compression of the brainstem and arteries at the level of the foramen magnum.
   b. The universally small foramen magnum may result in a high cervical myelopathy,[52,53] also detectable by the aforementioned early assessments.
   c. Macrocephaly with excessive extra-axial fluid and asymptomatic ventriculomegaly is a normal feature of achondroplasia[54] but may be complicated by hydrocephalus.
      i. Should head circumference increase unexpectedly on an achondroplasia-specific curve, the fontanelle bulge or become hard to palpation, or lethargy, irritability, poor weight gain, or marked developmental delay occur, the imaging and potential referral to a neurosurgical specialist is indicated.
      ii. Benign extra-axial fluid and asymptomatic ventriculomegaly visualized by MRI should not be misinterpreted as indicative of need for shunt placement.
   d. Restrictive pulmonary disease occurs in less than 5% of children with achondroplasia who are younger than 3 years.[55] Living at high elevation may exacerbate pulmonary complications as in average-stature individuals. Obstructive pulmonary disease is much more common and warrants systematic assessment.[15,56,57]
2. Be aware that most infants with achondroplasia develop thoracolumbar kyphosis. More severe kyphosis is associated with unsupported sitting before there is adequate trunk muscle strength and tone.[58,59] Borkhuu et al[60] observed developmental delays in motor skill acquisition (compared with other children with achondroplasia) to be highly associated with progression of thoracolumbar kyphosis.[61]
   a. Back support should be provided during bottle and/or breastfeeding.
   b. Unsupported sitting and devices that cause curved sitting or "C sitting," such as "umbrella-style" strollers and soft canvas seats, should be avoided during the first year of life.
   c. Care with a pediatric orthopedist should be established to monitor the spine.
3. Be aware that the common complication of spinal stenosis rarely occurs in childhood but manifests in older individuals with numbness, weakness, and altered deep tendon reflexes.[52] Severe thoracolumbar kyphosis can greatly exacerbate spinal stenosis; thus, the recommendation is to avoid unsupported sitting before there

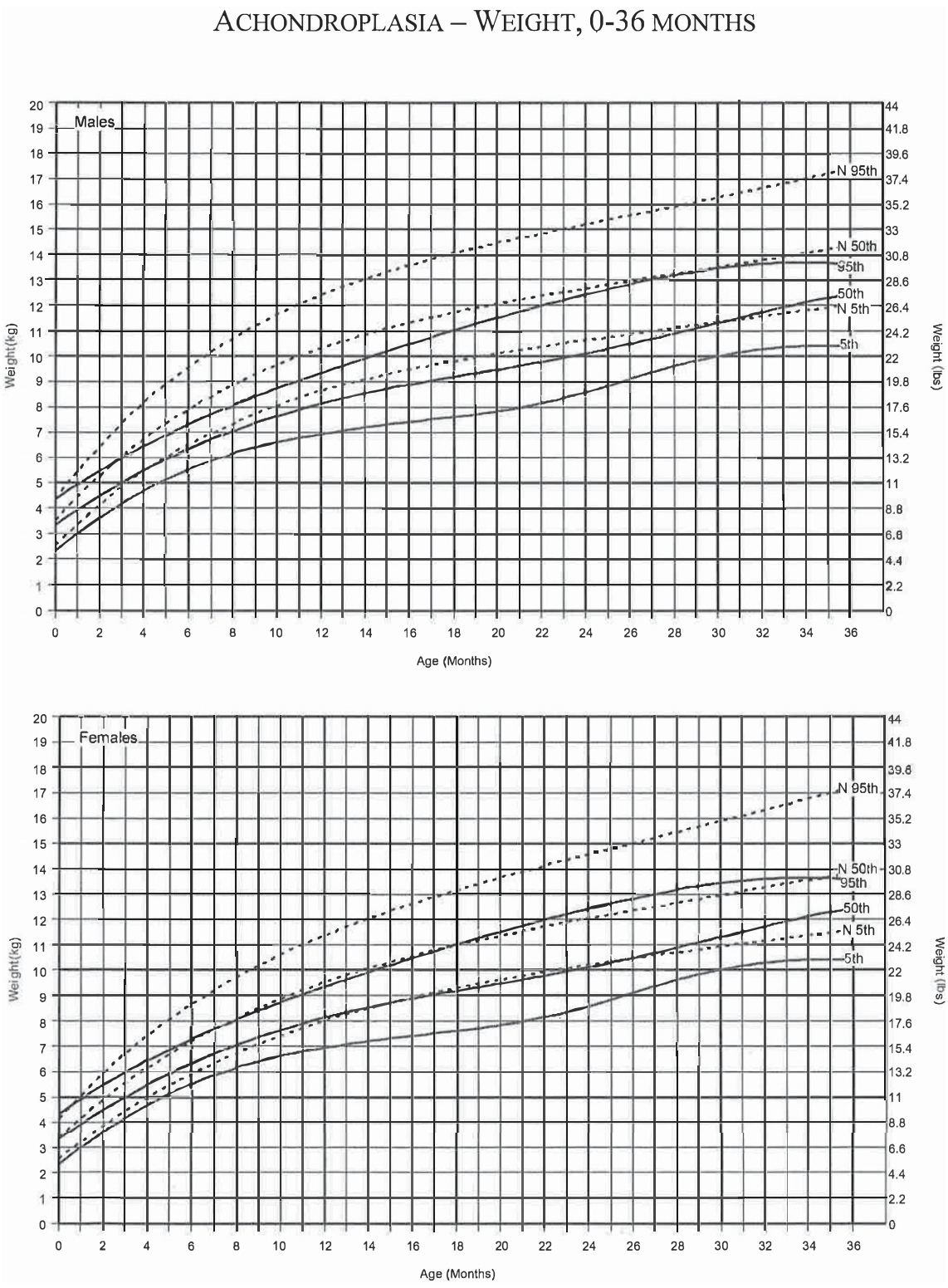


FIGURE 3

Fifth, 50th, and 95th percentiles for weight for boys (top) and girls (bottom) 0 to 36 months of age with achondroplasia (solid lines) compared with those of the general population (dotted lines), based on 1853 observations from 155 boys and 128 girls with achondroplasia. Adapted from Hoover-Fong JE, Schulze KJ, McGready J, Barnes H, Scott CI. Age-appropriate body mass index in children with achondroplasia: interpretation in relation to indexes of height. *Am J Clin Nutr.* 2008;88(2):364–371. Curves for the US population are from Kuczmarski RJ, Ogden CL, Guo SS, et al. *2000 CDC Growth Charts for the United States: Methods and Development.* Hyattsville, MD: National Center for Health Statistics; 2002. Illustration is from *Growth References.* Third edition. 2011. Permission for use was granted by the Greenwood Genetic Center.

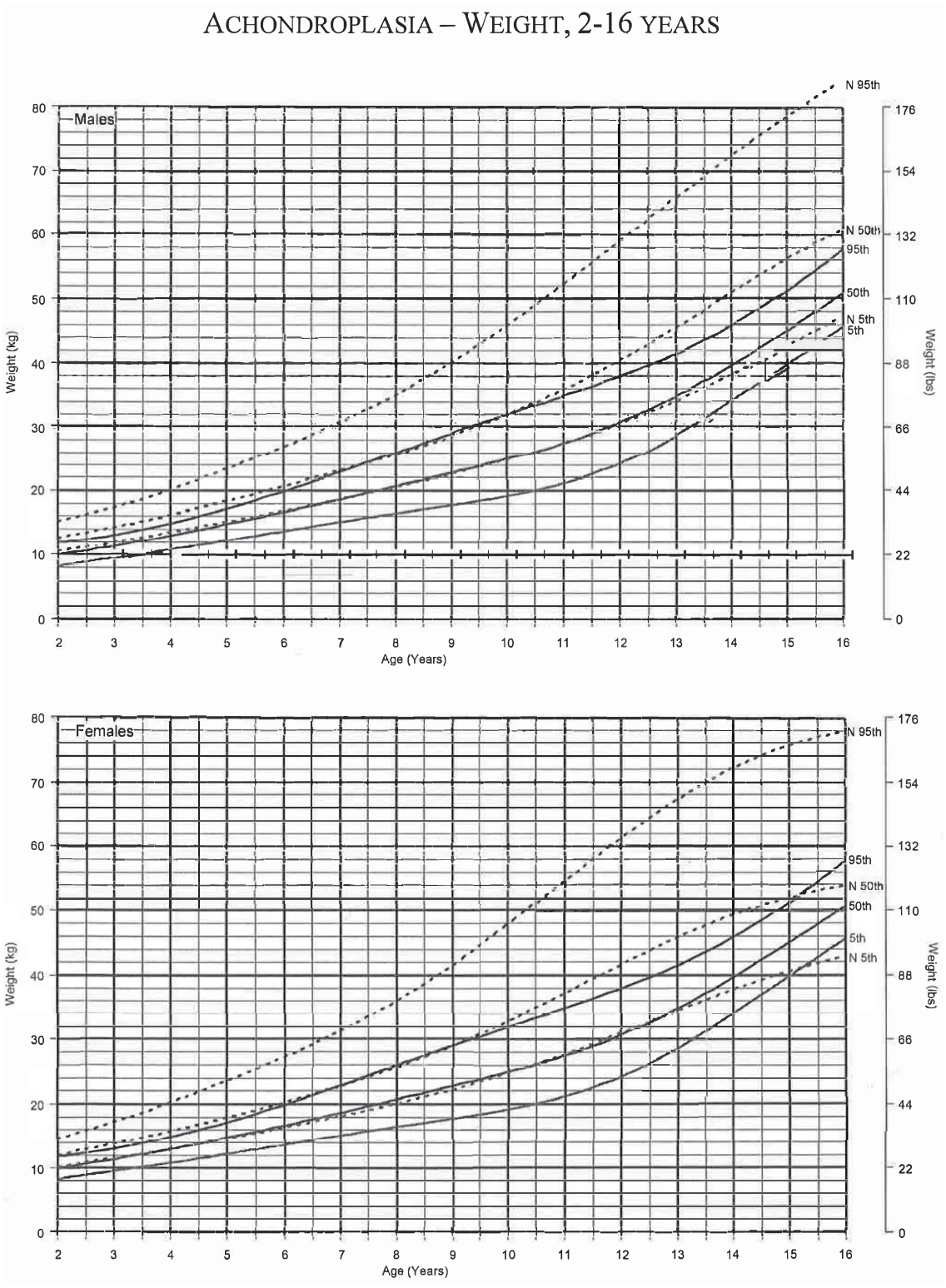


FIGURE 4

Fifth, 50th, and 95th percentiles for weight for boys (top) and girls (bottom) 2 to 16 years of age with achondroplasia (solid lines) compared with those of the general population (dotted lines), based on 1853 observations from 155 boys and 128 girls with achondroplasia. Adapted from Hoover-Fong JE, Schulze KJ, McGready J, Barnes H, Scott CI. Age-appropriate body mass index in children with achondroplasia: interpretation in relation to indexes of height. *Am J Clin Nutr.* 2008;88(2):364–371. Curves for the US population are from Kuczmarski RJ, Ogden CL, Guo SS, et al. *2000 CDC Growth Charts for the United States: Methods and Development.* Hyattsville, MD: National Center for Health Statistics; 2002. Illustration is from *Growth References.* Third edition. 2011. Permission for use was granted by the Greenwood Genetic Center.

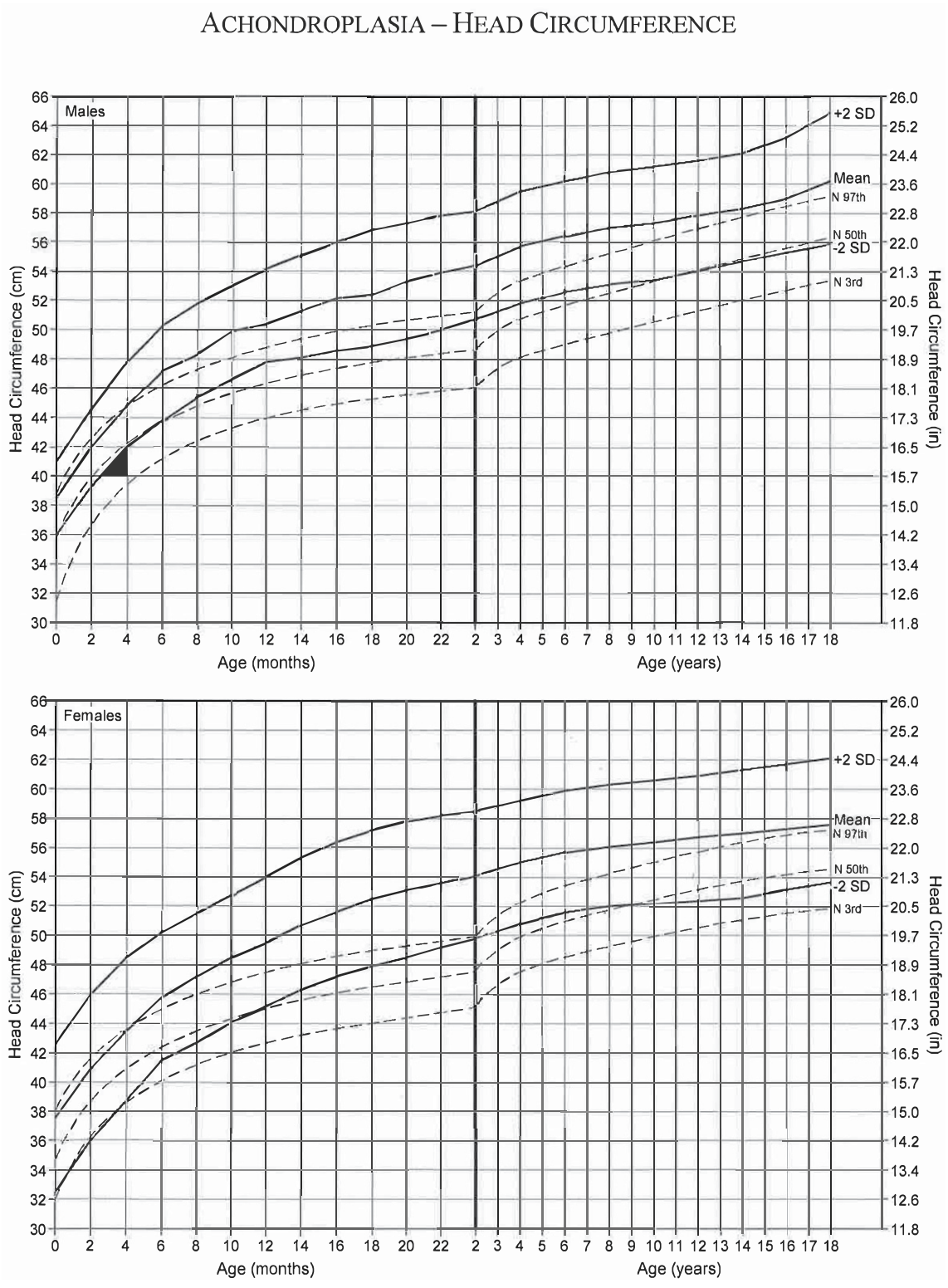


FIGURE 5

Head circumference curves (mean ± 2 SD) for children with achondroplasia (solid lines) compared with those for the general population (dashed lines). Data are derived from 114 boys and 145 girls. Graphs are adapted from Horton WA, Rotter JI, Rimoin DL, Scott CI, Hall JG. Standard growth curves for achondroplasia. *J Pediatr.* 1978;93(3):435–438. General population curves are from Rollins JD, Collins JS, Holden KR. United States head circumference growth reference charts: birth to 21 years. *J Pediatr.* 2010;156(6):907–913.e2. Illustration is from *Growth References.* Third edition. 2011. Permission for use was granted by the Greenwood Genetic Center.

is adequate trunk muscle strength and tone.

4. Advise parents to use an infant seat or infant carrier that has a firm back (not excessive padding) to support the neck and to use a rear-facing car safety seat for as long as possible.
    a. Car seat laws vary by state (and country) as to the age, weight, and/or height of a child required to convert their seat to forward-facing. Inquire with local experts (eg, police, hospital, or fire station where car seat installation clinics are offered) or online motor vehicle administration.
    b. Infants should not sleep unattended in car seats; this is especially important in those with achondroplasia because decreased axial tone and strength in combination with the large head creates great risk of craniocervical and airway compromise.
5. Avoid use of products like mechanical swings and carrying slings to limit uncontrolled head movement around the small foramen magnum. There is a risk of death if the cervicomedullary junction is compromised, even in infants in which there were no signs of abnormal neurologic status. Always support the head and neck with the caregiver's hand, minimizing flexion and extension (also known as head bobbling).
6. Advise parents that normal intelligence is expected.
7. Advise parents that overall, people with achondroplasia have fairly normal life expectancy. However, the following should be noted:
    a. Wynn et al[61] demonstrated 10-year earlier mortality.[62]
    b. Longitudinal studies are required to determine the cause for this, but serious problems may occur during infancy (eg, cervicomedullary compression, central sleep apnea), as noted.
8. Inform parents that growth hormone and vitamin supplements are not effective in significantly increasing stature. Growth hormone may cause a temporary increase in growth velocity, but little to no significant increase in end height has been shown.[8–11]
9. Discuss the availability of extended limb lengthening using a variety of surgical techniques, which can result in an increase in ultimate height.
    a. This is a long process with high cost and associated physical pain and can have postoperative adverse effects.
    b. If a family undertakes this procedure, it is critical that the affected child and parents have discussed this at great length and that they are in agreement that proceeding with this surgery is the appropriate decision for them.
    c. If pursued, it should be completed at a well-established surgical center with experience and the capability to manage these patients long-term for complications.
10. Inform parents that the final expected adult height for people with achondroplasia is approximately 120 to 135 cm (4–4.5 ft).
11. If an individual with achondroplasia requires anesthesia and surgery, consider the following[63]:
    a. Care should be taken in manipulation of the neck because uncontrolled neck movement (as may occur with intubation) could lead to unintentional spinal cord compression secondary to constriction of the foramen magnum.
    b. Medication should be dosed for patient size, not age.
    c. Venous access may be more difficult because of incomplete elbow extension.
    d. In general, spinal or epidural anesthesia should be avoided unless neuroimaging reveals adequate space inside the spinal canal and there are no signs of neurologic compromise.

HEALTH SUPERVISION FROM 1 MONTH TO 1 YEAR OF AGE: INFANCY

Diagnosis, Genetic Counseling

1. For infants not diagnosed in the newborn period, confirm diagnosis by radiographs and physical examination and offer molecular confirmation, if desired.
2. Inquire about personal support available to the family.
3. Inquire about contact with support groups.
4. Observe the emotional status of parents and intrafamily relationships.
5. Discuss the importance of normal socializing experiences with other children.
6. Ask the parents whether they have educated their family members about achondroplasia and offer resources to the Little People of America or local genetic counselors; discuss sibling adjustment.
7. Review genetics of achondroplasia as outlined in the Birth to 1 Month section, as needed.

Medical Evaluation

1. Assess growth (length, weight, head circumference) and

development only in comparison with children with achondroplasia (Figs 1–5).

2. Perform physical examination, including neurologic examination.
3. Check motor development and discuss development; note on the milestone charts for achondroplasia.[20,22] Expect motor delay as compared with average-stature, age-matched children but not social or cognitive delay.
4. For infants not diagnosed in the newborn period, arrange for polysomnography and neuroimaging at the time of diagnosis.
5. Refer the infant to a pediatric neurologist or pediatric neurosurgeon if any of the following are present:
   a. Head circumference disproportionately large for length and weight on achondroplasia-specific curves or head circumference crossing percentiles.
   b. Fontanelle bulging or becoming hard to palpation.
   c. Abnormal neurologic examination marked by hypotonia or "floppiness," lethargy, irritability, weakness, sustained lower extremity clonus, asymmetric reflexes, choking or gagging with eating, or early hand preference, which may be attributable to hydrocephalus or craniocervical junction compromise.
   d. Poor weight gain on achondroplasia-specific growth charts, especially if caloric intake is sufficient.
   e. Polysomnography showing hypoxemic episodes with oxygen saturation lower than 85% and/or central apnea beyond that expected in an average-stature, healthy infant.[50]
   f. Imaging showing marked smaller foramen magnum size, substantial deformation of the upper cervical spinal cord, or lack of CSF around spinal cord.
6. Check for serous otitis media. Formal behavioral audiometric assessment should be completed by 9 to 12 months of age and managed as part of routine health care for patients with achondroplasia, ideally on an annual basis.[62,64] Language delay may be present secondary to conductive hearing loss.
7. Continue to monitor for progression of kyphosis at the thoracolumbar junction.
   a. Parents and therapists (if used) should be instructed to provide back support during the first year of life.
   b. Avoid unsupported sitting and devices that cause curved sitting or "C sitting," such as "umbrella-style" strollers and soft canvas seats, during the first year of life.
   c. Position the infant for feeding with a straight back and head and neck in alignment, supported by firm pillows; a feeder seat may be a good option.
   d. Mild, mobile (nonfixed) thoracolumbar kyphosis will often improve or resolve when the child begins to walk.
   e. If severe kyphosis appears to be developing, seek pediatric orthopedic assessment to determine if bracing is needed. Rarely, surgical intervention may be necessary.[59,60]

Anticipatory Guidance

1. Discuss early-intervention services if needed. This is not a uniform recommendation simply because of the diagnosis of achondroplasia.
2. Review the increased risk of serous otitis media because of short eustachian tubes. Indicate that an ear examination is appropriate with any persistent or severe upper respiratory tract infection or when parents suspect that ear pain may be present.
3. Recommend annual audiology assessment as part of routine health care for patients with achondroplasia.[62,64]
4. There is a risk of jugular bulb dehiscence (absence of the temporal bone "roof" over the jugular bulb) in patients with achondroplasia. This malformation predisposes to accidental puncture of the jugular bulb during tympanostomy tube placement.[65]
5. Avoid infant carriers and seated positions that "curl up" the infant or young child and avoid prolonged unsupported sitting.
6. Advise parents to use an infant seat or infant carrier that has a firm back (reduced padding) to support the neck and to use a rear-facing car safety seat for as long as possible.
   a. Car seat laws vary by state (and country), so inquiry with local experts (eg, police, hospital, or fire station where car seat installation clinics are offered) or online motor vehicle administration is recommended.
   b. Infants should not sleep unattended in car seats; this is especially important in those with achondroplasia because decreased axial tone and strength in combination with the large head creates great risk of craniocervical and airway compromise.
7. Be aware that external rotation of the hips is commonly present and usually disappears spontaneously when the child begins to bear weight. This finding does not require bracing for the infant.

8. Discuss the option of filing for Supplemental Security Income benefits as appropriate.

HEALTH SUPERVISION FROM 1 YEAR TO 5 YEARS: EARLY CHILDHOOD

Diagnosis, Genetic Counseling

1. Review genetics of achondroplasia as outlined in the Birth to 1 Month section, as needed.
2. Inquire about contact with support groups.

Medical Evaluation

1. Assess growth (length or height, weight, head circumference) and development in comparison only with children with achondroplasia (Figs 1–5).
2. Assess BMI on achondroplasia-specific charts[66] in accordance with AAP recommendations to measure BMI.
3. Perform physical examination, including neurologic examination.
4. Check motor development and discuss development; note on the milestone charts for achondroplasia.[20,22] Expect motor delay as compared with average-stature, age-matched children but not social or cognitive delay.
5. Continue to monitor for thoracolumbar kyphosis. Any kyphosis present should resolve as the child begins to bear weight. Lumbar lordosis usually develops but rarely requires specific intervention. Weight bearing and walking may occur late; however, they are expected by 2 to 2.5 years of age. When weight bearing begins, the external rotation of the hips should self-correct to a normal orientation within 6 months.
6. Anticipate some bowing of the legs. Many children will also have instability of the soft tissues surrounding the knee and internal tibial torsion. If positional deformity and instability leads to difficulty walking, a thrust at the knee (uncontrolled lateral or medial movement with weight bearing), or chronic pain, consult a pediatric orthopedist.
7. Check the child's hips for hip flexion contractures. Refer to physical therapy or pediatric orthopedics for exercise recommendation to decrease lumbar lordosis and hip flexion contractures if indicated. Stretching of the hip is performed gently so as not to cause subluxation.
8. Ensure that the patient has an audiology assessment every year in conjunction with establishment of care with an otolaryngologist.[62,64]
9. Ensure that the patient has a speech evaluation at no later than 2 years of age. If speech is delayed, conductive hearing loss attributable to chronic serous otitis media should be excluded.
10. Because most children with achondroplasia snore, monitor closely for signs of obstructive sleep apnea (increased retraction, glottal stops, choking, intermittent breathing, apnea, deep compensatory sighs, secondary enuresis, recurrent nighttime awakening or emesis) is recommended. If obstructive sleep apnea is suspected, then pulmonary consultation and polysomnography are indicated.
11. Be aware that gastroesophageal reflux disease may be more common in children with achondroplasia and may be more common in those with neurorespiratory complications.[67] In addition to usual treatments for gastroesophageal reflux disease, consider referral to a pediatric gastroenterologist or pulmonologist.
12. Do not misinterpret greater-than-average sweating as indicative of serious medical problems; it is normal in many children with achondroplasia, particularly while sleeping. But if there is sweating with eating or the sweating increases dramatically while sleeping and airway obstruction is observed, consider further evaluation with a sleep study.
13. In rare instances in which diagnosis of achondroplasia is delayed beyond 1 year of age, arrange for polysomnography for all individuals and neuroimaging on the basis of clinical signs and symptoms concerning for craniocervical compression, as discussed previously.

Anticipatory Guidance

1. Consider adapting the home so that the child can become independent (eg, lower the light switches, use lever door handles and lever sink faucets, make the toilet accessible, and supply step stools). Determine if an occupational therapy consultation is needed to help adapt the home.
2. Discuss adapting age-appropriate clothing with snapless, easy-opening fasteners and tuckable loops because children with achondroplasia have smaller fingers and shorter arms. Determine if an occupational therapy consultation is needed.
3. Discuss adaptation of toys, such as tricycles, to accommodate short limbs.
4. Discuss adaptation of toilets to allow comfortable, independent use. An extended wand for

wiping is rarely needed in this age group, provided surgical spinal fusion has not been performed. Discuss toileting at school and special preparations needed by the school because of the child's short stature.

5. Discuss the use of a stool during sitting so that the child's feet are not hanging. Feet need support while the child is sitting at a desk, in a chair, or on the toilet. A cushion behind the child's back may be required for good posture and to prevent chronic back pain.
6. Counsel parents for optimal protection to use a convertible rear-facing car safety seat to the highest weight and height allowed by the manufacturer of the seat.[68] A rear-facing seat provides the best support protection and positioning angle for a child with macrocephaly and skeletal dysplasia.
7. Review weight control and eating habits to avoid obesity, which often becomes a problem in mid to late childhood and through adulthood.
8. Discuss orthodontic bracing and the potential need for palatal expansion in the future.
9. Encourage all physical activities in which the child can participate safely. All children should avoid trampolines[69] and high-impact, body-contact, and collision sports.[70]
10. Discuss how to talk with the child and friends or family members about short stature.
11. Encourage preschool attendance so that the child can learn to socialize in an age-appropriate way, and work with parents to prepare the teacher and the other children so that the child is treated in an age-appropriate manner (ie, not dictated by the child's height).

HEALTH SUPERVISION FROM 5 TO 13 YEARS: LATE CHILDHOOD

Diagnosis, Genetic Counseling

1. Review genetics of achondroplasia as outlined in the Birth to 1 Month section, as needed.
2. Inquire about contact with support groups. They are especially useful at this age.

Medical Evaluation

1. Assess growth (height, weight, head circumference) and development in comparison only with children with achondroplasia (Figs 1–5).
2. Review weight control.[44,66] Encouraging and maintaining physical activity with dietary intake is important.
3. Complete a general and neurologically oriented physical examination.
4. Check deep tendon reflexes yearly for asymmetry or increased reflexes that suggest spinal stenosis.
5. Continue to assess history for possible obstructive sleep apnea (increased retraction, glottal stops, choking, intermittent breathing, apnea, deep compensatory sighs, secondary enuresis, recurrent nighttime awakening or emesis). If obstructive sleep apnea is suspected, then pulmonary consultation and polysomnography are indicated.
6. Ensure that formal hearing assessment is conducted as part of annual health maintenance for patients with achondroplasia,[62,64] with ear, nose, and throat follow-up should problems be identified.
7. Assess for pain and its effects on activities of daily living and desired physical activity.[26]

Anticipatory Guidance

1. Determine school readiness.
2. Discuss preparation of the school and teacher for a child with short stature. Suggest adaptive aids for the school to cope with heavy doors, high doorknobs, reaching for the blackboard, foot support, and a regular-sized desk. Also, be sure that the child can use the restroom independently.
3. Prepare the child for the questions and curiosity of others.
4. Assure the parents that children with achondroplasia usually are included in the regular education program.
5. Counsel parents to use a child safety seat with a full harness to the highest weight allowed by the manufacturer of the seat and then to transition to the belt-positioning booster seat for optimal seatbelt positioning.
6. Review socialization and foster independence.
7. Maintain orthopedic surveillance every 1 to 2 years or sooner, if problems occur.
8. Emphasize supported sitting in school desks and while doing homework to avoid kyphosis.
9. Develop an activity program with acceptable activities, such as swimming and biking. The child should avoid competitive gymnastics and collision sports because of the potential for neurologic complications secondary to cervical spinal stenosis.
10. Review orthodontic and speech status.

HEALTH SUPERVISION FROM 13 TO 21 YEARS OR OLDER: ADOLESCENCE TO EARLY ADULTHOOD

Diagnosis, Genetic Counseling

1. Discuss the diagnosis with the adolescent to be sure that he or she has the vocabulary and the understanding of the genetic nature of achondroplasia.
2. Discuss contraception. People with achondroplasia usually are fertile. The importance and use of

contraception should be discussed with both male and female adolescents with achondroplasia, just as it should be for average-stature adolescents. Tailored to the maturity and sexual activity of the adolescent or young adult, review recurrence risk counseling with the patient, as outlined in the Prenatal Visit section previously. The parents of adolescents or young adults may have heard this information for their recurrence risk counseling; now the adolescent needs this information for his or her reproductive decision-making. Ideally, discussions about prenatal testing, pregnancy, and delivery are conducted before conception occurs.[38]

3. Continue to encourage participation in social activities and support groups. It is particularly useful during this age period.
4. Per the published AAP guidelines for adolescent health, proceed with discussions regarding smoking, drug use, alcohol use, sexual activity, gender identity, exposure to weapons, food and shelter security, and a focus on bullying and psychological health.

Medical Evaluation

1. Continue to record growth parameters.
2. Review weight control and diet. Encouraging and maintaining physical activity with dietary intake is necessary.
3. Complete a general and neurologically oriented physical examination. Monitor for any signs or symptoms of nerve compression and check deep tendon reflexes, tone, and sensory findings.
4. Continue to assess for possible obstructive sleep apnea and obtain polysomnography on the basis of symptoms.
5. Formal hearing assessment is recommended as part of routine health care for patients with achondroplasia, ideally on an annual basis.
6. Assess for pain and its effects on activities of daily living and desired physical activity.

Anticipatory Guidance

1. Check on social adaptation. Foster independence.
2. Review orthodontic status.
3. Continue weight counseling.
4. Encourage the family and affected patient to set career and life goals high and appropriate, as for other members of the family.
5. Discuss college, vocational planning and training, and other plans after high school.
6. Discuss driving. A driver's license is obtainable. Drivers usually require a vehicle that is adapted with pedal extenders; extenders that can be easily mounted and removed as needed are available. Consultation with a local driver rehabilitation specialist or the Association for Driver Rehabilitation Specialists (http://www.aded.net/; phone 866-672-9466) may be helpful if vehicle modifications are needed. Individuals who want to have an air bag on-off switch must read an informational brochure and submit an official request to the National Highway Traffic Safety Administration (1-888-327-4236; www.nhtsa.gov).
7. Assist in transition to adult health care.

HEALTH SUPERVISION FOR ADULTS WITH ACHONDROPLASIA

Health supervision for adults with achondroplasia, which includes genetic counseling, medical concerns and surveillance, and anticipatory guidance, is multifaceted. Health supervision requires specific management recommendations based on the scope of the disease and symptomatology of the patient. Several of the key features that should be addressed in adulthood are included in the Prenatal Visit section for short-stature adults and noted in Table 1.

LEAD AUTHORS

Julie Hoover-Fong, MD, PhD, FACMG
Charles I. Scott, MD, FAAP
Marilyn C. Jones, MD, FAAP

COUNCIL ON GENETICS EXECUTIVE COMMITTEE, 2017–2018

Emily Chen, MD, PhD, FAAP, Co-Chairperson
Tracy L. Trotter, MD, FAAP, Co-Chairperson
Susan A. Berry, MD, FAAP
Leah W. Burke, MD, FAAP
Timothy A. Geleske, MD, FAAP
Rizwan Hamid, MD, PhD, FAAP
Robert J. Hopkin, MD, FAAP
Wendy J. Introne, MD, FAAP
Michael J. Lyons, MD, FAAP
Angela Scheuerle, MD, FAAP
Joan M. Stoler, MD, FAAP

FORMER EXECUTIVE COMMITTEE MEMBERS

Robert A. Saul, MD, FAAP, Chairperson
Debra L. Freedenberg, MD, FAAP
Marilyn C. Jones, MD, FAAP
Beth Anne Tarini, MD, MS, FAAP

LIAISONS

Katrina M. Dipple, MD, PhD – *American College of Medical Genetics*
Melissa A. Parisi, MD, PhD – *Eunice Kennedy Shriver National Institute of Child Health and Human Development*
Britton D. Rink, MD – *American College of Obstetricians and Gynecologists*
Joan A. Scott, MS, CGC – *Health Resources and Services Administration, Maternal and Child Health Bureau*
Stuart K. Shapira, MD, PhD – *Centers for Disease Control and Prevention*

STAFF

Paul Spire

ABBREVIATIONS

AAP: American Academy of Pediatrics
CSF: cerebrospinal fluid
FGFR3: fibroblast growth factor receptor type 3

FINANCIAL DISCLOSURE: Dr Hoover-Fong received research support from Alexion and BioMarin, participated on Alexion's advisory board (not related to achondroplasia), and has a consultancy and educational relationship with BioMarin (related to achondroplasia); and Drs Scott and Jones have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. American Academy of Pediatrics Committee on Genetics. Health supervision for children with achondroplasia. *Pediatrics*. 1995;95(3):443–451
2. Trotter TL, Hall JG; American Academy of Pediatrics Committee on Genetics. Health supervision for children with achondroplasia [published correction appears in Pediatrics 2005;116(6):1615]. *Pediatrics*. 2005;116(3):771–783
3. Shiang R, Thompson LM, Zhu YZ, et al. Mutations in the transmembrane domain of FGFR3 cause the most common genetic form of dwarfism, achondroplasia. *Cell*. 1994;78(2):335–342
4. Horton WA, Hall JG, Hecht JT. Achondroplasia. *Lancet*. 2007;370(9582):162–172
5. Rousseau F, Bonaventure J, Legeai-Mallet L, et al. Mutations in the gene encoding fibroblast growth factor receptor-3 in achondroplasia. *Nature*. 1994;371(6494):252–254
6. Bellus GA, Hefferon TW, Ortiz de Luna RI, et al. Achondroplasia is defined by recurrent G380R mutations of FGFR3. *Am J Hum Genet*. 1995;56(2):368–373
7. Wright MJ, Ain MC, Clough MV, Bellus GA, Hurko O, McIntosh I. Achondroplasia and nail-patella syndrome: the compound phenotype. *J Med Genet*. 2000;37(9):E25
8. Tanaka N, Katsumata N, Horikawa R, Tanaka T. The comparison of the effects of short-term growth hormone treatment in patients with achondroplasia and with hypochondroplasia. *Endocr J*. 2003;50(1):69–75
9. Hertel NT, Eklöf O, Ivarsson S, et al. Growth hormone treatment in 35 prepubertal children with achondroplasia: a five-year dose-response trial. *Acta Paediatr*. 2005;94(10):1402–1410
10. Miccoli M, Bertelloni S, Massart F. Height outcome of recombinant human growth hormone treatment in achondroplasia children: a meta-analysis. *Horm Res Paediatr*. 2016;86(1):27–34
11. Stamoyannou L, Karachaliou F, Neou P, Papataxiarchou K, Pistevos G, Bartsocas CS. Growth and growth hormone therapy in children with achondroplasia: a two-year experience. *Am J Med Genet*. 1997;72(1):71–76
12. MacDonald IM, Hunter AG, MacLeod PM, MacMurray SB. Growth and development in thanatophoric dysplasia. *Am J Med Genet*. 1989;33(4):508–512
13. Pauli RM. Achondroplasia. In: Cassidy SB, Allanson JE, eds. *Management of Genetic Syndromes*, 3rd ed. New York, NY: Wiley-Liss; 2010:9–32
14. Baker KM, Olson DS, Harding CO, Pauli RM. Long-term survival in typical thanatophoric dysplasia type 1. *Am J Med Genet*. 1997;70(4):427–436
15. Pauli RM. Achondroplasia. In: Pagon RA, Bird TD, Dolan CR, eds., et al *GeneReviews*. Seattle, WA: University of Washington; 1993
16. Horton WA, Rotter JI, Rimoin DL, Scott CI, Hall JG. Standard growth curves for achondroplasia. *J Pediatr*. 1978;93(3):435–438
17. Hecht JT, Butler IJ. Neurologic morbidity associated with achondroplasia. *J Child Neurol*. 1990;5(2):84–97
18. Pyeritz RE, Sack GH Jr., Udvarhelyi GB. Thoracolumbosacral laminectomy in achondroplasia: long-term results in 22 patients. *Am J Med Genet*. 1987;28(2):433–444
19. Ain MC, Chang TL, Schkrohowsky JG, Carlisle ES, Hodor M, Rigamonti D. Rates of perioperative complications associated with laminectomies in patients with achondroplasia. *J Bone Joint Surg Am*. 2008;90(2):295–298
20. Todorov AB, Scott CI Jr., Warren AE, Leeper JD. Developmental screening tests in achondroplastic children. *Am J Med Genet*. 1981;9(1):19–23
21. Fowler ES, Glinski LP, Reiser CA, Horton VK, Pauli RM. Biophysical bases for delayed and aberrant motor development in young children with achondroplasia. *J Dev Behav Pediatr*. 1997;18(3):143–150
22. Ireland PJ, Donaghey S, McGill J, et al. Development in children with achondroplasia: a prospective clinical cohort study. *Dev Med Child Neurol*. 2012;54(6):532–537
23. Kopits SE. Genetics clinics of the Johns Hopkins Hospital. Surgical intervention in achondroplasia. Correction of bowleg deformity in achondroplasia. *Johns Hopkins Med J*. 1980;146(5):206–209
24. Thompson NM, Hecht JT, Bohan TP, et al. Neuroanatomic and neuropsychological outcome in school-age children with achondroplasia. *Am J Med Genet*. 1999;88(2):145–153
25. Thompson S, Shakespeare T, Wright MJ. Medical and social aspects of the life course for adults with a skeletal dysplasia: a review of current knowledge. *Disabil Rehabil*. 2008;30(1):1–12
26. Alade Y, Tunkel D, Schulze K, et al. Cross-sectional assessment of pain and physical function in skeletal dysplasia patients. *Clin Genet*. 2013;84(3):237–243
27. Mortier GR, Cohn DH, Cormier-Daire V, et al. Nosology and classification of genetic skeletal disorders: 2019 revision. *Am J Med Genet A*. 2019;179(12):2393–2419
28. American Board of Medical Genetics. Verify certification. Available at: http://

www.abmgg.org/pages/searchmem.shtml. Accessed March 2, 2017

29. Little People of America. Little people of America. Available at: www.lpaonline.org/. Accessed March 2, 2017

30. Launay F, Younsi R, Pithioux M, Chabrand P, Bollini G, Jouve JL. Fracture following lower limb lengthening in children: a series of 58 patients. *Orthop Traumatol Surg Res*. 2013;99(1):72–79

31. Kim SJ, Agashe MV, Song SH, Choi HJ, Lee H, Song HR. Comparison between upper and lower limb lengthening in patients with achondroplasia: a retrospective study. *J Bone Joint Surg Br*. 2012;94(1):128–133

32. Schiedel F, Rödl R. Lower limb lengthening in patients with disproportionate short stature with achondroplasia: a systematic review of the last 20 years. *Disabil Rehabil*. 2012; 34(12):982–987

33. Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2): e20161484

34. Laederich MB, Horton WA. FGFR3 targeting strategies for achondroplasia. *Expert Rev Mol Med*. 2012;14:e11

35. Lorget F, Kaci N, Peng J, et al. Evaluation of the therapeutic potential of a CNP analog in a Fgfr3 mouse model recapitulating achondroplasia. *Am J Hum Genet*. 2012;91(6):1108–1114

36. Boulet S, Althuser M, Nugues F, Schaal J-P, Jouk P-S. Prenatal diagnosis of achondroplasia: new specific signs. *Prenat Diagn*. 2009;29(7):697–702

37. Krakow D, Lachman RS, Rimoin DL. Guidelines for the prenatal diagnosis of fetal skeletal dysplasias. *Genet Med*. 2009;11(2):127–133

38. Savarirayan R, Rossiter JP, Hoover-Fong JE, et al; Skeletal Dysplasia Management Consortium. Best practice guidelines regarding prenatal evaluation and delivery of patients with skeletal dysplasia. *Am J Obstet Gynecol*. 2018;219(6):545–562

39. Little People of America. Adoption. Available at: www.lpaonline.org/adoption-. Accessed March 8, 2013

40. Pauli RM, Conroy MM, Langer LO Jr., et al. Homozygous achondroplasia with survival beyond infancy. *Am J Med Genet*. 1983;16(4):459–473

41. Mettler G, Fraser FC. Recurrence risk for sibs of children with "sporadic" achondroplasia. *Am J Med Genet*. 2000; 90(3):250–251

42. Henderson S, Sillence D, Loughlin J, Bennetts B, Sykes B. Germline and somatic mosaicism in achondroplasia. *J Med Genet*. 2000;37(12):956–958

43. Sobetzko D, Braga S, Rüdeberg A, Superti-Furga A. Achondroplasia with the FGFR3 1138g–>a (G380R) mutation in two sibs sharing a 4p haplotype derived from their unaffected father. *J Med Genet*. 2000;37(12):958–959

44. Hoover-Fong JE, McGready J, Schulze KJ, Barnes H, Scott CI. Weight for age charts for children with achondroplasia. *Am J Med Genet A*. 2007;143A(19):2227–2235

45. White KK, Bompadre V, Goldberg MJ, et al. Best practices in the evaluation and treatment of foramen magnum stenosis in achondroplasia during infancy. *Am J Med Genet A*. 2016; 170A(1):42–51

46. Hecht JT, Horton WA, Reid CS, Pyeritz RE, Chakraborty R. Growth of the foramen magnum in achondroplasia. *Am J Med Genet*. 1989;32(4):528–535

47. Hecht JT, Nelson FW, Butler IJ, et al. Computerized tomography of the foramen magnum: achondroplastic values compared to normal standards. *Am J Med Genet*. 1985;20(2):355–360

48. Danielpour M, Wilcox WR, Alanay Y, Pressman BD, Rimoin DL. Dynamic cervicomedullary cord compression and alterations in cerebrospinal fluid dynamics in children with achondroplasia. Report of four cases. *J Neurosurg*. 2007;107(6 suppl):504–507

49. Mukherjee D, Pressman BD, Krakow D, Rimoin DL, Danielpour M. Dynamic cervicomedullary cord compression and alterations in cerebrospinal fluid dynamics in children with achondroplasia: review of an 11-year surgical case series. *J Neurosurg Pediatr*. 2014;14(3):238–244

50. Pauli RM, Scott CI, Wassman ER Jr., et al. Apnea and sudden unexpected death in infants with achondroplasia. *J Pediatr*. 1984;104(3):342–348

51. Reid CS, Pyeritz RE, Kopits SE, et al. Cervicomedullary compression in young patients with achondroplasia: value of comprehensive neurologic and respiratory evaluation. *J Pediatr*. 1987; 110(4):522–530

52. Hecht JT, Butler IJ, Scott CI Jr.. Long-term neurological sequelae in achondroplasia. *Eur J Pediatr*. 1984; 143(1):58–60

53. Pauli RM, Horton VK, Glinski LP, Reiser CA. Prospective assessment of risks for cervicomedullary-junction compression in infants with achondroplasia. *Am J Hum Genet*. 1995;56(3):732–744

54. Steinbok P, Hall J, Flodmark O. Hydrocephalus in achondroplasia: the possible role of intracranial venous hypertension. *J Neurosurg*. 1989;71(1): 42–48

55. Stokes DC, Phillips JA, Leonard CO, et al. Respiratory complications of achondroplasia. *J Pediatr*. 1983;102(4): 534–541

56. Julliand S, Boulé M, Baujat G, et al. Lung function, diagnosis, and treatment of sleep-disordered breathing in children with achondroplasia. *Am J Med Genet A*. 2012;158A(8):1987–1993

57. Mogayzel PJ Jr., Carroll JL, Loughlin GM, Hurko O, Francomano CA, Marcus CL. Sleep-disordered breathing in children with achondroplasia. *J Pediatr*. 1998; 132(4):667–671

58. Hall JG. Kyphosis in achondroplasia: probably preventable. *J Pediatr*. 1988; 112(1):166–167

59. Pauli RM, Breed A, Horton VK, Glinski LP, Reiser CA. Prevention of fixed, angular kyphosis in achondroplasia. *J Pediatr Orthop*. 1997;17(6):726–733

60. Borkhuu B, Nagaraju DK, Chan G, Holmes L Jr., Mackenzie WG. Factors related to progression of thoracolumbar kyphosis in children with achondroplasia: a retrospective cohort study of forty-eight children treated in a comprehensive orthopaedic center. *Spine*. 2009;34(16): 1699–1705

61. Wynn J, King TM, Gambello MJ, Waller DK, Hecht JT. Mortality in achondroplasia study: a 42-year follow-up. *Am J Med Genet A*. 2007;143A(21): 2502–2511

62. Tunkel DE, Kerbavaz R, Smith B, Rose-Hardison D, Alade Y, Hoover-Fong J. Hearing screening in children with skeletal dysplasia. *Arch Otolaryngol Head Neck Surg*. 2011;137(12): 1236–1239

63. White KK, Bompadre V, Goldberg MJ, et al; Skeletal Dysplasia Management Consortium. Best practices in peri-operative management of patients with skeletal dysplasias. *Am J Med Genet A*. 2017;173(10):2584–2595

64. Tunkel D, Alade Y, Kerbavaz R, Smith B, Rose-Hardison D, Hoover-Fong J. Hearing loss in skeletal dysplasia patients. *Am J Med Genet A*. 2012; 158A(7):1551–1555

65. Pauli RM, Modaff P. Jugular bulb dehiscence in achondroplasia. *Int J Pediatr Otorhinolaryngol*. 1999;48(2): 169–174

66. Hoover-Fong JE, Schulze KJ, McGready J, Barnes H, Scott CI. Age-appropriate body mass index in children with achondroplasia: interpretation in relation to indexes of height. *Am J Clin Nutr*. 2008;88(2):364–371

67. Tasker RC, Dundas I, Laverty A, Fletcher M, Lane R, Stocks J. Distinct patterns of respiratory difficulty in young children with achondroplasia: a clinical, sleep, and lung function study. *Arch Dis Child*. 1998;79(2):99–108

68. Durbin DR; American Academy of Pediatrics, Committee on Injury, Violence, and Poison Prevention. Child passenger safety. *Pediatrics*. 2011; 127(4). Available at: www.pediatrics.org/cgi/content/full/127/4/e1050

69. Briskin S, LaBotz M; Council on Sports Medicine and Fitness; American Academy of Pediatrics. Trampoline safety in childhood and adolescence. *Pediatrics*. 2012;130(4):774–779

70. Rice SG; American Academy of Pediatrics Council on Sports Medicine and Fitness. Medical conditions affecting sports participation. *Pediatrics*. 2008;121(4):814–848

Identification, Evaluation, and Management of Children With Autism Spectrum Disorder

• *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Identification, Evaluation, and Management of Children With Autism Spectrum Disorder

Susan L. Hyman, MD, FAAP,[a] Susan E. Levy, MD, MPH, FAAP,[b] Scott M. Myers, MD, FAAP,[c] COUNCIL ON CHILDREN WITH DISABILITIES, SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS

Autism spectrum disorder (ASD) is a common neurodevelopmental disorder with reported prevalence in the United States of 1 in 59 children (approximately 1.7%). Core deficits are identified in 2 domains: social communication/interaction and restrictive, repetitive patterns of behavior. Children and youth with ASD have service needs in behavioral, educational, health, leisure, family support, and other areas. Standardized screening for ASD at 18 and 24 months of age with ongoing developmental surveillance continues to be recommended in primary care (although it may be performed in other settings), because ASD is common, can be diagnosed as young as 18 months of age, and has evidenced-based interventions that may improve function. More accurate and culturally sensitive screening approaches are needed. Primary care providers should be familiar with the diagnostic criteria for ASD, appropriate etiologic evaluation, and co-occurring medical and behavioral conditions (such as disorders of sleep and feeding, gastrointestinal tract symptoms, obesity, seizures, attention-deficit/hyperactivity disorder, anxiety, and wandering) that affect the child's function and quality of life. There is an increasing evidence base to support behavioral and other interventions to address specific skills and symptoms. Shared decision making calls for collaboration with families in evaluation and choice of interventions. This single clinical report updates the 2007 American Academy of Pediatrics clinical reports on the evaluation and treatment of ASD in one publication with an online table of contents and section view available through the American Academy of Pediatrics Gateway to help the reader identify topic areas within the report.

INTRODUCTION

Autism spectrum disorder (ASD) is a category of neurodevelopmental disorders characterized by social and communication impairment and

abstract

[a]*Golisano Children's Hospital, University of Rochester, Rochester, New York;* [b]*Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; and* [c]*Geisinger Autism & Developmental Medicine Institute, Danville, Pennsylvania*

Drs Hyman, Levy, and Myers all participated in development of the outline of material to be covered, generation of content, and editing of the document; and all authors approved the final manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2019-3447

Address correspondence to Susan L. Hyman. E-mail: susan_hyman@urmc.rochester.edu

To cite: Hyman SL, Levy SE, Myers SM, AAP COUNCIL ON CHILDREN WITH DISABILITIES, SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS. Identification, Evaluation, and Management of Children With Autism Spectrum Disorder. *Pediatrics.* 2020;145(1):e20193447

restricted or repetitive behaviors.[1] ASD affects more than 5 million Americans, with an estimated prevalence of approximately 1.7% in children.[2] The care needs of children with ASD are significant, affect parents and siblings as well, and require substantial community resources. Direct and indirect costs of caring for children and adults with ASD in the United States in 2015 were estimated to be $268 billion, more than the cost of stroke and hypertension combined.[3] The lifetime cost of education, health, and other service needs for an individual with ASD ranges from $1.4 to $2.4 million dollars, depending on whether he or she has any co-occurring intellectual disabilities.[4] To deliver timely and effective medical, behavioral, educational, and social services across the lifespan means that primary care providers must understand the needs of individuals with ASD and their families. ASD is more commonly diagnosed now than in the past, and the significant health, educational, and social needs of individuals with ASD and their families constitute an area of critical need for resources, research, and professional education.

In the 12 years since the American Academy of Pediatrics (AAP) published the clinical report "Identification and Evaluation of Children With Autism Spectrum Disorders"[5] and its companion, "Management of Children With Autism Spectrum Disorders,"[6] reported prevalence rates of ASD in children have increased, understanding of potential risk factors has expanded, awareness of co-occurring medical conditions and genetic contribution to etiology has improved, and the body of research supporting evidence-based interventions has grown substantially. This updated clinical report builds on previous reports and guidance for care of children and youth with ASD. It also reflects changes in diagnostic criteria after publication of the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5)[1] in 2013. The DSM-5 established a single category of ASD to replace the subtypes of autistic disorder, Asperger syndrome, and pervasive developmental disorder not otherwise specified in the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (DSM-IV-TR). With the current reported prevalence rate of 1: 59 children (approximately 1.7%), all primary care providers can expect to have children and youth with ASD in their practices.[2] As noted in earlier clinical reports, the primary care provider has critical access to the child in the context of the medical home to identify symptoms of ASD early in childhood, support the family through the process of diagnosis and intervention, address etiologic evaluations, help the family understand how to interpret the evidence supporting different interventions so they can effectively engage in shared decision-making, and manage co-occurring medical conditions that may influence outcome and affect daily function. The primary care provider can help minimize disparities in age of diagnosis of African American and Hispanic children and be alert to the potential for gender bias in symptom recognition.[7] This updated document aims to provide primary care providers with a summary of current information in a single report that will help guide them in providing a medical home for the patient with ASD.

SECTION 1: PREVALENCE

Incidence is the onset of new diagnoses over time in a selected cohort. Without consistent longitudinal data in a specified cohort, incidence cannot be determined. Because of the heterogeneity of symptoms and severity in ASD, it may be diagnosed in children at different ages. What is reported is age at recognition of symptoms, not the actual onset. As a result, prevalence is more typically reported than incidence, reflecting rates of ASD in the population at a point in time.

The reported prevalence of children with ASD has increased over time, and primary care providers are often asked about the reasons for this increase. This increase may be attributable to several factors, including broadening in the diagnostic criteria with ongoing revisions of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM), the more inclusive definition of pervasive developmental disorder with the adoption of the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* (DSM-IV) in 1994,[8] increased public awareness of the disorder and its symptoms, recommendations for universal screening for ASD,[5,9] and increased availability of early intervention and school-based services for children with ASD. In part, the increasing numbers of children with a diagnosis of ASD may reflect diagnostic substitution, the recognition of ASD in children previously primarily diagnosed with intellectual disability or a co-occurring genetic syndrome.[10] A true increase in the prevalence of ASD associated with other biological risk factors is also possible.

Prevalence rates in US populations are similar to those of other industrialized countries,[11] and lower rates are reported in resource-limited countries, where epidemiological data are more difficult to collect.[12] Data on national samples suggest that the prevalence of ASD is stabilizing.[2,13] Ongoing epidemiological studies help to understand changes in the reported prevalence over time. Epidemiological data help to predict the need for services and identify potential risk factors. Surveillance methods include regional, state, and/or national registry systems;

records- or services-based analyses; surveys; and other methods, including population-based case findings.

In 2000, the US Centers for Disease Control and Prevention (CDC) established the Autism and Developmental Disabilities Monitoring (ADDM) Network as a population-based public health surveillance system to estimate the prevalence of ASD in children 8 years of age. ADDM reports published in 2014 and 2016 revealed comparable prevalence rates (approximately 1 in 68),[14,15] but the report published in 2018[2] revealed a slightly increased rate (1 in 59). Additional data over time will help determine if rates have stabilized. The data also revealed some variation in prevalence rates across the participating states, with the highest rates in the locations where both educational and health records were available for chart abstraction and standardized application of diagnostic criteria. Regional variation in prevalence may also reflect availability of services, local provider practices for ASD screening, educational policies, school and/or community resources, and insurance mandates, among other factors. The CDC also published data on the prevalence of ASD in children who were 4 years of age in 2010. A lower prevalence rate for diagnosis (1.34%) was reported in these children (approximately 30% less than that of children 8 years of age). The lower identified prevalence and higher proportional rate of children 4 years of age with ASD and intellectual disabilities may be attributable, in part, to later diagnosis of children with ASD and average-range cognitive abilities.[16] The National Survey of Children's Health (2011–2012) and the National Survey of Children with Special Health Care Needs (2009–2010) were analyzed for the age the parents reported diagnosis as well as for parent-reported subjective severity. The minority of children were identified as having ASD before 3 years of age. Diagnosis later than 6 years of age was reported in one-third to half of children. Later age at diagnosis was associated with reported mild presentation.[16]

CDC surveillance data published in 2014 revealed that white, non-Hispanic children were approximately 20% more likely to be identified with ASD before the case review than were non-Hispanic African American children and were about 50% more likely to be identified with ASD than were Hispanic children.[14] Recent prevalence data reveal increasing rates of ASD in Hispanic and African American children. This may reflect more widespread awareness of the symptoms among parents, schools, and health care providers and improved rates of screening in health supervision care.[2] Studies examining the effects of race and ethnicity on age at diagnosis are conflicting,[7] but earlier diagnosis of ASD is associated with higher socioeconomic status and access to services. African American and Hispanic children diagnosed with ASD by age 4 years were more likely to have coexisting intellectual disability than were white, non-Hispanic children, suggesting that some African American and Hispanic children with ASD and average to above-average intelligence may not have been identified.[17]

SECTION 2: CLINICAL SYMPTOMS

Despite advances in understanding the neurobiology and genetics of ASD, the diagnosis of ASD continues to be based on identifying and reporting behaviorally defined clinical symptoms. The challenges in determining accurate prevalence rates, in part, relate to the need for consistency in clinical diagnosis of a very heterogeneous disorder. In 2013, the DSM-5 consolidated the diagnosis of ASD into a single category and emphasized the importance of identifying coexisting developmental and behavioral disorders and symptoms. In the years since the 2007 AAP clinical reports on ASD, both professional education and public awareness have promoted recognition of symptoms that might lead to early identification of ASD, use of standardized screening approaches, and management of associated medical and behavioral features of ASD from infancy through adolescence.

Core Symptoms

Although symptoms of ASD are neurologically based, they manifest as behavioral characteristics that present differently depending on age, language level, and cognitive abilities. Core symptoms cluster in 2 domains (social communication/interaction and restricted, repetitive patterns of behavior), as described in the DSM-5.[1] Atypical development in several functional areas contribute to symptoms of ASD. Abnormalities in understanding the intent of others, diminished interactive eye contact, and atypical use and understanding of gesture presage atypical development of social communication and pretend play as well as interest in other children. Symptoms of ASD are further shaped by deficits in imitation and of processing information across sensory modalities, such as vision (gesture) and hearing (language). Repetitive behaviors and perseveration may be primary compulsions but may also be related to atypical processing of sensory information or may reflect a desire to instill predictability when an individual does not understand the intent of others. The CDC "Learn the Signs. Act Early" Web site provides free resources to help families recognize developmental concerns, including autism (https://www.cdc.gov/ncbddd/actearly/), and Autism Navigator (www.autismnavigator.com) has a video glossary of early symptoms in toddlers.

Approximately one-quarter of children with ASD will be reported to have a regression in language or social skills, most typically between 18 and 24 months of age.[18,19] The reason for this loss of previously acquired milestones is not yet known. Although medical evaluation of loss of milestones is indicated, a history of regression in language and social interaction in children with ASD within the expected age range is not likely to be attributable to seizures or neurodegenerative disorders. Note that the processes underlying regression are not yet well understood. Current theories include synaptic "over pruning" in response to genetic factors.[20]

Diagnostic Criteria: DSM-5

The DSM has been central in establishing criteria for diagnosing mental and behavioral disorders. The diagnosis of infantile autism was introduced in the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition* nearly 30 years after the first edition of the DSM was published in 1952. The initial descriptions were narrow and referred to individuals with profound impairment. Publication of the DSM-IV in 1994 expanded the diagnosis to a spectrum of symptoms called pervasive developmental disorders (PDDs), which included the diagnoses of autistic disorder, Asperger disorder, pervasive developmental disorder not otherwise specified (PDD-NOS), childhood disintegrative disorder, and Rett disorder. The PDDs included individuals with lower- and higher-functioning cognitive skills. PDD-NOS was a diagnostic category requiring some, but not all, of the core symptoms necessary for other diagnoses in this category. Subsequent research has demonstrated that the subgroupings within PDD were not reproducible across research sites by using the same diagnostic data[21,22] and were not stable over time. The overlap between DSM-IV–defined subgroups paired with inconsistency in their application across research sites supports the decision to consolidate the subgroups into 1 diagnostic category, ASD, in the DSM-5. The DSM-IV divided the symptoms of ASD into 3 areas: qualitative impairment of social reciprocity, qualitative impairment of communication, and restricted and repetitive behaviors. In the DSM-5, core symptoms were divided into 2 domains (social communication and social interaction and restrictive, repetitive patterns of behaviors).[23] To fulfill diagnostic criteria for ASD by using the DSM-5, all 3 symptoms of social affective difference need to be present in addition to 2 of 4 symptoms related to restrictive and repetitive behaviors. Examples in Table 1 are illustrative but not exhaustive. The recognition of symptoms of ASD related to sensory processing led to the inclusion of sensory symptoms, such as hyper- or hyporeactivity to sensory input or unusual interests in sensory aspects of the environment. Examples include apparent indifference to pain or temperature; sensitivity to sound, taste, or textures; and intense visual interest in objects or movement. The DSM-5 notes that a diagnosis may be made at older ages, when the demands of the social or school environment may result in functional impairment.

Almost all individuals with a diagnosis of autistic disorder or Asperger syndrome by using DSM-IV criteria would be diagnosed with ASD by using DSM-5 criteria.[24] To determine if the same patients would be identified by the DSM-IV and DSM-5 criteria, the CDC ADDM Network looked at its chart abstraction data on 8-year-old children.[25] This analysis revealed that more than 80% of children diagnosed with PDD-NOS would also be diagnosed with ASD.[25] It is possible that the narrative in the charts that were abstracted was influenced by knowledge of the DSM-IV criteria.[26] There is a high level of agreement of surveillance data by using DSM-IV-TR and DSM-5 criteria.

The DSM-5 criteria have been shown to appropriately identify younger children and those with mild symptoms.[25,27] These children with milder cognitive and adaptive symptoms may be the ones most likely to have significant change with early intervention services.

The DSM-5 also introduced an approach to severity rating, which is summarized in Table 2. Severity rating reflects the impairment of the ASD symptoms and the resultant service needs of the individual. Severity rating is not a quantifiable score that can be used to monitor progress at this time; in clinical use, it often reflects the impact of cognitive limitations.[28] Measures have been published that attempt to capture severity of core symptoms[29,30] and allow for measurement of improvement with intervention.[31] To date, no single measure adequately reflects the combination of medical, behavioral, and educational severity in a fashion that will help clinicians and families determine progress with intervention across multiple functional domains. Coexisting medical disorders also affect the perception of severity and the prognosis for children with a diagnosis of ASD. The DSM-5 includes course specifiers that help describe the variation in symptoms of individuals with ASD. Course specifiers include the presence or absence of intellectual impairment, language impairment, catatonia, medical conditions, and known genetic or environmental etiologic factors. Patients with Rett syndrome are no longer automatically considered to have a diagnosis of ASD according the DSM-5, although individuals with this neurogenetic disorder may also meet diagnostic criteria for ASD. Specific genetic causes of ASD should be recorded as specifiers for individuals with ASD when identified. The DSM-5 promotes

TABLE 1 DSM-5 Criteria for Autism Spectrum Disorder

Domains	Criteria: Deficits	Examples
A. Persistent deficits in social communication and social interaction across multiple contexts, as manifested by the following, currently or by history; must have all 3 symptoms in this domain	1. Social-emotional reciprocity	Abnormal social approach and failure of normal back-and-forth conversation; reduced sharing of interests, emotions, or affect; failure to initiate or respond to social interactions
	2. Nonverbal communicative behaviors used for social interaction	Poorly integrated verbal and nonverbal communication; abnormalities in eye contact and body language or deficits in understanding and use of gestures; total lack of facial expressions and nonverbal communication
	3. Developing, maintaining, and understanding relationships	Difficulties adjusting behavior to suit various social contexts; difficulties in sharing imaginative play or in making friends; absence of interest in peers
B. Restricted, repetitive patterns of behavior, interests, or activities, as manifested by at least 2 of the following, currently or by history; must have 2 of the 4 symptoms	1. Stereotyped or repetitive motor movements, use of objects, or speech	Simple motor stereotypies, lining up toys or flipping objects, echolalia, idiosyncratic phrases
	2. Insistence on sameness, inflexible adherence to routines, or ritualized patterns or verbal nonverbal behavior	Extreme distress at small changes, difficulties with transitions, rigid thinking patterns, greeting rituals, need to take same route or eat food every day
	3. Highly restricted, fixated interests that are abnormal in intensity or focus	Strong attachment to or preoccupation with unusual objects, excessively circumscribed or perseverative interest
	4. Hyper- or hyporeactivity to sensory input or unusual interests in sensory aspects of the environment	Apparent indifference to pain/temperature, adverse response to specific sounds or textures, excessive smelling or touching of objects, visual fascination with lights or movement

Symptoms must be present in the early developmental period (but may not become fully manifest until social demands exceed limited capacities or may be masked by learned strategies in later life). Symptoms cause clinically significant impairment in social, occupational, or other important areas of current functioning. These disturbances are not better explained by intellectual disability (intellectual developmental disorder) or global developmental delay. Intellectual disability and ASD frequently co-occur; to make comorbid diagnoses of ASD and intellectual disability, social communication should be below that expected for the general developmental level. Specify whether: with or without accompanying intellectual impairment, language impairment or associated with a known medical or genetic condition or environmental factor. Add code 293.89 if catatonia is also present.

notation of all coexisting diagnoses as specifiers.

Social pragmatic communication disorder is a new diagnosis described within the DSM-5 that describes individuals who exhibit functionally impairing symptoms in social language use but do not have habitual or repetitive behaviors.[1] Individuals who are affected must have deficits in using language for social purposes, impaired ability to match their communication style with the context for communication, difficulty following the conventional rules for conversation, and difficulty with idioms and unstated meanings in language (Table 3). As with ASD, the symptoms cannot be better explained by another DSM-5 diagnosis. Research and experience with DSM-5 diagnoses over time will give clinicians a better sense of how ASD and social communication disorder are similar and different in terms of etiology, prognosis, and treatment. Evaluation of pragmatic (social) language use by a speech-language pathologist provides additional information to consider this diagnosis.[32] The characteristics of social pragmatic communication disorder and how best to address symptoms require additional study.

Although the DSM-5 provides the criteria and definitions to accurately assign mental health and behavioral diagnoses, the *International Classification of Diseases, 10th Revision, Clinical Modification* is the standardized code set used for payment as well as for statistical tracking through electronic medical records. The *International Classification of Diseases, 10th Revision, Clinical Modification* continues to include the subtypes of diagnoses as defined by the DSM-IV.[33] The DSM-5 provides the clinician with criteria and definitions for diagnosis of ASD and should guide the clinician in the diagnosis and management of ASD.

Co-occurring Symptoms and Conditions

Co-occurring conditions are common in children with ASD and may have great effects on child and family functioning and clinical management (see also Section 5: Interventions). Examples include medical conditions such as sleep disorders and seizures; other developmental or behavioral diagnoses, such as attention-deficit/hyperactivity disorder (ADHD), anxiety, and mood disorders; and behavioral disorders, such as food refusal, self-injury, and aggression.[34] Approximately 30% of children with

TABLE 2 ASD Symptoms by Level of Severity

Severity Level	Social Affective	Restricted and Repetitive Behaviors
Level 1. "Requiring support"	Without supports in place, deficits in social communication cause noticeable impairments. Difficulty initiating social interactions, and clear examples of atypical or unsuccessful response to social overtures of others. May appear to have decreased interest in social interactions.	Inflexibility of behavior causes significant interference with functioning in one or more contexts. Difficulty switching between activities. Problems of organization and planning hamper independence.
Level 2. "Requiring substantial support"	Marked deficits in verbal and nonverbal social communication skills. Social impairments apparent even with supports in place. Limited initiation of social interactions and reduced or abnormal responses to social overtures from others.	Inflexibility of behavior, difficulty coping with change, or other restricted and repetitive behaviors appear frequently enough to be obvious to the casual observer and interfere with functioning in a variety of contexts. Distress and/or difficulty changing focus or action.
Level 3. "Requiring very substantial support"	Severe deficits in verbal and nonverbal social communication skills cause severe impairments in functioning, very limited initiation of social interactions, and minimal response to social overtures from others.	Inflexibility of behavior, extreme difficulty coping with change, or other restricted and repetitive behaviors markedly interfere with functioning in all spheres. Great distress at or difficulty with changing focus or action.

a diagnosis of ASD will also have intellectual disability,[2] and 30% are minimally verbal.[35] Increasingly, researchers and clinicians recognize how co-occurring disorders help identify phenotypic differences within populations affected by ASD, which can influence prognosis and choice of interventions.

Prognosis

The prognosis and trajectory of development for a young child diagnosed with ASD typically cannot be predicted at the time of diagnosis. However, most children (≥80%) who are diagnosed with ASD after a comprehensive evaluation at less than 3 years have retained their diagnosis.[36,37] It may be more difficult to recognize mild symptoms of ASD in children younger than 3 years of age, especially if they have average or above-average cognitive abilities.[38] Across early childhood development, communication skills and social affective symptoms may improve, whereas repetitive behaviors may change, possibly reflecting maturation and/or intervention.[39] In general, young children with ASD with language impairment appear to have more social difficulty than do children with ASD without language impairment. Children with ASD and intellectual disability have the most difficulty developing social competence.[40] The prognosis for children with ASD in phenotypic and demographic subgroups (eg, girls, racial and ethnic subgroups, children with macrocephaly) needs additional study.

Approximately 9% of children who are diagnosed with ASD in early childhood may not meet diagnostic criteria for ASD by young adulthood. Youth who no longer meet criteria for ASD are more likely to have a history of higher cognitive skills at 2 years of age, to have participated in earlier intervention services, and to have demonstrated a decrease in their repetitive behaviors over time.[41] A change in clinical diagnosis (eg, to ADHD or obsessive-compulsive disorder [OCD]) is more likely in children who were diagnosed with ASD before 30 months of age or had a diagnosis of PDD-NOS per the DSM-IV.[42,43] Severity scores are most likely to improve in youth who have had the greatest increase in tested verbal IQ.[44] Executive function difficulties

TABLE 3 DSM-5 Social (Pragmatic) Communication Disorder (DSM-5 315.39)

A. Persistent difficulties in the social use of verbal and nonverbal communication as manifested by all of the following:
   1. Deficits in using communication for social purposes, such as greeting and sharing information, in a manner that is appropriate for the social context.
   2. Impairment of the ability to change communication to match context or the needs of the listener, such as speaking differently in a classroom than on the playground, talking differently to a child than to an adult, and avoiding use of overly formal language.
   3. Difficulties following rules for conversation and storytelling, such as taking turns in conversation, rephrasing when misunderstood, and knowing how to use verbal and nonverbal signals to regulate interaction.
   4. Difficulties understanding what is not explicitly stated (eg, making inferences) and nonliteral or ambiguous meanings of language (eg, idioms, humor, metaphors, multiple meanings that depend on the context for interpretation).

B. The deficits result in functional limitations in effective communication, social participation, social relationships, academic achievement, or occupational performance, individually or in combination.

C. The onset of the symptoms is in the early developmental period (but deficits may not become fully manifest until social communication demands exceed limited capacities).

D. The symptoms are not attributable to another medical or neurologic condition or to low abilities in the domains or word structure and grammar and are not better explained by ASD, intellectual disability (intellectual developmental disorder), global developmental delay, or another mental disorder.

are associated with poorer adaptive outcomes, independent of IQ.[45] Measured intelligence (eg, IQ) and language ability in childhood tend to predict outcome in adulthood.[46] However, reported quality of life in high-functioning adults with ASD was associated more with the presence of family and community supports than their symptoms related to ASD.[47]

TABLE 4 Red Flags: Early Symptoms of ASD

	Symptom
By 12 months	• Does not respond to name
By 14 months	• Does not point at objects to show interest
By 18 months	• Does not pretend play
General	• Avoids eye contact and may want to be alone
	• Has trouble understanding other people's feelings or talking about their own feelings
	• Has delayed speech and language skills
	• Repeats words or phrases over and over (echolalia)
	• Gives unrelated answers to questions
	• Gets upset by minor changes
	• Has obsessive interests
	• Makes repetitive movements like flapping hands, rocking, or spinning in circles
	• Has unusual reactions to the way things sound, smell, taste, look, or feel

Information from this table is adapted from http://www.cdc.gov/ncbddd/autism/signs.html.

SECTION 3: SCREENING AND DIAGNOSIS

The AAP recommends screening all children for symptoms of ASD through a combination of developmental surveillance at all visits and standardized autism-specific screening tests at 18 and 24 months of age in their primary care visits[5] because children with ASD can be identified as toddlers, and early intervention can and does influence outcomes.[48] This autism-specific screening complements the recommended general developmental screening at 9, 18, and 30 months of age.[9] Efficient screening of all children would be aided by inclusion of valid screening tools in the electronic health record with appropriate compensation for the staff and professional time necessary to complete the administration, scoring, and counseling related to screening.[49]

Screening tools are designed to help caregivers identify and report symptoms observed in children at high risk for ASD. The screens are based on early manifestations of symptoms of core deficits related to social communication. Some of these early symptoms that may alert the provider to the risk for ASD have been called "red flags" (Table 4).

Developmental surveillance for ASD includes asking caregivers about concerns they have about their child's development or behavior, informal observation, and monitoring of symptoms in the context of routine health supervision. The "Learn the Signs. Act Early" parent resources developed by the CDC may help educate families about developmental and behavioral milestones (https://www.cdc.gov/ncbddd/actearly/index.html). Developmental surveillance alone is not sufficient to identify children who need further evaluation because children with ASD may not demonstrate characteristic symptoms in brief office visits,[50] and caregivers may not volunteer social and emotional concerns unless specifically asked. Use of a standardized screening tool for ASD can help families identify potential symptoms. In a large study evaluating universal screening with the Modified Checklist for Autism in Toddlers (M-CHAT), researchers asked physicians to note whether they were concerned about ASD. Sensitivity of physician clinical concern was low (0.244; 30 of 123 cases; 95% confidence interval 0.17–0.32). The sensitivity of the M-CHAT when used as directed in this low-risk population was 0.91.[51] Accurate early identification has been a goal of the AAP since the publication of the 2 previous autism clinical reports in 2007, with focused continuing medical education and a tool kit (AAP Autism Toolkit: https://toolkits.solutions.aap.org/toolkits.aspx). The goal of universal screening, including screening for ASD, has been supported by public health agencies[52] and family support organizations.[53] Rates of screening for both developmental delays and ASD in primary pediatric care have increased steadily. In the 2015 AAP survey of screening practices, almost three-quarters of pediatricians who responded reported routine ASD screening.[54] Pediatricians increasingly report including office staff for efficient workflow, including administration and scoring of screening tests. Although time and remuneration remain as concerns, fewer pediatricians rate these as barriers. Referral for and tracking of evaluation and services remain a challenge associated with lack of office-based systems for making referrals and after screen-positive outcomes.[43]

The authors of the 2019 AAP developmental surveillance and screening clinical report discuss strategies for billing for screening and counseling in primary care.[49] The following sections describe tools commonly used to screen and diagnose ASD and emphasize the importance of ongoing surveillance, especially in children at high risk.

Screening

Results of a screening test are not diagnostic; they help the primary care provider identify children who are at risk for a diagnosis of ASD and require additional evaluation. General developmental screening tools used for screening at ages 9, 18, and 30 months identify language,

cognitive, and motor delays but may not be sensitive to social symptoms associated with identification of ASD.[43,55] This limitation associated with general developmental screening is why ASD-specific tools[56] are needed to capture differences in social interaction, play, and repetitive behaviors. See the AAP clinical report "Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening,"[49] Table 1 (developmental screening tests; a description of general developmental and behavioral screening tests), and Table 5 in this report for resources and guidance on developmental screening.

Parent-completed questionnaires are the most common screening tests used in primary care. Commonly used autism-specific screening tools that are based on questionnaires and observation are summarized in Table 6. Many clinician-administered screening tests require specific training (eg, the Screening Tool for Autism in Toddlers and Young Children [STAT]).[5,57] A clinician-administered test like the STAT increases the likelihood of an ASD diagnosis on further testing and may be used to support a preliminary diagnosis of ASD to obtain services.[58] Identification of infants and toddlers at risk for ASD based on neurophysiologic makers or other biomarkers is discussed in the subsection The Biology of ASD in Section 4: Etiologic Evaluation.

Screening by Age Group

Children Younger Than Age 18 Months

Earlier diagnosis of ASD may lead to earlier treatment. The M-CHAT is the most studied and widely used tool for screening toddlers for ASD. Additional tools are under investigation and are listed in Table 6 as promising autism screening tests. Language delay can be identified by using the Infant and Toddler Checklist (parent questionnaire) in low-risk infants and toddlers between 12 and 18 months of age.[43,59] This questionnaire might be useful in identifying infant siblings of children with ASD who are at increased risk for ASD. Additional research may allow for screening of toddlers as young as 12 months by using parent-administered questionnaires such the Communication and Symbolic Behavior Scales Development Profile and the Infant and Toddler Checklist.[58]

Primary care providers are tasked with identifying all children who would benefit from early intervention, not just children at risk for ASD (see the AAP clinical report "Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening"[49] for further information). It is important to identify all clinically significant delays in children with referral for appropriate diagnostic evaluation and intervention. Problems with sleep, eating, constipation, and state regulation are common in the general population but may be particularly challenging in young children with ASD. Pediatricians can help families with management of these symptoms.

Children Ages 18 to 30 Months

The most commonly used questionnaire-based screening tool is the M-CHAT. It has been further validated, and the scoring has been modified for ease of administration in primary care settings for children ages 16 to 30 months.[51] The Modified Checklist for Autism in Toddlers, Revised with Follow-Up (Questions) (M-CHAT-R/F) eliminates 3 questions from the previous version. Children who score ≥8 are at high risk for ASD or another developmental disorder and should be referred immediately for diagnostic assessment. For children with scores of 3 to 7, publicly available scripted follow-up interview questions are required for the items scored as positive. Children who continue to have 3 to 7 items positive for ASD diagnosis after clarifying follow-up questions have a 47% risk of having ASD diagnosed and a 95% chance of being identified with some other developmental delay that would benefit from intervention. Children screened with the M-CHAT-R/F are identified with ASD at younger ages than predicted by national statistics.[49] Children who do not pass ASD screening tests or who score as at risk for a diagnosis should be referred for both diagnostic assessment and intervention services. A definitive diagnosis is not necessary to institute services for documented delays that would be served through early intervention or school services. Although the M-CHAT-R/F appears to be useful for general screening of diverse populations,[60] decreasing the disparity in early diagnosis will require adapting and validating measures and addressing cultural and linguistic barriers to screening.[61]

Measures under development may provide rapid screening while addressing clinician concerns for compatibility with an electronic record system and open access.[62]

TABLE 5 Resources and Guidance for Developmental Screening

- AAP *Bright Futures: Guidelines for the Health Supervision of Infants, Children, and Adolescents*
- AAP early childhood screening
- AAP clinical report: "Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening"[49]
- Additional guidance for developmental and behavioral screening can be found in "Birth to 5: Watch Me Thrive!" which contains helpful information for the primary care provider about how to present the results of developmental screening (available at: https://www.acf.hhs.gov/sites/default/files/ecd/pcp_screening_guide_march2014.pdf).

TABLE 6 Commonly Used ASD Screening Tests

Autism Screening Tests	Description	Age Range	Average No. Items	Administration Time	Forms Available EHR compatible	Psychometric Properties	Scoring Method	Cultural Considerations	Source	Key References
M-CHAT-R/F	Parent-completed questionnaire designed to identify children at risk for autism from the general population; follow-up clinician-administered questions and repeat questionnaire required for specificity	16–30 mo	20	5–10 min	Yes	Standardization sample included 16 071 children screened; 115 had positive screen results, 348 needed evaluation, 221 were evaluated, and 105 diagnosed with an ASD; validated by using the ADI-R, ADOS-G, CARS, and DSM-IV-TR; sensitivity: 0.91; specificity: 0.95 for low-risk 18- and 24-mo-old children with follow-up questionnaire and interview; 45% of children with a score ≥3 on the initial screen and ≥2 on follow-up had ASD; 95% had clinically significant developmental delay	Risk categorization for questionnaire (pass/need interview/ fail); after interview (pass/fail)	Available in multiple languages; see test information for details	http://mchatscreen.com/	Ref 51
SCQ	Parent-completed questionnaire; designed to identify children at risk for ASD from the general population; based on items in the ADI-R	4+ y	40	5–10 min	No	Validated by using the ADI-R and DSM-IV on 200 subjects (160 with pervasive developmental disorder, 40 without pervasive developmental disorder); for use in children with mental age of at	Risk categorization (pass/fail)	Available in multiple languages; see test information for details.	Western Psychological Corporation: www.wpspublish.com	Refs 77 and 572

TABLE 6 Continued

Autism Screening Tests	Description	Age Range	Average No. Items	Administration Time	Forms Available EHR compatible	Psychometric Properties	Scoring Method	Cultural Considerations	Source	Key References
						least 2 y and chronologic age 4+ y; available in 2 forms: lifetime and current. overall test: sensitivity: 0.85 (moderate), specificity: 0.75 (moderate); sensitivity can be improved with lowering cutoff for children younger than 5 y and 5–7 y, specificity poor for younger children				
STAT	Clinician-directed, interactive, and observation measure; requires training of clinician for standardized administration; not for population screening	24–35 mo; <24 mo (exploratory)	12	20–30 min	No	Validated by comparison with ADOS-G results in 52 children 24–35 mo (26 with autism, 26 with developmental delay); sensitivity: 0.83, specificity: 0.86, PPV: 0.77, NPV: 0.90, for <24 mo: sensitivity: 0.95, specificity: 0.73, PPV: 0.56, NPV: 0.97; screening properties improved for children >14 mo	12 activities to observe early social-communicative behavior; risk categorization (high risk/low risk)	English	http://stat.vueinnovations.com/	Refs 573 and 574
Promising autism screening tests										
The Infant/Toddler Checklist (Communication and Symbolic Behavior Scales	Parent questionnaire: screens for language delay	6–24 mo	24	15 min	No	PPV DD: 0.43 (6–8 mo); PPV DD: 0.79 (21–24 mo)	Identifies language delays (alone/with ASD); risk for ASD; risk status for social,	Available in multiple languages; see test	Paul H. Brookes Publishing Co Inc: 800-638-3775 or www.	Ref 59

TABLE 6 Continued

Autism Screening Tests	Description	Age Range	Average No. Items	Administration Time	Forms Available EHR compatible	Psychometric Properties	Scoring Method	Cultural Considerations	Source	Key References
Developmental Profile)							speech, symbolic composites, and total score	information for details	brookespublishing.com	
Early Screening for Autism and Communication Disorders	Parent questionnaire: research edition, 47 items	12–36 mo	47	10–15 min	No	Sensitivity: 0.85–0.91; specificity: 0.82–0.84; PPV: 0.55–0.81; NPV: 0.88–0.98	Investigation ongoing of subset (24 items)	English	https://firstwordsproject.com/screen-my-child/	Not in peer-reviewed literature
First-Year Inventory	Parent questionnaire; promising in high-risk population to identify risk in 12-mo-old infants	12 mo	63	10 min	No	Sensitivity, specificity, PPV not reported	Scores at risk; promising in high-risk (infant sibling) cohort (Rowberry et al[575])	English	https://www.med.unc.edu/ahs/pearls/research/first-year-inventory-fyi-development/	Ref 575
Parent's Observations of Social Interactions	Parent questionnaire used to assess autism risk; ASD screening included on 18-, 24-, and 30-mo The Survey of Well-Being of Young Children: forms	16–35 mo	7	~5 min	Available through patient tools, epic, and CHADIS; available for free download as pdfs from www.theswyc.org	Sensitivity: 83%–93%, average 88.5%; specificity: 42%–75%, average 56.9%	3 of 7 symptoms in at-risk range	Available in multiple languages; see test information for details	Free download from www.theswyc.org	Publications and User's Manual available at www.theswyc.org; Refs 576 and 577
Rapid Interactive Screening Test for Autism in Toddlers 13	Clinician observation: administered by trained examiner	12–36 mo	9 interactive items	20–30 min	No	Cutoff >15; sensitivity: 1; specificity: 0.84; PPV: 0.88; NPV: 0.94; needs further study in larger samples	9 interactive activities; total score summed, cutoff score of 15 (for that sample)	English	https://umassmed.edu/AutismRITA-T/about-the-test/	Ref 578

The AAP does not approve/endorse any specific tool for screening purposes. This table is not exhaustive, and other tests may be available. ADOS-G, Autism Diagnostic Observation Schedule – Generic; CARS, Childhood Autism Rating Scale; CHADIS, Comprehensive Health and Decision Information System; EHR, electronic health record; ICD-10, *International Classification of Diseases, 10th revision*; IMFAR, International Meeting for Autism Research; NPV, negative predictive value; PPV, positive predictive value.

Further adaptations of the Communication Symbolic Behavior Scale for use in screening for language delays in addition to ASD have the potential to identify children at risk for both disorders (functional communication; ages 6–24 months).[49,59] Use of this or other screening tools may be coupled with the online support of a video glossary of symptoms of ASD, such as that in the Autism Navigator (http://www.autismnavigator.com/). These and other online approaches to support screening strategies may be integrated into efficient patterns of practice. Results of screening conducted online, in community settings, and in preschools should be communicated to the primary care provider to ensure appropriate evaluation of etiology, co-occurring conditions, referral for diagnosis, and follow-up to ensure that intervention is accessed.[49]

A systematic review by the US Preventive Services Task Force (USPSTF) concluded that the literature on existing screening tools did not demonstrate sufficient specificity to justify universal screening.[63] The USPSTF noted that no study has directly examined whether children with ASD detected by early screening have better outcomes than those detected by other means. However, such a study would require random assignment of large representative samples from across the country to either a screening or nonscreening condition, with follow-up of long-term outcomes and societal costs. Given that early treatment of children younger than 36 months has been shown to result in positive outcomes,[43,64] such a study would be challenging to support. The USPSTF concluded that further research is indicated to evaluate the appropriate ages and populations of children who should be screened for ASD and that more accurate and culturally sensitive measures should be developed. The AAP continues to recommend screening using the most valid of current measures at 18 and 24 months of age. Pediatricians cannot assume that early intervention systems will screen participants being served for language or global delays for ASD at the recommended ages. Universal screening is recommended because symptoms of ASD can be identified in early childhood, and a diagnosis of ASD by skilled professionals is accurate in children as young as 18 months of age.[65] Diagnostic stability is high for children who are diagnosed with ASD at 18 to 36 months of age.[43] Early screening does not identify many children with milder symptoms and typical cognitive ability as at risk for ASD; therefore, ongoing surveillance remains necessary.[16] Participation in early intervention in general is greatest among children who had screening and surveillance.[66]

Children Older Than 30 Months

At present, for children older than 30 months, there are no validated screening tools available for use in pediatric practice, nor are there current recommendations by the AAP for universal screening for ASD in that age group. The Social Communication Questionnaire (SCQ) (see Table 6) has been studied in different populations (eg, clinical sample, population reference sample, community sample, and convenience sample), with best results in population samples[67] when using the lifetime version, and appears to have reasonable psychometric properties. However, questionnaires like the SCQ may identify symptoms that overlap with other conditions, such as ADHD, that affect function at school age.[68,69] Further validation of population-based screening tools for children older than 30 months is needed before recommendations for universal screening of school-aged children can be made. At this time, ongoing surveillance in the context of primary care is recommended.

Barriers to Identifying Risk for ASD

Children with milder symptoms and/or average or above-average intelligence may not be identified with symptoms until school age, when differences in social language or personal rigidities affect function. Some children who are later diagnosed with ASD are initially believed to have precocious language, reading, or math skills, and it is not until the social demands of school that the social language symptoms become problematic. It has also been suggested that girls may have lesser intensity of symptoms and fewer externalizing behaviors. These differences may, in part, result in underdiagnosis in girls.[70] Specific coexisting conditions may prevent clinicians from recognizing symptoms of ASD in early childhood. For example, 1 study revealed that children who were initially identified with ADHD in primary care were diagnosed with ASD 3 years later compared with children who did not have earlier symptoms of ADHD.[69] Recognition and referral for older children with social-skill deficits would be facilitated by the development of accurate and brief screening tests for use in primary care and school settings.

Population surveillance data reveal later age at diagnosis for African American and Hispanic children, suggesting that there are barriers to screening and surveillance and referral for diagnosis in groups with other unmet health needs.[2] Race, ethnicity, and socioeconomic status did not affect the accuracy of routine screening tests for ASD in low-risk toddlers, suggesting that screening with appropriate supports for follow-up care can lower the age at diagnosis in diverse populations.[60] Language barriers, inaccurate translations, and low parental literacy may compromise use of parent-completed questionnaires.[71] Limited understanding of cultural differences experienced by the patient's family

and lack of trust in the health care provider may further limit identification and reporting of symptoms of autism.[72] Screening tools need to be developed for populations of individuals whose primary language is not English and who are also sensitive to cultural barriers that may limit reporting of symptoms of ASD.[73]

Diagnostic Evaluation

Once a child is determined to be at risk for a diagnosis of ASD, either by screening or surveillance, a timely referral for clinical diagnostic evaluation and early intervention or school services, depending on his or her age, is indicated.[74] Children with developmental delay with or without an ASD diagnosis should be referred to early intervention or school services, in which cognitive and language testing may be completed. The primary care provider should discuss with the family the importance of both the assessment of developmental status and evaluation for an ASD diagnosis and assist the family in navigating through the process, including connecting them with community resources. Families with low income or language barriers may need additional attention to take the next steps.

Although most children will need to see a specialist, such as a developmental-behavioral or neurodevelopmental pediatrician, psychologist, neurologist, or psychiatrist, for a diagnostic evaluation, general pediatricians and child psychologists comfortable with application of the DSM-5 criteria can make an initial clinical diagnosis. Having a clinical diagnosis may facilitate initiation of services. At this time, there are no laboratory tests that can be used to make a diagnosis of ASD, so careful review of the child's behavioral history and direct observation of symptoms are necessary.[75,76] To meet diagnostic criteria, the symptoms must impair function. Formal assessment of language, cognitive, and adaptive abilities and sensory status is an important component of the diagnostic process.

Short clinical visits may not allow even a skilled clinician the opportunity to accurately recognize symptoms of ASD.[50] An accurate history needs to reflect a longitudinal experience with the individual and reflect the effects of symptoms on the patient's ability to function in family, peer, and school settings. This history is obtained by interview with the patient and caregivers, reports of behavior in other environments (such as school), and descriptions of behavior during formal testing. The history of symptoms of ASD can be supported by questionnaires such as the SCQ[77] or Social Responsiveness Scale (SRS).[78] None of these questionnaires is sufficient alone to make a diagnosis of ASD, but all provide a structured approach to elicit symptoms of ASD. Measures such as the Behavior Assessment System for Children,[79] Diagnostic Interview for Social and Communication Disorders (DISCO),[80,81] and the Child Behavior Checklist[82] are used to assess children and youth for other behavioral health conditions but may also identify behavioral profiles consistent with ASD.

In some clinical and research settings, the behaviors associated with ASD are reported through the Autism Diagnostic Inventory-Revised (ADI-R), a lengthy, semistructured parent interview.[83,84] It supports a knowledgeable clinician in applying diagnostic criteria of ASD. The SCQ was designed to elicit similar information to the ADI-R in an abbreviated questionnaire format. The SRS is a 65-item questionnaire that may be used to measure autistic traits on a continuum as part of a more complete evaluation of ASD.[78,85] Elevated scores may be seen with greater severity of symptoms of ASD as well as with intellectual disability, communication difficulties, and behavioral challenges.

Structured observation of symptoms of ASD during clinical evaluation is helpful to inform the diagnostic application of the DSM-5 criteria. Validated observation tools used to provide structured data to confirm the diagnosis include the Autism Diagnostic Observation Schedule, Second Edition (ADOS-2) and the Childhood Autism Rating Scale, Second Edition (CARS-2).[86] No single observation tool is appropriate for all clinical settings. The observation tool is meant to support application of the DSM-5 criteria informed by history and other data.

The ADOS-2 was developed to elicit atypical social language and behaviors. With the ADOS-2, modules are specific for use across the age span of toddlers to adults.[87,88] The ADOS-2 requires intensive training to accurately administer and score and takes 30 to 45 minutes to administer. It is often a component of both research and clinical evaluations. The information obtained from the ADOS-2 is used by the clinician in conjunction with the history of peer interactions, social relationships, and functional impairment from symptoms to determine if the DSM-5 criteria are met. The CARS-2 is another structured approach a clinician might use to support a clinical diagnosis of ASD.[89] The clinician completes a 15-point scale that is based on history and observation. The ADOS-2, CARS-2, and SRS (Parent and Teacher) all rate children similarly in approximately half of identified cases.[90] The integration of historical information and objective observation by a clinician trained to diagnose autism and related conditions to inform the DSM-5 diagnostic criteria is the

critical element to diagnostic evaluation.

Evaluation of Co-occurring Developmental Conditions

Patients with ASD may have intellectual disabilities, learning disabilities, ADHD, anxiety disorders, or speech and language disorders, among others. These conditions may influence the presentation of the symptoms of ASD. These conditions may influence the presentation of symptoms of ASD and may influence the social and functional impairment of the individual in different ways at different ages. Valid assessment of cognitive and language ability is an important component of the diagnostic evaluation. In the United States, early intervention services and school systems will evaluate children in these domains to assess educational needs. In some areas, initial evaluations are performed in clinical settings and paid for by insurance.

Cognitive Testing

A range of standardized measures are used to determine developmental levels of younger children and IQ in children older than 3 years. The intelligence test selected by the psychologist will depend on the age and language level of the child. Administration of a valid cognitive test is important in ascribing symptoms to ASD as part of the initial diagnosis but also helps to establish co-occurring diagnoses with ASD, such as intellectual disability. There are valid tests that can be used in children who are nonverbal. Although the prevalence of a diagnosis of ASD is increased in children with an intellectual disability,[91] other children diagnosed with intellectual disability may have some symptoms of ASD without meeting diagnostic criteria for the disorder.

Language Testing

Inherent in the core symptoms of ASD are differences in the use of verbal and nonverbal communication for social interaction. Formal assessment of communication by a speech or language pathologist at the time of diagnosis should include the documentation of expressive and receptive language skills as well as the pragmatic or conversational use of language.[92]

Adaptive Function Testing

A caregiver report and/or teacher report of adaptive functioning complements objective cognitive testing. Determining the extent that ASD affects daily function is necessary to establish eligibility for some publicly funded programs as well as to identify and monitor developmental goals for treatment. Adaptive behaviors are typically delayed in people who have intellectual disability with ASD but can be impaired in people with ASD and an average-range IQ.[93,94] Commonly used adaptive measures include the Vineland Adaptive Behavior Scales and the Adaptive Behavior Assessment System.[95]

Motor Assessment

Children with ASD are more likely to have mild delays in gross motor skills and coordination compared with children in the general population and may meet DSM-5 criteria for developmental coordination disorder in addition to ASD.[96] General screening tests or adaptive measures may suggest motor delays that would benefit from formal evaluation by an occupational or physical therapist. A relationship of early motor delays and subsequent language and adaptive development in children with ASD has been proposed.[97,98]

Sensory Assessment: Hearing

Children with language delay or inattention to language should have an evaluation of their hearing as part of their initial evaluation.[99] Hearing loss may co-occur with ASD and needs to be considered in children with language delays, behavior problems, or inattention. Appropriate amplification should be offered, if indicated. The clinical utility of auditory processing evaluations available in current practice remain an area of study.[100,101]

Sensory Assessment: Vision

Visual function should be considered in the initial evaluation of children who are visually inattentive, have stereotypical behaviors (such as eye poking or close visual scrutiny), or do not make eye contact. Decreased visual acuity may affect interactive gaze and require accommodations in the educational setting.[102] Children with visual impairment may also demonstrate stereotyped motor behaviors.

Sensory Assessment: Sensory Processing

The DSM-5 includes sensory symptoms in the diagnostic criteria for ASD. The DSM-5 does not include sensory processing disorder as a discrete diagnosis. Commonly used evaluation tools (such as the Short Sensory Profile and others) quantify parent perception of sensory differences relative to smell, taste, vision, hearing, and touch.[103,104] In addition to capturing what is conventionally considered as a sensory disturbance, questionnaires that are used to assess sensory symptoms also capture motor hyperactivity and hypoactivity as sensory-seeking or sensory-avoiding behaviors. These latter symptoms may reflect co-occurring ADHD. Sensory symptoms may be more evident at younger ages and may define subtypes of the disorder.[105,106]

SECTION 4: ETIOLOGIC EVALUATION

Children with a diagnosis of ASD should be assessed for potential etiology and common coexisting medical conditions. At the time of the 2007 AAP clinical reports on autism, karyotype and DNA testing for fragile X syndrome were the state-of-the-art

etiologic investigations. Soon thereafter, chromosomal microarray (CMA) was endorsed by the American College of Medical Genetics and Genomics and the American Academy of Child and Adolescent Psychiatry as the most appropriate initial test for etiologic evaluation of children with ASD.[76,107–110] Despite rapid technological advances in neuroimaging and other areas, many of the recommendations for clinical evaluation published in 2007 are unchanged. This section summarizes recent advances in understanding the etiologies of ASD and how they translate into recommendations for clinical practice.

Medical Workup of the Child With ASD

Genetic Testing

Advances such as the development of CMA and next-generation sequencing technologies and the application of these technologies to well-characterized patient cohorts have led to progress in the understanding of the complex genetics of ASD and other neurodevelopmental disorders in the last decade. Identifying a genetic etiology provides clinicians with more information for families about prognosis and recurrence risk and may help to identify and treat or prevent co-occurring medical conditions, guide patients and families to condition-specific resources and supports, and avoid ordering unnecessary tests (Table 7).[111–117] Most parents find this information to be useful.[118] As research progresses, genetic testing may contribute to identifying effective interventions related to specific etiologies.

Etiologic investigation begins with a careful medical, developmental-behavioral, and family history and a thorough physical and neurologic examination.[109] The history should include potential prenatal exposure to teratogens (such as medications, alcohol, drugs) and other factors that increase risk for ASD.[109,119] The physical examination should include assessment of growth relative to typical curves (including head circumference), dysmorphic features, organomegaly, skin manifestations of neurocutaneous disorders (eg, tuberous sclerosis and neurofibromatosis), and neurologic abnormalities.[109] Genetic evaluation should be recommended and offered to all families as part of the etiologic workup. A stepwise general approach is provided in Table 8 as a practical guideline.[110,120] The presence of dysmorphic features or intellectual disability is generally associated with

TABLE 7 Potential Benefits of Establishing a Genetic Etiologic Diagnosis

- Improving accuracy of counseling provided to patients and families:
  - o Prognosis or expected clinical course
  - o Recurrence risk for the family and the individual affected
- Providing condition-specific family support, such as:
  - o Improving psychosocial outcomes for patients and their families (eg, knowledge and sense of empowerment, parental quality of life)
- Preventing morbidity and treating medical conditions associated with the genotype, such as:
  - o Conditions or anomalies likely to be present at diagnosis
  - o Conditions that may develop later
- Refining treatment options, including:
  - o Avoiding therapeutic interventions that may be based on unfounded etiologic theories
  - o Avoiding ineffective or potentially harmful treatments
  - o Providing access to emerging etiology-specific treatments
- Facilitating acquisition of needed services and access to research treatment protocols
- Avoiding additional diagnostic tests, which may be unnecessary, expensive, and/or uncomfortable

Adapted from Sun F, Oristaglio J, Levy SE, et al. *Genetic Testing for Developmental Disabilities, Intellectual Disability, and Autism Spectrum Disorder*. Rockville, MD: Agency for Healthcare Research and Quality (US); 2015; Amiet C, Couchon E, Carr K, Carayol J, Cohen D. Are there cultural differences in parental interest in early diagnosis and genetic risk assessment for autism spectrum disorder? *Front Pediatr*. 2014;2:32; Srivastava S, Cohen JS, Vernon H, et al. Clinical whole exome sequencing in child neurology practice. *Ann Neurol*. 2014;76(4):473–483; Iglesias A, Anyane-Yeboa K, Wynn J, et al. The usefulness of whole-exome sequencing in routine clinical practice. *Genet Med*. 2014;16(12):922–931; Lingen M, Albers L, Borchers M, et al. Obtaining a genetic diagnosis in a child with disability: impact on parental quality of life. *Clin Genet*. 2016;89(2):258–266; Riggs ER, Wain KE, Riethmaier D, et al. Chromosomal microarray impacts clinical management. *Clin Genet*. 2014;85(2):147–153; and ACMG Board of Directors. Clinical utility of genetic and genomic services: a position statement of the American College of Medical Genetics and Genomics. *Genet Med*. 2015;17(6):505–507.

TABLE 8 Genetic Etiologic Investigations in Patients With ASD

Step	Genetic Etiologic Investigations
1	Consider referral for pediatric genetics evaluation
2	Comprehensive history (including 3-generation family history with emphasis on individuals with ASD and other developmental, behavioral and/or psychiatric, and neurologic diagnoses) Physical examination (including dysmorphology, growth parameters [including head circumference], and skin examination) • If syndrome diagnosis or metabolic disorder is suspected, go back to step 1 (genetics and/or metabolism referral) and/or order the appropriate targeted testing • Otherwise, proceed to step 3
3	Laboratory studies • Discuss and offer CMA analysis • Discuss and offer fragile X analysis; if family history is suggestive of sex-linked intellectual disabilities, refer to genetics for additional testing • If patient is a girl, consider evaluation for Rett syndrome, *MECP2* testing • If these studies do not reveal the etiology, proceed to step 4
4	Consider referral to genetics, workup might include WES

Adapted from Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. *Genet Med*. 2013;15(5):399–407; Srivastava S, Love-Nichols JA, Dies KA, et al; NDD Exome Scoping Review Work Group. Meta-analysis and multidisciplinary consensus statement: exome sequencing is a first-tier clinical diagnostic test for individuals with neurodevelopmental disorders [published online ahead of print June 11, 2019]. *Genet Med*. and Shevell M, Ashwal S, Donley D, et al; Quality Standards Subcommittee of the American Academy of Neurology; Practice Committee of the Child Neurology Society. Practice parameter: evaluation of the child with global developmental delay: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2003;60(3):367–380.

increased likelihood of finding a genetic abnormality.[121] However, authors of some clinical studies have identified similar yield for genetic testing in children without these risk factors.[122,123]

In some cases, individuals with clinical genetic syndromes, such as fragile X syndrome, tuberous sclerosis complex, and others (such as those described in Supplemental Table 13), also meet criteria for ASD.[124,125] When a specific syndrome or metabolic disorder is suspected, the clinician should proceed with the appropriate targeted testing or referral to a pediatric geneticist or neurologist. For example, a girl with significant developmental delays, deceleration in head growth velocity, and characteristic midline hand movements should prompt genetic testing for a mutation or deletion or duplication of *MECP2*, the gene implicated in Rett syndrome.[109,126] Another specific example would be a boy with ASD with marked macrocephaly and pigmented macules on the penis, findings that would warrant sequencing and deletion or duplication analysis of the *PTEN* gene.[127] Descriptions of these and other clinical syndromes associated with ASD are provided in Supplemental Table 13.

CMA is recommended if the etiology for developmental disability is not known. CMA identifies copy number variants (CNVs) at this time, which are DNA duplications or deletions that alter the function of genes (Table 8, step 2). CMA reveals a definitively pathogenic CNV in 5.4% to 14% (median 9%) of individuals with ASD in clinical samples.[121,128–135] When CNVs of uncertain significance are included, approximately 17% to 42% of patients with ASD have findings on the CMA. Some of the variants of uncertain significance may be determined as pathogenic in the future. The most commonly identified recurrent pathogenic CNVs among individuals with ASD are provided in Supplemental Table 14.

Because fragile X syndrome increases risk for ASD, DNA testing for fragile X syndrome should be recommended for all children with ASD, but especially for boys and children with a suggestive family history of male members with intellectual disability. Physical examination might reveal the common features of a large head size, prominent jaw, large ears, ligamentous laxity, and, in male patients, large testes after puberty. The cytosine-guanine-guanine trinucleotide repeat expansion that is responsible for fragile X syndrome is not detected on CMA and must be ordered as a separate test. The current estimate is that approximately 0.45% of individuals with ASD have the full mutation for fragile X syndrome, and many of them are female.[130,132,135–137] Because fragile X syndrome testing is relatively inexpensive and the condition has important genetic counseling implications, it is reasonable to consider testing both male and female patients with ASD, at least until more data become available to clarify the issue.

When the history and physical examination, CMA, and fragile X analysis do not identify an etiology, the next step at this time in the etiologic evaluation for ASD is whole-exome sequencing (WES). WES technology allows for the identification of single-nucleotide variants, including pathogenic loss-of-function mutations and missense mutations, which have been found to be associated with ASD.[138–142] Examples of ASD risk genes identified or confirmed in WES studies are provided in Supplemental Table 15. As with other tests, clinicians ordering this test should be familiar with both pretest counseling and interpretation of the results. A genetic counselor is helpful in explaining the reason for testing as well as the results. Large clinical WES studies have consistently been used to identify a molecular diagnosis in 26% to 29% of individuals for whom neurodevelopmental disorders were the primary indication for testing.[143–145] Authors of studies of clinical populations with ASD have reported diagnostic yields of 8% to 20%.[121,144] The yield of WES is higher when both the parents and the child who is affected are evaluated[144] to allow for comparison of the child with parents who are unaffected.

Some geographic areas may have limited availability of pediatric subspecialists (eg, in genetics or metabolism) who can guide the genetic workup, so primary care providers may be in the position to consider and direct etiologic evaluation. The complexity of genetic testing is such that most primary care providers may want to consult with a specialist to plan testing and interpret results. The clinical etiologic evaluation should be tailored to the individual patient, taking into consideration information from the history and physical examination[109,110] and the values and wishes of the family. The stepwise general approach summarized in Table 8 can be used to guide this process.

It is important for families to understand that genetic tests may explain the cause of their child's ASD or provide information about the statistical risk of ASD, but they are not diagnostic of ASD; the diagnosis of ASD is made on the basis of clinical symptoms. Unlike CMA and WES, commercially marketed tests may not have the potential to provide a molecular etiologic diagnosis. Genomic testing technology is evolving rapidly, as is our understanding of the genetic architecture of ASD, and these recommendations for testing will need to be updated as new studies are published.[146] For example, it is anticipated that CMA and WES will soon be combined because of

improvements in accurate identification of CNVs using sequence data and that sequencing of the exome will be replaced by sequencing of the entire genome as issues with interpretation and cost become more manageable.[121,130,147–150]

Parents of a child with ASD should be counseled regarding recurrence risk in subsequent offspring, and the nature of the counseling depends greatly on whether a specific genetic cause of the child's ASD has been identified. When a specific genetic etiology has been determined, the family can be provided with information about the risk of recurrence in subsequent offspring. However, when genetic testing has not been completed or has not revealed the etiology of the child's ASD, recurrence risk counseling is based on group averages derived from the existing literature. For a couple with 1 child with ASD of unknown cause, the current best estimate of recurrence in a subsequent child is approximately 10% (range 4%–14%[151–153]). If a couple already has ≥2 children with ASD of unknown etiology (idiopathic), the chance of a subsequent child having ASD may be as high as 32% to 36%.[151,154] However, the risk is not limited to ASD. Siblings of children with ASD who do not have ASD themselves may have a 20% to 25% risk for language disorders and other neurodevelopmental and psychiatric disorders.[152,155,156]

Neuroimaging

Specific clinical neuroimaging findings are not more prevalent in ASD compared with other neurodevelopmental disorders, nor do specific abnormalities correlate with clinical, etiologic, or pathophysiological aspects of ASD.[120,157,158] Incidental findings are common in neuroimaging studies obtained in the workup of children diagnosed with ASD but rarely provide etiologic information or require intervention.[159,160] The need for clinical MRI should be directed by a history and physical examination. MRI may be indicated in the evaluation of atypical regression, microcephaly, macrocephaly, seizures, intracranial manifestations of genetic disorders, abnormal neurologic examination, or other clinical indications.[76,109,161,162] Imaging technology used to examine brain structure and function provides valuable insight into the neurobiology of ASD in research settings and may lead to useful clinical applications in the future.

Metabolic Testing

The yield of routine metabolic testing for children with ASD is low and not recommended for regular use.[163–167] However, large population-based studies are lacking, so accurate prevalence and diagnostic yield estimates are not available. Metabolic workup should be informed by history, family history, symptoms, and examination and might include measurement of fasting plasma amino acid levels, urine organic acid levels, and acylcarnitine metabolite levels and other testing for specific metabolic disorders. History of atypical regressions (later than 2 years of age, motor regression, or multiple regressions), family history of early childhood death or diagnosed metabolic disorders, and physical features, such as significant hypotonia or weakness, visual and hearing impairment, and dysmorphic features, would suggest consultation with a specialist to guide evaluation for metabolic or mitochondrial disorders.[109,168] Children who present with motor delay should be evaluated with creatine kinase and thyroid-stimulating hormone testing, according to AAP recommendations.[9,49] Although metabolic disorders are uncommon causes of ASD, the potential impact is high because treatment may be available and the inheritance pattern may be known.[109,124] Examples of metabolic conditions that may be associated with an ASD phenotype are provided in Supplemental Table 16. There is no evidence at this time for routine testing of hair, blood, or urine for environmental toxins or heavy metals outside of laboratory screening for lead exposure.[169]

EEG

Children with ASD have an increased risk for seizures, and EEG abnormalities are common in the absence of clinical seizures (see Seizures section for more information).[170–175] However, EEG is not recommended as a routine baseline evaluation in the absence of clinical concern about seizures, atypical regression, or other neurologic symptoms on history or examination that would suggest an EEG is indicated.[161,170,172,176] Late or atypical loss of language, as might be observed in electrical status epilepticus of sleep with loss of language, should be evaluated with an overnight EEG.[161,170,172,176] Primary care clinicians should discuss the increased risk and the signs and symptoms of seizures with the families of children diagnosed with ASD, maintain a high index of clinical suspicion for seizures, and consult with a pediatric neurologist when concerned about atypical regression or the possibility of seizures.[170,172,176]

The Biology of ASD

Genetics and ASD

ASD is clinically and etiologically heterogeneous yet highly heritable. The rate of ASD in siblings is much higher than the rate in the general population. Twin studies demonstrate substantially higher concordance rates for symptoms of ASD in monozygotic twins than in dizygotic twins.[177] A meta-analysis involving 6413 twin pairs revealed a 98% concordance in monozygotic twins, a 53% to 67% concordance in dizygotic twins, and heritability estimates from 64% to 91%.[177,178]

Siblings may also be at risk for symptoms related to ASD that do not meet the threshold for a diagnosis of ASD and have been described as the broader autism phenotype.[141,179] These data provide strong evidence for a genetic contribution to ASD risk.[180–184]

Risk for ASD also is increased in the children of both older fathers and older mothers.[185–187] The increased risk with parental age may be related to germline mutations in older fathers.[143,188] Mechanisms mediating the effect of advancing maternal age on ASD risk are less clear.[143] Increased maternal and paternal age are independently associated with ASD risk, and a joint effect seems to occur as well.[185–187]

Important aspects of the genetics of ASD are still poorly understood, including the role of common variants, epistasis (gene-gene interactions), and environmental modification of genotype effects. In contrast, advances such as CMA and next-generation sequencing technologies have resulted in identification of large-effect (pathogenic) rare variants that appear to be causally associated with ASD, including CNVs, which are deletions or duplications ≥1000 bp in size that alter the dosage of genes, and sequence-nucleotide variants.[189–192] Pathogenic rare variants may arise de novo or be inherited as autosomal dominant, autosomal recessive, or X-linked mutations. Researchers of CMA and WES studies have established that although de novo and inherited rare variants of large effect size are collectively common, no individual pathogenic variant accounts for more than 1% of cases of ASD.* Genes that contribute to ASD are involved in a variety of biological functions, with convergence on aspects of brain development and function, including synaptic structure and function, intracellular signaling, transcription regulation, and chromatin remodeling.[139,190,191,196] It is important to note that no specific mutation has been identified that is unique to ASD; there is substantial genetic overlap between ASD and other neurodevelopmental disorders, including intellectual disability, epilepsy, and schizophrenia.[197–204]

Genes, Environmental Exposures, and ASD

The potential environmental factors that may be related to increased reported prevalence of ASD is an area of active study that, as yet, is without firm conclusions.[119] Environmental factors associated with ASD include in utero exposure to medications such as valproate and thalidomide. Other prenatal influences, such as short interpregnancy interval, multiple gestation, maternal obesity, gestational bleeding, gestational diabetes, advanced parental age, and infections (eg, rubella and cytomegalovirus), may be associated with increased risk for ASD.[205–209] Perinatal factors, such as preterm birth, low birth weight, fetal growth restriction (ie, small for gestational age), intrapartum hypoxia, and neonatal encephalopathy, are associated with increased ASD risk.[205,210–212] Environmental factors may present independent risk to prenatal brain development or may affect gene function in individuals with genetic predisposition.[213] Population-level associations with ASD have been examined for organophosphates and certain other pesticides, metals, volatile organic compounds, and air pollution, particularly particulate matter and nitrogen dioxide.[214–216] Research on environmental exposures may be of great importance in identifying modifiable risk factors related to ASD and other developmental disorders. It is prudent to limit exposure of children and pregnant women to known neurotoxicants.

Genes, Immunologic Exposures, and ASD

It has been proposed that children with ASD-associated CNVs may be more susceptible to environmental insult in the form of maternal immune activation. Report of maternal infection or fever during pregnancy may be associated with increased severity of ASD-related symptoms in offspring who are affected.[217] The pathogenic role of circulating maternal antibodies directed to fetal brain tissue and the potential value of maternal antibody panels as biomarkers of ASD are currently being studied.[218–222] Unless otherwise indicated (eg, history suggestive of autoimmune or immunologic disorder), no immune testing is recommended in the etiologic workup of a child with ASD.

Epigenetics

Epigenetic modifications, such as DNA methylation and posttranslational histone modification, produce heritable changes in gene expression that do not involve a change in the DNA sequence. Some genetic disorders associated with ASD (eg, Rett syndrome; CHARGE syndrome; 15q duplication; Angelman syndrome; and fragile X syndrome), involve genes that either encode epigenetic regulators or are sensitive to alterations in their epigenetic regulation.[223,224] Because epigenetic modifications can be influenced by environmental factors, such as prenatal maternal exposures and postnatal experience, they represent 1 interface between genes and environment. However, epigenetic modifications are not the only mechanisms by which gene expression is regulated, and epigenetics should not be conflated with the broader category of environmental effects.[223,225] Currently, the evidence that alteration of gene expression by environmental factors plays a causal role in ASD is very limited.[223–228] Investigation of

* Refs 121, 144, 189–195.

the role of epigenetic and other nongenetic modifications that alter gene activity without changing the DNA sequence is an active area of etiologic research in ASD.

Vaccines

The scientific literature does not support an association of vaccination as an environmental factor that increases the risk for ASD. Children with ASD should be vaccinated according to the recommended schedule. Epidemiological studies do not demonstrate any association of the measles-mumps-rubella vaccine, mercury exposure by thimerosal-containing vaccines, aluminum in vaccines, or increased level of immunologic exposure attributable to a larger number of vaccines (either given at 1 time or cumulatively) with ASD.[214,229–246] Vaccines used for children in the United States have not contained thimerosal since 2001. The authors of a 2012 Cochrane review[234] and a 2014 quantitative meta-analysis of pooled data from cohort studies involving 1 256 407 children and case-control studies involving 9920 children reviewed the scientific literature and came to this conclusion.[231] Evidence implicating immunizations as a "second hit" conferring ASD risk in genetically susceptible subgroups is lacking. It has been shown that the measles-mumps-rubella vaccine is not associated with increased risk for ASD, even among children who are already at higher risk because of having an older sibling with ASD.[229] Media coverage of vaccine issues may inflate the perception of uncertainty by equal coverage of vaccine proponents and opponents. The overwhelming weight of evidence supports vaccine safety.[247] Communicating information about vaccine safety is a critical component of pediatric practice.[248]

Brain Structure and ASD: Neuropathology

Neuropathological research has been limited by the small number of postmortem brains available for study. Developmental brain abnormalities in people with ASD are reported in the cerebral neocortex; limbic system structures, including the hippocampal formation and amygdala; basal ganglia; thalamus; brainstem; and cerebellum. These brain abnormalities include dysplasia, altered neurogenesis, and abnormal neuronal migration.[249–251] The vast majority of abnormalities described originate during prenatal brain development.[249,251,252] Findings in the cerebral cortex may include focal disruption of neuronal migration, minicolumnar abnormalities, and variations in neuronal density.[249,251,252] A decreased number of Purkinje cells in the cerebellum is 1 of the most consistently reported neuropathologic findings associated with ASD. Although it was initially thought to be of prenatal onset, evidence now indicates that this phenomenon is more likely to be an acquired process that occurs postnatally, potentially related to seizures, medications, and/or ischemia near the time of death or factors other than ASD.[249] No uniform neuropathology has been identified in people with ASD.

Biomarkers

Objectively measured biological characteristics, or biomarkers, of ASD could potentially be used to predict ASD risk, enhance screening, and permit presymptomatic detection. Their use could improve the reliability and validity of clinical diagnosis (identifying clinically meaningful subgroups that would allow for prediction of prognosis or treatment response), identify mechanisms for developing treatment, and confirm the need for a specific intervention.[221,253–255]

Early Brain Overgrowth

Cross-sectional and longitudinal studies suggest that as a group, children later diagnosed with ASD may have an average or below-average head circumference at birth, with an acceleration in brain growth before 2 years of age.[256] This rapid brain growth leads to significantly above-average head circumferences and MRI brain volumes in toddlers, followed by a plateau in brain growth, with brain volumes in adolescence and adulthood similar to those of controls.[257,258] Almost 16% of young children with ASD have a head circumference greater than the 97th percentile.[258] A preliminary study suggested that infant siblings of children with ASD who exhibited a larger head circumference at 12 months and showed more slowing of head circumference growth from 12 to 24 months had an increased chance of demonstrating symptoms of ASD.[259,260] Although this finding raises the possibility that patterns of brain growth might be used for early identification, the rate of head growth did not predict which infants developed ASD in the first 3 years of life in a large prospective study of high-risk infants.[261] It is possible that a large head size is unrelated to ASD and/or may be part of general somatic overgrowth.[262–265]

Neuroimaging Patterns Associated With ASD in Research Studies

Although there are conflicting findings, structural MRI volumetric studies suggest that young children with ASD differ from controls in total brain volume, cortical gray and white matter volume (particularly frontal, temporal, and cingulate cortices), extraaxial cerebral spinal fluid volume, and amygdala volume.[266–271] A research-level analysis also has identified asymmetries in multiple brain structures in people with ASD.[272] Diffusion tensor imaging has been used to identify altered patterns in white matter by 6 months of age in

infants later diagnosed with ASD.[270,273] Functional MRI has demonstrated differences in people with ASD relative to controls in efficiency of visual processing, executive function, language, and basic and complex social processing skills.[274,275] Functional MRI in research settings demonstrate differences in the mechanisms of attention to social stimuli, modulation in response to task demands or intensity of stimuli, and executive function in people with ASD.[274] Functional underconnectivity has also been demonstrated across a wide variety of the brain regions that support language, executive function, social cognition, emotion processing, and motor tasks, especially for long-range, frontal-posterior networks.[274,276,277]

Electrophysiologic Testing and Measurement of Eye Tracking

Electrophysiologic research studies demonstrate differences in auditory processing (including language processing), visual processing (including face processing), somatosensory response, multisensory integration, attentional shifting, selective attention, recognition memory, and neural connectivity in people with ASD.[278–281] Continuous measures of resting-state and task-related quantitative EEG are used to calculate and describe spectral power, complexity, and coherence. Although promising, the clinical utility of these measures as biomarkers requires additional study.[279] Eye tracking has been used to determine if infants who are younger siblings of children with ASD and, therefore, at increased risk for ASD exhibit differences in fixation on faces.[282-284] Preliminary evidence suggests that infants later diagnosed with ASD exhibit a decline in gaze fixation from age 2 to age 6 months.[285]

Other Potential Biomarkers

Although some studies have attempted to differentiate people with and without ASD on the basis of differences in laboratory profiles of platelet serotonin, plasma melatonin, urine melatonin sulfate, redox status, placental trophoblast inclusions, and immune function, currently no diagnostic laboratory tests have been approved for ASD.[286,287] To date, none of these potential biomarkers under study has sufficient evidence to be recommended.

Biomarkers: Future Directions

Proposed biomarkers for ASD risk include genetic and biochemical findings in blood, urine, or brain tissue; placental pathology; maternal autoantibody profiles; structural and functional MRI patterns; electrophysiological test results on EEG, including event-related potentials; responses in eye tracking; and physical parameters such as head circumference growth trajectory. Although none of these proposed biomarkers has demonstrated sufficient predictive validity for clinical use at this time,[221,253–255,288] the search for biomarkers is a major research focus. Biomarker research has important ethical issues,[253] and concerns have appropriately been raised regarding premature translation of research data into commercially available tests marketed to patients and families.[221,253,289,290] However, the capabilities to screen large numbers of bioactive compounds, examine the entire genome, and simultaneously analyze large data sets have accelerated research into the neurobiology of ASD and may result in the identification of valid biomarkers.[221,255,291]

SECTION 5: INTERVENTIONS

The goals of treatment of children with ASD are to (1) minimize core deficits (social communication and interaction and restricted or repetitive behaviors and interests)[1] and co-occurring associated impairments[292-294]; (2) maximize functional independence by facilitating learning and acquisition of adaptive skills; and (3) eliminate, minimize, or prevent problem behaviors that may interfere with functional skills.[6,295,296] Treatments should be individualized, developmentally appropriate, and intensive, with performance data relevant to treatment goals to evaluate and adjust intervention.[6,297] All interventions should be based on sound theoretical constructs, rigorous methodologies, and objective scientific evidence of effectiveness. Since the publication of the 2007 AAP clinical reports on autism, a substantial published literature has examined the effectiveness of interventions.[48,295,297,298] Legal mandates in education law in the United States, which include the Individuals with Disabilities Education Improvement Act of 2004 (IDEA) (Public Law 108–446) and the No Child Left Behind Act of 2001 (Public Law 107–110) and its successor, the Every Student Succeeds Act of 2015 (Public Law 114–95), require the use of practices supported by scientifically based research (IDEA and the No Child Left Behind Act of 2001) or evidence-based practices (Every Student Succeeds Act of 2015) (https://www.ed.gov/). Early intervention services under part C of IDEA provide for assessment and intervention for children younger than 3 years with developmental delays, including ASD.

Interventions for children with ASD are provided through educational practices, developmental therapies, and behavioral interventions. Treatment strategies may vary by the age and strengths and weaknesses of the child. For example, intervention for a toddler with a recent diagnosis of ASD may include behavioral and developmental approaches (individually or in the context of

comprehensive approach) and, as he or she progresses, involvement in a specialized or typical preschool program. For older children, intervention is more likely to occur in educational settings, with integration of behavioral and developmental therapies to promote skill development. In addition to variation by age of the child, interventions differ in theoretical approach and scope (eg, focused and targeted or comprehensive), settings and/or modality of delivery (eg, individual versus group or classroom, delivered by a professional versus a trained parent, and school versus home setting), and targets of intervention.[48,297] Interventions may be provided through public and/or not-for-profit agencies, schools, and early intervention services, and some may be paid for through insurance.[299] Families should be involved in the selection of intervention approaches and remain an involved participant in subsequent educational and therapeutic decisions. There is regional variation in the availability of various types of therapy and providers that sometimes results in long waits for service, less-than-desired intensity, or inability to obtain a desired intervention altogether. By law, students with ASD should receive an appropriate educational program, although it may not include all of the components desired by the family. Advocacy is often necessary to obtain desired services through schools or through mechanisms paid for by insurance. It is noted that many of the interventions in common use do not have a strong evidence base. Some types of intervention may not be paid for by insurance.

Systematic reviews of the evidence base for treatment have been completed on early intensive intervention,[44,300] medical treatments,[301] behavioral interventions,[294,298] and evidence-based practice guidelines.[292,302]

Wong et al[295] described 2 categories of evidence-based interventions, the comprehensive treatment model (CTM) and focused interventions. These interventions may be provided in different settings (eg, the home, classroom, naturalistic environment, or community), by different providers (eg, developmental specialist, behavioral therapist, educator, or trained parent), individually or in group settings, and by using a set curriculum or guide.

The CTM uses a central conceptual framework to address a broad array of symptoms and is designed to address specific skill(s) or symptom(s). A CTM should be replicable, intense, and designed to address multiple therapeutic goals over a period of time. Provision of services may occur in individual instruction or class settings (specialized or inclusive), should include parents, and may involve technology-assisted intervention.[303]

Applied behavior analysis (ABA), developmental approaches, and/or naturalistic approaches may be used in CTMs.[303] Examples of CTMs include early intensive behavioral intervention, Treatment and Education of Autistic and Related Communication-Handicapped Children (TEACCH), and the Early Start Denver Model (ESDM).[295,303]

Focused intervention practices are designed to address a single or limited range of skills, such as increasing social communication or learning a specific task, and may be delivered over a short period of time.[295,297,303] Focused intervention practices may be behavioral, developmental, and/or educational. Focused interventions may be grounded in principles of ABA, in which specific skills are taught in a stepwise progression by using principles of reinforcement or developmental theory, in which the emerging skills inherent in neurobehavioral maturation are promoted. These interventions are provided in a structured setting by an adult, in naturalistic environments with peers, or as a component of a more comprehensive approach.[295] Focused interventions may be effective for promoting skill development and communication.[295,297,304,305]

Pediatricians may be asked to advise families on therapy choices or write prescriptions for therapies.[306] It is helpful for clinicians to have an understanding of intervention terminology and of the evidence base so they can effectively communicate the rationale for medically indicated treatment recommendations with families, educators, therapists, and other service providers as well as with insurance companies, health care administrators, funding agencies, and policy makers.[295]

This report describes various types of interventions provided for children and youth with ASD. Additional research is needed to evaluate the effectiveness of current approaches and develop interventions that address core deficits of ASD. At the time of diagnosis, parents of young preschool children may ask their provider to help them decide what type of intervention they should elect. Two common theoretical approaches to intervention for symptoms of ASD are ABA and developmental models.[296–298,307] Although these approaches have important distinctions, they also have significant overlap, and interventions increasingly are incorporating aspects of both. There is considerable regional variation in the availability of various interventions. Table 9 describes common characteristics of empirically supported interventions.[296,297,308,309]

Approaches to Intervention

ABA

Most evidence-based treatment models are based on principles of ABA. ABA has been defined as "the

TABLE 9 Characteristics of Effective Interventions

Features of Practice	Common Characteristics of Empirically Supported Interventions
Assessment and goals	Systematically assess skills
	Include input of family (shared decision-making)
	Select individualized measurable goals and instructional procedures on the basis of objective assessment of each child
	Use assessment-based, empirically supported instructional methods to build, generalize, and maintain skills and reduce problem behaviors
Instructional methods	Address core symptoms in social communication and restricted and repetitive behaviors as well as skill deficits
	Provide a student/teacher ratio low enough to address the child's individualized goals
	Interventions should be by providers who are properly trained and should maintain fidelity with the treatment approach selected
	Ensure that multiple providers work collaboratively
Services and supports	Individualize services and support
	Make use of the child's interests and preferences in determining reinforcement systems
	Incorporate preferred activities to increase engagement in activities
Environment	Provide a structured learning environment that helps children anticipate transition between activities, including a predictable routine and visual activity schedules
	Organize workspaces to minimize distraction and promote task completion
	Limit access to things that may distract a student
	The environment should promote opportunities for the student to initiate communication and interact with peers
Behavioral management	Implement a functional behavioral analysis to identify the reasons why challenging behaviors occur and develop a behavior improvement plan based on this assessment (IDEA-mandated approach)
	Teach children more appropriate responses using the behavior improvement plan
Progress	Systematically measure and document the individual child's progress
	Adjust instructional strategies as necessary to enable acquisition of target skills
Family support	Involve and educate families so they can use the behavioral strategies at home and in the community
Transition planning	Plan for transitions in school settings and to adulthood (eg, from home-based early intervention to preschool services, preschool to elementary school, elementary school to middle school, middle school to high school, high school to work or postsecondary education, and home to community living)

Adapted from Smith T, Iadarola S. Evidence base update for autism spectrum disorder. *J Clin Child Adolesc Psychol.* 2015;44(6):897–922; Myers SA, Pipinos II, Johanning JM, Stergiou N. Gait variability of patients with intermittent claudication is similar before and after the onset of claudication pain. *Clin Biomech (Bristol, Avon).* 2011;26(7):729–734; and Myers SM. Management of autism spectrum disorders in primary care. *Pediatr Ann.* 2009;38(1):42–49.

process of systematically applying interventions based upon the principles of learning theory to improve socially significant behaviors to a meaningful degree, and to demonstrate that the interventions employed are responsible for the improvement in behavior."[310] The use of ABA methods to treat symptoms of ASD suggests that behaviors exhibited can be altered by programmatically reinforcing skills related to communication and other skill acquisition.[311,312] Thus, ABA treatments may target development of new skills (eg, social engagement) and/or minimize behaviors (eg, aggression) that may interfere with a child's progress.

ABA interventions vary from highly structured adult-directed approaches (eg, discrete trial training or instruction, verbal behavior applications, and others) to interventions in natural environments that may be child led and implemented in the context of play activities or daily routines and activities and are altered on the basis of the child's skill development (eg, pivotal response training, reciprocal imitation training, and others).[297,309,312,313] To determine what intervention is most appropriate, the behavioral clinician works with the family and child to determine which skills to target for development and maintenance and what goals are appropriate.

ABA programs are typically designed and supervised by professionals certified in behavior analysis. The majority of states at this time have licensure for board-certified behavior analysts with provisions for payment by insurance. ABA may be prescribed or recommended by a physician or licensed psychologist.

A comprehensive ABA approach for younger children, also known as early intensive behavioral intervention, is supported by a few randomized controlled trials (RCTs) and a substantial single-subject literature.[297] When only RCTs are considered, few interventions have sufficient evidence to be endorsed either for children younger than 12 years[298] or for adolescents.[314]

Children younger than 12 years receiving more hours per week of ABA were found to be more likely to achieve the individualized goals identified in their programs.[315] In retrospective studies, more intense ABA therapy was associated with achieving optimal developmental outcomes.[316] Given the heterogeneity of the ASD phenotype, the service needs of children, youth, and adults need to be individualized by using available clinical data.

In some instances, a behavioral intervention is needed to address acute serious problem behaviors that

must be given priority, for example, because of safety issues.[295] Whether a student is getting formal ABA under IDEA or not, a family can request that challenging behaviors be evaluated in the school setting by using behavioral principles through a functional behavioral assessment. The target symptoms to treat may then be divided into component parts that are addressed in a stepwise fashion (task analysis).[313,317] Once the reasons for the behavior are understood, a behavior improvement plan may be implemented.

Developmental Relationship–Focused Interventions

Intervention for young children also may be derived from developmental theory, which is focused on the relationship between the caregiver's level of responsiveness and the child's development of social communication.[296,318–320] Through interaction with others, children learn to communicate and regulate emotions and establish a foundation for increasingly complex thinking and social interaction. Therefore, developmental models designed to promote social development in children with ASD are focused on the relationship between the child with ASD and his or her caregiver through coaching to help increase responsiveness to the adult (ie, the interventionist or parent or caregiver) through imitating, expanding on, or joining into child-initiated play activities. This approach may address core symptoms of ASD, such as joint attention, imitation, and affective social engagement.[296,297,321,322]

Developmental models for intervention are focused on teaching adults to engage in nondirective interactive strategies to foster interaction and development of communication in the context of play. One such approach is known as DIRFloortime (The Developmental, Individual Differences, and Relationship-Based model). In 1 RCT comparing parent coaching using this approach to community intervention alone (N = 112) in children ages 2 to 5 years, parents who were taught this approach were less directive, and their children were rated as more socially responsive, although IQ and language scores were no different between groups, and half of the children in the control group improved in their affective ratings.[323] A similar approach is relationship development intervention,[324] and more research is needed to evaluate efficacy and community use.

Naturalistic Developmental Behavioral Intervention

Naturalistic developmental behavioral interventions (NDBIs) incorporate elements of ABA and developmental principles, such as emphasis on developmentally based learning targets and foundational social learning skills, with delivery of interventions in the context of naturally occurring social activities within natural environments. They use child-initiated teaching episodes, naturally occurring opportunities for learning, and turn-taking interactions within play routines and implement ABA-based approaches to address measurable goals.[296]

The most extensively studied NDBI approach is the ESDM, which prepares children to learn in naturalistic environments.[325] In a multisite trial of ESDM, early age at entry to therapy and more hours of total therapy were associated with improved outcome.[326] Of note, the 48 children randomly assigned to ESDM or community treatment in the original trial were studied by using event-related potentials and spectral power on EEG while viewing faces as opposed to objects and were compared with typical controls on these tasks. This is an early demonstration of improvement on a neurophysiologic measure associated with improvement on a clinical measure of social behavior through an early intervention program.[327]

Combined Approaches

Common factors in combined developmental and behavioral approaches include use of principles of ABA to reinforce skill building; a systematic approach with a manual for training practitioners who would use the intervention in a standard fashion; individualized treatment goals for the child and means of measuring progress; child-initiated teaching, imitation, and modeling; and adult prompting that fades over time to promote independence.[296] It may be difficult to advise parents on specific programs in community settings because the way the program is conducted may differ from the research settings.[328] However, it is always accurate to describe the common characteristics of empirically supported interventions and recommend that families seek interventions that incorporate these features (Table 9).

Parent-Mediated Treatment or Parent Management Training

Increasing evidence reveals that focused interventions delivered by trained parents or other caregivers can be an important part of a therapeutic program.[297,329–332] More RCTs have been published on parent-mediated therapies than on other nonpharmacologic interventions. What is sometimes called parent management training is divided into 2 categories: parent support and parent-mediated interventions. Parent support interventions, which are knowledge-focused and provide indirect benefit to the child, include care coordination and psychoeducation. Parent-mediated interventions, which are technique-focused and provide direct benefit to the child, may target core symptoms of ASD or other behaviors or skills and may be built on ABA approaches in natural settings.[331]

Training sessions for caregivers may be delivered in the home, clinic, school, or other community settings or remotely by telehealth.[297,329–331,333–337] An RCT involving 86 toddlers and their primary caregivers demonstrated that 10 weeks of hands-on parent training in joint attention, symbolic play, engagement and regulation (an NDBI) was superior to a parent-only psychoeducational intervention for increasing joint engagement.[338] A parent training approach may be used to promote compliance with instruction, social communication, and other identified goals of the caregiver, such as reducing maladaptive behaviors.[331,339–342] Including parents in the intervention process is critically important.[43,326,343]

Educational Interventions

Classroom-Based Models

It is the expectation that school-aged children will be educated in classroom settings with supports for a broad effect on the symptoms of ASD and associated deficits. Educating students with ASD in the least restrictive environment typically requires an individualized program that is modified to meet the Individualized Education Program (IEP) goals set by the family, student, and school team. Some students who do not qualify for an IEP by educational criteria may be supported with accommodations through a Section 504 plan or with classroom-level accommodations. Many students with ASD are educated in inclusive classrooms with supports. Other school-aged children and youth benefit from disorder-specific approaches. Examples of classroom-based models include Learning Experiences and Alternative Programs for Preschoolers and their Parents (LEAP) and TEACCH.[344]

LEAP blends principles of ABA with special and general education teaching techniques for elementary-aged pupils in inclusive settings for teaching social interaction.[344–346] An RCT of 294 preschool-aged children revealed that LEAP was associated with improvement in socialization, cognition, language, and challenging behavior and that LEAP was superior to a treatment-as-usual method.[345]

TEACCH class settings are visually organized to promote engagement and learning.[344] The TEACCH approach to skill acquisition includes assessment-based curriculum development and an emphasis on structure, including predictable organization of activities and use of visual schedules, organization of the physical environment to optimize learning and avoid frustration (eg, by minimizing distractions and/or sensory dysregulation), and adaptation and organization of materials and tasks to promote independence from adult directions or prompts.[344,347] Instruction is organized in a predictable fashion and uses visual schedules with promotion of independence in activities planned into the instruction.[347] This approach is associated with a small, but measurable, benefit in perceptual, motor, verbal, and cognitive skills in students with ASD, with less measured effect on adaptive and motor function[347] and challenging behaviors. Rigorous studies of educational interventions for students with ASD at school age and beyond are necessary to understand the effectiveness of different models.[298]

A comparison of the effects of LEAP and TEACCH classrooms with those of standard special education classes taught by teachers familiar with ASD revealed that the common features of these interventions may be responsible for improvements seen in all students. TEACCH was associated with more reported improvement in ASD severity for students who had greater cognitive delays. This finding may speak to the benefit of the environmental and behavioral supports.[344] Research interventions may not be comparable with community-provided school programs. Future research is needed to address how best to provide evidence-based intervention in classroom settings.

Education in the Least Restrictive Educational Environment

Pediatricians have an important role in advocating for children and youth with special health care needs, including ASD, in the educational setting. Students have a right to a free and appropriate public education. Educational programs for school-aged children with ASD should promote language, academic, adaptive, and social skills development and prepare them for postsecondary education or employment.[348] Most, but not all, students with ASD will have some individualization of their education under the guidance of an IEP determined by the school multidisciplinary team in conjunction with the family. Others may receive accommodation and/or environmental modifications under Section 504 of the Rehabilitation Act of 1973.[349] A medical diagnosis of ASD alone does not automatically translate into eligibility for school-based services. Functional impairment that affects participation in the typical curriculum is required to qualify for supports in the educational setting and may lead to an IEP for the educational handicap of autism. Most youth with ASD and average-range intelligence will likely require academic intervention because of coexisting learning disabilities, executive function challenges, ADHD, motor processing deficits, the effects of their pragmatic language differences on reading and writing, and/or challenges in comprehension of spoken or written language.[350] Attention to the needs of the individual student must be central to the IEP process. Social skills of students with ASD may benefit

from students being in class and on the playground with peers with typical development.[351,352] However, spending more than 75% of their time in an inclusive educational setting alone was not sufficient in transition-aged youth to increase rates of college attendance, high school graduation, or functional ratings.[353] How to best support students with ASD in the least restricted environment requires further study.

Social Skills Instruction

Social skills deficits may present differently depending on language abilities, developmental level, and age. Examples of social skills deficits include the following:

- challenges with entering, sustaining, and exiting interactions;
- difficulty attending to, understanding, and using nonverbal and verbal social cues, such as eye contact, facial expressions, and gestures;
- difficulty in understanding "unwritten" social rules of the environment;
- not understanding the perspective of others;
- struggling with negotiation, compromise, and conflict resolution; and
- problems with interactive play or participation in leisure activities.

The importance of caregiver involvement in teaching social skills to preschool-aged children needs to be emphasized for families of young children with ASD. Reinforcing social interaction is central to the success of evidence-based ABA, developmental, and NDBI approaches.[296,354] Teaching and coaching social interaction involves both behavioral therapy and speech and language therapy approaches.

School-aged children and adolescents with ASD, including those with typical academic skills, should have social skills support considered in their school and perhaps in other therapeutic settings if indicated.[351,354–356] Although families identify the need to address social skill developments in settings outside of school, the success of these types of interventions is variable. Interventions may be divided into adult-mediated (skill building with the individual child), peer-mediated (skill building with the child and typically developing classmates), and mixed approaches. Child-directed social skills interventions are often delivered individually or in small groups with other children with similar needs. Therapy may be provided in behavioral health settings to complement the social skills interventions at school.

Interventions addressing social skills may increase the child's knowledge of the cues for social behavior and teach strategies for social problem-solving. A popular method uses the social narrative to help a child define the social context of an anticipated or experienced situation, put it in perspective, and then develop statements on how it makes the child feel and on what to do in response to the event and feelings.[357] This coached rehearsal strategy may be included within other programmatic approaches. Implementation may use a cognitive behavioral intervention strategy in which the child identifies feelings and thoughts and learns to substitute more socially appropriate alternatives.[354] Video- and computer-based social skill interventions may extend access to intervention once an evidence base is established. A systematic review of RCTs of social skills training for children aged 6 to 21 years revealed that interventions improved social competence and friendship quality but did not result in differences in emotional recognition and social communication. Transfer of skills to other settings was inconsistent.[356]

Because child-mediated interventions taught separately from social settings have not had consistently beneficial effects, interventions have been developed for implementation in the social settings that include peers, such as the classroom and playground. These interventions demonstrate improved playground interaction between children with and without ASD and improved identification as friends by typical peers.[351] Peer-mediated intervention for students with ASD have revealed improved social connectedness and reduced social isolation and provide evidence to support the use of these interventions in the classroom and playground. An evidence-based approach designed for group administration, the Program for the Education and Enrichment of Relational Skills, may improve both teacher-reported social functioning and adolescent-reported social cognition.[358] Fewer studies are available to guide programs to promote social skills development for adults with ASD. However, the Program for the Education and Enrichment of Relational Skills group model has been demonstrated to improve social skills in young adults with ASD.[359]

Families should be counseled to include development of social skills with discrete goals and interventions in the IEP or educational plan as well as to be cognizant of potential opportunities to promote social interaction in the natural environment and in the context of other therapies.[360] Implementing IEP goals across the day and generalizing specific skills to promote conversation and nonverbal communication, such as providing eye contact, directing facial expressions, and using appropriate gestures, is important, independent of age, and should involve both the caregivers and professionals. More information about IEPs in

general can be found at http://www.wrightslaw.com/info/iep.index.htm.

Other Therapeutic Interventions

Speech and Language Interventions

Delayed language is an early concern for many children who are later diagnosed with ASD. The communication symptoms included in the DSM-5 criteria for ASD reflect core deficits in social communication and interaction, such as failure of back-and-forth communication, deficits in nonverbal communication (such as eye gaze and use of gesture), difficulty adjusting behavior to suit the social context, and restricted and repetitive behaviors leading to perseverative vocalization, echolalia, and preoccupation with restricted topics of interest. All children with ASD should have documentation of specific coexisting speech and language diagnoses so that appropriate intervention might be provided.

Speech-language therapy is the most commonly identified intervention provided for children with ASD.[361] The strategies used by speech-language pathologists to reinforce sound repetition and word use in children with typical development are often initially used with young children with ASD. Such strategies include reinforcement of speech sounds and communicative acts, imitation of the sounds the child makes, and exaggerated imitation and slowed tempo.[362] The literature offers the most support for approaches with preverbal children with ASD in which adult prompts are used for communication, prompt fading, and reinforcement of their own attempts at communication. Intervention in naturalistic settings and involvement of caregivers may help reinforce the initiation of communication and functional use of sounds, gestures, and words.

A significant minority (up to 30%) of individuals with ASD ultimately do not acquire verbal speech.[363] Delayed onset of speech may be complicated by general delays in development (intellectual disabilities) or coexisting speech disorders, such as childhood apraxia of speech. Although using communicative spoken phrases before age 4 years is considered a good prognostic sign for language development in youth with ASD, emergence of phrase speech may occur to at least age 10 years, especially in children with preserved nonverbal skills and evidence of social engagement.[364]

When children do not spontaneously speak, augmentative and alternative communication (AAC) may be introduced. Examples of AAC strategies include sign language, the Picture Exchange Communication System, and speech-generating devices.[365,366] The use of AAC may help promote social interaction and understanding of the purpose of communication and does not delay onset of speech. Indeed, it may enhance emergence of spoken words by pairing nonverbal and verbal communication.

The Picture Exchange Communication System is used to build communication through picture identification and exchange as communication. With training, pictures can be sequenced to build on communicaiton.[367] Picture strips that sequentially explain medical procedures, for example, take advantage of this approach. Use of speech-generating devices and programs that use AAC on digital tablets also are increasing. These devices provide acoustic feedback to the child, and touch-screen tablets are relatively inexpensive and portable. Medical providers are often asked to justify the purchase of touch-screen tablets or AAC devices. It cannot be assumed that the use of AAC alone will lead to functional oral communication without a therapeutic plan.[368] Current scientific evidence does not support the use of facilitated communication in which a nonverbal individual is guided to communicate.[369,370] This differs from AAC, in which the individual is taught to communicate independently. Future strategies to promote communication are expected to incorporate evolving knowledge about sensory processing and connectivity of brain functions in people with ASD.

Children and youth with ASD often have deficits in pragmatic language that can affect social interaction with adults and peers and academic performance as more complex language becomes required for reading comprehension and analysis of information. In addition, literal interpretation of language and difficulty in understanding the intent of other people leads to behavioral challenges in some people with ASD and affects success in school, leisure activities, and employment. School-aged students with spoken language should have their pragmatic language assessed as part of their school-related reevaluations, with consideration of pragmatic language testing if academic problems and inattention are noted in the classroom. Interventions may include individual and group approaches that include teaching and practicing conversation. The pediatrician may refer the child for private speech-language therapy if he or she is not eligible for services in school or if increased intensity of intervention is desired. Although the impact of speech-language therapy on structural language improvement has not been adequately studied, improvement in ratings of conversational competence by parents and of classroom learning skills by teachers supports the recommendation for social skills and social language interventions for students with ASD.[371]

Motor Therapies

Children with ASD may have low muscle tone or a developmental

coordination disorder. Although the ages for sitting and walking do not differ between children with ASD and children with typical development, both fine and gross motor skills may be delayed in preschool-aged children with ASD.[372] Attention to position in space in children with a coexisting diagnosis of ADHD may further complicate delays in coordination.[373] Occupational therapy services may be indicated to promote fine motor and adaptive skills, including self-care, toy use, and handwriting. Almost two-thirds of preschool-aged children with ASD are reported to receive occupational therapy services.[374]

Similarly, some children with ASD may have gross motor impairment on formal testing that may benefit from therapeutic intervention focused on building strength, coordination, motor planning, or skill acquisition to promote safer mobility or play. Toe walking is common among children with ASD as well as in other developmental disorders in early childhood. The etiology of toe walking in ASD is unclear, although sensory aversion and habit or perseveration have been proposed. Common interventions for toe walking may include passive stretching, orthotics, and casting. Impairment in gross motor function may affect the capacity of a child with ASD to participate in leisure activities with the family or with peers and may impair participation in sports or interactive play beyond the effect of their social skills alone. Impaired motor skills may further decrease opportunities for social skills development and active learning and may be a risk factor for overweight and obesity.[375] For motor therapies to be provided in the educational setting, a significant delay for age that affects function in school must be identified on a valid assessment measure.

Sensory Therapies

In 2012, the AAP published a clinical report, "Sensory Integration Therapies for Children With Developmental and Behavioral Disorders," providing important background information and recommendations for pediatricians.[376] Since that publication, the DSM-5 criteria now includes sensory symptoms in the diagnostic criteria for ASD in recognition of the fact that individuals with ASD have sensory challenges that may be related to repetitive and other challenging behaviors.[377] Indeed, sensory symptoms exhibited by young children, such as food selectivity, covering their ears for certain sounds, and visual scrutiny of aspects of objects, may be among the earliest differences families identify in their children's development. Sensory goals may be included in treatment objectives for students with ASD. Adult-directed approaches provided through sensory-based interventions may be included in the context of motor and behavioral therapies and in educational settings. Despite the increasing scientific understanding of the neurobiological basis for sensory symptoms in individuals with ASD, empirical interventions in common practice have modest evidence to support their general use at this time.[378] Commonly used sensory-based interventions, including brushing of the skin, proprioceptive stimulation by using weighted vests, or kinesthetic stimulation (such as swinging or use of specialized seating, such as a therapy ball, to modulate level of arousal), are not yet supported in the peer-reviewed literature.

Proponents of sensory integration therapies distinguish them from interventions with sensory modalities because of the active engagement with the child in skill building or desensitization. This type of therapy requires a trained clinician, often an occupational therapist, to work with a child by using play and sensory activities to reinforce adaptive responses. The therapist explains the child's behaviors and responses to caregivers in sensory terms and provides them with strategies to help the caregivers accommodate the child's sensory needs to decrease functional impairment and tolerate environmental triggers. Advocates of these interventions claim that dysfunction in integration of sensory input contributes to inefficiencies in learning and to behavioral challenges and that therapeutic approaches to sensory integration need to be considered separately from focal sensory-based treatments.[379] Although sensory-based therapies are among the most commonly requested therapies by caregivers,[361] the evidence supporting their general use remains currently limited.[378,379] As with any other intervention, specific goals for sensory-based therapies should be identified, and outcomes should be monitored so that the utility for any given child can be documented.[376]

Medical Management of Co-occurring Conditions

Co-occurring medical and other conditions, such as seizures, sleep disorders, gastrointestinal (GI) disorders, feeding disorders, obesity, catatonia, and others, have a significant effect on the health and quality of life for children and youth with ASD and their families.[380,381] In this section, the co-existing conditions commonly observed in children and youth with ASD are described, and anticipatory guidance and management strategies that primary care providers may consider are provided.[380]

Seizures

There is both an increased risk for ASD among children and youth with epilepsy and an increased risk for seizures in those with ASD. The pooled risk for ASD among children

with epilepsy is 6.3%, with almost 5 times as many in samples with the highest rates of co-occurring intellectual disabilities.[173,382,383] The rate of seizures among people with ASD in community-based populations has been reported to range from 7% to 23%, with rates as high as 46% reported in clinically ascertained samples.[170] It has been suggested that the risk for seizures is not increased in individuals with ASD without intellectual disability. Risk factors for the increased likelihood of seizures in people with ASD include intellectual disability (as noted), female sex, and lower gestational age.[174] Specific genetic disorders associated with ASD, such as tuberous sclerosis, also may contribute to seizure risk in early childhood. Onset is bimodally distributed, with most first seizures occurring in early childhood and in adolescence; 20% of first seizures occur in adults with ASD.[170] Children with ASD and seizures tend to have more behavioral challenges, independent of cognitive skills.[382] Screening EEGs are not recommended for patients who are asymptomatic. An overnight EEG should be considered when the clinical history suggests seizures and atypical regression. Response to conventional antiepileptic drug therapy varies greatly, with some reports suggesting an increased risk for treatment-resistant epilepsy in individuals with early onset of seizures and delayed global development.[384]

GI Symptoms

GI symptoms, such as abdominal pain, constipation, diarrhea, gastroesophageal reflux, and feeding problems, are more commonly reported in children and adolescents with ASD than in those with developmental delay or typical development.[385–387] A large prospective cohort study revealed differences as early as 6 to 18 months of age in stooling patterns and feeding behaviors in children who were later diagnosed with ASD.[388] Because of language delays and atypical sensory perception or report of pain, individuals with ASD may be less likely to report specific GI discomfort and may present with agitation, sleep disruption, or other behavioral symptoms rather than GI discomfort.[387] Characteristics of ASD that might affect GI symptoms include resistance to change (feeding and constipation), comorbid anxiety (pain, feeding, and motility disorders),[389] and altered sensory perception (pain, feeding, and constipation). At present, there is no evidence of an association of ASD with celiac disease, specific immune dysfunction, or motility disorders (eg, gastroesophageal reflux) in children with ASD.

It would be expected that these disorders would occur at least as frequently among individuals with ASD as among individuals in the general population, and they should be considered when the child has a history of GI symptoms or a change in behavior.[390,391] Ongoing research is focused on whether differences are present in immunologic function, motility, or the microbiome in individuals with ASD.[392–394]

Selective eating is common in children with ASD.[386] A limited diet may influence GI symptoms, such as constipation,[395] and alter the intestinal microbiota. GI disorders should be considered in patients with ASD if they present with typical GI symptoms or with agitation, food refusal, or sleep disturbance.[387,396] The indicated GI workup will depend on the specific symptoms. Children with ASD should be offered the same approaches to treatment of GI disorders as other children. Modifications of conventional interventions to accommodate for symptoms of ASD might include consistent behaviorally informed approaches for constipation and encopresis.

Feeding Disorders

Up to three-quarters of children with ASD have problems related to eating, including food selectivity based on texture, color, or temperature; rituals around food presentation; and compulsive eating of certain foods.[397–399] Behavioral refusal may also present as the child holding food in the mouth, volitional gagging, and emesis. Common related problems include pica (eating of nonfood items) and rumination (self-stimulatory emesis and reswallowing of stomach contents). By age 16 months, children who are later diagnosed with ASD are observed to be more selective in their eating patterns than are other toddlers.[400] Problems around mealtime behavior and food choice often persist into adolescence. The frequency of feeding challenges in children and youth with ASD may relate to the core symptoms of restrictive and repetitive behavior and differences in sensory perception related to smell, taste, and texture.[401]

Children with developmental delays may also have delayed oral motor skill development and may demonstrate food refusal of textures that they cannot physically chew or swallow. Discomfort can lead to food refusal, so initial evaluation should include consideration of gastroesophageal reflux, dental pain, food allergies, lactose intolerance, and significant constipation.[387] If oral-motor concerns are observed, speech or occupational therapy assessment is indicated.

Because feeding problems are so common among children with ASD, a dietary history should be obtained at health supervision visits. Physiologic needs for macronutrients and micronutrients are the same for children with ASD as for other children. As with other children in the United States, insufficient intake of fiber, vitamin D, and calcium are common.[402] Rare cases of severe nutritional deficiencies, such as

rickets (vitamin D),[403] scurvy (vitamin C),[404] and keratoconus (vitamin A),[405] have been reported in children with ASD with severe food aversions. If supplements are used to correct for poor vitamin D or calcium intake, it is important to confirm that the dose is sufficient for the age and sex of the child.[406] Food fortification in the United States may supply adequate amounts of vitamins and minerals for some children with selective diets, so additional multivitamins may not be necessary.[407] Consultation with a registered dietitian may be helpful to be able to guide families regarding the nutritional sufficiency of their child's diet.

The clinician can counsel families about offering children routine meals and snacks, discouraging snacking through the day, promoting self-feeding, and using basic behavioral approaches to encourage mealtime structure and predictability with minimal distraction. Children with ASD need to be offered new foods multiple times to become familiar with them. Feeding problems that affect nutrition or family function or that are specialized, such as mouth packing, rumination, severe pica, and intense aversions, are likely to need the support of professionals with expertise in behavior management and/or oral-motor therapies (speech or occupational therapy).[408,409] Food refusal may stem from discomfort, so consultation with a gastroenterologist may be helpful. Gastrostomy-tube placement and nonoral feeding should only be considered after appropriate behavioral intervention has failed.

Obesity

Children and youth with ASD have greater risk for overweight and obesity than those in the general population.[410–413] People with ASD have fewer opportunities and perhaps less interest for active leisure or organized sports, have repetitive eating patterns that may include energy-dense foods, and are more likely to be prescribed medications, such as atypical neuroleptics (or antipsychotic medication) and anticonvulsants, that often contribute to excessive weight gain. Sleep disorders may further predispose them for obesity. Primary care providers should monitor a child's age-specific BMI percentile in the context of health supervision care and address modifiable risk factors through anticipatory guidance for their patients with ASD. Programs that address healthy weight for children and youth with typical development may need to be modified for successful use for patients with ASD.[414]

Dental Health

Children with ASD commonly have unmet dental needs. Difficulty cooperating with hygiene and professional care are reported barriers for dental care. Even when insurance coverage is available, children with ASD have fewer visits for routine care.[415] There are limited data about the prevalence of caries or gingival disease in children with ASD. As with other children, anticipatory guidance should include attention to dental hygiene and fluoride use, if appropriate, from a young age. Behavioral strategies may be helpful to prevent the need for dental care under sedation.

Pica

Children and youth with ASD may put nonfood items in their mouths long after the developmental period of early childhood, when pica is expected. Pica is reported in up to one-quarter of preschool-aged children with ASD and is documented to persist in individuals with intellectual disability.[416,417] The persistence of pica may be attributable to sensory differences, perseveration or obsession, and oral exploration of the environment. Clinicians need to be aware of persistence of pica in children and youth with ASD because of the risk for toxic ingestions, risk for lead intoxication, potential for infection, and the risk for mechanical ingestions ranging from batteries to bezoars.[418] Obstruction and perforation need to be considered in children with pica who have acute abdominal symptoms. Iron deficiency is associated with pica in the general population.[419] Laboratory monitoring of blood lead and iron deficiency in children with pica is suggested in the context of primary care. Behavioral intervention includes reinforcing appropriate behaviors, ensuring adult supervision, and putting into place environmental safeguards for prevention.

Sleep Problems

Sleep disturbance is common in individuals with ASD and may be associated with exacerbation of problematic daytime behavior.[420–427] Problems with initiating and maintaining sleep are reported for 50% to 80% of children with ASD.[428] Children who are later diagnosed with ASD are reported to have had sleep problems by 30 months of age.[429] Sleep problems in individuals with ASD persist; almost half of adolescents with ASD continue to have sleep symptoms.[430] Adolescents are more likely to have shorter sleep duration, daytime sleepiness, and delayed sleep onset compared with younger children with ASD, who are more likely to have bedtime resistance, parasomnias, and night-waking. Reasons for the increased frequency of sleep disturbances in children and youth with ASD may include differences in melatonin metabolism,[431] developmental disruption of other neurotransmitter systems critical to sleep, and lack of social expectations, among other explanations. Genetic disorders, such as Smith-Magenis syndrome, are associated with both ASD and sleep disruption.[432] Biological reasons for disrupted sleep that are not unique to

children with ASD may include restless leg syndrome, which may be associated with low iron stores,[433] and coexisting neurologic or behavioral diagnoses, such as epilepsy, anxiety, ADHD, or mood disorders. The most common cause of both delayed sleep onset and night wakings are learned behaviors. As with other children, the evaluation of the child with ASD with delayed sleep onset, night wakings, and/or early-morning wakings should include a history of comorbid medical conditions that might disrupt sleep, such as gastroesophageal reflux, seizures, asthma, allergies, eczema, or enuresis. Snoring might suggest obstructive sleep apnea and would prompt referral for additional assessment. Children who play video games or engage in other screen time close to bedtime have later bedtimes and may have more difficulty falling asleep.[434,435] Restless sleep and night wakings would suggest a need for laboratory evaluation for ferritin and other indicators of iron sufficiency to determine if low iron stores might be present.[428] An environmental history of the household may help to determine if household noise, parental work hours, or other factors may affect sleep. The bedtime routine and response to night-waking should be reviewed to determine the behavioral approaches to consider.

Empirical support exists for the effectiveness of parent education and behavioral interventions for children with ASD and sleep disturbances.[425,436–440] Behavioral intervention includes parents establishing bedtime routines and making clear their expectation that the child sleeps in his or her own bed. This may be difficult to establish for children with ASD, who may not appreciate the social conventions around sleep time and may have repetitive rituals and comorbid anxiety or ADHD. Despite these challenges, behavioral strategies are successful when consistently implemented.[440]

No medication is currently approved by the US Food and Drug Administration for the treatment of insomnia in children with or without ASD. Any medication elected should be started at a low dose and monitored for adverse effects.[427] Sleep onset may be aided by treatment with melatonin[441,442] at doses from 1 to 6 mg[443] and may be maintained with long-acting melatonin.[442] Adverse effects are uncommon but may include nightmares. α-adrenergic agents (eg, clonidine) and antihistamines (eg, diphenhydramine) are often prescribed to help with sleep onset or to address night-waking in children, but the literature provides little support for their use.[444,445] Disordered sleep is associated with challenging daytime behaviors in children with ASD[446]; addressing one may help with the other.

Wandering

Accidents, including drowning, are a major cause of morbidity and mortality in children and youth with developmental disabilities, including ASD.[447,448] Children and youth with ASD may have decreased awareness of social convention and community rules as well as impulsivity and perseverative interests that draw them to potential dangers, such as bodies of water and busy roads. Wandering off (also called elopement) places them at risk for injury. Wandering, if present, should be included in the problem list as a coexisting diagnosis in patients with ASD. In an online study, 1218 families of children with ASD were questioned about elopement.[447] Nearly half of children with ASD between the ages of 4 and 10 years had tried to elope. Almost half of those children were missing long enough for their parents to contact the police. Of those children, approximately two-thirds were at risk for traffic-related injury and almost one-third were reported to have had near-drowning episodes. Data from a national survey revealed that elopement attempts in the past year were reported by approximately one-third of parents whose children had ASD with or without intellectual disability.[449] Wandering may persist into adulthood.

In the survey by Anderson et al,[447] parents reported that the most common perceived reasons for elopement were enjoyment of running, attempts to get to a desired location (such as a park), pursuit of an intense interest (eg, water), and escape from situations or sensory events that made them anxious. Because the risk for elopement increases with the severity of ASD and with co-occurring intellectual disabilities, many of the individuals at greatest risk have limited language and cannot tell first responders their names, addresses, or phone numbers if they get lost. Police may interpret aggression caused by fear as combative behavior.

Prevention is the most important intervention for elopement. Parents participating in a large national survey of children with special health care needs reported primarily using physical and electronic barriers to try to prevent elopement, especially in children who also had intellectual disabilities.[447,449] Information on prevention and management of wandering is available for parents and clinicians (http://nationalautismassociation.org/big-red-safety-box/). Consistent, adequate adult supervision is important in all environments: school, home, and community settings. Families note that increased supervision needs result in increased family stress. Families may need to consider deadbolts, fencing, and alarm systems for safety as well as personal GPS devices and identification bracelets or other identification. Local law enforcement

agencies may support GPS tracking. Alerting neighbors and local law enforcement officials as well as securing pools in the neighborhood and creating a family emergency plan are suggested. If impulsivity and motor hyperactivity contribute to elopement, examining the utility of medication as part of an overall plan may be considered. Similarly, addressing sleep issues becomes important if the child is at risk for wandering at night. Teaching safety skills and appropriate community behaviors is critical to prevention. All children with ASD, no matter their level of cognitive skills, are at risk for wandering.[449]

Motor Disorders

There is increasing appreciation that individuals with ASD may have developmental coordination disorder and other neurologic problems. Tic disorders occur with an increased frequency in children with ASD.[450] Distinguishing complex tics from stereotyped movements may be challenging.

Catatonia was added as a possible coexisting condition to ASD in the DSM-5. Slow initiation of movement and reported deterioration in motor performance have been treated with lorazepam, electroconvulsive therapy, and behavioral interventions, but the therapies do not have a strong literature base.[451] Later loss of motor skills in adolescence should prompt evaluation by a neurologist for underlying reasons. Regression in language or social interest is reported in approximately one-quarter of children later diagnosed with ASD. It is recognized most commonly between 18 and 24 months of age. Regression later in childhood requires evaluation.

Co-occurring Behavioral Health Conditions

Co-occurring behavioral symptoms include hyperactivity or inattention, aggression, outbursts, and self-injurious behaviors. Although these behaviors are not core features of ASD, they commonly interfere with functioning in school, at home, and in the community and contribute substantially to the challenges faced by families.[293,294,381,452–457] Psychiatric conditions (such as ADHD, anxiety, OCD, mood disorders, conduct disorders, or others) are identified in 70% to 90% of children and youth with ASD.[458,459] Behavioral challenges have a significant effect on health and quality of life for children and adolescents with ASD and their families.[460] Patients with ASD, like other children and adolescents, should be regularly screened for behavioral and/or emotional conditions, as recommended by the AAP.[461] The effect of behavior on home and school functioning is often assessed as part of school testing by using parent and teacher questionnaires, such as the Behavior Assessment System for Children, Third Edition, Parent Rating Scales,[79,462] or the Child Behavior Checklist.[82,463,464]

With change in behavioral symptoms, physical sources of discomfort and behavioral intervention should be considered.[465] If behavioral interventions are insufficient to address the challenges or are unavailable at the time, medication might be considered (see Table 10 for guidance on prescribing medication).

ADHD

Changes in DSM-5 criteria have provided flexibility to diagnose other DSM-5 disorders in addition to ASD, which can help guide treatment. Approximately half of children and youth with ASD also may fulfill diagnostic criteria for ADHD.[459] Pediatricians should keep in mind that some children who are later diagnosed with ASD may have been initially identified as having ADHD.[69] Symptoms of ADHD may further compromise social skills function in children with ASD because of inattention to social cues and impulsivity. Standard rating scales used to assess symptoms of ADHD have not yet been validated for

TABLE 10 Considerations Surrounding Medication Use

No current medication corrects core social and communication symptoms of ASD
Accurate diagnosis of coexisting psychiatric conditions guide therapy
Medication is used to help manage
• Coexisting behavioral health disorders (eg, ADHD, mood disorders, or anxiety disorders)
• Associated problem behaviors or symptoms causing significant impairment and distress
o Examples include the following: aggression, self-injurious behavior, sleep disturbance, mood lability, anxiety, hyperactivity, impulsivity, inattention
Medication should only be considered after
• Careful accounting of when the behavior started and what seems to exacerbate it
• A functional behavioral assessment should guide development of a treatment plan in the school setting
o Consider whether the behavior serves as communication of distress or refusal
• Consider referral to a behavior therapist outside of school to assess the reasons for the behavior, provide the family with strategies, and collaborate in care
• Careful history and physical to look for medical factors that may cause or exacerbate challenging behaviors (eg, gastroesophageal reflux and acute sources of pain, such as otitis media, dental injury, fracture, and others)[34,380,391,485,579]
Consider medication after treatable medical conditions and behavioral factors assessed and intervention does not address the symptoms of concern
Include the family and patient in shared decision making that considers their goals and values[543]

individuals with ASD. However, they are useful in determining the clinical impact of symptoms for an individual patient and in monitoring treatment. It is important, however, to consider the differential diagnosis of inattention and hyperactivity in the context of the language impairment and perseverative focus that often accompanies ASD. Children with delayed language may appear more inattentive. If they are expected to perform activities (including schoolwork) that they are not able to understand or accomplish, a child with ASD may engage in behaviors to escape, which can be interpreted as inattention and hyperactivity. Patients with ASD may be focused on their perseverative interests and may be internally distracted, as opposed to distracted by the environment. Evaluation of the symptom of inattention or impulsivity includes assessing language and educational abilities. Appropriate educational modifications and use of language for instruction that the student can understand are critical for successful intervention. Behavioral strategies should address reinforcement of on-task behaviors, breaking down tasks into units that can be completed successfully, breaks for activity (often included in sensory activities), and adult supervision appropriate for the demands. The same medications that are used for symptoms of ADHD in children without ASD are used in similar doses for children with ASD.[466] Routine monitoring is important because children with ASD may be at greater risk for adverse effects[467] (Table 11). The evaluation of a child for a possible co-occurring diagnosis of ADHD also should include consideration of a co-occurring diagnosis of anxiety.[464,466]

Anxiety Disorders

The DSM-5 classification system separates anxiety disorders into separation anxiety disorder, selective mutism, specific phobia, social phobia, panic disorder, agoraphobia, and generalized anxiety disorder as well as unspecified anxiety disorder. As many as 40% to 66% of school-aged children and adults with ASD are reported to also have anxiety disorders.[458,459] Anxiety disorders are most commonly identified in children with ASD and typical cognitive and language abilities.[468,469] Symptoms may be present in early childhood and manifest as behavioral challenges, such as overreactivity. Biological predisposition to both ASD and anxiety may be attributable to common genetic factors and/or altered neurophysiologic responses to stress.[470]

Core symptoms of ASD decrease the ability of individuals with ASD to predict the actions or interpret the beliefs of others, which may lead to a constant state of heightened worry. Repetitive behaviors may, in part, serve to instill predictability, so anxiety may lead to increased stereotyped behaviors or perseverative thoughts. Evaluation of anxiety requires consideration of the language demands of the environment, academic expectations, social demands, and underlying fears or phobias. Youth with ASD may lack sufficient language or insight to describe their symptoms. Getting information from multiple sources and looking at the behavioral manifestations related to context will help to correctly identify anxiety in patients with ASD.[471]

Strong evidence from RCTs supports the use of cognitive behavioral therapy for anxiety symptoms in school-aged children with ASD, especially those with typical-range intelligence.[295,298,472–475] Anxiety may be associated with reported GI and sensory symptoms.[389] Some individuals find that sensory redirection or sensory activities used in the context of a behavioral program are helpful to diminish feelings of anxiety. Other individuals may find symptom relief with the introduction of routine and structure if anxiety is exacerbated by uncertainty or associated with sensory under- and overreactivity.[377] Nonpharmacologic approaches, such as neurofeedback and digitally delivered approaches to self-regulation, are being evaluated for their therapeutic potential. Medications used for anxiety in the general population may be considered as part of an overall treatment plan for children and youth with ASD (see Table 11 for psychopharmacotherapy of children with ASD and anxiety).

Mood Disorders

Depressive disorders are more common among children and adults with ASD than in the general population. Reported rates of coexisting depression in adults and children are highly variable, ranging from 12% to 33%.[458,476,477] Symptoms of depression are more likely to lead to dual mental health and developmental disability diagnoses in adolescents and adults with ASD than in children. The coexistence of mood disorders and ASD may be associated with genetic and neurobiological factors as well as environmental factors related to chronic stress and difficulty with understanding social situations. Both elevated and depressed mood may present as behavioral symptoms in youth with ASD. Changes in affect, participation, sleep habits, and eating may be symptoms of an underlying mood disorder. Attempted suicide is reported to occur more frequently in people with ASD than in the general population. Risk factors include peer victimization, behavioral problems, minority race or ethnicity, male sex, lower socioeconomic status, and lower level of education.[478] The AAP recommends screening for depression in patients older than 12 years. Until ASD-specific measures are developed, the same approaches used for all other adolescents at increased risk for depression should be considered.[479]

TABLE 11 Psychotropic Medication Options for Common Target Symptoms

Target Symptoms	Medication Class (Examples)	Comments
Hyperactivity Impulsivity Inattention Distractibility	Psychostimulants (methylphenidate, dexmethylphenidate, mixed amphetamine salts, lisdexamfetamine, dextroamphetamine)[466,580–587]	With other coexisting symptoms, medication may not appear as effective May be more sensitive to adverse effects Steps: • Behavioral approaches implemented • Problems persist, trial of medication management • Start with a low-dose stimulant (eg, methylphenidate or mixed dextroamphetamine salts) and increase as needed and tolerated May be most effective in children without comorbid intellectual disability Targets symptoms of impulsivity and hyperactivity • If there are adverse effects or if not effective: Consider atomoxetine, especially if also with social anxiety Consider α-2 agonists (eg, short- or long-acting guanfacine, clonidine) Other medications (less evidence): atypical antipsychotic medications may decrease hyperactivity; their primary use is for irritability and aggression Adverse effects: Psychostimulants: appetite suppression and insomnia; also irritability, depressive symptoms, and social withdrawal; it does not appear to worsen repetitive behavior or oppositional behavior Guanfacine, clonidine: drowsiness, fatigue and irritability; may also include appetite suppression, nausea, sleep disturbance, and decreased blood pressure and heart rate; rebound if not weaned
	SNRIs (atomoxetine)[588–590]	
	α-2 adrenergic agonists (clonidine, guanfacine)[591–594]	
	Atypical (second generation) antipsychotics (aripiprazole, risperidone)[595–598]	
Irritability and severe disruptive behavior • Vocal and motoric outbursts of anger, frustration, and distress • Acts of aggression, self-injury, property destruction • Behaviors referred to by caregivers as "agitation," "tantrums," "meltdowns," or "rages"	Atypical (second generation) antipsychotics (aripiprazole, risperidone)[595–608]	Medication most effective if combined with behavioral strategies addressing identified environmental causes for the behavior and developing more appropriate responses for the child DB/PCs strong support for 2 second-generation atypical antipsychotic medications (risperidone and aripiprazole) for reducing irritability, stereotyped or repetitive movements, self-injury, and hyperactivity • Risperidone and aripiprazole are currently the only medications with FDA-approved labeling specific to irritability in ASD Adverse effects and monitoring: • Common adverse effects include wt gain and dyslipidemia • Monitoring: periodic assessment for extrapyramidal symptoms; measurement of wt, height, and BMI; and laboratory monitoring of glucose and lipid levels • Metformin might be a useful treatment to help control wt gain.[609] Other agents in this class, such as olanzapine and quetiapine, may have utility on the basis of their adverse effect profiles but do not have current FDA package insert indication for use in children with ASD
	α-2 adrenergic agonists (clonidine, guanfacine)[591,610]	Small studies documenting beneficial effects on irritability; need larger trials; may have better adverse effect profiles than atypical antipsychotics
	SSRIs (fluvoxamine, citalopram)[611,612]	Few studies focused on irritability and/or aggression; some reporting improvement in irritability; insufficient evidence to advise practice

TABLE 11 Continued

Target Symptoms	Medication Class (Examples)	Comments
	Anticonvulsant mood stabilizers (valproic acid and divalproex sodium)[613–618]	Small studies suggestive of improvement in irritability; need larger studies; a limited number of placebo-controlled studies either do not support or are inconclusive regarding anticonvulsant medication as a treatment of irritability in patients with ASD
	Serotonin-norepinephrine reuptake inhibitor (venlafaxine)[619]	Effect size of improvement associated with venlafaxine was small, and irritability was not the primary outcome measured
Repetitive behavior • Stereotyped motor mannerisms • Compulsions • Behavioral rigidity, insistence on sameness	Atypical (second generation) antipsychotics (aripiprazole, risperidone)[595–598,620]	Multiple DB/PCs documenting improvement in repetitive behavior; short-term treatment Common adverse effects include increased appetite, fatigue, drowsiness, dizziness, and drooling More effective for targets of tantrums, aggression, and SIB
	Anticonvulsants (valproic acid and divalproex sodium)[613,621,622]	Modest improvement has been reported with divalproex sodium treatment May have improvement with topiramate as a second agent with risperidone Most antiseizure drugs have potential for sedation, cognitive adverse events
	SSRI (fluoxetine, fluvoxamine)[480,509,611,612,623–627]	Studies to date have not revealed effectiveness of SSRI medications for repetitive behaviors related to ASD, although they may diminish anxiety SSRIs may be effective for reducing symptoms of OCD and of anxiety when included in a comprehensive approach to treatment Need comprehensive behavioral approaches to minimize repetitive behaviors
Anxiety, depression	SSRIs[469,628]	Anxiety relief has been reported in trials of citalopram and buspirone, with fluvoxamine revealing some effect in female patients with ASD; documented utility in children and youth without ASD
	α-adrenergic (clonidine, guanfacine)	Hyperactivation is an adverse effect of SSRIs in children and youth with ASD that may result in stopping the medication The anxiety disorders most amenable to treatment are generalized anxiety disorder, separation anxiety disorder, and social phobias
	Atypical (second generation) antipsychotics[469,620]	If a mood dysregulation disorder is identified, treatment with a mood stabilizer and/or a second-generation antipsychotic is recommended, although an SSRI may be used to treat comorbid anxiety, OCD, or depression; behavioral activation with hypomanic or manic switches has been reported First-line treatment is a program of cognitive behavioral therapy to reduce symptoms[472–475] Few studies have examined the specific effects for these symptoms; clinicians may consider use of these agents; although SSRIs, SNRIs, and/or buspirone may be effective for the treatment of anxiety in children with ASD, they have not been rigorously evaluated for this purpose[507,626,627,629,630] Medications to consider include sertraline, fluoxetine, citalopram, or escitalopram for symptoms of anxiety and α-2 agonists (eg, guanfacine and clonidine and β-blockers such as propranolol), which may be useful for anxiety-related physiologic symptoms and behavioral dysregulation, and a short-acting benzodiazepine, such as lorazepam, could be considered for event related anxiety

DB/PC, double-blind placebo-controlled trial; FDA, US Food and Drug Administration; SIB, self-injurious behavior; SNRI, selective norepinephrine reuptake inhibitor. Adapted from Riddle MA. *Pediatric Psychopharmacology for Primary Care*. 1st ed. Elk Grove Village, IL: American Academy of Pediatrics; 2016.

As in children and youth with typical development, assessment of depression and other mood disorders must include family history, history of environmental stressors, the potential for toxic ingestions, and evaluation for comorbid conditions. Interventions for depression include supportive therapy, cognitive behavioral therapy, and medication, if indicated, as coordinated interventions (see Table 11 for medication use). Antidepressant use in people with ASD has not been demonstrated to address aggression and has inconsistent effect on anxiety.[480] Medication recommendations are based on data from the general pediatric population and expert consensus.[469]

The DSM-5 criteria for bipolar illness include changes in activity, energy, and mood. It may be difficult to make a diagnosis in people with ASD with limited language. The co-occurrence of bipolar illness and ASD in individuals with typical intelligence ranges from 6% to 21%.[481] Lifetime diagnosis of bipolar illness in adults with ASD is reported to be 9%.[458]

OCD-Related Disorders

Although restricted and repetitive behaviors are symptoms of ASD, some individuals with ASD may also have coexisting OCD. Obsessions are recurrent, unwanted, and persistent thoughts, images, or urges that cause distress. Compulsions are repetitive behaviors or thoughts with rigid rules performed to reduce anxiety. Unlike the stereotypic behaviors of ASD, compulsions usually follow an obsession, diminish anxiety, and are not desired by the individual or perceived as pleasurable.[482] Under the DSM-5, OCD-related disorders include hoarding disorder, excoriation (skin-picking) disorder, trichotillomania, substance- or medication-induced obsessive-compulsive and related disorder, and obsessive-compulsive and related disorder due to another medical condition. The perseverations associated with ASD may be qualitatively different and less sophisticated than the repetitive and intrusive thoughts and actions associated with OCD.[483] Repetitive behaviors in general may help an individual with ASD regain a sense of predictability. Anxiety, phobias, and/or depression may coexist with OCD in youth with ASD.

Behavioral approaches are recommended as the first line of treatment of symptoms of OCD, depending on the language and cognitive level of the patient. Cognitive behavioral therapy, including exposure and response prevention with or without a selective serotonin reuptake inhibiter, has been demonstrated to be the most effective treatment for youth with OCD who do not have ASD. Cognitive behavioral therapy may be less effective, with fewer remissions, in youth who also have ASD[484] (see Table 11 for medication management).

Disruptive Behavior Disorders: Aggression, Self-Injurious Behavior, and Tantrums

Disruptive behaviors, such as aggression, self-injury, and tantrums, may complicate home and community management of individuals with ASD. Behavioral outbursts may occur in response to stressful events in the environment, in reaction to a medical condition, as functional communication, or as a symptom supporting diagnosis of a co-occurring mental health disorder.[485] Functional behavioral analysis and implementation of behavioral strategies can be an important initial step in management.[486] A proposed pathway for the primary care setting for management of irritability that leads to disruptive behaviors in youth with ASD is proposed by McGuire et al.[485] Disruptive behaviors may serve as communication to escape from a demand or an undesired situation. If successful, they may become part of a behavioral pattern. New onset of severe behaviors requires consideration of potential medical reasons (see Table 12). Pharmacologic treatment should be considered if no medical etiology is identified and if the behavior is associated with irritability, is not responsive to available behavioral interventions, or is related to a co-occurring diagnosable behavioral health disorder, such as anxiety, mood

TABLE 12 Common Presentations of Self-Injurious Behavior and the Medical Conditions to Consider If New Onset

Type of Self-Injury	Potential Associated Conditions	Potential Associated Injury
Head banging	Headache, toothache, sinus infection, ear infection	Detached retina, abrasions, contusions
Head hitting or slapping	Headache, toothache, sinus infection, ear infection	Fracture of bones in hand, detached retina, abrasions, contusions
Eye poking	Vision loss, eye pain	Eye abrasion
Gum or tooth digging or banging	Dental pain, gingivitis	Gum injury, tooth autoextraction, tooth fracture
Scratching and skin picking	Allergy, eczema, drug reaction, skin infection or infestation (eg, fleas, scabies)	Infection, scarring
Finger and toenail biting or picking	Pain	Infection, nail removal, ingrown nails, paronychia
Kicking or stomping	Restless leg syndrome, leg pain	Bruises, fractures
Rumination	Gastroesophageal reflux, eosinophilic esophagitis	Esophageal ulceration and bleeding, dental damage, nutritional compromise, precancerous lesions of esophagus

disorders, thought disorders, and/or ADHD.

It has been reported that between 8% and 68% of children with ASD demonstrate aggressive behavior, depending on how stringent the definition is.[454] Aggressive behaviors were reported on the Child Behavior Checklist for one-quarter of children attending an ASD clinic, with similar rates from 2 to 16 years of age. Aggression was associated with hyperactivity, lower cognitive skills, sleep problems, and internalizing behaviors such as anxiety. There was no association with sex. Researchers of other studies have observed increased rates of physical aggression in children with ASD who have lower adaptive skills and frequent repetitive behavior.[487] Management of co-occurring sleep problems and hyperactivity may be helpful in a treatment plan[488] that includes behavioral intervention to address aggression and targeted pharmacotherapy.[487]

Self-injurious behaviors are reported in 40% to 50% of individuals with ASD at some point across the lifespan[489] and may occur more frequently in people with ASD who also have aggressive behaviors and sleep problems.[490] Self-injurious behaviors in individuals with ASD may be repetitive and self-stimulatory (such as scratching, pica, or rumination). Head banging and self-hitting may occur as part of a tantrum. Like aggression and other disruptive behaviors, self-injurious behaviors may serve as communication to escape from demands or situations that the individual does not want to be in. The type of self-injurious behavior may change if the intervention of prevention or blocking is not associated with addressing the underlying reason for the behavior. Persistence of self-injurious behaviors in individuals with ASD is associated with more limited cognitive and language abilities, hyperactivity, impulsivity, repetitive behavior, and more challenges with social interaction.[491] There is an association of self-injury with specific genetic disorders that are not associated with ASD, such as the severe self-biting of Lesch-Nyhan syndrome. Self-injurious behavior is associated with genetic disorders that are also associated with ASD, such as Cornelia de Lange syndrome, fragile X syndrome, and Smith-Magenis syndrome.[492] In the case of aggressive, self-injurious, and disruptive behaviors, the primary care provider needs to assess the safety of the child and family in an ongoing fashion. Referral to community services and for behavioral intervention should take place if behaviors are unsafe or if the patient is not responding to the treatment plan.

Psychopharmacologic Approaches to Management

The use of medications to treat behavioral and psychiatric symptoms in children and youth with ASD has increased significantly since the publication of the 2007 AAP clinical reports.[493,494] With a shortage of specialists, more medication management, including prescription of atypical antipsychotic medications, is taking place in the primary care setting.[495,496] Large national studies of insurance claim data from Medicaid and commercial insurers reveal rates of psychopharmacology prescription for patients with ASD to be 56% to 65%.[476,493,497] One or more psychotropic medications are prescribed for 1% of children with ASD younger than 3 years, for 10% to 11% of children aged 3 to 5 years, for 38% to 46% of children aged 6 to 11 years, and for 64% to 67% of adolescents aged 12 to 17 years.[498,499] Psychotropic medication use increases with increased age, lower range of cognitive skills and/or presence of intellectual disability, and higher prevalence levels of challenging behavior or coexisting psychiatric diagnoses.[476,497–501] Prescription of medication also appears to be affected by demographic factors, such as race, ethnicity, and geography.[497,498,502] Reported polypharmacy rates range from 12% in a registry cohort recruited from diagnostic clinics[499] to 29% to 35% in large studies of Medicaid claims data.[476,493]

Medication may be helpful to address co-occurring symptoms or disorders. Clinicians should carefully weigh potential risks and benefits before prescribing medication for behavior and use psychotropic medications as part of a comprehensive treatment approach. The prescribing clinician should understand the indications and contraindications, dosing, potential adverse effects, drug-drug interactions, and monitoring requirements of the medications they prescribe.[6] Table 10 provides guidance for principles of prescribing medication, and Table 11 lists pharmaceutical options for common behavioral-symptom clusters. Psychopharmacogenomic testing for genetic variants that increase the likelihood of adverse effects is an emerging area for precision medicine. Prescribers should consider CYP2D6 and CYP2C19 metabolizer status in making medication decisions for selective serotonin reuptake inhibitors (SSRIs), for example, despite limited data at present to guide practice.[503,504] The limited data on the utility of psychopharmacogenomic testing at the time of this publication limits insurance coverage for many patients. Recommendations for testing are expected to rapidly change with ongoing research.[503–505]

Areas of Psychopharmacologic Research

As the neurobiology of ASDs are better understood, novel psychopharmacologic agents might be developed that will better manage

co-occurring symptoms and/or address core deficits. Some potentially important lines of research involve medications that modulate metabolism of excitatory neurotransmitters (such as glutamate and γ-aminobutiric acid), block acetylcholinesterase and/or nicotinic acid receptors, and act as hormones that naturally promote social affiliation (such as oxytocin and vasopressin). Drug trials involve newly formulated agents as well as repurposing exiting medications used for other purposes.[506–509]

Better understanding of the neurobiology responsible for the symptoms of ASD will allow for the identification of targeted psychopharmacologic interventions. The use of psycho-pharmacogenomics to identify which patients might genetically be at greater likelihood of benefit or at increased risk for adverse effects from specific medications is an important area of research.[510]

Integrative, Complementary, and Alternative Therapies

Despite the advances in understanding the neurobiology of ASD, many unanswered questions remain about why ASD occurs and how best to treat it. Families often consider nutritional interventions and nonmedical therapies without a scientific evidence base to address the symptoms that conventional interventions cannot rapidly address, or there is limited access to conventional services in their community. Primary care providers are often asked about nonstandard interventions that are used in integrative practice or are promoted on the Internet, in the popular press, by other families, and by celebrities.[511–516] The National Center for Complementary and Integrative Health maintains a Web site in which current information on novel therapies in popular use for people with ASD is reviewed.[517] In the past decade, an increasing number of interventions based on theories of causation of ASD that are, as yet, unproven have been examined in clinical trials. Appropriately designed trials have provided evidence to support some interventions, such as the dietary supplement melatonin, and have disproven others, such as secretin.[518] Many interventions, although still widely used, remain unproven.

Complementary therapies are often attractive to families because they are purported to correct putative biological causes of behavioral symptoms and may be discussed with an optimism about outcome that is often not conveyed with the recommendation for conventional therapies. Between 28% and 74% of children with ASD are given at least 1, and usually more than 1, complementary therapy.[519–521] Although use of novel therapies is common among children with a range of developmental disabilities, children with ASD who are irritable or overactive or who are reported to have food allergies may be more likely to be given additional therapies.[522]

Complementary, alternative, and integrative therapies used for ASD can be grouped into 3 general areas: (1) natural products (including herbs, vitamins and minerals, and probiotics), (2) mind and body practices (including yoga, chiropractic, massage, acupuncture, progressive relaxation, and guided imagery), and (3) other therapies (including traditional medicine and naturopathy).[517]

Dietary interventions used to treat symptoms of ASD are perceived by many families as beneficial because they are natural and without adverse effects. Dietary elimination of gluten- and casein-containing foods is often implemented in an attempt to ameliorate core symptoms of ASD, not on the basis of allergy or celiac disease.[523,524] The double-blind clinical trials to date have not demonstrated a treatment effect with diet.[524,525] Whether a subgroup of children with GI symptoms might benefit from these or other dietary interventions requires additional study. Children may be adequately nourished on a casein-free diet with calcium and vitamin D supplementation. Nutritional counseling is recommended if a trial of this diet is elected.[406] It may be that improvement in unrelated conditions may influence behavioral symptoms (eg, removal of dairy products may decrease irritability attributable to lactose intolerance).

Dietary supplements are often given to children who are selective eaters by their families to compensate for a limited diet.[406] However, many children with ASD are given vitamins and minerals to treat proposed biochemical abnormalities that have been proposed to be unique to ASD. Popular dietary supplements include vitamin D,[526,527] vitamin B_{12},[528] vitamin B_6 with magnesium,[529] omega-3 fatty acids,[530] and multivitamin preparations. The literature to date is controversial with respect to vitamin supplementation as a treatment of symptoms of ASD, and at this time, no conclusive evidence exists that people with ASD require different nutrient intake than that recommended in the Dietary Reference Intakes (https://www.ncbi.nlm.nih.gov/books/NBK225472/). The long-term risks of high-dose supplementation have not been studied.[531] Although maternal folic acid status may provide biologically plausible risk for ASD, there is no evidence that supplementing with B vitamins has therapeutic benefit at this time, whether a child carries common variants in the *MTHFR* gene.[532,533] Of dietary supplements in common use, melatonin has been demonstrated to be a safe and effective intervention for sleep in children with ASD.[428]

Nonbiological interventions used for symptoms of ASD are popular and have also been increasingly studied. There has been conflicting evidence regarding the effect of music therapy,[534] yoga,[535,536] massage,[537] and equine-assisted therapy[538,539] on the symptoms of ASD in children, but evidence does not support these therapies for treatment of the core deficits of ASD at this time. Evidence to date does not support the use of auditory integration training, in which an individual listens to altered sounds through headphones in an effort to change auditory or other processing.[540] Existing studies are insufficient at this time to support dance therapy, drama therapy, and chiropractic therapy.[541]

Medical interventions used for nonstandard purposes also are sometimes prescribed for symptoms of ASD. Clinical trials do not support the use of antifungal agents, immunotherapy, or hyperbaric oxygen treatment, and concern for safety, in addition to lack of supporting data, cautions against chelation therapy for children with ASD.[516]

As with any intervention, families electing a novel therapy should work with their therapeutic team to identify target symptoms they hope to address and develop a monitoring system to track change. Interventions should be implemented in a stepwise fashion so that proper attribution of effect is possible and confounding factors can be identified. It is important that the medical home provider and family collaborate to select and monitor safe and effective interventions.[542]

SECTION 6: WORKING WITH FAMILIES

Families play a key role in effective treatment for children with ASD. Recognition that individuals who are affected and their families are partners with the professionals in all aspects of planning a personal, local, and national agenda for ASD has emerged and has shaped approaches to community services as well as research planning.[543] Provision of patient- and family-centered care requires the clinician to educate the family about the child's health and engage in respectful dialogue. Resources to support the clinician in talking to families about the diagnosis include a toolkit developed by the Autism Speaks Autism Treatment Network (https://www.autismspeaks.org/tool-kit/atnair-p-guide-providing-feedback-families-affected-autism).

Impact of ASD on the Family

The impact of having a child with ASD on other family members and on society is considerable. Parents of children with ASD report more stress[544,545] and increased costs[546] than do parents who do not have a child with ASD. More than half of families report that a parent needs to cut back on work or stop working because of the care needs of the child.[547] The largest societal costs associated with ASD are special education, residential care, and lost days of caregiver work.[4] Peer support for families of children with ASD is associated with less parental stress, less negative mood, and more positive perceptions.[548] Parents who understand more about their child's ASD can advocate for more intensive and appropriate services.[549] Best practice includes giving families contact information for a family support group at the time of diagnosis. This support may be a local group that provides face-to-face interaction and community activities or an online community.[550] Many families may not have the time or inclination at the time of diagnosis to communicate with other families affected by ASD but may find the support useful later when they are facing the transitions of preschool, adolescence, or adulthood. National support groups that address a wider community of children and youth with special health care needs (such as Family Voices and Parent2Parent), autism-specific national support organizations (such as Autism Speaks and the Autism Society), and local organizations are effective in helping families obtain information and feel supported. Clinicians should familiarize themselves with national and local sources of support and information so that families can be given Web sites or phone numbers at the time of diagnosis and again as indicated. State-specific information on services and Maternal and Child Health Bureau–supported programs are found online (https://mchb.hrsa.gov/maternal-child-health-initiatives/autism). It is important for providers to advocate for instructional material in other languages as well as be knowledgeable of other resources in their communities that can provide services or support to the culturally diverse groups they serve.

Comorbid conditions, such as intellectual disability and/or psychiatric disorders, add to the impact of ASD on family functioning and access to care.[551] Although families of older children and youth typically report fewer interactions with professionals, the stress on the parent related to the ASD diagnosis persists.[552] Primary care providers should speak with families about the stresses associated with ASD and the health of other family members and make appropriate referrals, either for supportive counseling for the caregivers or agencies that can address behavioral and respite needs of the child or to address unmet health needs in family members.

The effect on siblings also needs to be considered in the context of both anticipatory guidance and primary care. Most siblings of children with ASD do not report having a sibling with a disability to be a negative experience; however, they, too, are at risk for increased stress and subsequent emotional problems.[553]

Siblings may have precocious involvement in the care of the child with ASD, and some resent the amount of attention and resources the child with ASD requires or the family's inability to participate in activities in which they see their peers engaging. Proactively teaching siblings about ASD and providing them with peer support may be helpful (Autism Speaks Sibling tool kit: http://www.autismspeaks.org/sites/default/files/a_siblings_guide_to_autism.pdf). Many areas have groups to provide education and support to siblings. It appears that positive parental attitudes and a supportive family setting are associated with better sibling adjustment as well. The pediatrician should monitor the well-being and need for behavioral health supports of siblings as well as parents.

Medical Home

In the AAP's medical home model, primary care is envisioned as accessible, continuous, comprehensive, family centered, coordinated, compassionate, and culturally sensitive for all children and youth, including those with special health care needs. Children with ASD represent a population that has had difficulty accessing comprehensive coordinated services. The chronic care model provides the structure for clinicians to collaborate with patients and their families.[554] Parents of children with ASD perceive care to be less comprehensive, less well coordinated, and less family centered than they desire and report that they are less satisfied with their care compared with parents of children with other special health care needs.[555] Parents also perceive their providers as less well informed regarding treatments for ASD, especially complementary, alternative, and integrative therapies, than they would like them to be. Pediatricians report that they lack the knowledge to provide this support to patients with ASD[556] as well as the time and resources for specialized care.[555,557] Parents of children and youth with ASD would like better access to specialty care and report greater unmet medical and behavioral health care needs[558] and a higher financial burden for care compared with parents of children without ASD.[559]

Increasing family awareness and understanding of the medical home can promote partnership of the parents and primary care provider in planning and coordinating the child's care and advocating for their needs. National survey data reveal that family-centered and coordinated care through a medical home results in fewer unmet needs,[558] including dental needs.[560] Organizations, such as Family Voices and Family-to-Family Health Information Centers, can provide information and support as well as resources for guiding families in developing care notebooks for their child. Through their ongoing relationship, providers can help children understand their own diagnosis at their developmental level. Clinicians can remind their patients with ASD of their strengths, such as focus, memory, visual-spatial problem-solving, and others, as well as their personal accomplishments in building skills and mastering barriers to achieve goals. Recognition of achievement of milestones, whether it is toilet training or college graduation, should be acknowledged.

Shared decision-making promotes a collaborative process for planning care through dialogue among the individual who is affected, caregivers, and clinicians. It can be particularly useful when the evidence for an intervention is either controversial or if there is not a uniformly accepted approach.[561] Shared decision-making requires clarity of the question to be answered, the options to be understood, and the family context and beliefs to be respected. It is often a process rather than a single conversation. Helping children and youth with ASD understand their diagnosis within the context of their developmental level can help them understand their symptoms and participate in decision-making.[562]

Transition to Adulthood

Planning for children with ASD to understand and participate in their own health care should begin early in adolescence, with adaptation for developmental abilities. The AAP clinical report "Supporting the Health Care Transition From Adolescence to Adulthood in the Medical Home" provides guidance on the steps necessary to address health care transitions for all patients with chronic conditions.[563] Got Transition recommends 6 core elements that need to be addressed for health care transition without disruption in care, including (1) a transition policy for the practice, (2) tracking and monitoring transition, (3) assessing transition readiness for youth and/or family, (4) actively planning the details of transition, (5) transfer of care, and (6) transition completion.[564] The pediatric health care provider is also in a position to advise the family about teaching their adolescent with ASD about sexuality.[565] Planning for wellness requires considering young adult opportunities for exercise and leisure activities. Planning for medical transition for all aspects of health care should start around ages 12 to 14 years. Educational transition starts at the school level at age 14 years and should involve the student as much as possible.

As a child approaches legal adulthood, the family may need to consider guardianship, either full guardianship in cases in which an adult child cannot make health, financial, or other decisions because of cognitive impairment; limited guardianship in cases in which an individual can participate in decision-making; or conservatorship in cases in which the oversight extends only to

financial decision-making. Many young adults with ASD will be capable of independent decision-making and should be prepared for transition to adulthood like other teenagers. The young adult with ASD may be eligible for Supplemental Security Income (SSI) benefits. SSI is a federal program that provides funds for the care of individuals with developmental disabilities who will not be able to support themselves independently. Because of the strict guidelines regarding cognitive and adaptive delays, some adults with ASD may not be eligible for SSI even if their disability is a barrier to employment. Families may wish to meet with a counselor who can advise them on financial planning, with attention to the needs of an adult child with developmental disability.

Students with disabilities who plan to continue their education need to be advised of the transitioning process into postsecondary education. Students with disabilities are protected under IDEA (1990; amended 1997 and 2004); Section 504 of the Rehabilitation Act of 1973; the Americans with Disabilities Act (1990); and the ADA Amendments Act of 2008. Some colleges may provide accommodations to students with developmental disabilities with proper documentation of their needs, including recent academic testing. College students with ASD may benefit from continued supports around social skills development, medication monitoring, and mentoring on living independently.[566]

Although resources are still insufficient, attention is growing for the need to provide social skills training for youth with ASD with and without intellectual disabilities to enter the workforce in competitive employment as well as job skill development. There are insufficient group-home and supported community–living arrangements for adults with ASD to meet the demands in most communities. The clinician should initiate discussions with parents regarding their plans for where their child with ASD will progress to postsecondary school education and/or employment and their plans for where their child will live in adulthood early in adolescence so the family can plan appropriately with community agencies.

Families should work with their child's school throughout adolescence to target the skills their child will need to master to be successful in young adult programs, the workforce, or postsecondary education. Goals for increasing skills may include academic, social, communication, leisure, and self-care goals. Families need information to be as proactive as possible in planning for health, academic, job, and residential needs in young adulthood. Additional research is needed to develop and evaluate evidence-based and effective interventions for this age group.[314] The pediatric health care provider should provide anticipatory guidance to the family in the context of ongoing health supervision and communicate with identified adult providers for smooth health care transition.[567]

State Programs, Supports, and Laws

State laws related to education, social service, and insurance for individuals with ASD vary significantly. Although the federal government mandates early intervention for children at risk for developmental delay and a free and appropriate education for students aged 3 to 21 years who have specific educationally handicapping conditions, the implementation of educational services varies by state and locality. The law states that services need to be appropriate, not necessarily optimal. No legal mandate for adult services exists, although the agencies that provide residential services, service coordination, job training, and adult day services typically are funded through the states.

The social services and home- and community-based waiver services available to families whose children have developmental disabilities, including ASD, differ from state to state.[568] The clinician should be familiar with the requirements for programs in their state that might lead to a Medicaid waiver (medical assistance as a secondary insurance for children with special health care needs), service coordination, respite care, and other financial or behavioral supports afforded a family when a child has special health care needs. The clinician may need to complete a form to verify the diagnosis and needs for eligibility. Of note, some children with ASD who have typical cognitive abilities may not qualify for many special education and social service supports. However, later on, at the time of transition to adulthood, if they experience difficulty with employment and daily-living skills, they may qualify for support services.

SECTION 7: RESEARCH AND SERVICE NEEDS

More than $1.5 billion of private and public research funding was devoted to ASD between 2008 and 2010.[569] The passage of the Combating Autism Act of 2006 (Public Law 109–416) and its reauthorization in 2014 as the Autism Collaboration, Accountability, Research, Education and Support Act (CARES) Act (Public Law 113–157) continued a trend in funding to address the intervention needs of individuals diagnosed with ASD. Before this time, research funding was largely focused on the genetics and neurobiology of the disorder. However, this changed with the convening of the National Institutes of Health Interagency Autism Coordinating Committee in 2006. The committee was assembled to provide guidance to the agencies funding autism services, and the research agenda was expanded on the basis of the contributions of stakeholders, including families, individuals

affected, and federal agencies. The committee's 2009 strategic plan, updated in 2017,[570] identified 7 areas for research funding: (1) early detection, (2) underlying biology, (3) genetic and environmental risk factors, (4) treatments and interventions, (5) services and implementation science, (6) lifespan services and supports, and (7) epidemiological surveillance and infrastructure.[571] The committee recommended that multiple levels of inquiry be pursued simultaneously to inform evidence-based clinical care. These levels include the following:

- basic and translational science in the areas of genetics and epigenetics, neurobiology, and psychopharmacology to understand typical and atypical brain development and function to develop ASD-specific behavioral and pharmacologic therapies; additional research is needed to identify and understand ASD risk factors that might be mitigated to reduce ASD-related disability;
- research into the underlying neurobiology of sensory symptoms and restricted interests and repetitive behaviors to inform development of targeted interventions;
- clinical trials to test focused interventions based on the underlying biological processes involved with ASD to determine if they are appropriate for community application;
- epidemiological surveillance to gather data important for planning for current and future needs, including screening, diagnosis, and lifespan health and mental health services; and
- health services research to provide guidance for comprehensive, accessible, and culturally appropriate medical, educational, and behavioral care for children, youth, adults, and families affected by ASD.

Research in all of these areas is critical to move forward with early diagnosis, effective treatment, and evidence-based interventions at each age.

PEDIATRIC RECOMMENDATIONS

To provide appropriate care to all children and families affected by ASD, health, education, and public health systems need to collaborate and build integrated and adequately funded and staffed systems.

- Early identification and treatment: Pediatric providers should use screening and surveillance to provide accurate and early identification, cost-effective and timely diagnosis, prompt implementation of evidence-based interventions, and elimination of disparities to access to care for children with ASD. Clinicians should respond appropriately to family or clinical concerns and results of screening to avoid delays in diagnosis and treatment.
- Collaboration of systems of care: Children with ASD should be provided evidence-based services to address social, academic, and behavioral needs at home and school; access to appropriate pediatric and mental health care; respite services; and leisure activities.
- Planning for adolescence and transition to adult systems of care: Communities should build services to promote social skills appropriate for work and postsecondary education, access to appropriate medical and behavioral health services, job skills development, and community leisure opportunities. Pediatricians need to engage with families and youth to plan a transition to adult medical and behavioral health care. The medical home provider should support the family and youth in advocating for appropriate postsecondary work or schooling, residential supports, and activities to maintain a healthy lifestyle.
- Informed individuals and families: The pediatrician can educate youth with ASD and their families about the evidence for interventions, refer families for possible participation in clinical research when appropriate, refer families to support organizations, and prepare families to navigate transitions.
- Informed pediatric providers: To best serve patients and families affected by ASD, the clinician caring for children and youth with ASD should be familiar with issues related to diagnosis, coexisting medical and behavioral conditions, and the impact of ASD on the family to provide a medical home for these patients. Actively addressing capacity building to care for children and youth with ASD requires initiatives directed at provider education and practice quality improvement and public health, educational, and social programs to support families in their journey from diagnosis to service provision to transition to adult care.

LEAD AUTHORS

Susan L. Hyman, MD, FAAP
Susan E. Levy, MD, MPH, FAAP
Scott M. Myers, MD, FAAP

CONTRIBUTORS

Paul H. Lipkin, MD, FAAP
Michelle M. Macias, MD, FAAP

EDITOR

Anne B. Rodgers

COUNCIL ON CHILDREN WITH DISABILITIES EXECUTIVE COMMITTEE, 2019–2020

Dennis Z. Kuo, MD, MHS, FAAP, Chairperson
Susan Apkon, MD, FAAP
Lynn F. Davidson, MD, FAAP
Kathryn A. Ellerbeck, MD, FAAP
Jessica E.A. Foster, MD, MPH, FAAP

Susan L. Hyman, MD, FAAP
Garey H. Noritz, MD, FAAP
Mary O'Connor Leppert, MD, FAAP
Barbara S. Saunders, DO, FAAP
Christopher Stille, MD, MPH, FAAP
Larry Yin, MD, MSPH, FAAP

PAST COUNCIL ON CHILDREN WITH DISABILITIES EXECUTIVE COMMITTEE MEMBERS

Timothy Brei, MD, FAAP
Beth Ellen Davis, MD, MPH, FAAP
Susan E. Levy, MD, MPH, FAAP
Paul H. Lipkin, MD, FAAP
Scott M. Myers, MD, FAAP
Kenneth Norwood Jr, MD, FAAP, Immediate Past Chairperson

LIAISONS

Cara Coleman, MPH, JD – *Family Voices*
Marie Mann, MD, MPH, FAAP – *Maternal and Child Health Bureau*
Edwin Simpser, MD, FAAP – *Section on Home Care*
Peter J. Smith, MD, MA, FAAP – *Section on Developmental and Behavioral Pediatrics*
Marshalyn Yeargin-Allsopp, MD, FAAP – *Centers for Disease Control and Prevention*

STAFF

Alexandra Kuznetsov, RD akuznetsov@aap.org

SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS EXECUTIVE COMMITTEE, 2018–2019

Carol C. Weitzman, MD, FAAP, Chairperson
David Omer Childers Jr, MD, FAAP
Jack M. Levine, MD, FAAP
Myriam Peralta-Carcelen, MD, MPH, FAAP
Jennifer K. Poon, MD, FAAP
Peter J. Smith, MD, MA, FAAP
Nathan Jon Blum, MD, FAAP, Immediate Past Chairperson
John Ichiro Takayama, MD, MPH, FAAP, Website Editor
Rebecca Baum, MD, FAAP, Section Member, Committee on Psychosocial Aspects of Child and Family Health
Robert G. Voigt, MD, FAAP, Newsletter Editor
Carolyn Bridgemohan, MD, FAAP, Program Chairperson

PAST SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS EXECUTIVE COMMITTEE MEMBERS

Nerissa S. Bauer, MD, MPH, FAAP
Edward Goldson, MD, FAAP
Michelle M. Macias, MD, FAAP
Laura Joan McGuinn, MD, FAAP

LIAISONS

Marilyn Augustyn, MD, FAAP – *Society for Developmental and Behavioral Pediatrics*
Beth Ellen Davis, MD, MPH, FAAP – *Council on Children With Disabilities*
Alice Meng, MD – *Section on Pediatric Trainees*
Pamela C. High, MD, MS, FAAP – *Former liaison, Society for Developmental and Behavioral Pediatrics*

STAFF

Carolyn McCarty, PhD
cmccarty@aap.org
Linda Paul, MPH lpaul@aap.org

ABBREVIATIONS

AAC: augmentative and alternative communication
AAP: American Academy of Pediatrics
ABA: applied behavior analysis
ADDM: Autism and Developmental Disabilities Monitoring
ADHD: attention-deficit/hyperactivity disorder
ADI-R: Autism Diagnostic Inventory-Revised
ADOS-2: Autism Diagnostic Observation Schedule, Second Edition
ASD: autism spectrum disorder
CARS-2: Childhood Autism Rating Scale, Second Edition
CDC: Centers for Disease Control and Prevention
CMA: chromosomal microarray
CNV: copy number variant
CTM: comprehensive treatment model
DSM: *Diagnostic and Statistical Manual of Mental Disorders*
DSM-5: *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*
DSM-IV: *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*
DSM-IV-TR: *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*
ESDM: Early Start Denver Model
GI: gastrointestinal
IDEA: Individuals with Disabilities Education Improvement Act of 2004
IEP: Individualized Education Program
LEAP: Learning Experiences and Alternative Programs for Preschoolers and their Parents
M-CHAT: Modified Checklist for Autism in Toddlers
M-CHAT-R/F: Modified Checklist for Autism in Toddlers, Revised with Follow-Up (Questions)
NDBI: naturalistic developmental behavioral intervention
OCD: obsessive-compulsive disorder
PDD: pervasive developmental disorder
PDD-NOS: pervasive developmental disorder not otherwise specified
RCT: randomized controlled trial
SCQ: Social Communication Questionnaire
SRS: Social Responsiveness Scale
SSI: Supplemental Security Income
SSRI: selective serotonin reuptake inhibitor
STAT: Screening Tool for Autism in Toddlers and Young Children
TEACCH: Treatment and Education of Autistic and Related Communication-Handicapped Children
USPSTF: US Preventive Services Task Force
WES: whole-exome sequencing

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: MeMix LLC is a company that makes an application (for phones). Dr Levy is on the advisory board for the application's development. This application is being developed to assist in nutritional and dietary management of children with autism. Dr Levy has not received any money yet from this company. This application is the focus of a National Institutes of Health R21 grant, for which Dr Levy is funded for ∼2% of her salary. Once it is studied and marketed (if appropriate), Dr Levy will (possibly in the future) earn some money. Her years of relationship with the company are 2015 to the present. Dr Hyman has a relationship with Roche. Dr Hyman is the site principal investigator of a clinical trial of a novel agent being tested to promote social function in patients with autism. The University of Rochester (Dr Hyman's institution) was 1 of >40 sites and had 2 study participants in 2018. University of Rochester will be leaving the trial in 2019 (withdrawal submitted) because of staffing, and that reimbursement for staff time does not cover the cost of participation. Funding was for the staff to complete the assessments required for the clinical trial. Dr Hyman got no personal reimbursement from the company; the funding was for staff time for recruitment and assessment and clinical research center support for the trial.

COMPANION PAPER: A companion to this article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2019-3448.

REFERENCES

1. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-5)*, 5th ed. Washington, DC: American Psychiatric Association; 2013
2. Baio J, Wiggins L, Christensen DL, et al. Prevalence of autism spectrum disorder among children aged 8 years - autism and developmental disabilities monitoring network, 11 sites, United States, 2014. *MMWR Surveill Summ*. 2018;67(6):1–23
3. Leigh JP, Du J. Brief report: forecasting the economic burden of autism in 2015 and 2025 in the United States. *J Autism Dev Disord*. 2015;45(12): 4135–4139
4. Buescher AV, Cidav Z, Knapp M, Mandell DS. Costs of autism spectrum disorders in the United Kingdom and the United States. *JAMA Pediatr*. 2014; 168(8):721–728
5. Johnson CP, Myers SM; American Academy of Pediatrics Council on Children With Disabilities. Identification and evaluation of children with autism spectrum disorders. *Pediatrics*. 2007;120(5): 1183–1215
6. Myers SM, Johnson CP; American Academy of Pediatrics Council on Children With Disabilities. Management of children with autism spectrum disorders. *Pediatrics*. 2007; 120(5):1162–1182
7. Daniels AM, Mandell DS. Explaining differences in age at autism spectrum disorder diagnosis: a critical review. *Autism*. 2014;18(5):583–597
8. Kim YS, Fombonne E, Koh YJ, Kim SJ, Cheon KA, Leventhal BL. A comparison of DSM-IV pervasive developmental disorder and DSM-5 autism spectrum disorder prevalence in an epidemiologic sample. *J Am Acad Child Adolesc Psychiatry*. 2014;53(5): 500–508
9. Council on Children With Disabilities; Section on Developmental Behavioral Pediatrics; Bright Futures Steering Committee; Medical Home Initiatives for Children With Special Needs Project Advisory Committee. Identifying infants and young children with developmental disorders in the medical home: an algorithm for developmental surveillance and screening [published correction appears in *Pediatrics*. 2006;118(4): 1808–1809]. *Pediatrics*. 2006;118(1): 405–420
10. King M, Bearman P. Diagnostic change and the increased prevalence of autism. *Int J Epidemiol*. 2009;38(5): 1224–1234
11. Baxter AJ, Brugha TS, Erskine HE, Scheurer RW, Vos T, Scott JG. The epidemiology and global burden of autism spectrum disorders. *Psychol Med*. 2015;45(3):601–613
12. Tomlinson M, Yasamy MT, Emerson E, Officer A, Richler D, Saxena S. Setting global research priorities for developmental disabilities, including intellectual disabilities and autism. *J Intellect Disabil Res*. 2014;58(12): 1121–1130
13. Xu G, Strathearn L, Liu B, Bao W. Prevalence of autism spectrum disorder among US children and adolescents, 2014-2016 [published correction appears in *JAMA*. 2018; 319(5):505]. *JAMA*. 2018;319(1):81–82
14. Developmental Disabilities Monitoring Network Surveillance Year 2010 Principal Investigators; Centers for Disease Control and Prevention (CDC). Prevalence of autism spectrum disorder among children aged 8 years - autism and developmental disabilities monitoring network, 11 sites, United States, 2010. *MMWR Surveill Summ*. 2014;63(2):1–21
15. Christensen DL, Baio J, Van Naarden Braun K, et al; Centers for Disease Control and Prevention (CDC). Prevalence and characteristics of autism spectrum disorder among children aged 8 years–autism and developmental disabilities monitoring network, 11 sites, United States, 2012 [published correction appears in *MMWR Morb Mortal Wkly Rep*. 2016; 65(15):404]. *MMWR Surveill Summ*. 2016;65(3):1–23
16. Sheldrick RC, Maye MP, Carter AS. Age at first identification of autism spectrum disorder: an analysis of two US surveys. *J Am Acad Child Adolesc Psychiatry*. 2017;56(4):313–320
17. Christensen DL, Bilder DA, Zahorodny W, et al. Prevalence and characteristics of autism spectrum disorder among 4-

year-old children in the Autism and Developmental Disabilities Monitoring Network. *J Dev Behav Pediatr*. 2016; 37(1):1–8

18. Barbaresi WJ. The meaning of "regression" in children with autism spectrum disorder: why does it matter? *J Dev Behav Pediatr*. 2016;37(6):506–507
19. Bradley CC, Boan AD, Cohen AP, Charles JM, Carpenter LA. Reported history of developmental regression and restricted, repetitive behaviors in children with autism spectrum disorders. *J Dev Behav Pediatr*. 2016; 37(6):451–456
20. Tammimies K. Genetic mechanisms of regression in autism spectrum disorder. *Neurosci Biobehav Rev*. 2019; 102:208–220
21. Huerta M, Bishop SL, Duncan A, Hus V, Lord C. Application of DSM-5 criteria for autism spectrum disorder to three samples of children with DSM-IV diagnoses of pervasive developmental disorders. *Am J Psychiatry*. 2012; 169(10):1056–1064
22. Lord C, Petkova E, Hus V, et al. A multisite study of the clinical diagnosis of different autism spectrum disorders. *Arch Gen Psychiatry*. 2012;69(3): 306–313
23. Mandy WP, Charman T, Skuse DH. Testing the construct validity of proposed criteria for DSM-5 autism spectrum disorder. *J Am Acad Child Adolesc Psychiatry*. 2012;51(1):41–50
24. Mazurek MO, Lu F, Symecko H, et al. A prospective study of the concordance of DSM-IV and DSM-5 diagnostic criteria for autism spectrum disorder. *J Autism Dev Disord*. 2017;47(9):2783–2794
25. Maenner MJ, Rice CE, Arneson CL, et al. Potential impact of DSM-5 criteria on autism spectrum disorder prevalence estimates. *JAMA Psychiatry*. 2014;71(3): 292–300
26. Wiggins L, Christensen D, Van Naarden Braun K, Martin L, Baio J. Comparison of autism spectrum disorder surveillance status based on two different diagnostic schemes: findings from the Metropolitan Atlanta Developmental Disabilities Surveillance Program, 2012. *PLoS One*. 2018;13(11): e0208079
27. Wiggins LD, Rice CE, Barger B, et al. DSM-5 criteria for autism spectrum disorder maximizes diagnostic sensitivity and specificity in preschool children. *Soc Psychiatry Psychiatr Epidemiol*. 2019;54(6):693–701
28. Mazurek MO, Lu F, Macklin EA, Handen BL. Factors associated with DSM-5 severity level ratings for autism spectrum disorder. *Autism*. 2019;23(2): 468–476
29. Hus V, Lord C. The autism diagnostic observation schedule, module 4: revised algorithm and standardized severity scores. *J Autism Dev Disord*. 2014;44(8):1996–2012
30. Shumway S, Farmer C, Thurm A, Joseph L, Black D, Golden C. The ADOS calibrated severity score: relationship to phenotypic variables and stability over time. *Autism Res*. 2012;5(4): 267–276
31. Kanne SM, Mazurek MO, Sikora D, et al. The Autism Impact Measure (AIM): initial development of a new tool for treatment outcome measurement. *J Autism Dev Disord*. 2014;44(1): 168–179
32. Mandy W, Wang A, Lee I, Skuse D. Evaluating social (pragmatic) communication disorder. *J Child Psychol Psychiatry*. 2017;58(10): 1166–1175
33. World Health Organization. International classification of diseases for mortality and morbidity statistics (11th Revision). Geneva, Switzerland: World Health Organization; 2018. Available at: https://icd.who.int/ browse11/l-m/en. Accessed December 1, 2019
34. Coury D. Medical treatment of autism spectrum disorders. *Curr Opin Neurol*. 2010;23(2):131–136
35. Tager-Flusberg H, Kasari C. Minimally verbal school-aged children with autism spectrum disorder: the neglected end of the spectrum. *Autism Res*. 2013;6(6):468–478
36. Kim SH, Macari SL, Koller J, Chawarska K. Examining the phenotypic heterogeneity of early autism spectrum disorder: subtypes and short-term outcomes. *J Child Psychol Psychiatry*. 2016;57(1):93–102
37. Ozonoff S, Young GS, Landa R, et al. Diagnostic stability in young children at risk for autism spectrum disorder: a baby siblings research consortium study. *J Child Psychol Psychiatry*. 2015; 56(9):988–998
38. Jashar DT, Brennan LA, Barton ML, Fein D. Cognitive and adaptive skills in toddlers who meet criteria for autism in DSM-IV but not DSM-5. *J Autism Dev Disord*. 2016;46(12):3667–3677
39. Guthrie W, Swineford LB, Nottke C, Wetherby AM. Early diagnosis of autism spectrum disorder: stability and change in clinical diagnosis and symptom presentation. *J Child Psychol Psychiatry*. 2013;54(5):582–590
40. Bennett TA, Szatmari P, Georgiades K, et al; Pathways in ASD Study Team. Language impairment and early social competence in preschoolers with autism spectrum disorders: a comparison of DSM-5 profiles. *J Autism Dev Disord*. 2014;44(11): 2797–2808
41. Anderson DK, Liang JW, Lord C. Predicting young adult outcome among more and less cognitively able individuals with autism spectrum disorders. *J Child Psychol Psychiatry*. 2014;55(5):485–494
42. Wiggins LD, Baio J, Schieve L, Lee LC, Nicholas J, Rice CE. Retention of autism spectrum diagnoses by community professionals: findings from the autism and developmental disabilities monitoring network, 2000 and 2006. *J Dev Behav Pediatr*. 2012;33(5):387–395
43. Zwaigenbaum L, Bauman ML, Fein D, et al. Early screening of autism spectrum disorder: recommendations for practice and research. *Pediatrics*. 2015;136(suppl 1):S41–S59
44. Gotham K, Pickles A, Lord C. Trajectories of autism severity in children using standardized ADOS scores. *Pediatrics*. 2012;130(5). Available at: www. pediatrics.org/cgi/content/full/130/5/ e1278
45. Pugliese CE, Anthony L, Strang JF, Dudley K, Wallace GL, Kenworthy L. Increasing adaptive behavior skill deficits from childhood to adolescence in autism spectrum disorder: role of executive function. *J Autism Dev Disord*. 2015;45(6):1579–1587

46. Magiati I, Tay XW, Howlin P. Cognitive, language, social and behavioural outcomes in adults with autism spectrum disorders: a systematic review of longitudinal follow-up studies in adulthood. *Clin Psychol Rev*. 2014; 34(1):73–86

47. Renty JO, Roeyers H. Quality of life in high-functioning adults with autism spectrum disorder: the predictive value of disability and support characteristics. *Autism*. 2006;10(5): 511–524

48. Zwaigenbaum L, Bauman ML, Choueiri R, et al. Early intervention for children with autism spectrum disorder under 3 years of age: recommendations for practice and research. *Pediatrics*. 2015; 136(suppl 1):S60–S81

49. Lipkin PH, Macias MM; American Academy of Pediatrics, Council on Children With Disabilities, Section on Developmental and Behavioral Pediatrics. Promoting optimal development: identifying infants and young children with developmental disorders through developmental surveillance and screening. *Pediatrics*. 2020;145(1):e20193449

50. Gabrielsen TP, Farley M, Speer L, Villalobos M, Baker CN, Miller J. Identifying autism in a brief observation. *Pediatrics*. 2015;135(2). Available at: www.pediatrics.org/cgi/content/full/135/2/e330

51. Robins DL, Casagrande K, Barton M, Chen CM, Dumont-Mathieu T, Fein D. Validation of the modified checklist for autism in toddlers, revised with follow-up (M-CHAT-R/F). *Pediatrics*. 2014; 133(1):37–45

52. Centers for Disease Control and Prevention. Screening and diagnosis of autism spectrum disorder. Available at: https://www.cdc.gov/ncbddd/autism/screening.html. Accessed December 1, 2019

53. Autism Speaks. Learn the signs. Available at: https://www.autismspeaks.org/what-autism/from-first-concern-to-action/get-child-screened. Accessed December 1, 2019

54. American Academy of Pediatrics. Periodic survey: cross-survey results and findings. 2018. Available at: https://www.aap.org/en-us/professional-resources/Research/pediatrician-surveys/Pages/Periodic-Survey-List-of-Surveys-and-Summary-of-Findings.aspx. Accessed December 16, 2018

55. Pinto-Martin JA, Young LM, Mandell DS, Poghosyan L, Giarelli E, Levy SE. Screening strategies for autism spectrum disorders in pediatric primary care. *J Dev Behav Pediatr*. 2008;29(5):345–350

56. Norris M, Lecavalier L. Screening accuracy of level 2 autism spectrum disorder rating scales. A review of selected instruments. *Autism*. 2010; 14(4):263–284

57. Zwaigenbaum L, Bauman ML, Stone WL, et al. Early identification of autism spectrum disorder: recommendations for practice and research. *Pediatrics*. 2015;136(suppl 1):S10–S40

58. Rotholz DA, Kinsman AM, Lacy KK, Charles J. Improving early identification and intervention for children at risk for autism spectrum disorder. *Pediatrics*. 2017;139(2):e20161061

59. Wetherby AM, Brosnan-Maddox S, Peace V, Newton L. Validation of the Infant-Toddler Checklist as a broadband screener for autism spectrum disorders from 9 to 24 months of age. *Autism*. 2008;12(5):487–511

60. Herlihy LE, Brooks B, Dumont-Mathieu T, et al. Standardized screening facilitates timely diagnosis of autism spectrum disorders in a diverse sample of low-risk toddlers. *J Dev Behav Pediatr*. 2014; 35(2):85–92

61. Zuckerman KE, Mattox K, Donelan K, Batbayar O, Baghaee A, Bethell C. Pediatrician identification of Latino children at risk for autism spectrum disorder. *Pediatrics*. 2013;132(3): 445–453

62. Sheldrick RC, Perrin EC. Evidence-based milestones for surveillance of cognitive, language, and motor development. *Acad Pediatr*. 2013;13(6):577–586

63. Siu AL, Bibbins-Domingo K, Grossman DC, et al; US Preventive Services Task Force (USPSTF). Screening for autism spectrum disorder in young children: US Preventive Services Task Force recommendation statement. *JAMA*. 2016;315(7):691–696

64. Rogers SJ, Vismara LA. Evidence-based comprehensive treatments for early autism. *J Clin Child Adolesc Psychol*. 2008;37(1):8–38

65. Zwaigenbaum L, Bryson SE, Brian J, et al. Stability of diagnostic assessment for autism spectrum disorder between 18 and 36 months in a high-risk cohort. *Autism Res*. 2016;9(7):790–800

66. Barger B, Rice C, Wolf R, Roach A. Better together: developmental screening and monitoring best identify children who need early intervention. *Disabil Health J*. 2018;11(3):420–426

67. Chesnut SR, Wei T, Barnard-Brak L, Richman DM. A meta-analysis of the social communication questionnaire: screening for autism spectrum disorder. *Autism*. 2017;21(8):920–928

68. Schwenck C, Freitag CM. Differentiation between attention-deficit/hyperactivity disorder and autism spectrum disorder by the social communication questionnaire. *Atten Defic Hyperact Disord*. 2014;6(3):221–229

69. Miodovnik A, Harstad E, Sideridis G, Huntington N. Timing of the diagnosis of attention-deficit/hyperactivity disorder and autism spectrum disorder. *Pediatrics*. 2015;136(4). Available at: www.pediatrics.org/cgi/content/full/136/4/e830

70. Ratto AB, Kenworthy L, Yerys BE, et al. What about the girls? Sex-based differences in autistic traits and adaptive skills. *J Autism Dev Disord*. 2018;48(5):1698–1711

71. Scarpa A, Reyes NM, Patriquin MA, et al. The modified checklist for autism in toddlers: reliability in a diverse rural American sample. *J Autism Dev Disord*. 2013;43(10):2269–2279

72. Burkett K, Morris E, Manning-Courtney P, Anthony J, Shambley-Ebron D. African American families on autism diagnosis and treatment: the influence of culture. *J Autism Dev Disord*. 2015;45(10): 3244–3254

73. Zuckerman KE, Lindly OJ, Reyes NM, et al. Disparities in diagnosis and treatment of autism in Latino and non-Latino white families. *Pediatrics*. 2017; 139(5):e20163010

74. Daniels AM, Halladay AK, Shih A, Elder LM, Dawson G. Approaches to enhancing the early detection of autism spectrum disorders: a systematic review of the literature. *J Am Acad*

Child Adolesc Psychiatry. 2014;53(2):141–152

75. Jones RM, Lord C. Diagnosing autism in neurobiological research studies. *Behav Brain Res*. 2013;251:113–124
76. Volkmar F, Siegel M, Woodbury-Smith M, King B, McCracken J, State M; American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. *J Am Acad Child Adolesc Psychiatry*. 2014;53(2):237–257
77. Corsello C, Hus V, Pickles A, et al. Between a ROC and a hard place: decision making and making decisions about using the SCQ. *J Child Psychol Psychiatry*. 2007;48(9):932–940
78. Constantino JN, Davis SA, Todd RD, et al. Validation of a brief quantitative measure of autistic traits: comparison of the social responsiveness scale with the autism diagnostic interview-revised. *J Autism Dev Disord*. 2003;33(4):427–433
79. Bradstreet LE, Juechter JI, Kamphaus RW, Kerns CM, Robins DL. Using the BASC-2 parent rating scales to screen for autism spectrum disorder in toddlers and preschool-aged children. *J Abnorm Child Psychol*. 2017;45(2):359–370
80. Leekam SR, Libby SJ, Wing L, Gould J, Taylor C. The Diagnostic Interview for Social and Communication Disorders: algorithms for ICD-10 childhood autism and Wing and Gould autistic spectrum disorder. *J Child Psychol Psychiatry*. 2002;43(3):327–342
81. Wing L, Leekam SR, Libby SJ, Gould J, Larcombe M. The Diagnostic Interview for Social and Communication Disorders: background, inter-rater reliability and clinical use. *J Child Psychol Psychiatry*. 2002;43(3):307–325
82. Havdahl KA, von Tetzchner S, Huerta M, Lord C, Bishop SL. Utility of the Child Behavior Checklist as a screener for autism spectrum disorder. *Autism Res*. 2016;9(1):33–42
83. Kim SH, Lord C. New autism diagnostic interview-revised algorithms for toddlers and young preschoolers from 12 to 47 months of age. *J Autism Dev Disord*. 2012;42(1):82–93
84. Lord C, Rutter M, Le Couteur A. Autism Diagnostic Interview-Revised: a revised version of a diagnostic interview for caregivers of individuals with possible pervasive developmental disorders. *J Autism Dev Disord*. 1994;24(5):659–685
85. Aldridge FJ, Gibbs VM, Schmidhofer K, Williams M. Investigating the clinical usefulness of the Social Responsiveness Scale (SRS) in a tertiary level, autism spectrum disorder specific assessment clinic. *J Autism Dev Disord*. 2012;42(2):294–300
86. Dawkins T, Meyer AT, Van Bourgondien ME. The relationship between the Childhood Autism Rating Scale: Second Edition and clinical diagnosis utilizing the DSM-IV-TR and the DSM-5. *J Autism Dev Disord*. 2016;46(10):3361–3368
87. Lord C, Luyster R, Gotham K, Guthrie W. *Autism Diagnostic Observation Schedule, Second Edition (ADOS-2) Manual (Part II): Toddler Module*. Torrance, CA: Western Psychological Services; 2012
88. Lord C, Rutter M, DiLavore PC, Risi S, Gotham K, Bishop SL. *Autism Diagnostic Observation Schedule, Second Edition (ADOS-2) Manual (Part 1): Modules 1-4*. Torrance, CA: Western Psychological Services; 2012
89. Chlebowski C, Green JA, Barton ML, Fein D. Using the childhood autism rating scale to diagnose autism spectrum disorders. *J Autism Dev Disord*. 2010;40(7):787–799
90. Reszka SS, Boyd BA, McBee M, Hume KA, Odom SL. Brief report: concurrent validity of autism symptom severity measures. *J Autism Dev Disord*. 2014;44(2):466–470
91. Bryson SE, Bradley EA, Thompson A, Wainwright A. Prevalence of autism among adolescents with intellectual disabilities. *Can J Psychiatry*. 2008;53(7):449–459
92. O'Hare A, Bremner L. Management of developmental speech and language disorders: part 1. *Arch Dis Child*. 2016;101(3):272–277
93. Kanne SM, Gerber AJ, Quirmbach LM, Sparrow SS, Cicchetti DV, Saulnier CA. The role of adaptive behavior in autism spectrum disorders: implications for functional outcome. *J Autism Dev Disord*. 2011;41(8):1007–1018
94. Liss M, Harel B, Fein D, et al. Predictors and correlates of adaptive functioning in children with developmental disorders. *J Autism Dev Disord*. 2001;31(2):219–230
95. Kenworthy L, Case L, Harms MB, Martin A, Wallace GL. Adaptive behavior ratings correlate with symptomatology and IQ among individuals with high-functioning autism spectrum disorders. *J Autism Dev Disord*. 2010;40(4):416–423
96. Dewey D, Cantell M, Crawford SG. Motor and gestural performance in children with autism spectrum disorders, developmental coordination disorder, and/or attention deficit hyperactivity disorder. *J Int Neuropsychol Soc*. 2007;13(2):246–256
97. Bhat AN, Galloway JC, Landa RJ. Relationship between early motor delay and later communication delay in infants at risk for autism. *Infant Behav Dev*. 2012;35(4):838–846
98. Provost B, Lopez BR, Heimerl S. A comparison of motor delays in young children: autism spectrum disorder, developmental delay, and developmental concerns. *J Autism Dev Disord*. 2007;37(2):321–328
99. Beers AN, McBoyle M, Kakande E, Dar Santos RC, Kozak FK. Autism and peripheral hearing loss: a systematic review. *Int J Pediatr Otorhinolaryngol*. 2014;78(1):96–101
100. Bennetto L, Keith JM, Allen PD, Luebke AE. Children with autism spectrum disorder have reduced otoacoustic emissions at the 1 kHz mid-frequency region. *Autism Res*. 2017;10(2):337–345
101. Dawes P, Bishop D. Auditory processing disorder in relation to developmental disorders of language, communication and attention: a review and critique. *Int J Lang Commun Disord*. 2009;44(4):440–465
102. Anketell PM, Saunders KJ, Gallagher SM, Bailey C, Little JA. Brief report: vision in children with autism spectrum disorder: what should clinicians expect? *J Autism Dev Disord*. 2015;45(9):3041–3047
103. Rogers SJ, Hepburn S, Wehner E. Parent reports of sensory symptoms in

toddlers with autism and those with other developmental disorders. *J Autism Dev Disord*. 2003;33(6): 631–642

104. McCormick C, Hepburn S, Young GS, Rogers SJ. Sensory symptoms in children with autism spectrum disorder, other developmental disorders and typical development: a longitudinal study. *Autism*. 2016;20(5): 572–579

105. Lane AEAE, Molloy CA, Bishop SL. Classification of children with autism spectrum disorder by sensory subtype: a case for sensory-based phenotypes. *Autism Res*. 2014;7(3):322–333

106. Ausderau KK, Furlong M, Sideris J, et al. Sensory subtypes in children with autism spectrum disorder: latent profile transition analysis using a national survey of sensory features. *J Child Psychol Psychiatry*. 2014;55(8): 935–944

107. Miller DT, Adam MP, Aradhya S, et al. Consensus statement: chromosomal microarray is a first-tier clinical diagnostic test for individuals with developmental disabilities or congenital anomalies. *Am J Hum Genet*. 2010;86(5): 749–764

108. Manning M, Hudgins L; Professional Practice and Guidelines Committee. Array-based technology and recommendations for utilization in medical genetics practice for detection of chromosomal abnormalities. *Genet Med*. 2010;12(11):742–745

109. Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. *Genet Med*. 2013;15(5): 399–407

110. Muhle RA, Reed HE, Vo LC, et al. Clinical diagnostic genetic testing for individuals with developmental disorders. *J Am Acad Child Adolesc Psychiatry*. 2017;56(11):910–913

111. Sun F, Oristaglio J, Levy SE, et al. *Genetic Testing for Developmental Disabilities, Intellectual Disability, and Autism Spectrum Disorder*. Rockville, MD: Agency for Healthcare Research and Quality (US); 2015

112. Amiet C, Couchon E, Carr K, Carayol J, Cohen D. Are there cultural differences in parental interest in early diagnosis and genetic risk assessment for autism spectrum disorder? *Front Pediatr*. 2014; 2:32

113. Srivastava S, Cohen JS, Vernon H, et al. Clinical whole exome sequencing in child neurology practice. *Ann Neurol*. 2014;76(4):473–483

114. Iglesias A, Anyane-Yeboa K, Wynn J, et al. The usefulness of whole-exome sequencing in routine clinical practice. *Genet Med*. 2014;16(12):922–931

115. Lingen M, Albers L, Borchers M, et al. Obtaining a genetic diagnosis in a child with disability: impact on parental quality of life. *Clin Genet*. 2016;89(2): 258–266

116. Riggs ER, Wain KE, Riethmaier D, et al. Chromosomal microarray impacts clinical management. *Clin Genet*. 2014; 85(2):147–153

117. ACMG Board of Directors. Clinical utility of genetic and genomic services: a position statement of the American College of Medical Genetics and Genomics. *Genet Med*. 2015;17(6): 505–507

118. Reiff M, Giarelli E, Bernhardt BA, et al. Parents' perceptions of the usefulness of chromosomal microarray analysis for children with autism spectrum disorders. *J Autism Dev Disord*. 2015; 45(10):3262–3275

119. Mandy W, Lai MC. Annual research review: the role of the environment in the developmental psychopathology of autism spectrum condition. *J Child Psychol Psychiatry*. 2016;57(3):271–292

120. Myers S, Challman C; American Academy of Pediatrics. Autism Spectrum Disorders. In: *Developmental and Behavioral Pediatrics*. Itasca, IL: American Academy of Pediatrics; 2018: 407–475

121. Tammimies K, Marshall CR, Walker S, et al. Molecular diagnostic yield of chromosomal microarray analysis and whole-exome sequencing in children with autism spectrum disorder. *JAMA*. 2015;314(9):895–903

122. Alvarez-Mora MI, Calvo Escalona R, Puig Navarro O, et al. Comprehensive molecular testing in patients with high functioning autism spectrum disorder. *Mutat Res*. 2016;784–785:46–52

123. Fernandez BA, Scherer SW. Syndromic autism spectrum disorders: moving from a clinically defined to a molecularly defined approach. *Dialogues Clin Neurosci*. 2017;19(4): 353–371

124. Carter MT, Scherer SW. Autism spectrum disorder in the genetics clinic: a review. *Clin Genet*. 2013;83(5): 399–407

125. Persico AM, Napolioni V. Autism genetics. *Behav Brain Res*. 2013;251: 95–112

126. Schönewolf-Greulich B, Bisgaard AM, Møller RS, et al. Clinician's guide to genes associated with Rett-like phenotypes-investigation of a Danish cohort and review of the literature. *Clin Genet*. 2019;95(2):221–230

127. McBride KL, Varga EA, Pastore MT, et al. Confirmation study of PTEN mutations among individuals with autism or developmental delays/mental retardation and macrocephaly. *Autism Res*. 2010;3(3):137–141

128. Battaglia A, Doccini V, Bernardini L, et al. Confirmation of chromosomal microarray as a first-tier clinical diagnostic test for individuals with developmental delay, intellectual disability, autism spectrum disorders and dysmorphic features. *Eur J Paediatr Neurol*. 2013;17(6):589–599

129. Bremer A, Giacobini M, Nordenskjöld M, et al. Screening for copy number alterations in loci associated with autism spectrum disorders by two-color multiplex ligation-dependent probe amplification. *Am J Med Genet B Neuropsychiatr Genet*. 2010;153B(1): 280–285

130. Eriksson MA, Liedén A, Westerlund J, et al. Rare copy number variants are common in young children with autism spectrum disorder. *Acta Paediatr*. 2015; 104(6):610–618

131. Ho KS, Wassman ER, Baxter AL, et al. Chromosomal microarray analysis of consecutive individuals with autism spectrum disorders using an ultra-high resolution chromosomal microarray optimized for neurodevelopmental disorders. *Int J Mol Sci*. 2016;17(12): E2070

132. McGrew SG, Peters BR, Crittendon JA, Veenstra-Vanderweele J. Diagnostic yield of chromosomal microarray analysis in an autism primary care practice: which guidelines to implement? *J Autism Dev Disord*. 2012; 42(8):1582–1591

133. Rosenfeld JA, Ballif BC, Torchia BS, et al. Copy number variations associated with autism spectrum disorders contribute to a spectrum of neurodevelopmental disorders. *Genet Med*. 2010;12(11):694–702

134. Schaefer GB, Starr L, Pickering D, Skar G, Dehaai K, Sanger WG. Array comparative genomic hybridization findings in a cohort referred for an autism evaluation. *J Child Neurol*. 2010; 25(12):1498–1503

135. Shen Y, Dies KA, Holm IA, et al; Autism Consortium Clinical Genetics/DNA Diagnostics Collaboration. Clinical genetic testing for patients with autism spectrum disorders. *Pediatrics*. 2010; 125(4). Available at: www.pediatrics.org/cgi/content/full/125/4/e727

136. Roesser J. Diagnostic yield of genetic testing in children diagnosed with autism spectrum disorders at a regional referral center. *Clin Pediatr (Phila)*. 2011;50(9):834–843

137. Tassone F, Choudhary NS, Tassone F, et al. Identification of expanded alleles of the FMR1 gene in the CHildhood Autism Risks from Genes and Environment (CHARGE) study. *J Autism Dev Disord*. 2013;43(3):530–539

138. Iossifov I, Ronemus M, Levy D, et al. De novo gene disruptions in children on the autistic spectrum. *Neuron*. 2012; 74(2):285–299

139. Krumm N, O'Roak BJ, Shendure J, Eichler EE. A de novo convergence of autism genetics and molecular neuroscience. *Trends Neurosci*. 2014; 37(2):95–105

140. Krumm N, Turner TN, Baker C, et al. Excess of rare, inherited truncating mutations in autism. *Nat Genet*. 2015; 47(6):582–588

141. Pisula E, Ziegart-Sadowska K, et al. Braoder autism phenotype in siblings of children with ASD—a review. *Int J Mol Sci*. 2015;16(6):13217–13258

142. O'Roak BJ, Vives L, Fu W, et al. Multiplex targeted sequencing identifies recurrently mutated genes in autism spectrum disorders. *Science*. 2012; 338(6114):1619–1622

143. Lee BK, McGrath JJ. Advancing parental age and autism: multifactorial pathways. *Trends Mol Med*. 2015;21(2): 118–125

144. Retterer K, Juusola J, Cho MT, et al. Clinical application of whole-exome sequencing across clinical indications. *Genet Med*. 2016;18(7):696–704

145. Yang Y, Muzny DM, Xia F, et al. Molecular findings among patients referred for clinical whole-exome sequencing. *JAMA*. 2014;312(18):1870–1879

146. Srivastava S, Love-Nichols JA, Dies KA, et al; NDD Exome Scoping Review Work Group. Meta-analysis and multidisciplinary consensus statement: exome sequencing is a first-tier clinical diagnostic test for individuals with neurodevelopmental disorders [published online ahead of print June 11, 2019]. *Genet Med*. 2019;21(11): 2413–2421

147. Glusman G, Severson A, Dhankani V, et al. Identification of copy number variants in whole-genome data using reference coverage profiles. *Front Genet*. 2015;6:45

148. Jiang YH, Wang Y, Xiu X, Choy KW, Pursley AN, Cheung SW. Genetic diagnosis of autism spectrum disorders: the opportunity and challenge in the genomics era. *Crit Rev Clin Lab Sci*. 2014;51(5):249–262

149. Jiang YH, Yuen RK, Jin X, et al. Detection of clinically relevant genetic variants in autism spectrum disorder by whole-genome sequencing. *Am J Hum Genet*. 2013;93(2):249–263

150. Retterer K, Scuffins J, Schmidt D, et al. Assessing copy number from exome sequencing and exome array CGH based on CNV spectrum in a large clinical cohort. *Genet Med*. 2015;17(8): 623–629

151. Ozonoff S, Young GS, Carter A, et al. Recurrence risk for autism spectrum disorders: a Baby Siblings Research Consortium study. *Pediatrics*. 2011; 128(3). Available at: www.pediatrics.org/cgi/content/full/128/3/e488

152. Jokiranta-Olkoniemi E, Cheslack-Postava K, Sucksdorff D, et al. Risk of psychiatric and neurodevelopmental disorders among siblings of probands with autism spectrum disorders. *JAMA Psychiatry*. 2016;73(6):622–629

153. Sandin S, Lichtenstein P, Kuja-Halkola R, Larsson H, Hultman CM, Reichenberg A. The familial risk of autism. *JAMA*. 2014; 311(17):1770–1777

154. Werling DM, Geschwind DH. Recurrence rates provide evidence for sex-differential, familial genetic liability for autism spectrum disorders in multiplex families and twins. *Mol Autism*. 2015;6: 27

155. Constantino JN, Zhang Y, Frazier T, Abbacchi AM, Law P. Sibling recurrence and the genetic epidemiology of autism. *Am J Psychiatry*. 2010;167(11): 1349–1356

156. Lindgren KA, Folstein SE, Tomblin JB, Tager-Flusberg H. Language and reading abilities of children with autism spectrum disorders and specific language impairment and their first-degree relatives. *Autism Res*. 2009; 2(1):22–38

157. Erbetta A, Bulgheroni S, Contarino VE, et al. Low-functioning autism and nonsyndromic intellectual disability: magnetic resonance imaging (MRI) findings. *J Child Neurol*. 2015;30(12): 1658–1663

158. Vasa RA, Ranta M, Huisman TA, Pinto PS, Tillman RM, Mostofsky SH. Normal rates of neuroradiological findings in children with high functioning autism. *J Autism Dev Disord*. 2012;42(8): 1662–1670

159. Cooper AS, Friedlaender E, Levy SE, et al. The implications of brain MRI in autism spectrum disorder. *J Child Neurol*. 2016;31(14):1611–1616

160. Monterrey JC, Philips J, Cleveland S, et al. Incidental brain MRI findings in an autism twin study. *Autism Res*. 2017; 10(1):113–120

161. Filipek PA, Accardo PJ, Ashwal S, et al. Practice parameter: screening and diagnosis of autism: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Child Neurology Society. *Neurology*. 2000;55(4):468–479

162. Moeschler JB, Shevell M; Committee on Genetics. Comprehensive evaluation of the child with intellectual disability or global developmental delays.

Pediatrics. 2014;134(3). Available at: www.pediatrics.org/cgi/content/full/134/3/e903

163. Campistol J, Díez-Juan M, Callejón L, et al. Inborn error metabolic screening in individuals with nonsyndromic autism spectrum disorders. *Dev Med Child Neurol*. 2016;58(8):842–847

164. Hadjixenofontos A, Schmidt MA, Whitehead PL, et al. Evaluating mitochondrial DNA variation in autism spectrum disorders. *Ann Hum Genet*. 2013;77(1):9–21

165. Herman GE, Henninger N, Ratliff-Schaub K, Pastore M, Fitzgerald S, McBride KL. Genetic testing in autism: how much is enough? *Genet Med*. 2007;9(5):268–274

166. Schiff M, Benoist JF, Aïssaoui S, et al. Should metabolic diseases be systematically screened in nonsyndromic autism spectrum disorders? [published correction appears in *PLoS One*. 2011;6(8)]. *PLoS One*. 2011;6(7):e21932

167. Shevell M, Ashwal S, Donley D, et al; Quality Standards Subcommittee of the American Academy of Neurology; Practice Committee of the Child Neurology Society. Practice parameter: evaluation of the child with global developmental delay: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2003;60(3):367–380

168. Zecavati N, Spence SJ. Neurometabolic disorders and dysfunction in autism spectrum disorders. *Curr Neurol Neurosci Rep*. 2009;9(2):129–136

169. Council on Environmental Health. Prevention of childhood lead toxicity [published correction appears in *Pediatrics*. 2017;140(2):e20171490]. *Pediatrics*. 2016;138(1):e20161493

170. El Achkar CM, Spence SJ. Clinical characteristics of children and young adults with co-occurring autism spectrum disorder and epilepsy. *Epilepsy Behav*. 2015;47:183–190

171. Ghacibeh GA, Fields C. Interictal epileptiform activity and autism. *Epilepsy Behav*. 2015;47:158–162

172. Jeste SS, Tuchman R. Autism spectrum disorder and epilepsy: two sides of the same coin? *J Child Neurol*. 2015;30(14):1963–1971

173. Jokiranta E, Sourander A, Suominen A, Timonen-Soivio L, Brown AS, Sillanpää M. Epilepsy among children and adolescents with autism spectrum disorders: a population-based study. *J Autism Dev Disord*. 2014;44(10):2547–2557

174. Woolfenden S, Sarkozy V, Ridley G, Coory M, Williams K. A systematic review of two outcomes in autism spectrum disorder - epilepsy and mortality. *Dev Med Child Neurol*. 2012;54(4):306–312

175. Yasuhara A. Correlation between EEG abnormalities and symptoms of autism spectrum disorder (ASD). *Brain Dev*. 2010;32(10):791–798

176. Kagan-Kushnir T, Roberts SW, Snead OC III. Screening electroencephalograms in autism spectrum disorders: evidence-based guideline. *J Child Neurol*. 2005;20(3):197–206

177. Tick B, Bolton P, Happé F, Rutter M, Rijsdijk F. Heritability of autism spectrum disorders: a meta-analysis of twin studies. *J Child Psychol Psychiatry*. 2016;57(5):585–595

178. Nordenbæk C, Jørgensen M, Kyvik KO, Bilenberg N. A Danish population-based twin study on autism spectrum disorders. *Eur Child Adolesc Psychiatry*. 2014;23(1):35–43

179. Charman T, Young GS, Brian J, et al. Non-ASD outcomes at 36 months in siblings at familial risk for autism spectrum disorder (ASD): a baby siblings research consortium (BSRC) study. *Autism Res*. 2017;10(1):169–178

180. Bailey A, Le Couteur A, Gottesman I, et al. Autism as a strongly genetic disorder: evidence from a British twin study. *Psychol Med*. 1995;25(1):63–77

181. Robinson EB, Neale BM, Hyman SE. Genetic research in autism spectrum disorders. *Curr Opin Pediatr*. 2015;27(6):685–691

182. Bourgeron T. Current knowledge on the genetics of autism and propositions for future research. *C R Biol*. 2016;339(7–8):300–307

183. Tick B, Bolton P, Happé F, Rutter M, Rijsdijk F. Heritability of autism spectrum disorders: a meta-analysis of twin studies. *J Child Psychol Psychiatry*. 2016;57(5):585–595

184. Colvert E, Tick B, McEwen F, et al. Heritability of autism spectrum disorder in a UK population-based twin sample. *JAMA Psychiatry*. 2015;72(5):415–423

185. Sandin S, Hultman CM, Kolevzon A, Gross R, MacCabe JH, Reichenberg A. Advancing maternal age is associated with increasing risk for autism: a review and meta-analysis [published correction appears in *J Am Acad Child Adolesc Psychiatry*. 2012;51(6):660]. *J Am Acad Child Adolesc Psychiatry*. 2012;51(5):477–486.e1

186. Sandin S, Schendel D, Magnusson P, et al. Autism risk associated with parental age and with increasing difference in age between the parents. *Mol Psychiatry*. 2016;21(5):693–700

187. Hultman CM, Sandin S, Levine SZ, Lichtenstein P, Reichenberg A. Advancing paternal age and risk of autism: new evidence from a population-based study and a meta-analysis of epidemiological studies. *Mol Psychiatry*. 2011;16(12):1203–1212

188. Kong A, Frigge ML, Masson G, et al. Rate of de novo mutations and the importance of father's age to disease risk. *Nature*. 2012;488(7412):471–475

189. Bourgeron T. From the genetic architecture to synaptic plasticity in autism spectrum disorder. *Nat Rev Neurosci*. 2015;16(9):551–563

190. de la Torre-Ubieta L, Won H, Stein JL, Geschwind DH. Advancing the understanding of autism disease mechanisms through genetics. *Nat Med*. 2016;22(4):345–361

191. De Rubeis S, Buxbaum JD. Genetics and genomics of autism spectrum disorder: embracing complexity. *Hum Mol Genet*. 2015;24(R1):R24–R31

192. Sanders SJ, He X, Willsey AJ, et al; Autism Sequencing Consortium. Insights into autism spectrum disorder genomic architecture and biology from 71 risk loci. *Neuron*. 2015;87(6):1215–1233

193. Lee H, Deignan JL, Dorrani N, et al. Clinical exome sequencing for genetic identification of rare Mendelian disorders. *JAMA*. 2014;312(18):1880–1887

194. Liu X, Takumi T. Genomic and genetic aspects of autism spectrum disorder. *Biochem Biophys Res Commun*. 2014; 452(2):244–253

195. Rossi M, El-Khechen D, Black MH, Farwell Hagman KD, Tang S, Powis Z. Outcomes of diagnostic exome sequencing in patients with diagnosed or suspected autism spectrum disorders. *Pediatr Neurol*. 2017;70: 34–43.e2

196. Brandler WM, Sebat J. From de novo mutations to personalized therapeutic interventions in autism. *Annu Rev Med*. 2015;66:487–507

197. Coe BP, Girirajan S, Eichler EE. The genetic variability and commonality of neurodevelopmental disease. *Am J Med Genet C Semin Med Genet*. 2012;160C(2): 118–129

198. Gonzalez-Mantilla AJ, Moreno-De-Luca A, Ledbetter DH, Martin CL. A cross-disorder method to identify novel candidate genes for developmental brain disorders. *JAMA Psychiatry*. 2016; 73(3):275–283

199. Li J, Cai T, Jiang Y, et al. Genes with de novo mutations are shared by four neuropsychiatric disorders discovered from NPdenovo database [published correction appears in *Mol Psychiatry*. 2016;21(2):298]. *Mol Psychiatry*. 2016; 21(2):290–297

200. Moreno-De-Luca A, Myers SM, Challman TD, Moreno-De-Luca D, Evans DW, Ledbetter DH. Developmental brain dysfunction: revival and expansion of old concepts based on new genetic evidence [published correction appears in *Lancet Neurol*. 2013;12(5):423]. *Lancet Neurol*. 2013;12(4):406–414

201. Mullin AP, Gokhale A, Moreno-De-Luca A, Sanyal S, Waddington JL, Faundez V. Neurodevelopmental disorders: mechanisms and boundary definitions from genomes, interactomes and proteomes. *Transl Psychiatry*. 2013;3: e329

202. Pescosolido MF, Gamsiz ED, Nagpal S, Morrow EM. Distribution of disease-associated copy number variants across distinct disorders of cognitive development. *J Am Acad Child Adolesc Psychiatry*. 2013;52(4):414–430.e14

203. Vorstman JAS, Parr JR, Moreno-De-Luca D, Anney RJL, Nurnberger JI Jr., Hallmayer JF. Autism genetics: opportunities and challenges for clinical translation. *Nat Rev Genet*. 2017; 18(6):362–376

204. Waltereit R, Banaschewski T, Meyer-Lindenberg A, Poustka L. Interaction of neurodevelopmental pathways and synaptic plasticity in mental retardation, autism spectrum disorder and schizophrenia: implications for psychiatry. *World J Biol Psychiatry*. 2014;15(7):507–516

205. Gardener H, Spiegelman D, Buka SL. Perinatal and neonatal risk factors for autism: a comprehensive meta-analysis. *Pediatrics*. 2011;128(2):344–355

206. Christensen J, Grønborg TK, Sørensen MJ, et al. Prenatal valproate exposure and risk of autism spectrum disorders and childhood autism. *JAMA*. 2013; 309(16):1696–1703

207. Bromley RL, Mawer G, Clayton-Smith J, Baker GA; Liverpool and Manchester Neurodevelopment Group. Autism spectrum disorders following in utero exposure to antiepileptic drugs. *Neurology*. 2008;71(23):1923–1924

208. Dodds L, Fell DB, Shea S, Armson BA, Allen AC, Bryson S. The role of prenatal, obstetric and neonatal factors in the development of autism. *J Autism Dev Disord*. 2011;41(7):891–902

209. Wu S, Wu F, Ding Y, Hou J, Bi J, Zhang Z. Advanced parental age and autism risk in children: a systematic review and meta-analysis. *Acta Psychiatr Scand*. 2017;135(1):29–41

210. Pinto-Martin JA, Levy SE, Feldman JF, Lorenz JM, Paneth N, Whitaker AH. Prevalence of autism spectrum disorder in adolescents born weighing <2000 grams. *Pediatrics*. 2011;128(5): 883–891

211. Lampi KM, Lehtonen L, Tran PL, et al. Risk of autism spectrum disorders in low birth weight and small for gestational age infants. *J Pediatr*. 2012; 161(5):830–836

212. Guinchat V, Thorsen P, Laurent C, Cans C, Bodeau N, Cohen D. Pre-, peri- and neonatal risk factors for autism. *Acta Obstet Gynecol Scand*. 2012;91(3): 287–300

213. Duncan LE, Keller MC. A critical review of the first 10 years of candidate gene-by-environment interaction research in psychiatry. *Am J Psychiatry*. 2011; 168(10):1041–1049

214. Kalkbrenner AE, Schmidt RJ, Penlesky AC. Environmental chemical exposures and autism spectrum disorders: a review of the epidemiological evidence. *Curr Probl Pediatr Adolesc Health Care*. 2014;44(10):277–318

215. Becerra TA, Wilhelm M, Olsen J, Cockburn M, Ritz B. Ambient air pollution and autism in Los Angeles county, California. *Environ Health Perspect*. 2013;121(3):380–386

216. Volk HE, Lurmann F, Penfold B, Hertz-Picciotto I, McConnell R. Traffic-related air pollution, particulate matter, and autism. *JAMA Psychiatry*. 2013;70(1): 71–77

217. Mazina V, Gerdts J, Trinh S, et al. Epigenetics of autism-related impairment: copy number variation and maternal infection. *J Dev Behav Pediatr*. 2015;36(2):61–67

218. Braunschweig D, Van de Water J. Maternal autoantibodies in autism. *Arch Neurol*. 2012;69(6):693–699

219. Brimberg L, Sadiq A, Gregersen PK, Diamond B. Brain-reactive IgG correlates with autoimmunity in mothers of a child with an autism spectrum disorder. *Mol Psychiatry*. 2013;18(11):1171–1177

220. Bauman MD, Iosif AM, Ashwood P, et al. Maternal antibodies from mothers of children with autism alter brain growth and social behavior development in the rhesus monkey. *Transl Psychiatry*. 2013; 3:e278

221. Anderson GM. Autism biomarkers: challenges, pitfalls and possibilities. *J Autism Dev Disord*. 2015;45(4): 1103–1113

222. McDougle CJ, Landino SM, Vahabzadeh A, et al. Toward an immune-mediated subtype of autism spectrum disorder. *Brain Res*. 2015;1617:72–92

223. Isles AR. Neural and behavioral epigenetics; what it is, and what is hype. *Genes Brain Behav*. 2015;14(1): 64–72

224. Tordjman S, Somogyi E, Coulon N, et al. Gene × Environment interactions in autism spectrum disorders: role of epigenetic mechanisms. *Front Psychiatry*. 2014;5:53

225. Bohacek J, Mansuy IM. Molecular insights into transgenerational non-genetic inheritance of acquired behaviours. *Nat Rev Genet*. 2015;16(11): 641–652

226. Ladd-Acosta C, Hansen KD, Briem E, Fallin MD, Kaufmann WE, Feinberg AP. Common DNA methylation alterations in multiple brain regions in autism. *Mol Psychiatry*. 2014;19(8):862–871

227. Loke YJ, Hannan AJ, Craig JM. The role of epigenetic change in autism spectrum disorders. *Front Neurol*. 2015; 6:107

228. Wong CC, Meaburn EL, Ronald A, et al. Methylomic analysis of monozygotic twins discordant for autism spectrum disorder and related behavioural traits. *Mol Psychiatry*. 2014;19(4):495–503

229. Jain A, Marshall J, Buikema A, Bancroft T, Kelly JP, Newschaffer CJ. Autism occurrence by MMR vaccine status among US children with older siblings with and without autism. *JAMA*. 2015; 313(15):1534–1540

230. Uno Y, Uchiyama T, Kurosawa M, Aleksic B, Ozaki N. Early exposure to the combined measles-mumps-rubella vaccine and thimerosal-containing vaccines and risk of autism spectrum disorder. *Vaccine*. 2015;33(21): 2511–2516

231. Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies. *Vaccine*. 2014;32(29):3623–3629

232. Maglione MA, Das L, Raaen L, et al. Safety of vaccines used for routine immunization of U.S. children: a systematic review. *Pediatrics*. 2014; 134(2):325–337

233. DeStefano F, Price CS, Weintraub ES. Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. *J Pediatr*. 2013;163(2):561–567

234. Demicheli V, Rivetti A, Debalini MG, Di Pietrantonj C. Vaccines for measles, mumps and rubella in children. *Cochrane Database Syst Rev*. 2012;(2): CD004407

235. Gerber JS, Offit PA. Vaccines and autism: a tale of shifting hypotheses. *Clin Infect Dis*. 2009;48(4):456–461

236. Schechter R, Grether JK. Continuing increases in autism reported to California's developmental services system: mercury in retrograde. *Arch Gen Psychiatry*. 2008;65(1):19–24

237. Baird G, Pickles A, Simonoff E, et al. Measles vaccination and antibody response in autism spectrum disorders. *Arch Dis Child*. 2008;93(10): 832–837

238. Fombonne E, Zakarian R, Bennett A, Meng L, McLean-Heywood D. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. *Pediatrics*. 2006; 118(1). Available at: www.pediatrics.org/cgi/content/full/118/1/e139

239. Institute of Medicine Immunization Safety Review Committee. *Immunization Safety Review: Vaccines and Autism*. Washington, DC: National Academies Press; 2004

240. Jefferson T, Price D, Demicheli V, Bianco E; European Research Program for Improved Vaccine Safety Surveillance (EUSAFEVAC) Project. Unintended events following immunization with MMR: a systematic review. *Vaccine*. 2003; 21(25–26):3954–3960

241. Klein KC, Diehl EB. Relationship between MMR vaccine and autism. *Ann Pharmacother*. 2004;38(7–8):1297–1300

242. Mutter J, Naumann J, Schneider R, Walach H, Haley B. Mercury and autism: accelerating evidence? *Neuro Endocrinol Lett*. 2005;26(5):439–446

243. Kimmel SR, Burns IT, Wolfe RM, Zimmerman RK. Addressing immunization barriers, benefits, and risks. *J Fam Pract*. 2007;56(suppl 2): S61–S69

244. Parker SK, Schwartz B, Todd J, Pickering LK. Thimerosal-containing vaccines and autistic spectrum disorder: a critical review of published original data [published correction appears in *Pediatrics*. 2005;115(1):200]. *Pediatrics*. 2004;114(3):793–804

245. Ortqvist Å, Blennow M, Carlsson RM, et al. Vaccination of children–a systematic review. *Acta Paediatr*. 2010; 99(461):1–192

246. Wilson K, Mills E, Ross C, McGowan J, Jadad A. Association of autistic spectrum disorder and the measles, mumps, and rubella vaccine: a systematic review of current epidemiological evidence. *Arch Pediatr Adolesc Med*. 2003;157(7):628–634

247. Clarke CE, Weberling McKeever B, Holton A, Dixon GN. The influence of weight-of-evidence messages on (vaccine) attitudes: a sequential mediation model. *J Health Commun*. 2015;20(11):1302–1309

248. Nyhan B, Reifler J, Richey S, Freed GL. Effective messages in vaccine promotion: a randomized trial. *Pediatrics*. 2014;133(4). Available at: www.pediatrics.org/cgi/content/full/133/4/e835

249. Casanova MF. The neuropathology of autism. In: Volkmar FR, Rogers SJ, Paul R, Pelphrey KA, eds. Handbook of Autism and Pervasive Developmental Disorders, *4th ed, Vol 1. Hoboken, NJ: Wiley & Sons*; 2014:346–531

250. Chen JA, Peñagarikano O, Belgard TG, Swarup V, Geschwind DH. The emerging picture of autism spectrum disorder: genetics and pathology. *Annu Rev Pathol*. 2015;10:111–144

251. Wegiel J, Kuchna I, Nowicki K, et al. The neuropathology of autism: defects of neurogenesis and neuronal migration, and dysplastic changes. *Acta Neuropathol*. 2010;119(6):755–770

252. Stoner R, Chow ML, Boyle MP, et al. Patches of disorganization in the neocortex of children with autism. *N Engl J Med*. 2014;370(13):1209–1219

253. Walsh P, Elsabbagh M, Bolton P, Singh I. In search of biomarkers for autism: scientific, social and ethical challenges. *Nat Rev Neurosci*. 2011;12(10):603–612

254. Goldani AAS, Downs SR, Widjaja F, Lawton B, Hendren RL. Biomarkers in autism. *Front Psychiatry*. 2014;5:100

255. Ruggeri B, Sarkans U, Schumann G, Persico AM. Biomarkers in autism spectrum disorder: the old and the new. *Psychopharmacology (Berl)*. 2014; 231(6):1201–1216

256. Hazlett HC, Gu H, Munsell BC, et al; IBIS Network. Early brain development in infants at high risk for autism spectrum disorder. *Nature*. 2017; 542(7641):348–351

257. Courchesne E, Campbell K, Solso S. Brain growth across the life span in autism: age-specific changes in

anatomical pathology. *Brain Res*. 2011; 1380:138–145

258. Sacco R, Gabriele S, Persico AM. Head circumference and brain size in autism spectrum disorder: a systematic review and meta-analysis. *Psychiatry Res*. 2015;234(2):239–251

259. Elder LM, Dawson G, Toth K, Fein D, Munson J. Head circumference as an early predictor of autism symptoms in younger siblings of children with autism spectrum disorder. *J Autism Dev Disord*. 2008;38(6):1104–1111

260. Dawson G, Munson J, Webb SJ, Nalty T, Abbott R, Toth K. Rate of head growth decelerates and symptoms worsen in the second year of life in autism. *Biol Psychiatry*. 2007;61(4):458–464

261. Zwaigenbaum L, Young GS, Stone WL, et al. Early head growth in infants at risk of autism: a baby siblings research consortium study. *J Am Acad Child Adolesc Psychiatry*. 2014;53(10): 1053–1062

262. Chaste P, Klei L, Sanders SJ, et al. Adjusting head circumference for covariates in autism: clinical correlates of a highly heritable continuous trait. *Biol Psychiatry*. 2013;74(8):576–584

263. Chawarska K, Campbell D, Chen L, Shic F, Klin A, Chang J. Early generalized overgrowth in boys with autism. *Arch Gen Psychiatry*. 2011;68(10):1021–1031

264. Gray KM, Taffe J, Sweeney DJ, Forster S, Tonge BJ. Could head circumference be used to screen for autism in young males with developmental delay? *J Paediatr Child Health*. 2012;48(4): 329–334

265. Raznahan A, Wallace GL, Antezana L, et al. Compared to what? Early brain overgrowth in autism and the perils of population norms. *Biol Psychiatry*. 2013; 74(8):563–575

266. Schumann CM, Bloss CS, Barnes CC, et al. Longitudinal magnetic resonance imaging study of cortical development through early childhood in autism. *J Neurosci*. 2010;30(12):4419–4427

267. Shen MD, Nordahl CW, Young GS, et al. Early brain enlargement and elevated extra-axial fluid in infants who develop autism spectrum disorder. *Brain*. 2013; 136(pt 9):2825–2835

268. Schultz RT, Grelotti DJ, Klin A, et al. The role of the fusiform face area in social cognition: implications for the pathobiology of autism. *Philos Trans R Soc Lond B Biol Sci*. 2003;358(1430): 415–427

269. Nordahl CW, Scholz R, Yang X, et al. Increased rate of amygdala growth in children aged 2 to 4 years with autism spectrum disorders: a longitudinal study. *Arch Gen Psychiatry*. 2012;69(1): 53–61

270. Blackmon K. Structural MRI biomarkers of shared pathogenesis in autism spectrum disorder and epilepsy. *Epilepsy Behav*. 2015;47:172–182

271. Chen R, Jiao Y, Herskovits EH. Structural MRI in autism spectrum disorder. *Pediatr Res*. 2011;69(5, pt 2):63R–68R

272. Nickl-Jockschat T, Habel U, Michel TM, et al. Brain structure anomalies in autism spectrum disorder–a meta-analysis of VBM studies using anatomic likelihood estimation. *Hum Brain Mapp*. 2012;33(6):1470–1489

273. Wolff JJ, Gu H, Gerig G, et al; IBIS Network. Differences in white matter fiber tract development present from 6 to 24 months in infants with autism. *Am J Psychiatry*. 2012;169(6):589–600

274. Philip RC, Dauvermann MR, Whalley HC, Baynham K, Lawrie SM, Stanfield AC. A systematic review and meta-analysis of the fMRI investigation of autism spectrum disorders. *Neurosci Biobehav Rev*. 2012;36(2):901–942

275. Mahajan R, Mostofsky SH. Neuroimaging endophenotypes in autism spectrum disorder. *CNS Spectr*. 2015;20(4):412–426

276. Cerliani L, Mennes M, Thomas RM, Di Martino A, Thioux M, Keysers C. Increased functional connectivity between subcortical and cortical resting-state networks in autism spectrum disorder. *JAMA Psychiatry*. 2015;72(8):767–777

277. Doyle-Thomas KA, Lee W, Foster NE, et al; NeuroDevNet ASD Imaging Group. Atypical functional brain connectivity during rest in autism spectrum disorders. *Ann Neurol*. 2015;77(5): 866–876

278. Jeste SS, Nelson CA III. Event related potentials in the understanding of autism spectrum disorders: an analytical review. *J Autism Dev Disord*. 2009;39(3):495–510

279. Jeste SS, Frohlich J, Loo SK. Electrophysiological biomarkers of diagnosis and outcome in neurodevelopmental disorders. *Curr Opin Neurol*. 2015;28(2):110–116

280. Marco EJ, Hinkley LB, Hill SS, Nagarajan SS. Sensory processing in autism: a review of neurophysiologic findings. *Pediatr Res*. 2011;69(5, pt 2):48R–54R

281. Massand E, Bowler DM, Mottron L, Hosein A, Jemel B. ERP correlates of recognition memory in autism spectrum disorder. *J Autism Dev Disord*. 2013;43(9):2038–2047

282. Di Giorgio E, Frasnelli E, Salva OR, et al. ifference in visual social predispositions between newborns at low- and high-risk for autism. *Sci Rep*. 2016;6:29860

283. Constantino J, Kennon-McGill S, Weichselbaum C, et al. Infant viewing of social scenes is under genetic control and atypical in autism. *Nature*. 2017; 547(7663):340–344

284. Simion F, Di Giorgio E. Face perception and processing in early infancy: inborn predispositions and developmental changes. *Front Psychol*. 2015;6:969

285. Jones W, Klin A. Attention to eyes is present but in decline in 2–6-month-old infants later diagnosed with autism. *Nature*. 2013;504(7480):427–431

286. Walker CK, Anderson KW, Milano KM, et al. Trophoblast inclusions are significantly increased in the placentas of children in families at risk for autism. *Biol Psychiatry*. 2013;74(3): 204–211

287. Anderson GM, Jacobs-Stannard A, Chawarska K, Volkmar FR, Kliman HJ. Placental trophoblast inclusions in autism spectrum disorder. *Biol Psychiatry*. 2007;61(4):487–491

288. Voineagu I, Yoo HJ. Current progress and challenges in the search for autism biomarkers. *Dis Markers*. 2013;35(1): 55–65

289. Anderson GM, Stahl SS. Two proposed early biomarker tests of ASD: more harm than good. *J Autism Dev Disord*. 2014;44(4):988–989

290. Jordan BR, Tsai DF. Whole-genome association studies for multigenic

diseases: ethical dilemmas arising from commercialization–the case of genetic testing for autism. *J Med Ethics*. 2010;36(7):440–444

291. Hernandez LM, Rudie JD, Green SA, Bookheimer S, Dapretto M. Neural signatures of autism spectrum disorders: insights into brain network dynamics. *Neuropsychopharmacology*. 2015;40(1):171–189
292. Ameis SH, Kassee C, Corbett-Dick P, et al. ystemic review and guide to management of core and psychiatric symptoms in youth with autism. *Acta Psychiatr Scand*. 2018;138(5):379–400
293. Mannion A, Leader G. Comorbidity in autism spectrum disorder: a literature review. *Res Autism Spectr Disord*. 2013; 7(12):1595–1616
294. Lyra L, Rizzo LE, Sunahara CS, et al. What do Cochrane systematic reviews say about interventions for autism spectrum disorders? *Sao Paulo Med J*. 2017;135(2):192–201
295. Wong C, Odom SL, Hume KA, et al. Evidence-based practices for children, youth, and young adults with autism spectrum disorder: a comprehensive review. *J Autism Dev Disord*. 2015;45(7): 1951–1966
296. Schreibman L, Dawson G, Stahmer AC, et al. Naturalistic developmental behavioral interventions: empirically validated treatments for autism spectrum disorder. *J Autism Dev Disord*. 2015;45(8):2411–2428
297. Smith T, Iadarola S. Evidence base update for autism spectrum disorder. *J Clin Child Adolesc Psychol*. 2015;44(6): 897–922
298. Weitlauf AS, McPheeters ML, Peters B, et al. *Therapies for Children With Autism Spectrum Disorder: Behavioral Interventions Update*. Rockville, MD: Agency for Healthcare Research and Quality; 2014
299. Wang L, Mandell DS, Lawer L, Cidav Z, Leslie DL. Healthcare service use and costs for autism spectrum disorder: a comparison between Medicaid and private insurance. *J Autism Dev Disord*. 2013;43(5):1057–1064
300. Warren Z, McPheeters ML, Sathe N, Foss-Feig JH, Glasser A, Veenstra-Vanderweele J. A systematic review of early intensive intervention for autism spectrum disorders. *Pediatrics*. 2011; 127(5). Available at: www.pediatrics.org/cgi/content/full/127/5/e1303
301. McPheeters ML, Warren Z, Sathe N, et al. A systematic review of medical treatments for children with autism spectrum disorders. *Pediatrics*. 2011; 127(5). Available at: www.pediatrics.org/cgi/content/full/127/5/e1312
302. National Autism Center. *Findings and Conclusions: National Standards Project, Phase 2*. Randolph, MA: National Autism Center at May Institute; 2015
303. Odom SL, Boyd BA, Hall LJ, Hume K. Evaluation of comprehensive treatment models for individuals with autism spectrum disorders. *J Autism Dev Disord*. 2010;40(4):425–436
304. Schreibman L, Stahmer AC. A randomized trial comparison of the effects of verbal and pictorial naturalistic communication strategies on spoken language for young children with autism. *J Autism Dev Disord*. 2014; 44(5):1244–1251
305. Murza KA, Schwartz JB, Hahs-Vaughn DL, Nye C. Joint attention interventions for children with autism spectrum disorder: a systematic review and meta-analysis. *Int J Lang Commun Disord*. 2016;51(3):236–251
306. Houtrow A, Murphy N; Council on Children With Disabilities. Prescribing physical, occupational, and speech therapy services for children with disabilities. *Pediatrics*. 2019;143(4): e20190285
307. Maglione MA, Gans D, Das L, Timbie J, Kasari C; Technical Expert Panel; HRSA Autism Intervention Research – Behavioral (AIR-B) Network. Nonmedical interventions for children with ASD: recommended guidelines and further research needs. *Pediatrics*. 2012; 130(suppl 2):S169–S178
308. Stahmer AC. Effective strategies by any other name. *Autism*. 2014;18(3):211–212
309. Roane HS, Fisher WW, Carr JE. Applied behavior analysis as treatment for autism spectrum disorder. *J Pediatr*. 2016;175:27–32
310. Baer DM, Wolf MM, Risley TR. Some current dimensions of applied behavior analysis. *J Appl Behav Anal*. 1968;1(1): 91–97
311. Lovaas OI, Smith T. A comprehensive behavioral theory of autistic children: paradigm for research and treatment. *J Behav Ther Exp Psychiatry*. 1989;20(1): 17–29
312. Smith T, Eikeseth S. O. Ivar lovaas: pioneer of applied behavior analysis and intervention for children with autism. *J Autism Dev Disord*. 2011;41(3): 375–378
313. Leaf JB, Leaf JA, Milne C, et al. An evaluation of a behaviorally based social skills group for individuals diagnosed with autism spectrum disorder. *J Autism Dev Disord*. 2017; 47(2):243–259
314. Lounds Taylor J, Dove D, Veenstra-VanderWeele J, et al. *Interventions for Adolescents and Young Adults With Autism Spectrum Disorders*. Rockville, MD: Agency for Healthcare Research and Quality; 2012
315. Linstead E, Dixon DR, French R, et al. Intensity and learning outcomes in the treatment of children with autism spectrum disorder. *Behav Modif*. 2017; 41(2):229–252
316. Orinstein AJ, Helt M, Troyb E, et al. Intervention for optimal outcome in children and adolescents with a history of autism. *J Dev Behav Pediatr*. 2014; 35(4):247–256
317. Granpeesheh D, Tarbox J, Dixon DR. Applied behavior analytic interventions for children with autism: a description and review of treatment research. *Ann Clin Psychiatry*. 2009;21(3):162–173
318. Landry SH, Smith KE, Swank PR, Miller-Loncar CL. Early maternal and child influences on children's later independent cognitive and social functioning. *Child Dev*. 2000;71(2): 358–375
319. Tamis-LeMonda CS, Bornstein MH, Baumwell L. Maternal responsiveness and children's achievement of language milestones. *Child Dev*. 2001;72(3): 748–767
320. Siller M, Sigman M. The behaviors of parents of children with autism predict the subsequent development of their children's communication. *J Autism Dev Disord*. 2002;32(2):77–89
321. Green J, Charman T, McConachie H, et al; PACT Consortium. Parent-mediated communication-focused treatment in

children with autism (PACT): a randomised controlled trial. *Lancet*. 2010;375(9732):2152–2160

322. Kasari C, Gulsrud AC, Wong C, Kwon S, Locke J. Randomized controlled caregiver mediated joint engagement intervention for toddlers with autism. *J Autism Dev Disord*. 2010;40(9): 1045–1056

323. Solomon R, Van Egeren LA, Mahoney G, Quon Huber MS, Zimmerman P. PLAY Project Home Consultation intervention program for young children with autism spectrum disorders: a randomized controlled trial. *J Dev Behav Pediatr*. 2014;35(8):475–485

324. Gutstein SE. Empowering families through relationship development intervention: an important part of the biopsychosocial management of autism spectrum disorders. *Ann Clin Psychiatry*. 2009;21(3):174–182

325. Estes A, Munson J, Rogers SJ, Greenson J, Winter J, Dawson G. Long-term outcomes of early intervention in 6-year-old children with autism spectrum disorder. *J Am Acad Child Adolesc Psychiatry*. 2015;54(7):580–587

326. Rogers SJ, Estes A, Lord C, et al. Effects of a brief Early Start Denver model (ESDM)-based parent intervention on toddlers at risk for autism spectrum disorders: a randomized controlled trial. *J Am Acad Child Adolesc Psychiatry*. 2012;51(10):1052–1065

327. Dawson G, Jones EJ, Merkle K, et al. Early behavioral intervention is associated with normalized brain activity in young children with autism. *J Am Acad Child Adolesc Psychiatry*. 2012;51(11):1150–1159

328. Ingersoll BR, Wainer AL. Pilot study of a school-based parent training program for preschoolers with ASD. *Autism*. 2013;17(4):434–448

329. Oono IP, Honey EJ, McConachie H. Parent-mediated early intervention for young children with autism spectrum disorders (ASD). *Cochrane Database Syst Rev*. 2013;(4):CD009774

330. Beaudoin AJ, Sébire G, Couture M. Parent training interventions for toddlers with autism spectrum disorder. *Autism Res Treat*. 2014;2014: 839890

331. Bearss K, Johnson C, Smith T, et al. Effect of parent training vs parent education on behavioral problems in children with autism spectrum disorder: a randomized clinical trial. *JAMA*. 2015;313(15):1524–1533

332. Bearss K, Burrell TL, Stewart L, Scahill L. Parent training in autism spectrum disorder: what's in a name? [published correction appears in *Clin Child Fam Psychol Rev*. 2015;18(2):183]. *Clin Child Fam Psychol Rev*. 2015;18(2):170–182

333. Wainer AL, Ingersoll BR. Increasing access to an ASD imitation intervention via a telehealth parent training program. *J Autism Dev Disord*. 2015; 45(12):3877–3890

334. Ingersoll B, Berger NI. Parent engagement with a telehealth-based parent-mediated intervention program for children with autism spectrum disorders: predictors of program use and parent outcomes [published correction appears in *J Med Internet Res*. 2015;17(11):e239]. *J Med Internet Res*. 2015;17(10):e227

335. Ingersoll B, Wainer AL, Berger NI, Pickard KE, Bonter N. Comparison of a self-directed and therapist-assisted telehealth parent-mediated intervention for children with ASD: a pilot RCT. *J Autism Dev Disord*. 2016;46(7): 2275–2284

336. Turner-Brown L, Hume K, Boyd BA, Kainz K. Preliminary efficacy of family implemented TEACCH for toddlers: effects on parents and their toddlers with autism spectrum disorder. *J Autism Dev Disord*. 2019;49(7): 2685–2698

337. Lindgren S, Wacker D, Suess A, et al. Telehealth and autism: treating challenging behavior at lower cost. *Pediatrics*. 2016;137(suppl 2): S167–S175

338. Kasari C, Gulsrud A, Paparella T, Hellemann G, Berry K. Randomized comparative efficacy study of parent-mediated interventions for toddlers with autism. *J Consult Clin Psychol*. 2015;83(3):554–563

339. Harrop C. Evidence-based, parent-mediated interventions for young children with autism spectrum disorder: the case of restricted and repetitive behaviors. *Autism*. 2015;19(6): 662–672

340. Scahill L, Bearss K, Lecavalier L, et al. Effect of parent training on adaptive behavior in children with autism spectrum disorder and disruptive behavior: results of a randomized trial. *J Am Acad Child Adolesc Psychiatry*. 2016;55(7):602–609.e3

341. Bearss K, Lecavalier L, Minshawi N, et al. Toward an exportable parent training program for disruptive behaviors in autism spectrum disorders. *Neuropsychiatry (London)*. 2013;3(2):169–180

342. Grahame V, Brett D, Dixon L, et al. Managing repetitive behaviours in young children with autism spectrum disorder (ASD): pilot randomised controlled trial of a new parent group intervention. *J Autism Dev Disord*. 2015; 45(10):3168–3182

343. Wetherby AM, Guthrie W, Woods J, et al. Parent-implemented social intervention for toddlers with autism: an RCT. *Pediatrics*. 2014;134(6):1084–1093

344. Boyd BA, Hume K, McBee MT, et al. Comparative efficacy of LEAP, TEACCH and non-model-specific special education programs for preschoolers with autism spectrum disorders. *J Autism Dev Disord*. 2014;44(2): 366–380

345. Strain PS, Bovey EH II. Randomized, controlled trial of the LEAP model of early intervention for young children with autism spectrum disorders. *Topics Early Child Spec Educ*. 2011;31(3): 133–154

346. Strain PS, Hoyson M. The need for longitudinal, intensive social skill intervention: LEAP follow-up outcomes for children with autism. *Topics Early Child Spec Educ*. 2000;20(2):116–122

347. Virues-Ortega J, Julio FM, Pastor-Barriuso R. The TEACCH program for children and adults with autism: a meta-analysis of intervention studies. *Clin Psychol Rev*. 2013;33(8):940–953

348. Lipkin PH, Okamoto J; Council on Children with Disabilities; Council on School Health. The Individuals With Disabilities Education Act (IDEA) for children with special educational needs. *Pediatrics*. 2015;136(6). Available at: www.pediatrics.org/cgi/content/full/136/6/e1650

349. US Department of Education. Protecting students with disabilities. Available at: https://www2.ed.gov/about/offices/list/ocr/504faq.html. Accessed December 1, 2019

350. Ricketts J. Research review: reading comprehension in developmental disorders of language and communication. *J Child Psychol Psychiatry*. 2011;52(11):1111–1123

351. Kasari C, Rotheram-Fuller E, Locke J, Gulsrud A. Making the connection: randomized controlled trial of social skills at school for children with autism spectrum disorders. *J Child Psychol Psychiatry*. 2012;53(4):431–439

352. Kretzmann M, Shih W, Kasari C. Improving peer engagement of children with autism on the school playground: a randomized controlled trial. *Behav Ther*. 2015;46(1):20–28

353. Foster EM, Pearson E. Is inclusivity an indicator of quality of care for children with autism in special education? *Pediatrics*. 2012;130(suppl 2): S179–S185

354. Otero TL, Schatz RB, Merrill AC, Bellini S. Social skills training for youth with autism spectrum disorders: a follow-up. *Child Adolesc Psychiatr Clin N Am*. 2015; 24(1):99–115

355. Whalon KJ, Conroy MA, Martinez JR, Werch BL. School-based peer-related social competence interventions for children with autism spectrum disorder: a meta-analysis and descriptive review of single case research design studies. *J Autism Dev Disord*. 2015;45(6):1513–1531

356. Reichow B, Steiner AM, Volkmar F. Cochrane review: social skills groups for people aged 6 to 21 with autism spectrum disorders (ASD). *Evid Based Child Health*. 2013;8(2):266–315

357. Reichow B, Volkmar FR. Social skills interventions for individuals with autism: evaluation for evidence-based practices within a best evidence synthesis framework. *J Autism Dev Disord*. 2010;40(2):149–166

358. Laugeson EA, Ellingsen R, Sanderson J, Tucci L, Bates S. The ABC's of teaching social skills to adolescents with autism spectrum disorder in the classroom: the UCLA PEERS (®) Program. *J Autism Dev Disord*. 2014;44(9):2244–2256

359. Laugeson EA, Gantman A, Kapp SK, Orenski K, Ellingsen R. A randomized controlled trial to improve social skills in young adults with autism spectrum disorder: The UCLA PEERS(®) program. *J Autism Dev Disord*. 2015;45(12): 3978–3989

360. Krasny L, Williams BJ, Provencal S, Ozonoff S. Social skills interventions for the autism spectrum: essential ingredients and a model curriculum. *Child Adolesc Clin North Am*. 2003;12(1): 107–122

361. Green VA, Pituch KA, Itchon J, Choi A, O'Reilly M, Sigafoos J. Internet survey of treatments used by parents of children with autism. *Res Dev Disabil*. 2006; 27(1):70–84

362. DeThorne LS, Johnson CJ, Walder L, Mahurin-Smith J. When "Simon says" doesn't work: alternatives to imitation for facilitating early speech development. *Am J Speech Lang Pathol*. 2009;18(2):133–145

363. Anderson DK, Lord C, Risi S, et al. Patterns of growth in verbal abilities among children with autism spectrum disorder. *J Consult Clin Psychol*. 2007; 75(4):594–604

364. Wodka EL, Mathy P, Kalb L. Predictors of phrase and fluent speech in children with autism and severe language delay. *Pediatrics*. 2013;131(4). Available at: www.pediatrics.org/cgi/content/full/131/4/e1128

365. Schlosser RW, Wendt O. Effects of augmentative and alternative communication intervention on speech production in children with autism: a systematic review. *Am J Speech Lang Pathol*. 2008;17(3):212–230

366. Ganz JB, Mason RA, Goodwyn FD, Boles MB, Heath AK, Davis JL. Interaction of participant characteristics and type of AAC with individuals with ASD: a meta-analysis. *Am J Intellect Dev Disabil*. 2014;119(6):516–535

367. Knight V, Sartini E, Spriggs AD. Evaluating visual activity schedules as evidence-based practice for individuals with autism spectrum disorders. *J Autism Dev Disord*. 2015;45(1): 157–178

368. Ganz JB. AAC interventions for individuals with autism spectrum disorders: state of the science and future research directions. *Augment Altern Commun*. 2015;31(3):203–214

369. American Academy of Pediatrics Committee on Children with Disabilities. Auditory integration training and facilitated communication for autism. *Pediatrics*. 1998;102(2, pt 1):431–433

370. Schlosser RW, Balandin S, Hemsley B, Iacono T, Probst P, von Tetzchner S. Facilitated communication and authorship: a systematic review. *Augment Altern Commun*. 2014;30(4): 359–368

371. Adams C, Lockton E, Freed J, et al. The Social Communication Intervention Project: a randomized controlled trial of the effectiveness of speech and language therapy for school-age children who have pragmatic and social communication problems with or without autism spectrum disorder. *Int J Lang Commun Disord*. 2012;47(3): 233–244

372. Lloyd M, MacDonald M, Lord C. Motor skills of toddlers with autism spectrum disorders. *Autism*. 2013;17(2):133–146

373. Ament K, Mejia A, Buhlman R, et al. Evidence for specificity of motor impairments in catching and balance in children with autism. *J Autism Dev Disord*. 2015;45(3):742–751

374. Bilaver LA, Cushing LS, Cutler AT. Prevalence and correlates of educational intervention utilization among children with autism spectrum disorder. *J Autism Dev Disord*. 2016; 46(2):561–571

375. Srinivasan SM, Pescatello LS, Bhat AN. Current perspectives on physical activity and exercise recommendations for children and adolescents with autism spectrum disorders. *Phys Ther*. 2014;94(6):875–889

376. Zimmer M, Desch L; Section on Complementary and Integrative Medicine; Council on Children with Disabilities; American Academy of Pediatrics. Sensory integration therapies for children with developmental and behavioral disorders. *Pediatrics*. 2012;129(6): 1186–1189

377. Wigham S, Rodgers J, South M, McConachie H, Freeston M. The interplay between sensory processing abnormalities, intolerance of

uncertainty, anxiety and restricted and repetitive behaviours in autism spectrum disorder. *J Autism Dev Disord*. 2015;45(4):943–952

378. Barton EE, Reichow B, Schnitz A, Smith IC, Sherlock D. A systematic review of sensory-based treatments for children with disabilities. *Res Dev Disabil*. 2015; 37:64–80

379. Case-Smith J, Weaver LL, Fristad MA. A systematic review of sensory processing interventions for children with autism spectrum disorders. *Autism*. 2015;19(2):133–148

380. Bauman ML. Medical comorbidities in autism: challenges to diagnosis and treatment. *Neurotherapeutics*. 2010; 7(3):320–327

381. Joshi G, Petty C, Wozniak J, et al. The heavy burden of psychiatric comorbidity in youth with autism spectrum disorders: a large comparative study of a psychiatrically referred population. *J Autism Dev Disord*. 2010;40(11):1361–1370

382. Viscidi EW, Triche EW, Pescosolido MF, et al. Clinical characteristics of children with autism spectrum disorder and co-occurring epilepsy. *PLoS One*. 2013;8(7): e67797

383. van Eeghen AM, Pulsifer MB, Merker VL, et al. Understanding relationships between autism, intelligence, and epilepsy: a cross-disorder approach. *Dev Med Child Neurol*. 2013;55(2): 146–153

384. Sansa G, Carlson C, Doyle W, et al. Medically refractory epilepsy in autism. *Epilepsia*. 2011;52(6):1071–1075

385. Ibrahim SH, Voigt RG, Katusic SK, Weaver AL, Barbaresi WJ. Incidence of gastrointestinal symptoms in children with autism: a population-based study. *Pediatrics*. 2009;124(2):680–686

386. Chaidez V, Hansen RL, Hertz-Picciotto I. Gastrointestinal problems in children with autism, developmental delays or typical development. *J Autism Dev Disord*. 2014;44(5):1117–1127

387. Buie T, Campbell DB, Fuchs GJ III, et al. Evaluation, diagnosis, and treatment of gastrointestinal disorders in individuals with ASDs: a consensus report. *Pediatrics*. 2010;125(suppl 1): S1–S18

388. Bresnahan M, Hornig M, Schultz AF, et al. Association of maternal report of infant and toddler gastrointestinal symptoms with autism: evidence from a prospective birth cohort. *JAMA Psychiatry*. 2015;72(5):466–474

389. Mazurek MO, Vasa RA, Kalb LG, et al. Anxiety, sensory over-responsivity, and gastrointestinal problems in children with autism spectrum disorders. *J Abnorm Child Psychol*. 2013;41(1): 165–176

390. Buie T, Fuchs GJ III, Furuta GT, et al. Recommendations for evaluation and treatment of common gastrointestinal problems in children with ASDs. *Pediatrics*. 2010;125(suppl 1):S19–S29

391. Maenner MJ, Arneson CL, Levy SE, Kirby RS, Nicholas JS, Durkin MS. Brief report: association between behavioral features and gastrointestinal problems among children with autism spectrum disorder. *J Autism Dev Disord*. 2012; 42(7):1520–1525

392. McElhanon BO, McCracken C, Karpen S, Sharp WG. Gastrointestinal symptoms in autism spectrum disorder: a meta-analysis. *Pediatrics*. 2014;133(5): 872–883

393. Santocchi E, Guiducci L, Fulceri F, et al. Gut to brain interaction in autism spectrum disorders: a randomized controlled trial on the role of probiotics on clinical, biochemical and neurophysiological parameters. *BMC Psychiatry*. 2016;16:183

394. Son JS, Zheng LJ, Rowehl LM, et al. Comparison of fecal microbiota in children with autism spectrum disorders and neurotypical siblings in the Simons simplex collection. *PLoS One*. 2015;10(10):e0137725

395. Levy SE, Souders MC, Ittenbach RF, Giarelli E, Mulberg AE, Pinto-Martin JA. Relationship of dietary intake to gastrointestinal symptoms in children with autistic spectrum disorders. *Biol Psychiatry*. 2007;61(4):492–497

396. Hollway JA, Aman MG, Butter E. Correlates and risk markers for sleep disturbance in participants of the Autism Treatment Network. *J Autism Dev Disord*. 2013;43(12):2830–2843

397. Sharp WG, Berry RC, McCracken C, et al. Feeding problems and nutrient intake in children with autism spectrum disorders: a meta-analysis and comprehensive review of the literature. *J Autism Dev Disord*. 2013;43(9): 2159–2173

398. Bandini LG, Anderson SE, Curtin C, et al. Food selectivity in children with autism spectrum disorders and typically developing children. *J Pediatr*. 2010; 157(2):259–264

399. Hubbard KL, Anderson SE, Curtin C, Must A, Bandini LG. A comparison of food refusal related to characteristics of food in children with autism spectrum disorder and typically developing children. *J Acad Nutr Diet*. 2014;114(12):1981–1987

400. Emond A, Emmett P, Steer C, Golding J. Feeding symptoms, dietary patterns, and growth in young children with autism spectrum disorders. *Pediatrics*. 2010;126(2). Available at: www.pediatrics.org/cgi/content/full/126/2/e337

401. Johnson CR, Turner K, Stewart PA, et al. Relationships between feeding problems, behavioral characteristics and nutritional quality in children with ASD. *J Autism Dev Disord*. 2014;44(9): 2175–2184

402. Hyman SL, Stewart PA, Schmidt B, et al. Nutrient intake from food in children with autism. *Pediatrics*. 2012;130(suppl 2):S145–S153

403. Keown K, Bothwell J, Jain S. Nutritional implications of selective eating in a child with autism spectrum disorder. *BMJ Case Rep*. 2014;2014: bcr2013202581

404. Ma NS, Thompson C, Weston S. Brief report: scurvy as a manifestation of food selectivity in children with autism. *J Autism Dev Disord*. 2016;46(4): 1464–1470

405. Chiu M, Watson S. Xerophthalmia and vitamin A deficiency in an autistic child with a restricted diet. *BMJ Case Rep*. 2015;2015:bcr2015209413

406. Stewart PA, Hyman SL, Schmidt BL, et al. Dietary supplementation in children with autism spectrum disorders: common, insufficient, and excessive. *J Acad Nutr Diet*. 2015;115(8):1237–1248

407. Bailey RL, Fulgoni VL III, Keast DR, Lentino CV, Dwyer JT. Do dietary supplements improve micronutrient

sufficiency in children and adolescents? *J Pediatr*. 2012;161(5):837–842

408. Marshall J, Ware R, Ziviani J, Hill RJ, Dodrill P. Efficacy of interventions to improve feeding difficulties in children with autism spectrum disorders: a systematic review and meta-analysis. *Child Care Health Dev*. 2015;41(2): 278–302

409. Sharp WG, Jaquess DL, Morton JF, Herzinger CV. Pediatric feeding disorders: a quantitative synthesis of treatment outcomes. *Clin Child Fam Psychol Rev*. 2010;13(4):348–365

410. de Vinck-Baroody O, Shui A, Macklin EA, Hyman SL, Leventhal JM, Weitzman C. Overweight and obesity in a sample of children with autism spectrum disorder. *Acad Pediatr*. 2015;15(4): 396–404

411. Broder-Fingert S, Brazauskas K, Lindgren K, Iannuzzi D, Van Cleave J. Prevalence of overweight and obesity in a large clinical sample of children with autism. *Acad Pediatr*. 2014;14(4): 408–414

412. Zuckerman KE, Hill AP, Guion K, Voltolina L, Fombonne E. Overweight and obesity: prevalence and correlates in a large clinical sample of children with autism spectrum disorder. *J Autism Dev Disord*. 2014;44(7):1708–1719

413. Phillips KL, Schieve LA, Visser S, et al. Prevalence and impact of unhealthy weight in a national sample of US adolescents with autism and other learning and behavioral disabilities. *Matern Child Health J*. 2014;18(8): 1964–1975

414. Hinckson EA, Dickinson A, Water T, Sands M, Penman L. Physical activity, dietary habits and overall health in overweight and obese children and youth with intellectual disability or autism. *Res Dev Disabil*. 2013;34(4): 1170–1178

415. Du RY, Yiu CKY, King NM. Oral health behaviours of preschool children with autism spectrum disorders and their barriers to dental care. *J Autism Dev Disord*. 2019;49(2):453–459

416. Call NA, Simmons CA, Mevers JE, Alvarez JP. Clinical outcomes of behavioral treatments for pica in children with developmental disabilities. *J Autism Dev Disord*. 2015;45(7):2105–2114

417. Fields V. Prevalence of pica in preschool children with and without autism spectrum disorder, study to explore early development — United States 2008–2016. In: Proceedings from the Epidemic Intelligence Service Conference; April 29–May 2, 2019; Atlanta, GA

418. Mohanty PH, Gabel M. Agitation and decreased oral intake in an adolescent with autism. *Pediatr Ann*. 2012;41(6): 1–3

419. Barton JC, Barton JC, Bertoli LF. Pica associated with iron deficiency or depletion: clinical and laboratory correlates in 262 non-pregnant adult outpatients. *BMC Blood Disord*. 2010;10: 9

420. Miano S, Ferri R. Epidemiology and management of insomnia in children with autistic spectrum disorders. *Paediatr Drugs*. 2010;12(2):75–84

421. Cortesi F, Giannotti F, Ivanenko A, Johnson K. Sleep in children with autistic spectrum disorder. *Sleep Med*. 2010;11(7):659–664

422. Cohen S, Conduit R, Lockley SW, Rajaratnam SM, Cornish KM. The relationship between sleep and behavior in autism spectrum disorder (ASD): a review. *J Neurodev Disord*. 2014;6(1):44

423. Fadini CC, Lamônica DA, Fett-Conte AC, et al. Influence of sleep disorders on the behavior of individuals with autism spectrum disorder. *Front Hum Neurosci*. 2015;9:347

424. Veatch OJ, Maxwell-Horn AC, Malow BA. Sleep in autism spectrum disorders. *Curr Sleep Med Rep*. 2015;1(2):131–140

425. Blackmer AB, Feinstein JA. Management of sleep disorders in children with neurodevelopmental disorders: a review. *Pharmacotherapy*. 2016;36(1): 84–98

426. Mazurek MO, Sohl K. Sleep and behavioral problems in children with autism spectrum disorder. *J Autism Dev Disord*. 2016;46(6):1906–1915

427. Malow BA, Katz T, Reynolds AM, et al. Sleep difficulties and medications in children with autism spectrum disorders: a registry study. *Pediatrics*. 2016;137(suppl 2):S98–S104

428. Malow BA, Byars K, Johnson K, et al; Sleep Committee of the Autism Treatment Network. A practice pathway for the identification, evaluation, and management of insomnia in children and adolescents with autism spectrum disorders. *Pediatrics*. 2012;130(suppl 2):S106–S124

429. Humphreys JS, Gringras P, Blair PS, et al. Sleep patterns in children with autistic spectrum disorders: a prospective cohort study. *Arch Dis Child*. 2014;99(2):114–118

430. Goldman SE, Richdale AL, Clemons T, Malow BA. Parental sleep concerns in autism spectrum disorders: variations from childhood to adolescence. *J Autism Dev Disord*. 2012;42(4): 531–538

431. Veatch OJ, Pendergast JS, Allen MJ, et al. Genetic variation in melatonin pathway enzymes in children with autism spectrum disorder and comorbid sleep onset delay. *J Autism Dev Disord*. 2015;45(1):100–110

432. Williams SR, Zies D, Mullegama SV, Grotewiel MS, Elsea SH. Smith-Magenis syndrome results in disruption of CLOCK gene transcription and reveals an integral role for RAI1 in the maintenance of circadian rhythmicity. *Am J Hum Genet*. 2012;90(6):941–949

433. Dosman C, Witmans M, Zwaigenbaum L. Iron's role in paediatric restless legs syndrome - a review. *Paediatr Child Health*. 2012;17(4):193–197

434. Engelhardt CR, Mazurek MO, Sohl K. Media use and sleep among boys with autism spectrum disorder, ADHD, or typical development. *Pediatrics*. 2013; 132(6):1081–1089

435. Foley LS, Maddison R, Jiang Y, Marsh S, Olds T, Ridley K. Presleep activities and time of sleep onset in children. *Pediatrics*. 2013;131(2):276–282

436. Weiskop S, Richdale A, Matthews J. Behavioural treatment to reduce sleep problems in children with autism or fragile X syndrome. *Dev Med Child Neurol*. 2005;47(2):94–104

437. Reed HE, McGrew SG, Artibee K, et al. Parent-based sleep education workshops in autism. *J Child Neurol*. 2009;24(8):936–945

438. Johnson CR, Turner KS, Foldes E, Brooks MM, Kronk R, Wiggs L. Behavioral

parent training to address sleep disturbances in young children with autism spectrum disorder: a pilot trial. *Sleep Med*. 2013;14(10):995–1004

439. Vriend JL, Corkum PV, Moon EC, Smith IM. Behavioral interventions for sleep problems in children with autism spectrum disorders: current findings and future directions. *J Pediatr Psychol*. 2011;36(9):1017–1029
440. Malow BA, Adkins KW, Reynolds A, et al. Parent-based sleep education for children with autism spectrum disorders. *J Autism Dev Disord*. 2014; 44(1):216–228
441. Tordjman S, Najjar I, Bellissant E, et al. Advances in the research of melatonin in autism spectrum disorders: literature review and new perspectives. *Int J Mol Sci*. 2013;14(10):20508–20542
442. Cortesi F, Giannotti F, Sebastiani T, Panunzi S, Valente D. Controlled-release melatonin, singly and combined with cognitive behavioural therapy, for persistent insomnia in children with autism spectrum disorders: a randomized placebo-controlled trial. *J Sleep Res*. 2012;21(6):700–709
443. Malow B, Adkins KW, McGrew SG, et al. Melatonin for sleep in children with autism: a controlled trial examining dose, tolerability, and outcomes. *J Autism Dev Disord*. 2012;42(8): 1729–1737; author reply 1738
444. Merenstein D, Diener-West M, Halbower AC, Krist A, Rubin HR. The trial of infant response to diphenhydramine: the TIRED study–a randomized, controlled, patient-oriented trial. *Arch Pediatr Adolesc Med*. 2006;160(7):707–712
445. Fiks AG, Mayne SL, Song L, et al. Changing patterns of alpha agonist medication use in children and adolescents 2009-2011. *J Child Adolesc Psychopharmacol*. 2015;25(4):362–367
446. Sikora DM, Johnson K, Clemons T, Katz T. The relationship between sleep problems and daytime behavior in children of different ages with autism spectrum disorders. *Pediatrics*. 2012; 130(suppl 2):S83–S90
447. Anderson C, Law JK, Daniels A, et al. Occurrence and family impact of elopement in children with autism spectrum disorders. *Pediatrics*. 2012; 130(5):870–877
448. Guan J, Li G. Injury mortality in individuals with autism. *Am J Public Health*. 2017;107(5):791–793
449. Rice CE, Zablotsky B, Avila RM, et al. Reported wandering behavior among children with autism spectrum disorder and/or intellectual disability. *J Pediatr*. 2016;174:232–239.e2
450. Canitano R, Vivanti G. Tics and Tourette syndrome in autism spectrum disorders. *Autism*. 2007;11(1):19–28
451. DeJong H, Bunton P, Hare DJ. A systematic review of interventions used to treat catatonic symptoms in people with autistic spectrum disorders. *J Autism Dev Disord*. 2014;44(9): 2127–2136
452. Gurney JG, McPheeters ML, Davis MM. Parental report of health conditions and health care use among children with and without autism: National Survey of Children's Health. *Arch Pediatr Adolesc Med*. 2006;160(8): 825–830
453. Simonoff E, Jones CR, Baird G, Pickles A, Happé F, Charman T. The persistence and stability of psychiatric problems in adolescents with autism spectrum disorders. *J Child Psychol Psychiatry*. 2013;54(2):186–194
454. Hill AP, Zuckerman KE, Hagen AD, et al. Aggressive behavior problems in children with autism spectrum disorders: prevalence and correlates in a large clinical sample. *Res Autism Spectr Disord*. 2014;8(9):1121–1133
455. Orinstein A, Tyson KE, Suh J, et al. Psychiatric symptoms in youth with a history of autism and optimal outcome. *J Autism Dev Disord*. 2015; 45(11):3703–3714
456. Gotham K, Brunwasser SM, Lord C. Depressive and anxiety symptom trajectories from school age through young adulthood in samples with autism spectrum disorder and developmental delay. *J Am Acad Child Adolesc Psychiatry*. 2015;54(5): 369–376.e3
457. Verheij C, Louwerse A, van der Ende J, et al. The stability of comorbid psychiatric disorders: a 7 year follow up of children with pervasive developmental disorder-not otherwise specified. *J Autism Dev Disord*. 2015; 45(12):3939–3948
458. Buck TR, Viskochil J, Farley M, et al. Psychiatric comorbidity and medication use in adults with autism spectrum disorder. *J Autism Dev Disord*. 2014; 44(12):3063–3071
459. Salazar F, Baird G, Chandler S, et al. Co-occurring psychiatric disorders in preschool and elementary school-aged children with autism spectrum disorder. *J Autism Dev Disord*. 2015; 45(8):2283–2294
460. Kuhlthau KA, McDonnell E, Coury DL, Payakachat N, Macklin E. Associations of quality of life with health-related characteristics among children with autism. *Autism*. 2018;22(7):804–813
461. Weitzman C, Wegner L; Section on Developmental and Behavioral Pediatrics; Committee on Psychosocial Aspects of Child and Family Health; Council on Early Childhood; Society for Developmental and Behavioral Pediatrics; American Academy of Pediatrics. Promoting optimal development: screening for behavioral and emotional problems. *Pediatrics*. 2015;135(2):384–395
462. Volker MA, Lopata C, Smerbeck AM, et al. BASC-2 PRS profiles for students with high-functioning autism spectrum disorders. *J Autism Dev Disord*. 2010; 40(2):188–199
463. Ooi YP, Rescorla L, Ang RP, Woo B, Fung DS. Identification of autism spectrum disorders using the Child Behavior Checklist in Singapore. *J Autism Dev Disord*. 2011;41(9):1147–1156
464. Rosen TE, Mazefsky CA, Vasa RA, Lerner MD, et al. Co-occuring psychiatric conditions in autism spectrum disorder. *Int Rev Psychiatry*. 2018;30(1): 40–61
465. American Academy of Pediatrics. Caring for Children With Autism Spectrum Disorder: A Practical Resource Toolkit for Clinicians, 3rd edition. Available at: https://toolkits.solutions.aap.org/autism/home. Accessed December 1, 2019
466. Mahajan R, Bernal MP, Panzer R, et al; Autism Speaks Autism Treatment Network Psychopharmacology Committee. Clinical practice pathways for evaluation and medication choice for attention-deficit/hyperactivity disorder symptoms in autism spectrum

disorders. *Pediatrics*. 2012;130(suppl 2):S125–S138

467. Doyle CA, McDougle CJ. Pharmacologic treatments for the behavioral symptoms associated with autism spectrum disorders across the lifespan. *Dialogues Clin Neurosci*. 2012; 14(3):263–279

468. Sukhodolsky DG, Scahill L, Gadow KD, et al. Parent-rated anxiety symptoms in children with pervasive developmental disorders: frequency and association with core autism symptoms and cognitive functioning. *J Abnorm Child Psychol*. 2008;36(1):117–128

469. Vasa RA, Mazurek MO, Mahajan R, et al. Assessment and treatment of anxiety in youth with autism spectrum disorders. *Pediatrics*. 2016;137(suppl 2): S115–S123

470. Bitsika V, Sharpley CF, Andronicos NM, Agnew LL. Hypothalamus-pituitary-adrenal axis daily fluctuation, anxiety and age interact to predict cortisol concentrations in boys with an autism spectrum disorder. *Physiol Behav*. 2015; 138:200–207

471. Kerns CM, Maddox BB, Kendall PC, et al. Brief measures of anxiety in non-treatment-seeking youth with autism spectrum disorder. *Autism*. 2015;19(8): 969–979

472. Kreslins A, Robertson AE, Melville C. The effectiveness of psychosocial interventions for anxiety in children and adolescents with autism spectrum disorder: a systematic review and meta-analysis. *Child Adolesc Psychiatry Ment Health*. 2015;9:22

473. Lickel A, MacLean WE Jr., Blakeley-Smith A, Hepburn S. Assessment of the prerequisite skills for cognitive behavioral therapy in children with and without autism spectrum disorders. *J Autism Dev Disord*. 2012;42(6): 992–1000

474. Sukhodolsky DG, Bloch MH, Panza KE, Reichow B. Cognitive-behavioral therapy for anxiety in children with high-functioning autism: a meta-analysis. *Pediatrics*. 2013;132(5). Available at: www.pediatrics.org/cgi/content/full/132/5/e1341

475. Ung D, Selles R, Small BJ, Storch EA. A systematic review and meta-analysis of cognitive-behavioral therapy for anxiety in youth with high-functioning autism spectrum disorders. *Child Psychiatry Hum Dev*. 2015;46(4):533–547

476. Spencer D, Marshall J, Post B, et al. Psychotropic medication use and polypharmacy in children with autism spectrum disorders. *Pediatrics*. 2013; 132(5):833–840

477. De-la-Iglesia M, Olivar JS. Risk factors for depression in children and adolescents with high functioning autism spectrum disorders. *ScientificWorldJournal*. 2015;2015: 127853

478. Segers M, Rawana J. What do we know about suicidality in autism spectrum disorders? A systematic review. *Autism Res*. 2014;7(4):507–521

479. Zuckerbrot RA, Cheung A, Jensen PS, Stein REK, Laraque D; GLAD-PC Steering Group. Guidelines for Adolescent Depression in Primary Care (GLAD-PC): part I. Practice preparation, identification, assessment, and initial management. *Pediatrics*. 2018;141(3): e20174081

480. Williams K, Brignell A, Randall M, Silove N, Hazell P. Selective serotonin reuptake inhibitors (SSRIs) for autism spectrum disorders (ASD). *Cochrane Database Syst Rev*. 2013;(8):CD004677

481. Vannucchi G, Masi G, Toni C, Dell'Osso L, Erfurth A, Perugi G. Bipolar disorder in adults with Asperger's syndrome: a systematic review. *J Affect Disord*. 2014;168:151–160

482. Krebs G, Heyman I. Obsessive-compulsive disorder in children and adolescents. *Arch Dis Child*. 2015; 100(5):495–499

483. Zandt F, Prior M, Kyrios M. Repetitive behaviour in children with high functioning autism and obsessive compulsive disorder. *J Autism Dev Disord*. 2007;37(2):251–259

484. Murray K, Jassi A, Mataix-Cols D, Barrow F, Krebs G. Outcomes of cognitive behaviour therapy for obsessive-compulsive disorder in young people with and without autism spectrum disorders: A case controlled study. *Psychiatry Res*. 2015;228(1):8–13

485. McGuire K, Fung LK, Hagopian L, et al. Irritability and problem behavior in autism spectrum disorder: a practice pathway for pediatric primary care. *Pediatrics*. 2016;137(suppl 2): S136–S148

486. Doehring P, Reichow B, Palka T, Phillips C, Hagopian L. Behavioral approaches to managing severe problem behaviors in children with autism spectrum and related developmental disorders: a descriptive analysis. *Child Adolesc Psychiatr Clin N Am*. 2014;23(1):25–40

487. Fitzpatrick SE, Srivorakiat L, Wink LK, Pedapati EV, Erickson CA. Aggression in autism spectrum disorder: presentation and treatment options. *Neuropsychiatr Dis Treat*. 2016;12: 1525–1538

488. Chen C, Shen YD, Xun GL, et al. Aggressive behaviors and treatable risk factors of preschool children with autism spectrum disorder. *Autism Res*. 2017;10(6):1155–1162

489. Richards C, Davies L, Oliver C. Predictors of self-injurious behavior and self-restraint in autism spectrum disorder: towards a hypothesis of impaired behavioral control. *J Autism Dev Disord*. 2017;47(3):701–713

490. Soke GN, Rosenberg SA, Rosenberg CR, Vasa RA, Lee LC, DiGuiseppi C. Self-injurious behaviors in children with autism spectrum disorder enrolled in the Study to Explore Early Development. *Autism*. 2018;22(5):625–635

491. Richards C, Moss J, Nelson L, Oliver C. Persistence of self-injurious behaviour in autism spectrum disorder over 3 years: a prospective cohort study of risk markers. *J Neurodev Disord*. 2016; 8:21

492. Powis L, Oliver C. The prevalence of aggression in genetic syndromes: a review. *Res Dev Disabil*. 2014;35(5): 1051–1071

493. Schubart JR, Camacho F, Leslie D. Psychotropic medication trends among children and adolescents with autism spectrum disorder in the Medicaid program. *Autism*. 2014;18(6):631–637

494. Jobski K, Höfer J, Hoffmann F, Bachmann C. Use of psychotropic drugs in patients with autism spectrum disorders: a systematic review. *Acta Psychiatr Scand*. 2017;135(1):8–28

495. Rettew DC, Greenblatt J, Kamon J, et al. Antipsychotic medication prescribing in children enrolled in Medicaid. *Pediatrics*. 2015;135(4):658–665

496. Riddle MA. *Pediatric Psychopharmacology for Primary Care*, 1st ed. Elk Grove Village, IL: American Academy of Pediatrics; 2016

497. Mandell DS, Morales KH, Marcus SC, Stahmer AC, Doshi J, Polsky DE. Psychotropic medication use among Medicaid-enrolled children with autism spectrum disorders. *Pediatrics*. 2008; 121(3). Available at: www.pediatrics.org/cgi/content/full/121/3/e441

498. Rosenberg RE, Mandell DS, Farmer JE, Law JK, Marvin AR, Law PA. Psychotropic medication use among children with autism spectrum disorders enrolled in a national registry, 2007-2008. *J Autism Dev Disord*. 2010;40(3):342–351

499. Coury DL, Anagnostou E, Manning-Courtney P, et al. Use of psychotropic medication in children and adolescents with autism spectrum disorders. *Pediatrics*. 2012;130(suppl 2):S69–S76

500. Mire SS, Nowell KP, Kubiszyn T, Goin-Kochel RP. Psychotropic medication use among children with autism spectrum disorders within the Simons Simplex Collection: are core features of autism spectrum disorder related? *Autism*. 2014;18(8):933–942

501. Witwer A, Lecavalier L. Treatment incidence and patterns in children and adolescents with autism spectrum disorders. *J Child Adolesc Psychopharmacol*. 2005;15(4):671–681

502. Frazier TW, Shattuck PT, Narendorf SC, Cooper BP, Wagner M, Spitznagel EL. Prevalence and correlates of psychotropic medication use in adolescents with an autism spectrum disorder with and without caregiver-reported attention-deficit/hyperactivity disorder. *J Child Adolesc Psychopharmacol*. 2011;21(6):571–579

503. Bousman CA, Hopwood M. Commercial pharmacogenetic-based decision-support tools in psychiatry. *Lancet Psychiatry*. 2016;3(6):585–590

504. Hicks JK, Bishop JR, Sangkuhl K, et al; Clinical Pharmacogenetics Implementation Consortium. Clinical Pharmacogenetics Implementation Consortium (CPIC) guideline for CYP2D6 and CYP2C19 genotypes and dosing of selective serotonin reuptake inhibitors. *Clin Pharmacol Ther*. 2015;98(2): 127–134

505. Hess GP, Fonseca E, Scott R, Fagerness J. Pharmacogenomic and pharmacogenetic-guided therapy as a tool in precision medicine: current state and factors impacting acceptance by stakeholders. *Genet Res*. 2015;97:e13

506. Farmer C, Thurm A, Grant P. Pharmacotherapy for the core symptoms in autistic disorder: current status of the research. *Drugs*. 2013; 73(4):303–314

507. Politte LC, Henry CA, McDougle CJ. Psychopharmacological interventions in autism spectrum disorder. *Harv Rev Psychiatry*. 2014;22(2):76–92

508. Baribeau DA, Anagnostou E. An update on medication management of behavioral disorders in autism. *Curr Psychiatry Rep*. 2014;16(3):437

509. Accordino RE, Kidd C, Politte LC, Henry CA, McDougle CJ. Psychopharmacological interventions in autism spectrum disorder. *Expert Opin Pharmacother*. 2016;17(7):937–952

510. Brown JT, Eum S, Cook EH, Bishop JR. Pharmacogenomics of autism spectrum disorder. *Pharmacogenomics*. 2017;18(4): 403–414

511. Nath D. Complementary and alternative medicine in the school-age child with autism. *J Pediatr Health Care*. 2017; 31(3):393–397

512. Lindly OJ, Thorburn S, Heisler K, Reyes NM, Zuckerman KE. Parents' use of complementary health approaches for young children with autism spectrum disorder. *J Autism Dev Disord*. 2018; 48(5):1803–1818

513. Höfer J, Hoffmann F, Bachmann C. Use of complementary and alternative medicine in children and adolescents with autism spectrum disorder: a systematic review. *Autism*. 2017;21(4): 387–402

514. Green RR, Santoro N, Allshouse AA, Neal-Perry G, Derby C. Prevalence of complementary and alternative medicine and herbal remedy use in Hispanic and non-Hispanic white women: results from the study of women's health across the nation. *J Altern Complement Med*. 2017;23(10): 805–811

515. Hopf KP, Madren E, Santianni KA. Use and perceived effectiveness of complementary and alternative medicine to treat and manage the symptoms of autism in children: a survey of parents in a community population. *J Altern Complement Med*. 2016;22(1):25–32

516. Levy SE, Hyman SL. Complementary and alternative medicine treatments for children with autism spectrum disorders. *Child Adolesc Psychiatr Clin N Am*. 2015;24(1):117–143

517. National Center for Complementary and Integrative Health. Autism. 2017. Available at: https://nccih.nih.gov/health/autism. Accessed November 12, 2017

518. Levy SE. Repeated doses of porcine secretin did not improve symptoms, language, or cognitive functioning in children with autism or autism spectrum disorder. *Evid Based Ment Health*. 2002;5(1):22

519. Perrin JM, Coury DL, Hyman SL, Cole L, Reynolds AM, Clemons T. Complementary and alternative medicine use in a large pediatric autism sample. *Pediatrics*. 2012; 130(suppl 2):S77–S82

520. Akins RS, Krakowiak P, Angkustsiri K, Hertz-Picciotto I, Hansen RL. Utilization patterns of conventional and complementary/alternative treatments in children with autism spectrum disorders and developmental disabilities in a population-based study. *J Dev Behav Pediatr*. 2014;35(1):1–10

521. Hanson E, Kalish LA, Bunce E, et al. Use of complementary and alternative medicine among children diagnosed with autism spectrum disorder. *J Autism Dev Disord*. 2007;37(4): 628–636

522. Valicenti-McDermott M, Burrows B, Bernstein L, et al. Use of complementary and alternative medicine in children with autism and other developmental disabilities: associations with ethnicity, child comorbid symptoms, and parental stress. *J Child Neurol*. 2014;29(3): 360–367

523. Marí-Bauset S, Zazpe I, Mari-Sanchis A, Llopis-González A, Morales-Suárez-Varela M. Evidence of the gluten-free and casein-free diet in autism spectrum disorders: a systematic

review. *J Child Neurol*. 2014;29(12):1718–1727

524. Dosman C, Adams D, Wudel B, Vogels L, Turner J, Vohra S. Complementary, holistic, and integrative medicine: autism spectrum disorder and gluten- and casein-free diet. *Pediatr Rev*. 2013;34(10):e36–e41
525. Hyman SL, Stewart PA, Foley J, et al. The gluten-free/casein-free diet: a double-blind challenge trial in children with autism. *J Autism Dev Disord*. 2016;46(1):205–220
526. Jia F, Wang B, Shan L, Xu Z, Staal WG, Du L. Core symptoms of autism improved after vitamin D supplementation. *Pediatrics*. 2015;135(1). Available at: www.pediatrics.org/cgi/content/full/135/1/e196
527. Saad K, Abdel-Rahman AA, Elserogy YM, et al. Vitamin D status in autism spectrum disorders and the efficacy of vitamin D supplementation in autistic children. *Nutr Neurosci*. 2016;19(8):346–351
528. Bertoglio K, Jill James S, Deprey L, Brule N, Hendren RL. Pilot study of the effect of methyl B12 treatment on behavioral and biomarker measures in children with autism. *J Altern Complement Med*. 2010;16(5):555–560
529. Nye C, Brice A. Combined vitamin B6-magnesium treatment in autism spectrum disorder. *Cochrane Database Syst Rev*. 2005;(4):CD003497
530. Mankad D, Dupuis A, Smile S, et al. A randomized, placebo controlled trial of omega-3 fatty acids in the treatment of young children with autism. *Mol Autism*. 2015;6:18
531. Valerie T. Discretionary fortification–a public health perspective. *Nutrients*. 2014;6(10):4421–4433
532. DeVilbiss EA, Gardner RM, Newschaffer CJ, Lee BK. Maternal folate status as a risk factor for autism spectrum disorders: a review of existing evidence. *Br J Nutr*. 2015;114(5):663–672
533. Hickey SE, Curry CJ, Toriello HV. ACMG practice guideline: lack of evidence for MTHFR polymorphism testing. *Genet Med*. 2013;15(2):153–156
534. Geretsegger M, Elefant C, Mössler K, Gold C, et al. Music therapy for people with autism spectrum disorde. *Cochrane Database Syst Rev*. 2014;6:CD004381
535. Koenig KP, Buckley-Reen A, Garg S. Efficacy of the Get Ready to Learn yoga program among children with autism spectrum disorders: a pretest-posttest control group design. *Am J Occup Ther*. 2012;66(5):538–546
536. Hourston S, Atchley R. Autism and mind-body therapies: a systematic review. *J Altern Complement Med*. 2017;23(5):331–339
537. Wan Yunus F, Liu KP, Bissett M, Penkala S. Sensory-based intervention for children with behavioral problems: a systematic review. *J Autism Dev Disord*. 2015;45(11):3565–3579
538. Borgi M, Loliva D, Cerino S, et al. Effectiveness of a standardized equine-assisted therapy program for children with autism spectrum disorder. *J Autism Dev Disord*. 2016;46(1):1–9
539. Hoagwood KE, Acri M, Morrissey M, Peth-Pierce R. Animal-assisted therapies for youth with or at risk for mental health problems: a systematic review. *Appl Dev Sci*. 2017;21(1):1–13
540. Sinha Y, Silove N, Hayen A, Williams K. Auditory integration training and other sound therapies for autism spectrum disorders (ASD). *Cochrane Database Syst Rev*. 2011;(12):CD003681
541. Brondino N, Fusar-Poli L, Rocchetti M, Provenzani U, Barale F, Politi P. Complementary and alternative therapies for autism spectrum disorder. *Evid Based Complement Alternat Med*. 2015;2015:258589
542. Committee on Children With Disabilities. Counseling families who choose complementary and alternative medicine for their child with chronic illness or disability [published correction appears in *Pediatrics*. 2001;108(2):507]. *Pediatrics*. 2001;107(3):598–601
543. Levy SE, Frasso R, Colantonio S, et al. Shared decision making and treatment decisions for young children with autism spectrum disorder. *Acad Pediatr*. 2016;16(6):571–578
544. Estes A, Olson E, Sullivan K, et al. Parenting-related stress and psychological distress in mothers of toddlers with autism spectrum disorders. *Brain Dev*. 2013;35(2):133–138
545. Hayes SA, Watson SL. The impact of parenting stress: a meta-analysis of studies comparing the experience of parenting stress in parents of children with and without autism spectrum disorder. *J Autism Dev Disord*. 2013;43(3):629–642
546. Horlin C, Falkmer M, Parsons R, Albrecht MA, Falkmer T. The cost of autism spectrum disorders. *PLoS One*. 2014;9(9):e106552
547. Child and Adolescent Health Measurement Initiative. National profile of children with special health care needs and autism spectrum disorders: key findings from the 2009/10 NS-CSHCN & 2011/12 NSCH. 2013. Available at: https://www.childhealthdata.org/docs/drc/asd-data-brief_7-30-13.pdf. Accessed December 1, 2019
548. Clifford T, Minnes P. Who participates in support groups for parents of children with autism spectrum disorders? The role of beliefs and coping style. *J Autism Dev Disord*. 2013;43(1):179–187
549. Siller M, Reyes N, Hotez E, Hutman T, Sigman M. Longitudinal change in the use of services in autism spectrum disorder: understanding the role of child characteristics, family demographics, and parent cognitions. *Autism*. 2014;18(4):433–446
550. Mohd Roffeei SH, Abdullah N, Basar SK. Seeking social support on Facebook for children with autism spectrum disorders (ASDs). *Int J Med Inform*. 2015;84(5):375–385
551. Zablotsky B, Kalb LG, Freedman B, Vasa R, Stuart EA. Health care experiences and perceived financial impact among families of children with an autism spectrum disorder. *Psychiatr Serv*. 2014;65(3):395–398
552. McStay RL, Trembath D, Dissanayake C. Maternal stress and family quality of life in response to raising a child with autism: from preschool to adolescence. *Res Dev Disabil*. 2014;35(11):3119–3130
553. Green L. The well-being of siblings of individuals with autism. *ISRN Neurol*. 2013;2013:417194
554. Kuo DZ, Houtrow AJ; Council on Children With Disabilities. Recognition and

management of medical complexity. *Pediatrics*. 2016;138(6):e20163021

555. Carbone PS, Behl DD, Azor V, Murphy NA. The medical home for children with autism spectrum disorders: parent and pediatrician perspectives. *J Autism Dev Disord*. 2010;40(3):317–324

556. Golnik A, Ireland M, Borowsky IW. Medical homes for children with autism: a physician survey. *Pediatrics*. 2009;123(3):966–971

557. Liptak GS, Orlando M, Yingling JT, et al. Satisfaction with primary health care received by families of children with developmental disabilities. *J Pediatr Health Care*. 2006;20(4):245–252

558. Cheak-Zamora NC, Farmer JE. The impact of the medical home on access to care for children with autism spectrum disorders. *J Autism Dev Disord*. 2015;45(3):636–644

559. Kogan MD, Strickland BB, Blumberg SJ, Singh GK, Perrin JM, van Dyck PC. A national profile of the health care experiences and family impact of autism spectrum disorder among children in the United States, 2005-2006. *Pediatrics*. 2008;122(6). Available at: www.pediatrics.org/cgi/content/full/122/6/e1149

560. McKinney CM, Nelson T, Scott JM, Heaton LJ, Vaughn MG, Lewis CW. Predictors of unmet dental need in children with autism spectrum disorder: results from a national sample. *Acad Pediatr*. 2014;14(6):624–631

561. Adams RC, Levy SE; Council on Children with Disabilities. Shared decision-making and children with disabilities: pathways to consensus. *Pediatrics*. 2017;139(6):e20170956

562. Huws JC, Jones RS. Diagnosis, disclosure, and having autism: an interpretative phenomenological analysis of the perceptions of young people with autism. *J Intellect Dev Disabil*. 2008;33(2):99–107

563. White PH, Cooley WC; Transitions Clinical Report Authoring Group; American Academy of Pediatrics; American Academy of Family Physicians; American College of Physicians. Supporting the health care transition from adolescence to adulthood in the medical home [published correction appears in *Pediatrics*. 2019;143(2):e20183610]. *Pediatrics*. 2018;142(5):e20182587

564. Got Transition. Health care providers. Available at: http://www.gottransition.org/providers/index.cfm. Accessed December 1, 2019

565. Autism Speaks. Puberty and adolescence resource: a guide for parents of adolescents with autism spectrum disorder. Available at: https://www.autismspeaks.org/sites/default/files/documents/atn/puberty_tool_kit.pdf. Accessed December 1, 2019

566. Kuder SJ, Accardo A. What works for college students with autism spectrum disorder. *J Autism Dev Disord*. 2018;48(3):722–731

567. Nicolaidis C, Kripke CC, Raymaker D. Primary care for adults on the autism spectrum. *Med Clin North Am*. 2014;98(5):1169–1191

568. Velott DL, Agbese E, Mandell D, et al. Medicaid 1915(c) Home- and Community-Based Services waivers for children with autism spectrum disorder. *Autism*. 2016;20(4):473–482

569. Interagency Autism Coordinating Committee. IACC strategic plan for autism spectrum disorder research: 2013 update. 2013. Available at: https://iacc.hhs.gov/publications/strategic-plan/2013/. Accessed March 25, 2017

570. Interagency Autism Coordinating Committee. IACC strategic plan for autism spectrum disorder: 2017 update. Available at: https://iacc.hhs.gov/publications/strategic-plan/2017/. Accessed December 1, 2019

571. Interagency Autism Coordinating Committee. IACC strategic plan for autism spectrum disorder research: 2011 update. 2011. Available at: https://iacc.hhs.gov/publications/strategic-plan/2011/. Accessed March 25, 2017

572. Rutter M, Bailey A, Lord C. *The Social Communication Questionnaire (SCQ) Manual*. Los Angeles, CA: Western Psychological Services; 2003

573. Stone WL, Coonrod EE, Ousley O. Brief report: screening tool for autism in two-year-olds (STAT): development and preliminary data. *J Autism Dev Disord*. 2000;30(6):607–612

574. Stone WL, Coonrod EE, Turner LM, Pozdol SL. Psychometric properties of the STAT for early autism screening. *J Autism Dev Disord*. 2004;34(6):691–701

575. Rowberry JJ, Macari S, Chen G, et al. Screening for autism spectrum disorders in 12-mo-old high-risk siblings by parental report. *J Autism Dev Disord*. 2015;45:221–229

576. Smith NJ, Sheldrick RC, Perrin EC. An Abbreviated Screening Instrument for Autism Spectrum Disorders. *Infant Ment Health J*. 2012;34(2):149–155

577. Salisbury LA, Nyce JD, Hannum CD, Sheldrick RC, Perrin EC. Sensitivity and specificity of 2 autism screeners among referred children between 16 and 48 mo of age. *J Dev Behav Pediatr*. 2018;39(3):254–258

578. Choueiri R, Wagner S. A new interactive screening test for autism spectrum disorders in toddlers. *J Pediatr*. 2015;167(2):460–466

579. Myers SM. Management of autism spectrum disorders in primary care. *Pediatr Ann*. 2009;38(1):42–49

580. Quintana H, Birmaher B, Stedge D, et al. Use of methylphenidate in the treatment of children with autistic disorder. *J Autism Dev Disord*. 1995;25(3):283–294

581. Handen BL, Johnson CR, Lubetsky M. Efficacy of methylphenidate among children with autism and symptoms of attention-deficit hyperactivity disorder. *J Autism Dev Disord*. 2000;30(3):245–255

582. Research Units on Pediatric Psychopharmacology Autism Network. Randomized, controlled, crossover trial of methylphenidate in pervasive developmental disorders with hyperactivity. *Arch Gen Psychiatry*. 2005;62(11):1266–1274

583. Pearson DA, Santos CW, Aman MG, et al. Effects of extended release methylphenidate treatment on ratings of attention-deficit/hyperactivity disorder (ADHD) and associated behavior in children with autism spectrum disorders and ADHD symptoms. *J Child Adolesc Psychopharmacol*. 2013;23(5):337–351

584. Posey DJ, Aman MG, McCracken JT, et al. Positive effects of

methylphenidate on inattention and hyperactivity in pervasive developmental disorders: an analysis of secondary measures. *Biol Psychiatry*. 2007;61(4):538–544

585. Reichow B, Volkmar FR, Bloch MH. Systematic review and meta-analysis of pharmacological treatment of the symptoms of attention-deficit/hyperactivity disorder in children with pervasive developmental disorders. *J Autism Dev Disord*. 2013;43(10):2435–2441

586. Jahromi LB, Kasari CL, McCracken JT, et al. Positive effects of methylphenidate on social communication and self-regulation in children with pervasive developmental disorders and hyperactivity. *J Autism Dev Disord*. 2009;39(3):395–404

587. Santosh PJ, Baird G, Pityaratstian N, Tavare E, Gringras P. Impact of comorbid autism spectrum disorders on stimulant response in children with attention deficit hyperactivity disorder: a retrospective and prospective effectiveness study. *Child Care Health Dev*. 2006;32(5):575–583

588. Arnold LE, Aman MG, Cook AM, et al. Atomoxetine for hyperactivity in autism spectrum disorders: placebo-controlled crossover pilot trial. *J Am Acad Child Adolesc Psychiatry*. 2006;45(10):1196–1205

589. Harfterkamp M, Buitelaar JK, Minderaa RB, van de Loo-Neus G, van der Gaag RJ, Hoekstra PJ. Long-term treatment with atomoxetine for attention-deficit/hyperactivity disorder symptoms in children and adolescents with autism spectrum disorder: an open-label extension study. *J Child Adolesc Psychopharmacol*. 2013;23(3):194–199

590. Handen BL, Aman MG, Arnold LE, et al. Atomoxetine, parent training, and their combination in children with autism spectrum disorder and attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2015;54(11):905–915

591. Jaselskis CA, Cook EH Jr., Fletcher KE, Leventhal BL. Clonidine treatment of hyperactive and impulsive children with autistic disorder. *J Clin Psychopharmacol*. 1992;12(5):322–327

592. Fankhauser MP, Karumanchi VC, German ML, Yates A, Karumanchi SD. A double-blind, placebo-controlled study of the efficacy of transdermal clonidine in autism. *J Clin Psychiatry*. 1992;53(3):77–82

593. Handen BL, Sahl R, Hardan AY. Guanfacine in children with autism and/or intellectual disabilities. *J Dev Behav Pediatr*. 2008;29(4):303–308

594. Scahill L, McCracken JT, King BH, et al; Research Units on Pediatric Psychopharmacology Autism Network. Extended-release guanfacine for hyperactivity in children with autism spectrum disorder. *Am J Psychiatry*. 2015;172(12):1197–1206

595. McCracken JT, McGough J, Shah B, et al; Research Units on Pediatric Psychopharmacology Autism Network. Risperidone in children with autism and serious behavioral problems. *N Engl J Med*. 2002;347(5):314–321

596. Shea S, Turgay A, Carroll A, et al. Risperidone in the treatment of disruptive behavioral symptoms in children with autistic and other pervasive developmental disorders. *Pediatrics*. 2004;114(5). Available at: www.pediatrics.org/cgi/content/full/114/5/e634

597. Marcus RN, Owen R, Kamen L, et al. A placebo-controlled, fixed-dose study of aripiprazole in children and adolescents with irritability associated with autistic disorder. *J Am Acad Child Adolesc Psychiatry*. 2009;48(11):1110–1119

598. Owen R, Sikich L, Marcus RN, et al. Aripiprazole in the treatment of irritability in children and adolescents with autistic disorder. *Pediatrics*. 2009;124(6):1533–1540

599. Arnold LE, Vitiello B, McDougle C, et al. Parent-defined target symptoms respond to risperidone in RUPP autism study: customer approach to clinical trials. *J Am Acad Child Adolesc Psychiatry*. 2003;42(12):1443–1450

600. Aman MG, McDougle CJ, Scahill L, et al; Research Units on Pediatric Psychopharmacology Autism Network. Medication and parent training in children with pervasive developmental disorders and serious behavior problems: results from a randomized clinical trial. *J Am Acad Child Adolesc Psychiatry*. 2009;48(12):1143–1154

601. Aman MG, Lam KS, Van Bourgondien ME. Medication patterns in patients with autism: temporal, regional, and demographic influences. *J Child Adolesc Psychopharmacol*. 2005;15(1):116–126

602. Aman M, Rettiganti M, Nagaraja HN, et al. Tolerability, safety, and benefits of risperidone in children and adolescents with autism: 21-month follow-up after 8-week placebo-controlled trial. *J Child Adolesc Psychopharmacol*. 2015;25(6):482–493

603. Research Units on Pediatric Psychopharmacology Autism Network. Risperidone treatment of autistic disorder: longer-term benefits and blinded discontinuation after 6 months. *Am J Psychiatry*. 2005;162(7):1361–1369

604. Pandina GJ, Bossie CA, Youssef E, Zhu Y, Dunbar F. Risperidone improves behavioral symptoms in children with autism in a randomized, double-blind, placebo-controlled trial. *J Autism Dev Disord*. 2007;37(2):367–373

605. Marcus RN, Owen R, Manos G, et al. Safety and tolerability of aripiprazole for irritability in pediatric patients with autistic disorder: a 52-week, open-label, multicenter study. *J Clin Psychiatry*. 2011;72(9):1270–1276

606. Kent JM, Kushner S, Ning X, et al. Risperidone dosing in children and adolescents with autistic disorder: a double-blind, placebo-controlled study. *J Autism Dev Disord*. 2013;43(8):1773–1783

607. Findling RL, Mankoski R, Timko K, et al. A randomized controlled trial investigating the safety and efficacy of aripiprazole in the long-term maintenance treatment of pediatric patients with irritability associated with autistic disorder. *J Clin Psychiatry*. 2014;75(1):22–30

608. Troost PW, Lahuis BE, Steenhuis MP, et al. Long-term effects of risperidone in children with autism spectrum disorders: a placebo discontinuation study. *J Am Acad Child Adolesc Psychiatry*. 2005;44(11):1137–1144

609. Anagnostou E, Aman MG, Handen BL, et al. Metformin for treatment of overweight induced by atypical antipsychotic medication in young people with autism spectrum disorder:

a randomized clinical trial. *JAMA Psychiatry.* 2016;73(9):928–937

610. Fung LK, Mahajan R, Nozzolillo A, et al. Pharmacologic treatment of severe irritability and problem behaviors in autism: a systematic review and meta-analysis. *Pediatrics.* 2016;137(suppl 2): S124–S135

611. King BH, Hollander E, Sikich L, et al; STAART Psychopharmacology Network. Lack of efficacy of citalopram in children with autism spectrum disorders and high levels of repetitive behavior: citalopram ineffective in children with autism. *Arch Gen Psychiatry.* 2009;66(6):583–590

612. McDougle CJ, Naylor ST, Cohen DJ, Volkmar FR, Heninger GR, Price LH. A double-blind, placebo-controlled study of fluvoxamine in adults with autistic disorder. *Arch Gen Psychiatry.* 1996; 53(11):1001–1008

613. Hollander E, Chaplin W, Soorya L, et al. Divalproex sodium vs placebo for the treatment of irritability in children and adolescents with autism spectrum disorders. *Neuropsychopharmacology.* 2010;35(4):990–998

614. Belsito KM, Law PA, Kirk KS, Landa RJ, Zimmerman AW. Lamotrigine therapy for autistic disorder: a randomized, double-blind, placebo-controlled trial. *J Autism Dev Disord.* 2001;31(2): 175–181

615. Hellings JA, Nickel EJ, Weckbaugh M, McCarter K, Mosier M, Schroeder SR. The overt aggression scale for rating aggression in outpatient youth with autistic disorder: preliminary findings. *J Neuropsychiatry Clin Neurosci.* 2005; 17(1):29–35

616. Wasserman S, Iyengar R, Chaplin WF, et al. Levetiracetam versus placebo in childhood and adolescent autism: a double-blind placebo-controlled study. *Int Clin Psychopharmacol.* 2006;21(6): 363–367

617. Hirota T, Veenstra-Vanderweele J, Hollander E, Kishi T. Antiepileptic medications in autism spectrum disorder: a systematic review and meta-analysis. *J Autism Dev Disord.* 2014;44(4):948–957

618. Canitano R. Mood stabilizers in children and adolescents with autism spectrum disorders. *Clin Neuropharmacol.* 2015; 38(5):177–182

619. Niederhofer H. Venlafaxine has modest effects in autistic children. *Therapy.* 2004;1(1):87–90

620. McDougle CJ, Holmes JP, Carlson DC, Pelton GH, Cohen DJ, Price LH. A double-blind, placebo-controlled study of risperidone in adults with autistic disorder and other pervasive developmental disorders. *Arch Gen Psychiatry.* 1998;55(7):633–641

621. Hollander E, Soorya L, Wasserman S, Esposito K, Chaplin W, Anagnostou E. Divalproex sodium vs. placebo in the treatment of repetitive behaviours in autism spectrum disorder. *Int J Neuropsychopharmacol.* 2006;9(2): 209–213

622. Rezaei V, Mohammadi MR, Ghanizadeh A, et al. Double-blind, placebo-controlled trial of risperidone plus topiramate in children with autistic disorder. *Prog Neuropsychopharmacol Biol Psychiatry.* 2010;34(7):1269–1272

623. Hollander E, Soorya L, Chaplin W, et al. A double-blind placebo-controlled trial of fluoxetine for repetitive behaviors and global severity in adult autism spectrum disorders. *Am J Psychiatry.* 2012;169(3):292–299

624. Hollander E, Phillips A, Chaplin W, et al. A placebo controlled crossover trial of liquid fluoxetine on repetitive behaviors in childhood and adolescent autism. *Neuropsychopharmacology.* 2005;30(3): 582–589

625. Ji N, Findling RL. An update on pharmacotherapy for autism spectrum disorder in children and adolescents. *Curr Opin Psychiatry.* 2015;28(2):91–101

626. Couturier JL, Nicolson R. A retrospective assessment of citalopram in children and adolescents with pervasive developmental disorders. *J Child Adolesc Psychopharmacol.* 2002; 12(3):243–248

627. Namerow L, Thomas P, Bostic JQ, Prince J, Monuteaux MC. Use of citalopram in pervasive developmental disorders. *J Dev Behav Pediatr.* 2003;24(2):104–108

628. Strawn JR, Welge JA, Wehry AM, Keeshin B, Rynn MA. Efficacy and tolerability of antidepressants in pediatric anxiety disorders: a systematic review and meta-analysis. *Depress Anxiety.* 2015; 32(3):149–157

629. Buitelaar JK, van der Gaag RJ, van der Hoeven J. Buspirone in the management of anxiety and irritability in children with pervasive developmental disorders: results of an open-label study. *J Clin Psychiatry.* 1998; 59(2):56–59

630. Vasa RA, Carroll LM, Nozzolillo AA, et al. A systematic review of treatments for anxiety in youth with autism spectrum disorders. *J Autism Dev Disord.* 2014; 44(12):3215–3229

Supplemental Information

SUPPLEMENTAL TABLE 14 Recurrent CNVs Most Commonly Identified in Cohorts With ASD by Using CMA Analysis

CNV Region	Frequency[a]	Common Clinical Features
16p11.2 deletion	1 in 304	ASD, DD or ID, expressive language impairment, relative or absolute macrocephaly, overweight
16p11.2 duplication	1 in 396	ASD, schizophrenia, bipolar disorder, ADHD, relative or absolute microcephaly, underweight
15q11.2-q13 (BP2–BP3) duplication	1 in 494	ASD, DD or ID, epilepsy, hypotonia, ataxia, behavior problems
15q13.2-q13.3 (BP4–BP5) deletion	1 in 659	ASD, DD or ID, epilepsy, schizophrenia, cardiac defects
1q21.1 duplication	1 in 659	ASD, DD or ID, schizophrenia, ADHD, relative macrocephaly, hypertelorism
22q11.2 duplication	1 in 659	ASD, DD or ID, hypotonia, motor delay
16p13.11 deletion	1 in 791	ASD, DD or ID, epilepsy, schizophrenia, congenital anomalies
7q11.23 duplication	1 in 989	ASD, DD or ID, growth retardation, hypotonia
16p12.2 deletion	1 in 989	ASD, DD or ID, schizophrenia, epilepsy, growth retardation, cardiac defects, microcephaly, hypotonia
17q12 deletion	1 in 1978	ASD, DD or ID, schizophrenia, renal cysts, mature-onset diabetes of the young type 5
15q13.2–13.3 (BP4–BP5) duplication	1 in 1978	ASD, DD or ID, obesity

BP2 breakpoint 2; BP3 breakpoint 3; BP4 breakpoint 4; BP5 breakpoint 5; DD developmental delay; ID intellectual disability.

[a] Moreno-De-Luca D et al[631]; the frequency of each CNV among 3955 probands with ASD from the Autism Genetic Resource Exchange, Autism Genome Project, and Simons Foundation Autism Research Initiative Simplex Collection cohorts.

SUPPLEMENTAL TABLE 13 Selected Genetic Syndromes Associated With ASD

Condition	Physical Findings	Gene	Confirmatory Testing	Importance
Fragile X syndrome	Long face, prominent forehead and jaw, large ears, joint laxity, macroorchidism after puberty in boys	*FMR1* (CGG repeat expansion, abnormal methylation)	Targeted mutation analysis (PCR and Southern blot)	Genetic counseling (X-linked dominant inheritance); all mothers of individuals with an *FMR1* full mutation are carriers of an *FMR1* premutation or full mutation; extended family counseling is necessary; premutation carriers are at risk for fragile X–associated tremor/ataxia syndrome and *FMR1*-related primary ovarian insufficiency in female patients; several targeted pharmacologic therapies are under investigation
Neurofibromatosis 1	Multiple café-au-lait macules, axillary and inguinal freckling, iris Lisch nodules, cutaneous neurofibromas	*NF1*	Clinical criteria; optimized protein truncation testing, sequence analysis, and deletion or duplication analysis are available but infrequently required	Genetic counseling (autosomal dominant inheritance); 50% de novo, 50% inherited; associated problems requiring investigation or monitoring (optic gliomas, other CNS tumors, peripheral nerve sheath tumors, vasculopathy, hypertension, orthopedic issues, osteopenia)
PTEN hamartoma tumor syndrome (includes Cowden syndrome and Bannayan-Riley-Ruvalcaba syndrome)	Marked macrocephaly, skin hamartomas, pigmented macules of the glans penis	*PTEN*	*PTEN* sequence analysis, deletion or duplication analysis	Genetic counseling (autosomal dominant inheritance with highly variable expression); associated problems requiring investigation or monitoring (significant risk of benign and malignant tumors of the thyroid, breast, and endometrium as well as intestinal polyps, colorectal cancer, renal cell carcinoma, cutaneous melanoma, and cerebellar dysplastic gangliocytoma)
Rett syndrome	Deceleration of head growth velocity, acquired microcephaly, loss of purposeful hand use, prominent hand stereotypies (especially hand wringing or clasping), apraxia, hyperventilation or breath-holding, seizures	*MECP2*	*MECP2* sequence analysis, deletion or duplication analysis	Genetic counseling (>99% de novo, <1% germline mosaicism); associated problems requiring investigation or monitoring and anticipatory guidance (failure to thrive, gastroesophageal reflux, respiratory problems, osteopenia, sudden death); targeted pharmacologic therapy under investigation
Smith-Lemli-Opitz syndrome	Characteristic facial features (narrow forehead, low-set ears, ptosis, epicanthal folds, short nose, anteverted nares), microcephaly, cleft palate, 2- to 3-toe syndactyly, postaxial polydactyly, hypospadias in male	*DHCR7*	7-dehydrocholesterol level (elevated); *DHCR7* sequence analysis available	Genetic counseling (autosomal recessive inheritance); potential role for treatment with cholesterol

SUPPLEMENTAL TABLE 13 Continued

Condition	Physical Findings	Gene	Confirmatory Testing	Importance
	patients, prenatal and postnatal growth retardation			
Timothy syndrome	Long QT interval, other ECG abnormalities (atrioventricular block, macroscopic T-wave alternans), congenital heart defects, cutaneous syndactyly, low-set ears, flat nasal bridge, thin upper lip, round facies, baldness for the first 2 y of life followed by thin scalp hair, dental abnormalities, frequent infections because of altered immune response, intermittent hypoglycemia	*CACNA1C*	Targeted mutation analysis, sequence analysis, deletion or duplication analysis	Genetic counseling, autosomal dominant, usually de novo, but parental germline mosaicism has been observed; treatment related to long QTc (β-blocker, pacemaker, implantable defibrillator) and avoidance of hypoglycemia
Tuberous sclerosis	Hypopigmented macules, angiofibromas, shagreen patches (connective tissue nevi), ungual fibromas, retinal hamartomas	*TSC1*, *TSC2*	Clinical criteria; *TSC1* and *TSC2* sequencing available	Genetic counseling (autosomal dominant inheritance); associated problems requiring investigation or monitoring (CNS tumors, seizures, renal angiomyolipomas or cysts, cardiac rhabdomyomas and arrhythmias); potential role for targeted pharmacologic therapy (mTOR inhibitors)

CACNA1C, calcium channel, voltage-dependent, L-type, α-1c subunit; CGG, cytosine-guanine-guanine; CNS, central nervous system; *DHCR7*, 7-dehydrocholesterol reductase; ECG, electrocardiogram; *FMR1*, fragile X mental retardation 1; *MECP2*, methyl CpG binding protein 2; mTOR, mammalian target of rapamycin; PCR, polymerase chain reaction; *PTEN*, phosphatase and tensin homolog; QTc, corrected QT interval; *TSC1*, tuberous sclerosis 1; *TSC2*, tuberous sclerosis 2. Adapted with permission from Myers SM, Challman TD. Autism Spectrum Disorders. In: Voigt RG, Macias MM, Myers SM, eds. *Developmental and Behavioral Pediatrics*. Elk Grove Village, IL: American Academy of Pediatrics; 2011:249–291.

SUPPLEMENTAL TABLE 15 Selected ASD Risk Genes Identified or Confirmed in Whole-Exome Studies

Gene	Gene Name	Broad Functional Categorization
SCN2A	sodium channel, voltage-gated, type II, α subunit	Synaptic functions (eg, ion channels, neurotransmitter receptors, cell adhesion molecules, microtubule assembly, scaffolding proteins, actin cytoskeleton)
GRIN2B	glutamate receptor, ionotropic, N-methyl-D-aspartate 2B	
KATNAL2	katanin p60 subunit A-like 2	
ANK2	ankyrin 2, neuronal	
DSCAM	Down syndrome cell adhesion molecule	
NRXN1	neurexin 1	
SHANK2	SH3 and multiple ankyrin repeat domains 2	
SHANK3	SH3 and multiple ankyrin repeat domains 3	
PTEN	phosphatase and tensin homolog	Intracellular signaling, activity-dependent synaptic protein synthesis and degradation
SYNGAP1	synaptic Ras GTPase activating protein 1	
DYRK1A	dual-specificity tyrosine-(Y)-phosphorylation regulated kinase 1A	
POGZ	pogo transposable element with ZNF domain	
CUL3	cullin 3	
CHD2	chromodomain helicase DNA binding protein 2	Transcription regulation, chromatin remodeling
CHD8	chromodomain helicase DNA binding protein 8	
ADNP[a]	activity-dependent neuroprotector homeobox	
ARID1B	AT rich interactive domain 1B (SWI1-like)	
ASH1L	ASH1 (absent, small, or homeotic)-like	
KDM5B	lysine-specific demethylase 5B	
KMT2C	lysine-specific methyltransferase 2C	
SETD5	SET domain containing 5	
TBR1	T-box, brain, 1	

Based on de novo loss of function variants and small de novo deletions (false discovery rate < 0.01). Adapted from Sanders SJ, He X, Willsey AJ, et al; Autism Sequencing Consortium. Insights into autism spectrum disorder genomic architecture and biology from 71 risk loci. *Neuron*. 2015;87(6):1215–1233; Krumm N, O'Roak BJ, Shendure J, Eichler EE. A de novo convergence of autism genetics and molecular neuroscience. *Trends Neurosci*. 2014;37(2):95–105; Brandler WM, Sebat J. From de novo mutations to personalized therapeutic interventions in autism. *Annu Rev Med*. 2015;66:487–507; De Rubeis S, He X, Goldberg AP, et al; DDD Study; Homozygosity Mapping Collaborative for Autism; UK10K Consortium. Synaptic, transcriptional and chromatin genes disrupted in autism. *Nature*. 2014;515(7526):209–215; Bourgeron T. From the genetic architecture to synaptic plasticity in autism spectrum disorder. *Nat Rev Neurosci*. 2015;16(9):551–563; and Sanders SJ, Murtha MT, Gupta AR, et al. De novo mutations revealed by whole-exome sequencing are strongly associated with autism. *Nature*. 2012; 485(7397):237–241.

[a] Also involved in microtubule dynamics at the synapse.

SUPPLEMENTAL TABLE 16 Selected Metabolic Conditions That May (Rarely) Be Associated With an ASD Phenotype

Disorders of amino acid metabolism
Phenylketonuria (untreated)
Homocystinuria
Branched-chain ketoacid dehydrogenase kinase deficiency
Disorders of γ-aminobutyric acid metabolism
Succinic semialdehyde dehydrogenase deficiency
Disorders of cholesterol metabolism
Smith-Lemli-Opitz syndrome (7-dehydrocholesterol reductase deficiency)
Disorders associated with cerebral folate deficiency
Folate receptor 1 gene mutations
Dihydrofolate reductase deficiency
Disorders of creatine transport or metabolism
Arginine-glycine amidinotransferase deficiency
Guanidinoacetate methyltransferase deficiency
X-linked creatine transporter deficits
Disorders of carnitine biosynthesis
6-*N*-trimethyllysine dioxygenase deficiency
Disorders of purine and pyrimidine metabolism
Adenylosuccinate lyase deficiency
Adenosine deaminase deficiency
Cytosolic 5′-nucleotidase superactivity
Dihydropyrimidine dehydrogenase deficiency
Phosphoribosyl pyrophosphate synthetase superactivity
Lysosomal storage disorders
Sanfilippo syndrome (mucopolysaccharidosis type III)
Mitochondrial disorders
Mitochondrial DNA mutations
Nuclear DNA mutations
Others
Biotinidase deficiency
Urea cycle defects

Adapted from Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. *Genet Med.* 2013;15(5):399–407; Legido A, Jethva R, Goldenthal MJ. Mitochondrial dysfunction in autism. *Semin Pediatr Neurol.* 2013;20(3): 163–175; Jiang YH, Wang Y, Xiu X, Choy KW, Pursley AN, Cheung SW. Genetic diagnosis of autism spectrum disorders: the opportunity and challenge in the genomics era. *Crit Rev Clin Lab Sci.* 2014;51(5):249–262; and Frye RE. Metabolic and mitochondrial disorders associated with epilepsy in children with autism spectrum disorder. *Epilepsy Behav.* 2015; 47:147–157.

SUPPLEMENTAL REFERENCES

631. Moreno-De-Luca D, Sanders SJ, Willsey AJ, et al. Using large clinical data sets to infer pathogenicity for rare copy number variants in autism cohorts. *Mol Psychiatry.* 2013;18(10): 1090–1095

Identifying the Misshapen Head: Craniosynostosis and Related Disorders

• *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Identifying the Misshapen Head: Craniosynostosis and Related Disorders

Mark S. Dias, MD, FAAP, FAANS,[a] Thomas Samson, MD, FAAP,[b] Elias B. Rizk, MD, FAAP, FAANS,[a] Lance S. Governale, MD, FAAP, FAANS,[c] Joan T. Richtsmeier, PhD,[d] SECTION ON NEUROLOGIC SURGERY, SECTION ON PLASTIC AND RECONSTRUCTIVE SURGERY

Pediatric care providers, pediatricians, pediatric subspecialty physicians, and other health care providers should be able to recognize children with abnormal head shapes that occur as a result of both synostotic and deformational processes. The purpose of this clinical report is to review the characteristic head shape changes, as well as secondary craniofacial characteristics, that occur in the setting of the various primary craniosynostoses and deformations. As an introduction, the physiology and genetics of skull growth as well as the pathophysiology underlying craniosynostosis are reviewed. This is followed by a description of each type of primary craniosynostosis (metopic, unicoronal, bicoronal, sagittal, lambdoid, and frontosphenoidal) and their resultant head shape changes, with an emphasis on differentiating conditions that require surgical correction from those (bathrocephaly, deformational plagiocephaly/brachycephaly, and neonatal intensive care unit-associated skill deformation, known as NICUcephaly) that do not. The report ends with a brief discussion of microcephaly as it relates to craniosynostosis as well as fontanelle closure. The intent is to improve pediatric care providers' recognition and timely referral for craniosynostosis and their differentiation of synostotic from deformational and other nonoperative head shape changes.

INTRODUCTION

Pediatric health care providers evaluate and care for children with a variety of head shapes, some of which represent craniosynostosis and other craniofacial disorders, some of which are deformational in nature, and some of which are simply normal variants. Identifying the various types of head shape abnormalities is important for aesthetics, to identify candidates for future monitoring, and, at least in some, to prevent increases in intracranial pressure (ICP) and allow proper brain development. This report reviews several of the important head shape abnormalities and normal variants that pediatric health care providers are

abstract

[a]Section of Pediatric Neurosurgery, Department of Neurosurgery and [b]Division of Plastic Surgery, Department of Surgery, College of Medicine and [d]Department of Anthropology, College of the Liberal Arts and Huck Institutes of the Life Sciences, Pennsylvania State University, State College, Pennsylvania; and [c]Lillian S. Wells Department of Neurosurgery, College of Medicine, University of Florida, Gainesville, Florida

DOI: https://doi.org/10.1542/peds.2020-015511

Address correspondence to Mark S. Dias, MD, FAAP, FAANS. E-mail: mdias@pennstatehealth.psu.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Dias MS, Rizk EB, et al. AAP SECTION ON NEUROLOGIC SURGERY, SECTION ON PLASTIC AND RECONSTRUCTIVE SURGERY. Identifying the Misshapen Head: Craniosynostosis and Related Disorders. *Pediatrics.* 2020;146(3):e2020015511

likely to see, describes their salient clinical and radiologic features, and discusses the optimal timing for referral and surgical correction. The report begins with an overview of the normal development of the skull and sutures and the pathophysiology of craniosynostosis.

NORMAL DEVELOPMENT OF THE CALVARIUM AND MOLECULAR DETERMINANTS OF CRANIOSYNOSTOSIS

The skull is a complex skeletal system that meets the dual needs of protecting the brain and other sensory organs while allowing its ongoing growth during development. The calvarial vault (Fig 1) is composed of paired frontal, parietal, and temporal bones and a single occipital bone. The paired frontal bones are separated from each other by the midline metopic suture, and the paired parietal bones are separated from each other by the midline sagittal suture. The frontal and parietal bones are separated by the paired coronal sutures, the parietal and temporal bones are separated by the paired squamosal sutures, and the parietal and occipital bones are separated by the paired lambdoid sutures. There are also a number of sutures and synchondroses involving the skull base. The anterior fontanelle (bregma) forms at the junction of the paired frontal and parietal bones, whereas the posterior fontanelle (λ) forms at the junction of the paired parietal bones with the midline occipital bone.

The skull encompasses the skull base, calvarial vault, and pharyngeal skeleton.[1,2] The bones of the skull base mineralize through endochondral ossification involving the replacement of a fully formed cartilaginous anlagen with bone matrix. In contrast, the bones of the calvarial vault form by intramembranous ossification involving the mineralization of bone matrix from osteoblasts without a cartilaginous intermediate. Craniosynostosis involves the abnormal mineralization of suture(s) and fusion of one or multiple contiguous bones of the cranial vault and can include additional abnormalities of both the soft and hard tissues of the head.[3] The role of cartilage growth disturbance within the cranial base in craniosynostosis is still a matter of debate.[4–7]

The bones of the cranial vault ossify directly from undifferentiated mesenchyme.[8,9] Differentiating osteoblasts accumulate on the leading edges of cranial vault bones as the brain expands during prenatal and early postnatal growth.

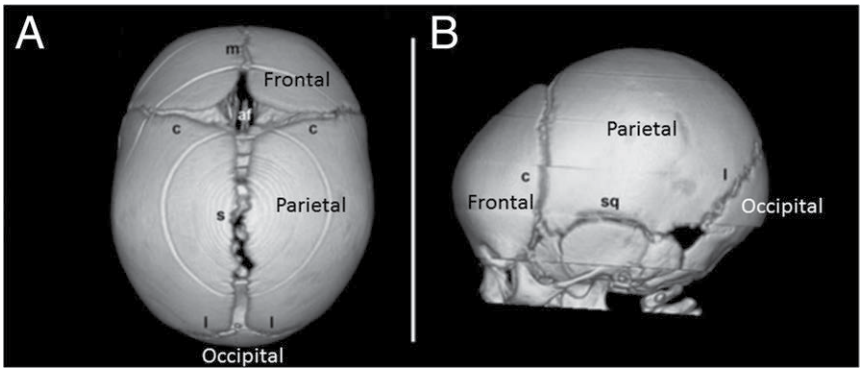


FIGURE 1
Three-dimensional CT scan showing (A) top and (B) side views of the skull bones with metopic (m), sagittal (s), coronal (c), lambdoid (l), and squamosal (sq) sutures, as well as the anterior fontanelle (af). Reproduced with permission from Governale LS. Craniosynostosis. *Pediatr Neurol.* 2015;53(5): 394-401.

Undifferentiated cells between these osteogenic bone fronts form the cranial vault sutures, which function to keep the suture patent while allowing rapid and continual bone formation at the edges of the bone front until brain growth is complete.[10] Sutures are fibrous "joints" that allow temporary deformation of the skull during parturition or trauma, inhibit bone separation for the protection of underlying soft tissues, and, perhaps most importantly, enable growth along the edges of the 2 opposing bones until they ossify and fuse later in life.[10,11] Sutures normally remain unossified well into adolescence. When sutures mineralize (close) abnormally, growth is prevented at the fused suture and is instead redirected to other patent sutures, which, in turn, alters the shape of the skull in predictable ways.

Research has revealed multiple genetic factors, involving several major cellular signaling pathways such as wingless and Int-1 (WNT), bone morphogenetic protein (BMP), fibroblast growth factor (FGR), and others, that interact to direct the behavior of particular subpopulations of cells within the suture. In craniosynostosis, these cells receive and emit signals that stimulate osteogenic differentiation far earlier than expected,[12] resulting in mineralization and progressive ossification that unites the bones on either side of the suture. Pathogenic variants of fibroblast growth factor receptors (*FGFR*s) are the most common genetic variants associated with craniosynostosis.[13–15] *FGFR*s are transcription factors that initiate and regulate the transcription of multiple genes throughout prenatal development.[16–21] Various mouse models expressing *FGFR* pathogenic variants have been developed and demonstrate phenotypes analogous to the human craniosynostosis syndromes, including premature coronal suture closure and midface

flattening (retrusion).[22–31] Pathogenic variants in *TWIST1* (twist family basic Helix-Loop-Helix transcription factor 1) gene, another transcription factor associated with craniosynostosis,[32–34] directly affect BMP signaling of skull preosteoblasts, leading to variations in cerebral brain angiogenesis.[35] These animal models as well as studies of cellular behavior in human craniosynostosis cell lines provide the means to examine the structural, cellular, and molecular changes that occur during prenatal development.[36,37]

THE EFFECT OF CRANIOSYNOSTOSIS ON ICP AND DEVELOPMENT

Aesthetic consequences aside, there are concerns that craniosynostosis, in some cases, affects brain growth and intellectual development. A recent systematic review strongly suggests that craniosynostosis is associated with a higher risk for presurgical neurocognitive deficits compared with the population unaffected by craniosynostosis; these deficits persist postoperatively, suggesting that they may occur independent of surgical correction.[38] Generalized IQ is shifted downward with increased learning disabilities, language delays, and behavioral difficulties.[39] At least 4 mechanisms have been proposed: (1) globally elevated ICP, (2) global brain hypoperfusion, (3) localized compression and deformity, and (4) genetic predisposition. It has proven difficult to extract the exact contributions of each factor, and studies have provided conflicting data. Moreover, many studies suffer from a variety of methodologic flaws, including the inclusion of several types of craniosynostosis, varying definitions of ICP elevations (and lack of normative data), the use of different neurocognitive testing strategies, lack of randomization, inconsistent operative approaches, variations in operative timing, and small study cohorts, to name a few.

To what extent, if any, treatable causes contribute to neurocognitive deficits in craniosynostosis, and whether prompt surgical treatment can improve neurobehavioral outcomes, is a matter of debate. Elevated ICP is present in 4% to 42% of children with single-suture craniosynostosis and approximately 50% to 68% with multisutural involvement[40–44]; the incidence of intracranial hypertension is higher among older untreated individuals.[42,44] Elevated ICP correlates with developmental and cognitive outcomes in some studies[40] but not others.[39,45,46] Neither has the severity of the deformity correlated with the presence of neurocognitive deficits.[39] A few studies have suggested that earlier treatment of craniosynostosis may result in better early and late neurocognitive outcomes,[45,47] but the majority have not found such an association.[12,48–50] Finally, genes involved in craniosynostosis syndromes have recently been found to be involved in brain development,[51] and syndromic craniosynostosis syndromes having virtually identical patterns of skull fusion may carry widely different risks for neurodevelopmental deficits (see below).

THE IMPACT OF SUTURAL SYNOSTOSIS ON DIRECTED CALVARIAL GROWTH

Single sutural synostosis results in predictable changes in skull shape (Fig 2, Table 1). Persing et al[52] proposed 4 rules that govern calvarial growth and predict the head shape in cases of craniosynostosis. These rules are based on the principle that calvarial growth occurs by osseous deposition from calvarial bones lying adjacent to each suture, and this deposition is oriented perpendicular to the intervening suture:

1. Bones that are fused as a result of craniosynostosis act as a "combined growth plate," having reduced growth potential at all of the margins of the plate;
2. Bone is, therefore, deposited asymmetrically, with greater osseous deposition in the bones opposite the perimeter sutures of the combined growth plate;
3. Non-perimeter sutures that are in-line with the combined bone plate deposit bone symmetrically at their suture edges; and
4. Both perimeter and in-line (abutting) sutures nearest the combined bone plate compensate with greater osseous deposition than more distant sutures.

To use sagittal synostosis as an example, the fused parietal bones act as a single, combined growth plate with reduced growth perpendicular to the sagittal suture; accelerated bone deposition occurs within the frontal and occipital bones. The metopic suture, as an abutting in-line suture, deposits bone symmetrically at an accelerated rate. The result is an elongated head (scaphocephaly) with parietal narrowing as well as frontal and occipital bossing. A similar analysis predicts the head shape for the other sutural synostoses (Fig 2). Multisutural synostosis can be appreciated as the combined effect of fusion involving each of the individual component sutures.

SCAPHOCEPHALY (SAGITTAL SYNOSTOSIS), DOLICHOCEPHALY (NICUCEPHALY), AND BATHROCEPHALY

Sagittal synostosis is the most common form of craniosynostosis, accounting for approximately 40% to 45% of cases[53–55] and having a prevalence of 2 to 3.2 per 10 000 live births.[53,56,57] Sagittal synostosis has a distinct male predominance of 2.5 to 3.8:1.[53,55] Sagittal synostosis produces scaphocephaly, characterized by both an elongated head and biparietal narrowing that is evident at birth. The head elongation is best appreciated by looking at the infant from the side (Fig 3). Some patients have an associated saddle deformity at the vertex, giving an

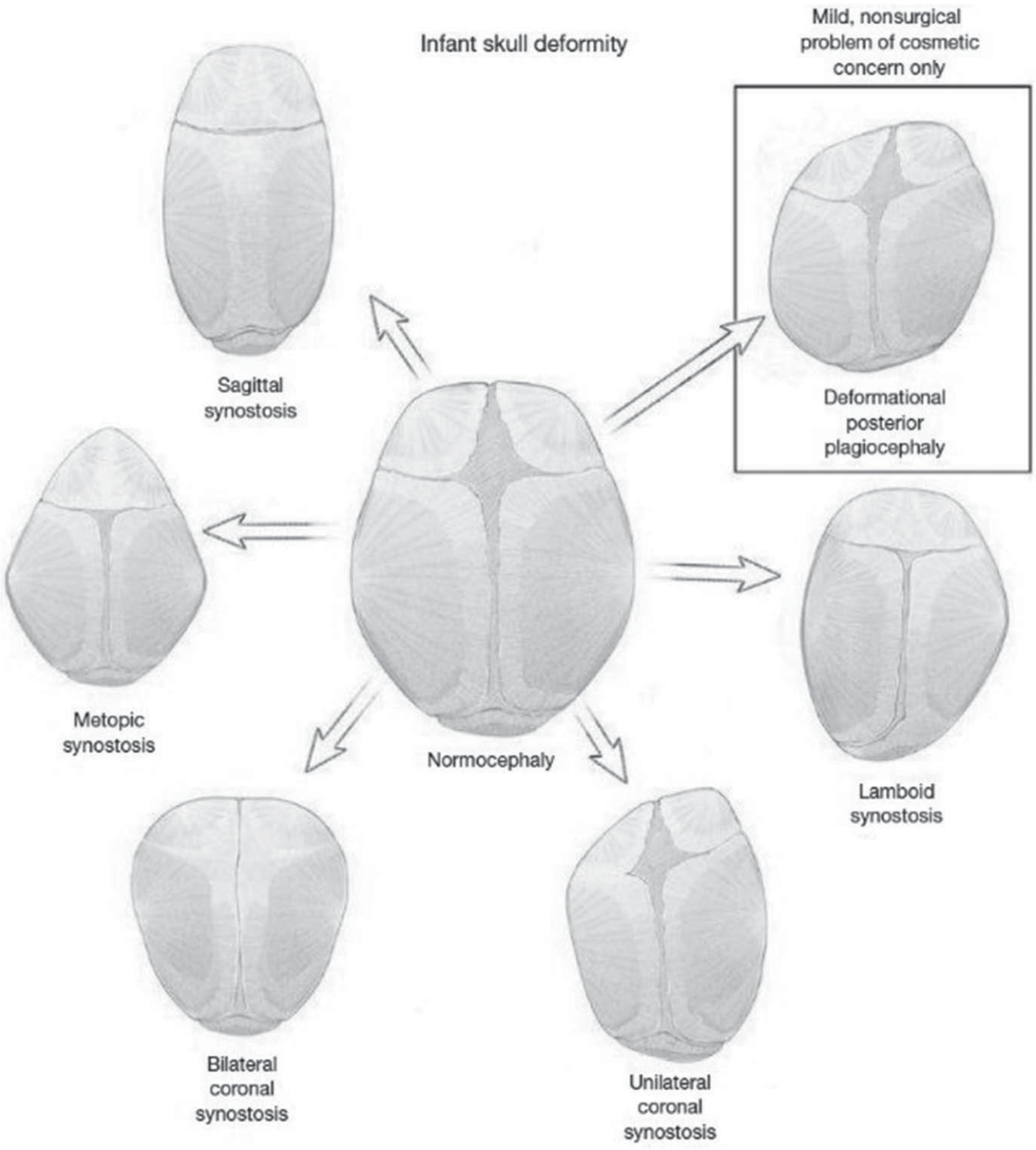


FIGURE 2

Drawing showing the various head shape changes that occur with single-suture synostosis and deformational posterior plagiocephaly. Reproduced with permission from the cover of the May 2016 issue of the *Journal of Neurosurgery: Pediatrics*. ©2016 American Association of Neurologic Surgeons. Artist: Stacey Krumholtz.

overall "peanut" shape to the head. The second consistent abnormality is the biparietal narrowing when looked at from the front or from above. Normally, the parietal bones project straight up or even bowed outward from the temporal region. Biparietal narrowing in sagittal synostosis produces a "cone-head" or bullet-shaped head when viewed from the front and a bicycle racing helmet shape when viewed from above

TABLE 1 Head Shapes Resulting From Craniosynostosis and Positional Deformations

Type	Head Shape Name	1° Change	2° Change(s)
Sagittal	Scaphocephaly	Elongated AP distance	Biparietal narrowing, frontal and/or occipital bossing, and occasional saddle deformity
NICUcephaly	Dolichocephaly	Elongated AP distance	Lack of biparietal narrowing and frontal/occipital bossing
Metopic	Trigonocephaly	Triangular forehead	Bilateral orbital retrusion, bitemporal narrowing, and hypotelorism
Unicoronal	Plagiocephaly	Trapezoid	Flattened ipsilateral forehead, retruded and elevated ipsilateral orbit (Harlequin eye), ipsilateral nasal root and contralateral nasal tip deviation, and anterior displacement of ipsilateral ear
Bicoronal	Brachycephaly and turricephaly	Shortened AP distance; flat, tall, and wide forehead	Exorbitism if associated midface hypoplasia is present
Unilambdoid	Plagiocephaly	Trapezoid	Bulge behind ipsilateral ear or mastoid and ear displaced posterior and inferior
Bilambdoid	Brachycephaly	Shortened AP distance, flat occiput	Bulge behind both ears or mastoid and both ears displaced posterior and inferior
Frontosphenoidal	Plagiocephaly	Trapezoid	Retruded and depressed ipsilateral orbit and contralateral nasal root and ipsilateral nasal tip deviation
DP	Plagiocephaly	Parallelogram	Ipsilateral occiput, ear, and forehead all displaced anteriorly
DB	Brachycephaly	Shortened AP distance	Flattened occiput with normal forehead and orbits

(Fig 3). Frontal or occipital bossing is a variable feature and tends to worsen as the infant ages. Physical examination also demonstrates a prominent midline interparietal, or sagittal, ridge that extends between the anterior and posterior fontanelles; the sagittal suture is longer, as measured from the anterior to the posterior fontanelles. Partial synostosis may cause an incomplete ridge involving only a portion of the suture. One may demonstrate the fusion of the 2 parietal bones by placing a thumb on each of them near the midline and alternatingly depressing each of them; there should be no independent movement.

Sagittal synostosis produces an elongated head on lateral radiographs and a bullet-shaped head on anterior-posterior (AP) radiographs (Fig 4A and B). The normal sagittal suture tapers toward the midline on AP radiographs; in sagittal synostosis, the fused sagittal suture may not be visible, but, more commonly, it appears to have an abrupt, more squared-off appearance (Fig 4B), paradoxically appearing to be open when, in fact, it is not. Computed tomography (CT) scans demonstrate the elongated head with biparietal narrowing (Fig 4C); the fused sagittal suture is best appreciated on coronal reconstructions by using bone algorithms (Fig 4D); three-dimensional reconstructions are particularly well suited to demonstrate the midline sagittal ridge (Fig 4E) but may involve more radiation exposure, particularly with thin slices.

It is important to distinguish scaphocephaly from dolichocephaly. Although these 2 terms have been used interchangeably by many, dolichocephaly refers to an elongated head without associated biparietal narrowing and is caused by positioning. Dolichocephaly most commonly occurs in preterm infants in the NICU: so-called NICUcephaly. Of course, there is no midline sagittal ridge as there is in sagittal synostosis, and, with the thumb maneuver described above, the parietal bones will move independently, often making the infant cry because this appears to be painful.

Infants with frontal bossing from hydrocephalus or chronic subdural hematomas or hygromas may generate confusion. However, these infants have neither an elongated head nor biparietal narrowing, and they have no midline sagittal ridge. Metopic synostosis is readily differentiated from sagittal synostosis by the presence of a prominent midline ridge that extends from the nasion to the anterior fontanelle, anterior to the sagittal suture, and is often associated with a triangular or keel-shaped forehead (trigonocephaly) with recession of the lateral orbits and narrow set eyes.

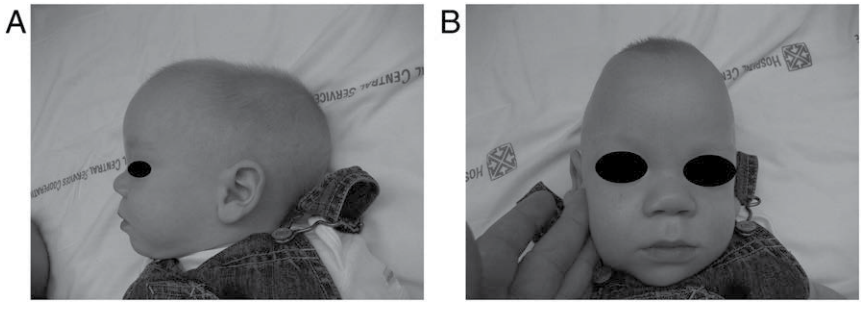


FIGURE 3
Scaphocephaly attributable to sagittal synostosis. A, Lateral view shows elongated antero-posterior dimension with modest frontal bossing and saddle deformity at vertex. B, Frontal view in same child shows parietal bones that curve inward giving a conical head shape attributable to parietal narrowing.

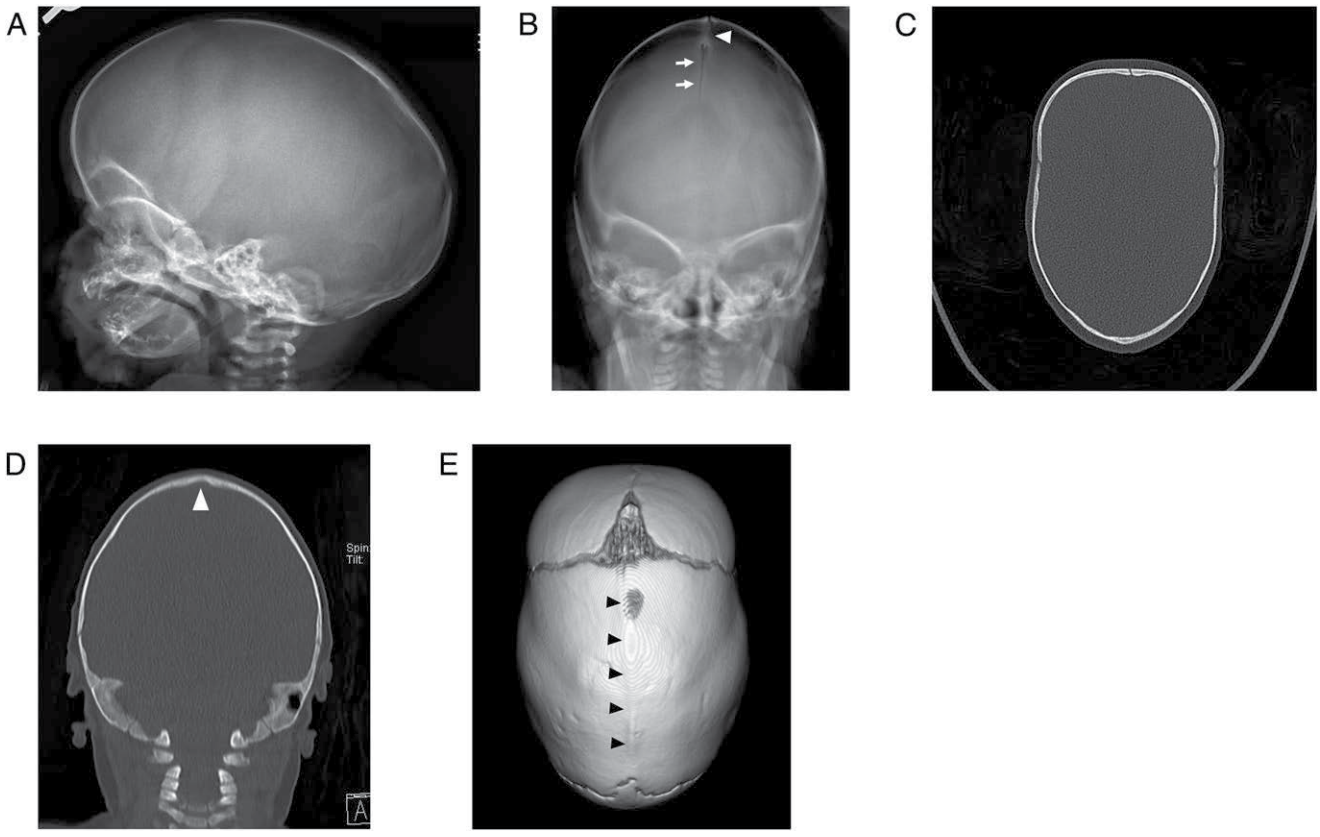


FIGURE 4
Radiologic features of sagittal synostosis. A, Lateral skull radiograph demonstrates an elongated head (sagittal suture is difficult to see from this perspective). B, Anteroposterior skull radiograph shows conical head shape. Note that part of the sagittal suture appears fused (arrowhead), whereas some appears open with sharp borders and adjacent hyperdensities (arrows). The entire suture was fused at surgery. C, Axial CT scan shows elongated head shape with prominent frontal bossing and fused posterior sagittal suture (arrowhead). D, Coronal CT scan shows conical shape of head with fusion of the sagittal suture (arrowheads). E, Three-dimensional CT scan shows prominent midline ridged sagittal suture (arrowheads); both coronal and lambdoid sutures are patent.

Bathrocephaly is another condition that can produce confusion. Bathrocephaly results in a prominent occiput that angles sharply inward toward the neck but without frontal bossing, biparietal narrowing, or sagittal ridging (Fig 5). Bathrocephaly is associated with a persistent mendosal suture, an embryonic suture that extends transversely between the 2 lambdoid sutures and, normally, is gone by birth Fig 5C.[58] Bathrocephaly does not require treatment.

Infants who have sagittal synostosis should be referred to a specialist for repair as early as possible because surgical correction is usually performed much earlier (often at 6–12 weeks of age) than for other forms of synostosis. Surgical management options include both open and endoscopic repairs; adjunctive postoperative helmet therapy is recommended for up to 1 year postoperatively, after more limited endoscopic repairs.[59,60] The importance of early recognition and referral for surgical management cannot be overemphasized because infants treated after 6 to 10 months of age increasingly require more extensive and morbid complete calvarial vault remodeling to achieve adequate correction.

TRIGONOCEPHALY (METOPIC SYNOSTOSIS)

Metopic synostosis is presently the second most common form of craniosynostosis, accounting for 19% to 28% of cases[53–55] and having a prevalence of 0.9 to 2.3 per 10 000 live births.[53,57] The prevalence of metopic synostosis may have increased over the past decades (without a corresponding increase in other synostoses) for uncertain reasons.[54] Metopic synostosis also has a distinct male preponderance of 1.8 to 2.8:1.[53,55] Metopic synostosis produces trigonocephaly with reduced growth potential perpendicular to the metopic suture, a pronounced metopic ridge, and hypotelorism; the forehead forms a keel, similar to the prow of a boat, with bilateral orbital retrusion and bitemporal narrowing (Fig 5). Reduced bifrontal and accelerated biparietal growth along the coronal

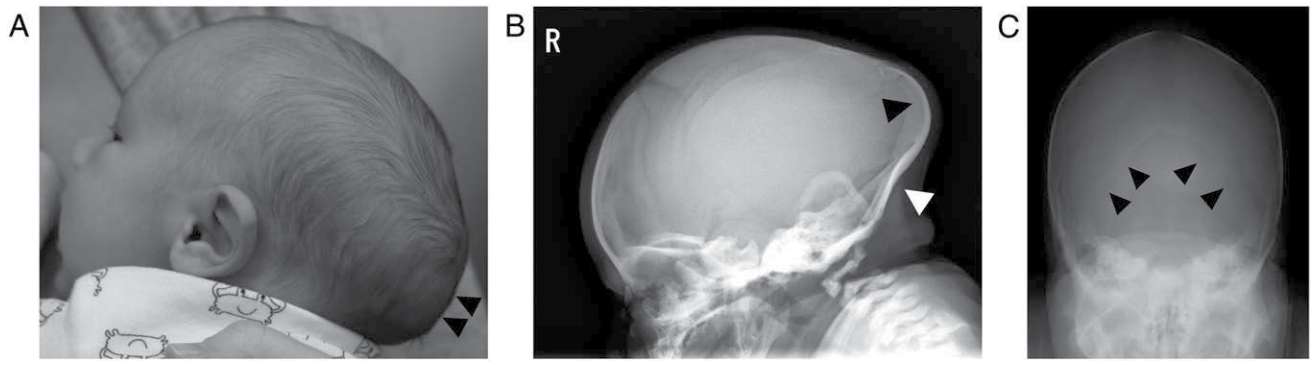


FIGURE 5
Bathrocephaly attributable to persistent mendosal suture. A, Infant with focal prominent occiput (arrowheads). Note the lack of frontal bossing. B, Lateral skull radiograph shows prominent occiput (black arrowhead) and steep angle of the posterior skull (white arrowhead). C, CT scan shows persistent mendosal suture (arrowheads).

sutures, with additional symmetrical growth along the in-line sagittal suture, results in a widened, pear-shaped calvarium behind the coronal suture (Fig 6B).

Some infants may display only a palpable (and sometimes visible) metopic ridge with little or no trigonocephaly; whether this represents a forme fruste of metopic synostosis or another distinct process is unknown. Infants with an isolated metopic ridge and minimal or no trigonocephaly do not require surgical correction.

Plain radiographs may display prominent bony fusion of the metopic suture; however, care must be taken because the metopic suture may normally begin closing as early as 3 months of age and all are closed by 9 months of age.[61] CT scans readily demonstrate the triangular-shaped anterior fossa with midline thickening of the metopic suture and hypotelorism (Fig 7).

ANTERIOR PLAGIOCEPHALY (UNICORONAL SYNOSTOSIS)

Unicoronal synostosis is the third most common form of craniosynostosis, accounting for 12% to 24%[53,55] of nonsyndromic cases and with a prevalence of 0.7 per 10 000 live births.[57] Unlike other forms of synostosis that have a male predominance, unicoronal synostosis has a female preponderance of 1.6 to 3.6:1.[53,57] Unicoronal synostosis produces anterior plagiocephaly in which growth along the ipsilateral coronal suture is reduced and results in a flattening of the ipsilateral forehead (Fig 8). Accelerated growth of the contralateral frontal bone along the perimeter (metopic) and in-line (contralateral frontal) sutures results in compensatory bossing of the contralateral forehead. Some parents and providers may focus on the contralateral compensatory bossing rather than the ipsilateral flattening on the involved side. The metopic suture is bowed toward the side of the flattening. Accelerated growth along the squamosal suture (another perimeter suture) also produces a degree of ipsilateral temporal bossing as well as posterior and inferior ear displacement. The net effect of these changes is a trapezoidal head shape with flattening of the ipsilateral calvarium (both frontally and occipitally) compared to the contralateral side (Fig 8A). This presentation stands in distinct contrast to the parallelogram head shape that accompanies most

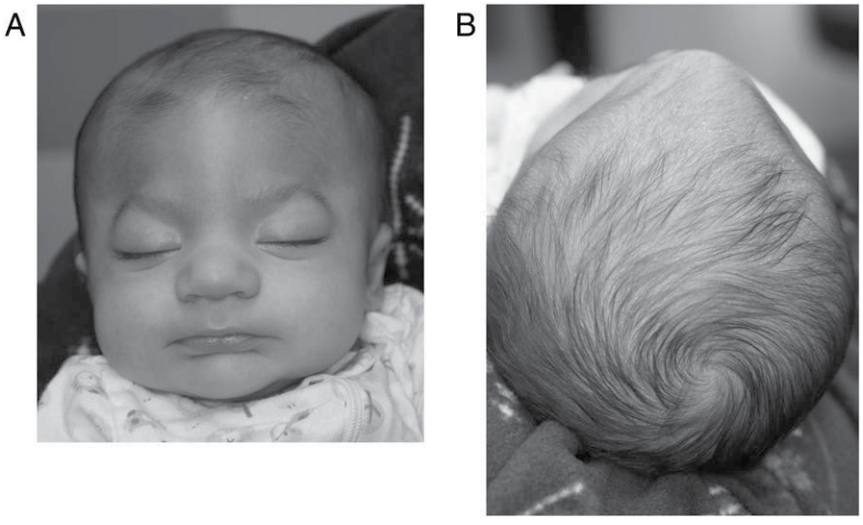


FIGURE 6
Trigonocephaly attributable to metopic synostosis. A, Frontal view of infant showing pronounced midline metopic ridge and bilateral temporal narrowing. B, Vertex view in the same infant shows triangular-shaped forehead.

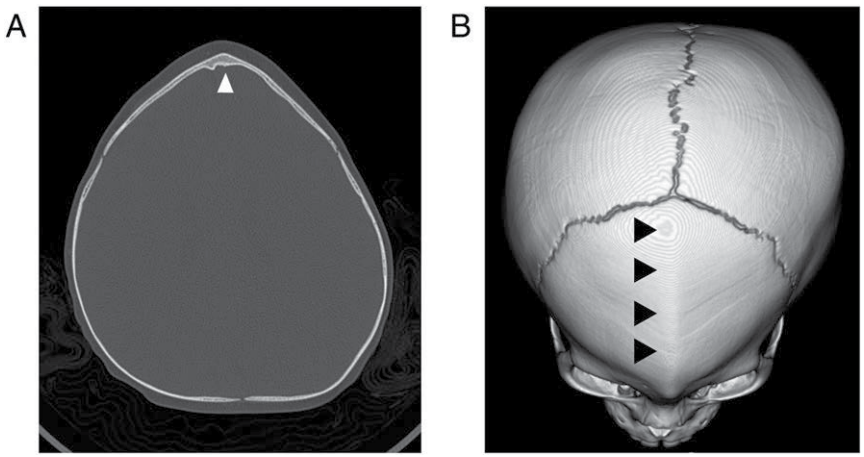


FIGURE 7
Radiologic features of trigonocephaly. A, Axial CT shows triangular-shaped forehead with fused metopic suture (arrowhead) and bitemporal narrowing. B, Three-dimensional CT scan vertex reconstructions show prominent midline metopic ridge with triangular-shaped forehead, bilateral orbital retrusion, and hypotelorism.

cases of occipital deformational plagiocephaly (DP) (see below).

Coronal synostosis additionally involves the sphenozygomatic, frontosphenoidal, and sphenoethmoidal sutures along the frontal skull base, which produces additional secondary morphologic changes involving the orbits and face. Elevation of the lateral sphenoid wing with foreshortening of the zygoma and orbit results in a characteristic elevation of the ipsilateral eyebrow, a seemingly larger palpebral fissure, and/or mild proptosis (Fig 8). The contralateral orbit may be comparatively smaller and is displaced inferiorly and laterally, sometimes leading to a vertical orbital malalignment (dystopia). Diminished growth along the ipsilateral anterior skull base deviates the nasal root toward the involved side and the nasal tip toward the contralateral side (Fig 8B), and the ipsilateral tragus is often displaced anteriorly and inferiorly. In some cases, the entire face appears to be curved with its convexity toward the involved side, leading to a "facial scoliosis" (Fig 8B).

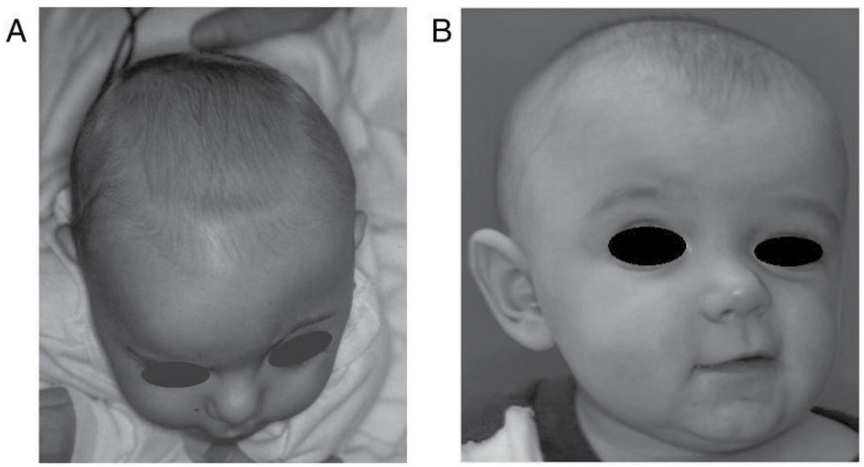


FIGURE 8
Anterior plagiocephaly attributable to unilateral coronal synostosis. A, Vertex view in a child with left coronal synostosis shows flattening of the left forehead and compensatory prominence of the right forehead, upward displacement of the left eyebrow, deviation of the nasal root toward the right and nasal tip toward the left, and trapezoidal head shape. B, Frontal view in another infant with right coronal synostosis shows elevation of the right eyebrow and misshapen orbit, deviation of the nasal root toward the right and nasal tip toward the left, and significant facial scoliosis.

Plain radiographs demonstrate poor visualization of the involved coronal suture. If visible, the ipsilateral suture is deviated anteriorly compared to the contralateral suture; one caveat is that the radiograph must be truly lateral by demonstrating that the ears and/or external ear canals are properly aligned. On the AP view, a characteristic "Harlequin" (or "Mephistophelean") orbit is visible on the involved side and is attributable to elevation of the lesser sphenoid wing (Fig 9A). The nasal bone is also askew, with its upper part deviated toward the involved side.

The findings of unicoronal synostosis are also readily apparent on CT scans. The involved coronal suture is not visible over most or all of its length, whereas the contralateral side is readily apparent on axial images. The ipsilateral flattening and contralateral bossing are also readily evident on axial images. Finally, the sphenoid wing elevation produces a distinct asymmetry to the skull base, with the ipsilateral orbital roof being visible on more superior axial images (and elevated on coronal images) compared to the contralateral orbital roof (Fig 9B). Coronal images also demonstrate the Harlequin orbit to good advantage. Three-dimensional CT reconstructions also demonstrate all of the findings.

The differential diagnosis would include occipital DP and frontosphenoidal synostosis, both discussed below. Hemifacial microsomia is another consideration, although the latter is manifest by primary underdevelopment of the

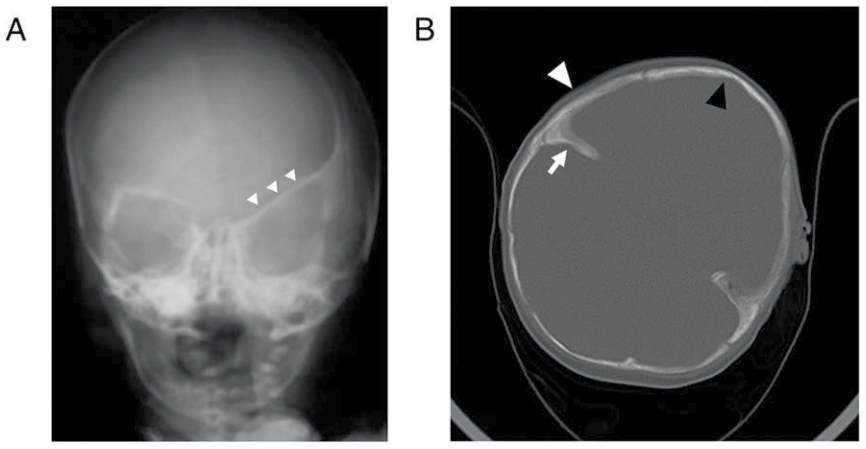


FIGURE 9
Radiologic features of unilateral coronal synostosis. A, A-P radiograph shows elevated ipsilateral sphenoid wing giving rise to the Harlequin eye deformity (arrowheads). The nasal bone is deviated superiorly toward the fused suture. B, Axial CT scan shows trapezoidal head shape with retrusion of the right forehead (white arrowhead), prominence of the left forehead (black arrowhead), and elevation of the sphenoid wing (white arrow).

midface and mandible, with relative sparing of the forehead and orbits; the ear is also malformed, and there are often preauricular skin tags.

ANTERIOR BRACHYCEPHALY (BICORONAL SYNOSTOSIS)

Bicoronal synostosis accounts for about 3% of nonsyndromic and most syndromic synostoses,[53] with a prevalence of approximately 0.5 per 10 000 live births.[57] In bicoronal synostosis, the coronal sutures are palpable on both sides, the entire forehead is flattened, the head is reduced in the anteroposterior dimension (anterior brachycephaly), and the forehead often has a towered appearance (turricephaly). The combination of frontal and maxillary foreshortening results in shallow orbits and produces significant exophthalmos; in addition, the orbits are recessed (retruded) or shallow bilaterally (Fig 10). The nasal bone is short and upturned in many cases.

On radiographs, the anterior fossa and orbits are short and both coronal sutures are radio dense or difficult to see and anteriorly deviated. Bilateral Harlequin orbit deformities are present with elevation of both sphenoid wings. Because both frontal bones are involved, the nasal bone remains midline. CT scans demonstrate brachycephaly, thickening and/or nonvisualization of both coronal sutures, a shallow anterior fossa and orbits, and bilateral sphenoid wing elevation (Fig 11). Coronal images nicely demonstrate bilateral Harlequin orbits as well.

POSTERIOR SYNOSTOTIC PLAGIOCEPHALY (LAMBDOID SYNOSTOSIS)

Lambdoid synostosis is rare; in contemporary series, lambdoid synostosis accounts for only 2% of cases and has a prevalence of 0.1 per 10 000 live births.[55,57] Older studies likely included children with DP and their prevalence rates are, therefore, higher. In one small series, male and female patients were equally represented.[55] True lambdoid synostosis is usually readily differentiated from occipital DP (see below), with which it is most commonly confused. True lambdoid synostosis is most commonly characterized by a flattening of both the ipsilateral occiput and forehead, leading to a trapezoidal or rhomboidal head shape (Fig 12). The contralateral occiput may be prominent by comparison. The lambdoid suture is prominently ridged. The ipsilateral ear is deviated posteriorly (in contrast to DP, in which it is deviated anteriorly), and the mastoid process and associated retromastoid occipital bone are unusually prominent, producing a retroauricular "bulge" (Fig 12). Bilateral involvement produces

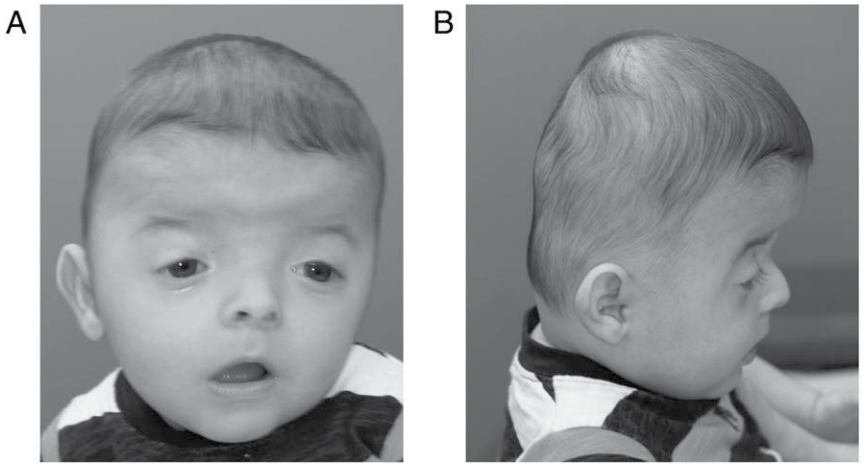


FIGURE 10
Brachycephaly attributable to bicoronal synostosis in a child with Saethre-Chotzen syndrome. A,-Frontal view shows flattened forehead, shallow orbits with bilateral orbital retrusion, a modestly upturned (beaked) nose, bilateral ptosis, and midface hypoplasia. B, Lateral view of the same infant shows flattened and tall (turricephaly) forehead, with shallow orbits and midface hypoplasia.

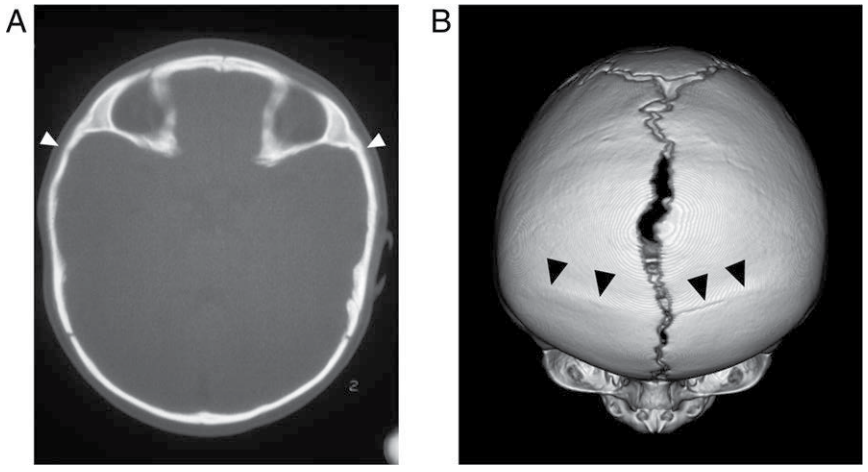


FIGURE 11
Radiologic features of bilateral coronal synostosis. A, Axial CT scan shows shallow anterior fossa and absence of both coronal sutures (arrowheads). B, Three-dimensional CT scan reconstructed vertex view shows shallow anterior fossa, bilateral superior orbital retrusion, and bilaterally fused coronal sutures (arrowheads).

a flattened occiput with ridging of both lambdoid sutures and retromastoid bulge on both sides. The posterior sagittal suture may also be involved, producing an element of scaphocephaly as well as ridging of both lambdoid and posterior sagittal sutures (the "Mercedes-Benz" sign).

Plain radiographs commonly demonstrate significant prominence and hyperostosis or nonvisualization of the involved lambdoid suture(s). CT scans also demonstrate hyperostosis or nonvisualization of the involved lambdoid suture(s). The retromastoid bulge and posterior displacement of the petrous ridge are prominent; the posterior midline and the foramen magnum at the base of the skull are also drawn toward the ipsilateral side (Fig 12C). Three-dimensional CT scans also demonstrate these findings to good advantage (Fig 12D). Treatment involves open posterior cranial vault reconstruction between 5 and 9 months of age or endoscopic repair as early as 2 to 3 months of age, followed by molding helmet treatment for up to 1 year.

FRONTOSPHENOIDAL SYNOSTOSIS

An extremely rare form of synostosis involves the frontosphenoidal suture, located at the anterior skull base and contiguous with the coronal suture and orbital roof.[62,63] Synostosis involving the frontosphenoidal suture produces plagiocephaly with ipsilateral forehead flattening that resembles unilateral coronal synostosis but differs from the latter in that the ipsilateral orbit is deviated inferiorly rather than superiorly, and the nasal root is deviated away from rather than toward the side of the synostosis (Fig 13 A and B). The coronal suture is visible on neuroimaging studies, and there is no Harlequin eye orbital deformity (Fig 13 C and D); CT demonstrates the fusion of the frontosphenoidal suture (Fig 13E). Treatment involves a fronto-orbital reconstruction.[62,63]

SYNDROMIC CRANIOFACIAL MALFORMATIONS

A number of craniosynostosis syndromes have been described phenotypically (Table 2). All of these, most commonly, include elements of bicoronal synostosis and midface hypoplasia. Ophthalmologic manifestations are also common and include shallow orbits, some degree of exorbitism, and extraocular muscle dysfunction with strabismus and resultant amblyopia and poor visual

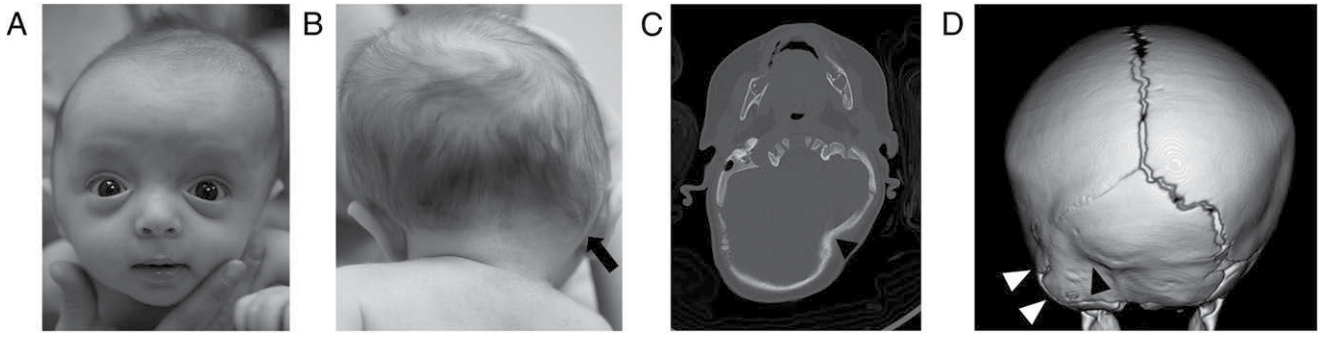


FIGURE 12
Unilateral lambdoid synostosis. A, Anterior view shows asymmetric head with calvarium deviated toward the left. Note the symmetry of orbits. B, Posterior view shows prominent curvature of the occiput toward the left with a retromastoid bulge on the right (arrow) and flattening inferior to the bulge. C, Axial CT scan shows prominent left mastoid bulge and indentation of the occipital skull (arrowhead). D, Three-dimensional CT scan posterior view shows the fused left lambdoid suture, retromastoid bulge (white arrowheads), and indentation of the occipital bone (black arrowhead).

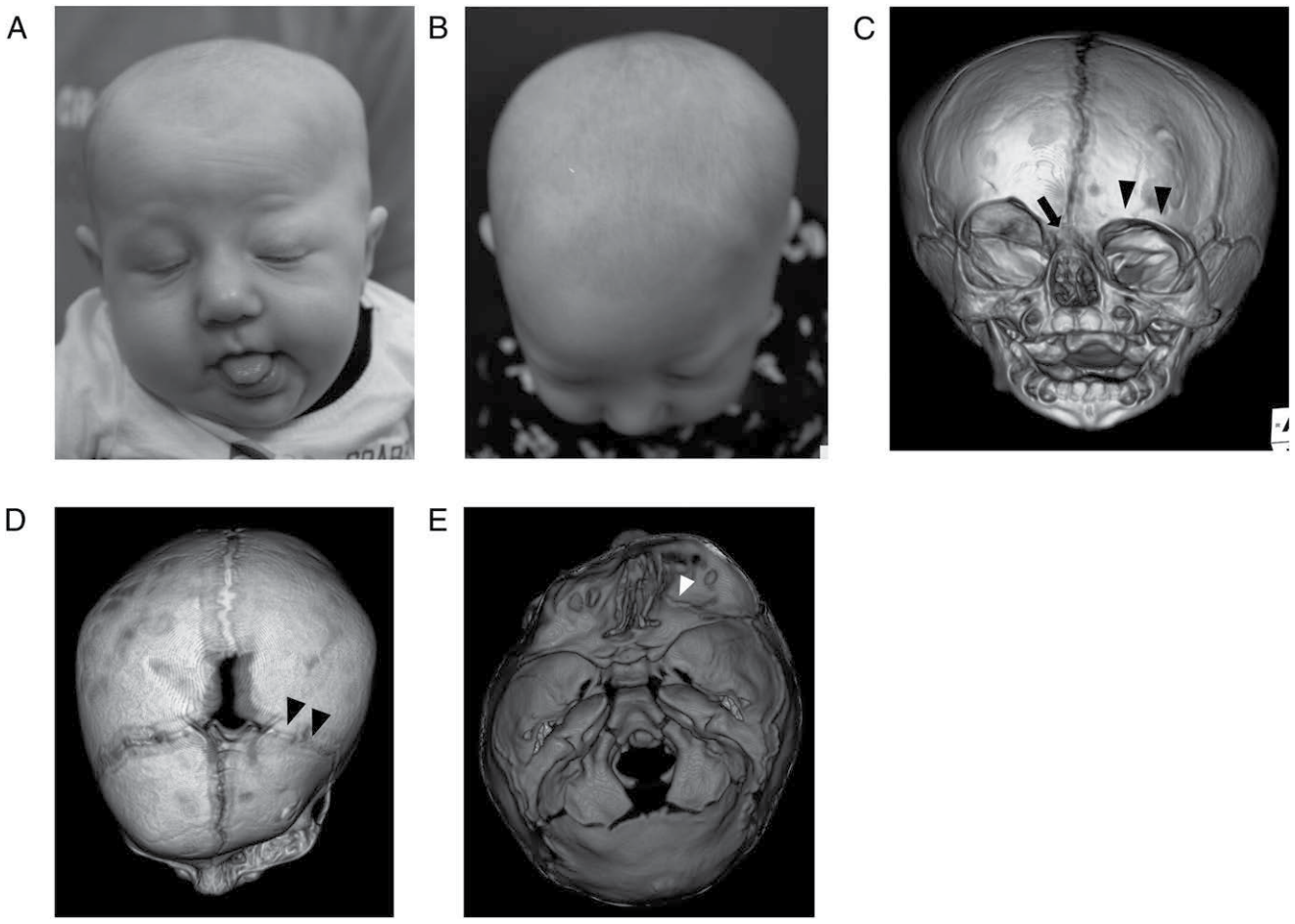


FIGURE 13
Frontosphenoidal synostosis. A, Frontal view of infant with left frontosphenoidal synostosis, with left forehead depression and retrusion and depression of left orbit. B, Vertex view demonstrating left forehead and orbital retrusion. Note in both images the deviation of the nasal root away from, and the nasal tip toward, the involved side, in contrast to coronal synostosis. C, Frontal three-dimensional reconstruction CT scan shows inferiorly displaced ipsilateral eyebrow and orbital roof (arrowheads) and deviation of the nasal root (arrow) toward the contralateral side (in contrast to unicoronal synostosis, see Fig 8). D, Vertex three-dimensional reconstruction CT scan shows left forehead flattening but open coronal suture on that side (arrowheads). E, Three-dimensional reconstruction CT scan with a view of the inside of the skull base with the calvarium digitally subtracted shows flattening of the left orbit. The right frontosphenoidal suture is patent (arrowhead), whereas the left is fused.

acuity.[64,65] More recent genetic testing has revealed significant genotypic overlap, with the same genetic mutation capable of producing distinctly different phenotypes, and a single phenotype resulting from different genetic pathogenic variants. It is beyond the scope of this report to describe all of the various syndromes in detail; brief descriptions of the more common syndromes are provided. The interested reader is referred elsewhere for more detailed information.[66,67]

TABLE 2 Genetics of Craniofacial Syndromes

Syndrome	Transmission	Identified Gene Variants
Crouzon	AD	*FGFR1, FGR2*
Apert	AD	*FGFR2*
Pfeiffer	AD	*FGFR1, FGR2*
Saethre-Chotzen	AD	*TWIST*
Carpenter	AR	*RAB23, MEGF8*
Antley-Bixler	AR and sporadic AD transmission	Uncertain (for AR) and *FGFR2* (for AD)
Muenke	AD	*FGFR3*

AD, autosomal-dominant; AR, autosomal-recessive.

Crouzon Syndrome

Crouzon syndrome is most frequently characterized by bicoronal synostosis leading to a shallow anterior fossa, a high and flat forehead (turricephaly) with reduced anteroposterior cranial measurement (brachycephaly), shallow orbits and prominent globes (exorbitism), midface hypoplasia leading to an underbite and malocclusion, and upturned (or "beaked") nose. Involvement of other sutures may

also occur, and progressive sutural fusion has been described during the first 2 years of life.[68] Craniosynostosis is a variable feature and, rarely, may be absent. Syndactyly is notably absent. Rarely, vertebral fusion, ankylosis (particularly the elbows), and acanthosis nigricans may be present. Cognitive development is often normal, and neurocognitive deficits are uncommon. Crouzon syndrome is transmitted as an autosomal-dominant condition with varying penetrance; pathogenic variants in the *FGFR1* or *FGFR2* genes are responsible for all but Crouzon with acanthosis nigricans, which is caused by pathogenic variants in the *FGFR3* gene.

Apert Syndrome

The craniosynostosis pattern in Apert syndrome is similar to that in Crouzon syndrome, although progressive fusion of additional sutures during the first 2 years occurs more commonly in Apert syndrome. Like in Crouzon syndrome, turricephaly, brachycephaly, exorbitism, beaked nose, and malocclusion are cardinal clinical manifestations in Apert syndrome. Down-slanting palpebral fissures are typical. Palatal abnormalities may be present and include narrowing, bifid uvula, and cleft palate,[69] and vertebral fusion abnormalities (most commonly involving C5-C6) may be present.[70] Structural brain abnormalities may be present, including agenesis of the corpus callosum, gyral malformations, absent or defective septum pellucidum, megalencephaly, and static or progressive ventriculomegaly. Unlike Crouzon syndrome, neurocognitive deficits are more common, with more than one-half having subnormal IQ scores. The most striking extracranial abnormality in Apert syndrome is osseous and/or soft tissue syndactyly involving fingers and/or toes, particularly the second, third, and fourth digits (Fig 14). The digits are short, and broad distal phalanges may also be present. Apert syndrome is transmitted as an autosomal-dominant condition; a mutation in the *FGFR2* gene is responsible.

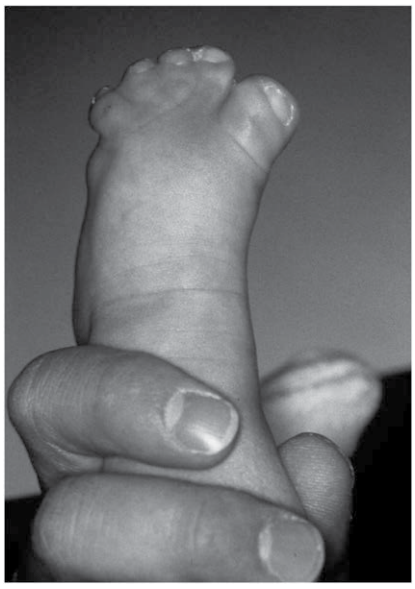


FIGURE 14
Syndactyly involving the toes in an infant with Apert syndrome.

Pfeiffer Syndrome

Pfeiffer syndrome is characterized by bicoronal synostosis, and the midface is narrow but not generally retruded; there is, therefore, less significant exorbitism and malocclusion. Like Crouzon and Apert syndromes, cranial sutures in Pfeiffer syndrome may progressively fuse over time. The nose is generally small with a low nasal bridge. Partial syndactyly of the second and third fingers and/or toes are cardinal features of Pfeiffer syndrome, and the distal phalanges of the thumb and great toe are often wide. Pfeiffer syndrome is transmitted as an autosomal-dominant condition with variable penetrance; a mutation in the *FGFR2* gene is responsible.

Cohen has described 3 types of Pfeiffer syndrome.[71] Type I is characterized by typical coronal synostosis, midface hypoplasia, and digital malformations with normal neurocognitive development. Types II and III are associated with much more severe involvement, usually involving all of the sutures (and, in type II, producing a cloverleaf skull), with shallow orbits and severe exorbitism sufficient to produce corneal exposure, airway obstruction, partial syndactyly and elbow ankylosis, various visceral abnormalities, and moderate to severe neurocognitive impairment.

Saethre-Chotzen Syndrome

Saethre-Chotzen syndrome is characterized by bicoronal synostosis (with occasional involvement of other sutures) leading to turricephaly and brachycephaly with biparietal foramina but less severe midface hypoplasia and modest exorbitism. Differentiating manifestations include ptosis of the eyelids (Fig 10A), a low anterior hairline, and a prominent nose. Lacrimal duct abnormalities and a characteristic prominent ear crus may be present. Extracranial abnormalities can include partial soft tissue syndactyly, most commonly involving the second and third fingers and third and fourth toes; the digits are often short and the great toes may be broad. Saethre-Chotzen syndrome is transmitted as an autosomal-dominant condition; a mutation in the *TWIST* gene is responsible.

Carpenter Syndrome

Carpenter syndrome is characterized by synostosis most commonly involving both coronal sutures and variably others as well, with shallow supraorbital ridges and flat nasal bridge, midface, and/or mandibular hypoplasia, low-set and malformed ears and a high arched palate. A number of digital malformations may occur including brachydactyly, clinodactyly, and camptodactyly (medial deviation and flexion deformity of the distal phalanges, respectively) and polydactyly involving the toes. Cardiac malformations occur in one-half of affected individuals and include septal defects, tetralogy of Fallot,

transposition of the great vessels, and persistent ductus arteriosus. Carpenter syndrome is transmitted as an autosomal-recessive condition; pathogenic variants in the *RAB23* or *MEGF8* genes are responsible.

Antley-Bixler Syndrome

Antley-Bixler syndrome is characterized by bicoronal synostosis (in 70%) with turricephaly but with frontal bossing, midface hypoplasia with exorbitism, and a flat and depressed nasal bridge. Low-set and dysplastic ears are a consistent feature, and choanal atresia or stenosis is present in 80%. Limited limb mobility and a diminished range of motion involving virtually all joints, phalangeal abnormalities (including long fingers with tapering fingernails), radiohumeral synostosis, and femoral bowing are common features as well. Impaired steroidogenesis and genital abnormalities are associated features. Antley-Bixler syndrome is most commonly related to pathogenic variants in the *POR* gene (with impaired steroidogenesis) and autosomal-recessive transmission and pathogenic variants of the *FGFR2* gene (without impaired steroidogenesis), with autosomal-dominant transmission.

Muenke Syndrome

Muenke syndrome is characterized by fusion of one or both coronal sutures with a broad and shallow supraorbital ridge and prominent forehead (bossing). Hypertelorism and flattened maxillae are variable features. Hearing loss is present in approximately one-third of patients, and macrocephaly is present in approximately 5%.[72] Muenke syndrome is transmitted as an autosomal-dominant condition and is unusual among the syndromic synostoses in that it involves a mutation in the *FGFR3* gene.

SURGICAL MANAGEMENT OF CRANIOSYNOSTOSIS

The evaluation and management of craniosynostosis are beyond the scope of this review, but a few general comments are helpful. Imaging of suspected craniosynostosis most commonly includes either plain skull radiographs or CT scans. In general, plain skull radiographs are of limited value if craniosynostosis is strongly suspected because CT scans will likely be performed by the craniofacial team as part of surgical planning. On the other hand, obtaining a CT scan in children with low suspicion for craniosynostosis is often unnecessary. Cranial ultrasonography is used by some, and studies suggest that it is as effective as plain radiographs or CT scans in identifying a fused suture.[73] However, not all radiologists are equally experienced at identifying fused sutures on ultrasonography, so it is recommended that the provider check with the radiologist first before obtaining this study. Many craniofacial teams prefer that providers refer these children early and postpone imaging until after the child is seen by specialists. For children with occipital DP, the diagnosis is usually obvious by clinical inspection, the absence of significant deformity at birth, and the absence of a retroauricular bulge; questionable cases might require neuroimaging, but these are rare.

The timing of surgery (and, by extension, referral) is another important consideration. Traditional repairs of coronal, metopic, and frontosphenoidal synostosis are generally delayed until 6 to 10 months of age. However, the child with symptomatic increased ICP may require earlier repair. Moreover, sagittal synostosis repairs and endoscopic approaches are performed much earlier, some as early as 8 weeks of age. Delays in referral often lead to more extensive surgical repairs; early referral is, therefore, preferable, even in questionable cases of craniosynostosis.

There are many accepted surgical options for craniosynostosis that are influenced by which suture(s) are involved, the clinical indication, the experience and expertise of the craniofacial surgical team, and, most importantly, the timing of the operation. It is not the intent of this review to recommend any particular operative technique because they all have their merits.

Surgical techniques may include endoscopic suturectomy with helmet therapy, spring-assisted cranioplasty, and subtotal and complete calvarial vault remodeling. Advantages of endoscopic suturectomy include smaller incisions and less operative time and blood loss, but correction should be performed early (during the first few months of life) and followed by up to 12 months of postoperative molding helmet therapy (23 hours a day) to achieve correction comparable to open techniques. Spring-assisted cranioplasty is another surgical adjunct that can be used, in which spring-loaded devices are inserted temporarily to help distract the freed bones.

The advantages of open operative correction include more immediate and complete correction, without the need for extended molding helmet therapy. Disadvantages include a larger incision, longer operative times, greater intraoperative blood loss, and, for coronal and metopic synostosis, the need to remodel the superior orbital rim (which generally requires that the surgery be performed after the infant has reached 6 months of age so the orbital rim is thick enough to hold the surgical screws). A variety of open techniques exist, but surgical timing is important. Open sagittal synostosis repairs are performed much earlier (ideally between 2 and 6 months of

age) than are metopic or coronal synostosis. Sagittal synostosis repair includes a midline or paramedian (so-called π) craniectomy coupled with a variable degree of posterior (parietal and occipital) vault reconstruction with barrel stave osteotomies. Later surgery (generally beyond 6–8 months of age) may require a more extensive total calvarial vault remodeling. Lambdoid suture repair is also, generally, performed early. In contrast, for open coronal or metopic synostosis, in which both cranial and orbital reconstruction are performed, later surgical correction, usually between 6 and 10 months, is preferred so that the orbital rim is thick enough to hold the surgical constructs used to advance and remodel the bone. All open surgical approaches involve a full release of the fused suture and immediate surgical remodeling of the skull; postoperative helmeting is not routinely used after open repair.

The surgical management of midface hypoplasia deserves special mention because it is a frequent component of syndromic synostosis. Severe midface hypoplasia can lead to airway obstruction that requires an immediate intervention, such as a tracheostomy to secure the airway. Definitive midface correction is usually performed when the child is older (6–8 years or more) and is usually accomplished by using distraction osteogenesis, in which the midface is surgically separated from the skull base and distraction plates are applied to the maxillary bones. By using distraction screws that are turned by the patient or family on a daily basis, the midface is slowly advanced forward, and bone grows in the intervening gap, much like an Ilizarov procedure accomplishes for long bones.

OCCIPITAL (DEFORMATIONAL) PLAGIOCEPHALY AND BRACHYCEPHALY

The most common head shape abnormality is deformational (also called positional or nonsynostotic) plagiocephaly (DP) or brachycephaly (DB). The incidence of DP/DB has been estimated at 20% to 50% in 6-month-old children.[74] It is more common (approximately 60% of cases) in male children.[75] DP/DB in 80% of cases presents as an acquired postnatal condition that is most commonly noted during the first 4 to 12 postnatal weeks, although 20% of cases appear to be noted at birth, likely attributable to intrauterine forces (relative fetal restraint, such as primiparity, oligohydramnios, multiple gestation, or bicornuate uterus).[75] Eighty percent of cases are right sided, and the flattening corresponds to the side to which the infant naturally turns the head; this correlates well with observations made by Volpe[76] that normal supine infants look toward the right 80% of the time, toward the left 20%, and almost never look straight up. In addition, 15% to 20% of infants with DP/DB have some degree of neck muscle imbalance or torticollis.[75] It is now apparent that DP/DB is not synostotic but rather is caused by persistent pressure on the skull in the supine infant. The incidence increased significantly after the 1992 "Back to Sleep" campaign, which recommended supine sleep (although the decreased rate of sudden unexpected death in infancy certainly supports the continued endorsement of this strategy).[74]

It is important to differentiate DP/DB from true coronal or lambdoid craniosynostosis. The majority of cases can be readily identified by the history (as described above) and clinical examination. The infant is examined from the front, back, and, most importantly, top of the head. DP/DB is characterized by occipital flattening: unilaterally in DP (Fig 15) and bilaterally in DB. The ipsilateral ear is deviated anteriorly with respect to the contralateral side (which can be most readily identified by placing a finger in each ear and looking down from above the infant's head); the pinna may be rotated outward as well. Finally, there is often some anterior displacement of the ipsilateral forehead. The resulting deformation results in a parallelogram head shape (Fig 15A) in which the entire ipsilateral head appears to have been displaced anteriorly. In contrast, the child with unilateral coronal or lambdoid synostosis will have a trapezoidal-shaped head with ipsilateral flattening of both frontal and occipital calvarium and posterior and inferior deviation of the ipsilateral ear, as discussed above. Patients with DP may have an element of facial scoliosis (Fig 15B). Although the ipsilateral orbit in DP may be slightly misshapen, the Harlequin orbit deformity observed in unicoronal synostosis is not present. Similarly, the bulging retromastoid area in lambdoid synostosis is absent in DP and DB. In DB, the occiput is flattened bilaterally, and the head is, therefore, brachycephalic and widened in the transverse dimension, leading to a round face. However, the absence of turricephaly, orbital retrusion, Harlequin orbit, and exophthalmos differentiate DB from bicoronal synostosis.

Other abnormalities observed in some cases with DP include an element of facial scoliosis. Some have elevation and shortening of the mandible with a "hollow" space in the submandibular region, superficially resembling hemifacial microsomia. This variant seems to be more common among those whose DP is present at birth and/or those with torticollis; it is suggested that perhaps the shoulder may lie within this hollow and restrict neck rotation in utero. Another less common variant of DP is what is referred to as the "Gumby" head shape in which, when viewed from the front, the ipsilateral calvarium is flattened and the vertex slopes upward toward the opposite side (Fig 15B).

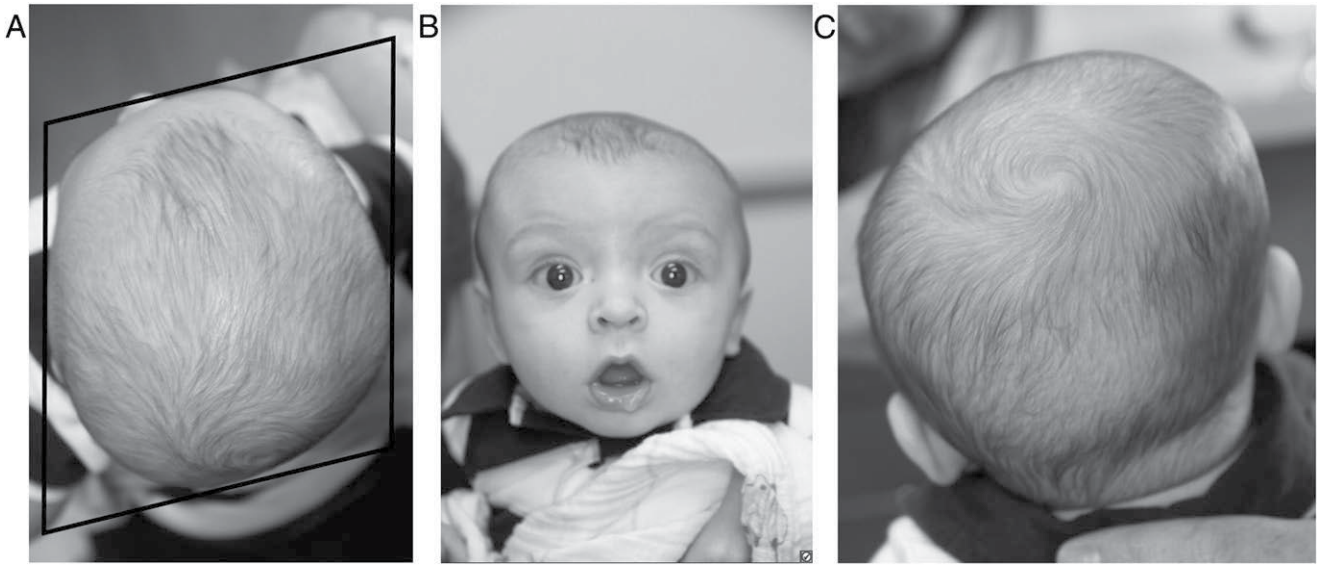


FIGURE 15
Occipital deformational flattening (plagiocephaly and brachycephaly). A, Vertex view of DP shows parallelogram-shaped head with ipsilateral flattening, anterior deviation of the ipsilateral ear, and mildly prominent ipsilateral frontal bossing. B, Frontal view shows the calvarium deviated toward the right but no elevated eyebrow and/or orbit or deviation of the nasal root or tip. Note the upward slanting cranial vault from patient's left to right ("Gumby" deformity). C, Posterior view of DP shows flattened right occiput with parietal boss.

A number of centers quantify the severity of DP and DB, both for the initial assessment and at subsequent follow-up visits, by measuring certain anthropometric indices with cranial calipers. The severity of DP is described by using the cranial vault asymmetry index (CVAI), which describes the difference between the longest and shortest head axes along the diagonal when viewed from above (Fig 16). In general, a CVAI of >3.5 is consistent with DP.[74] The severity of DB is described by using the cranial index (CI), which measures the ratio of head width to head length when viewed from above. A CI of $\geq 85\%$ is consistent with brachycephaly.[77]

The differential diagnosis of DP includes unilateral coronal and unilateral lambdoid craniosynostosis, both described above. In most cases, the diagnosis of DP or DB is readily apparent on clinical examination, and adjunctive imaging such as plain radiographis or CT scans is unnecessary and would expose the child to ionizing radiation. The use of imaging should be reserved for equivocal cases. Plain radiographs are usually difficult to interpret, except in cases of DB in which the occipital flattening is evident on lateral films. Partial nonvisualization or focal areas of calcification adjacent to the lambdoid suture may be identified on plain radiographs and CT scans but should not be interpreted as lambdoid synostosis. Axial CT scans readily differentiate DP and DB from coronal synostosis, demonstrating the parallelogram head shape, open coronal sutures, and normally formed anterior skull base with normal sphenoid wing and absent Harlequin orbit.

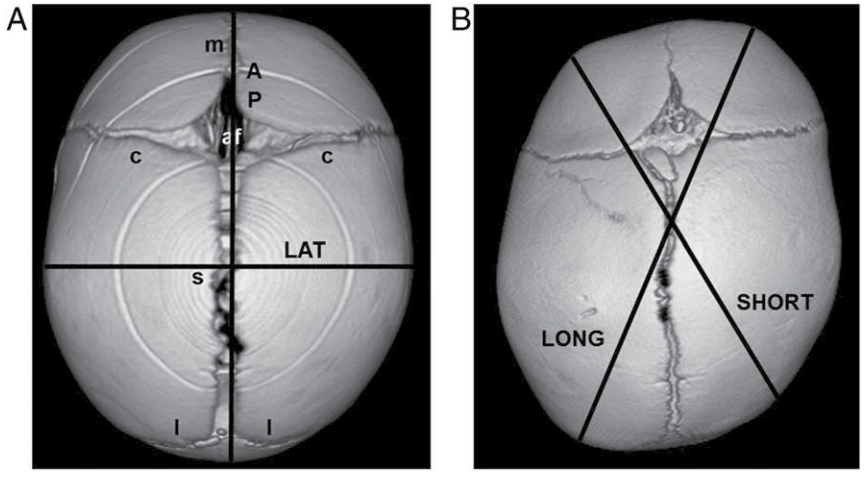


FIGURE 16
Diagram showing the calculation of the (A) CVAI and (B) CI. See text for definitions.

It is not our intent with this report to discuss treatment options for DP and DB. However, the parents of infants with DP or DB should be reassured that since the infant does not have

craniosynostosis, surgery is not indicated; they should be counseled that DP and DB are solely aesthetic conditions, with no credible medical evidence suggesting that DP and DB affect brain development or cause any other medical condition. The head shape often improves as the child gains developmental milestones and lies less frequently on the flattened side.[74] Supervised "tummy time" as well as varying head positions while holding the child can help; alternating head positions for sleep can be attempted, but, to reduce the incidence of sudden unexplained death in infancy, it should be emphasized that the infant should sleep alone, on his or her back, and in a crib (the ABCs of safe sleep). A recent study noted a correlation (not necessarily causal) between DP and poorer cognitive outcomes[78]; children with DP should, therefore, be monitored for possible developmental delays. The child with muscular neck imbalance or torticollis may be referred to physical therapy to teach the parents stretching and muscle strengthening exercises to reduce the tension of the sternocleidomastoid muscle and improve the strength of contralateral muscles. Use of a molding helmet may be considered for the infant with a moderate or severe deformity but is not required; a detailed evidence-based review of DP and DB treatment options can be found in a recent publication by the Congress of Neurological Surgeons and is endorsed by the American Academy of Pediatrics.[79–84]

EARLY FONTANELLE CLOSURE AND MICROCEPHALY

Two other common referrals to craniofacial clinics are concerns about early closure of the anterior fontanelle and microcephaly. Although the anterior fontanelle most commonly closes at approximately 12 months of age, there is a wide variation in the timing of fontanelle closure, with the fontanelle closing between 4 and 26 months.[85] Moreover, it is important to note that closure of the fontanelle does not mean that the sutures are closed, nor does it mean that further calvarial growth is not possible. Rather, closure of the fontanelle simply reflects the apposition of the 2 frontal and 2 parietal bones in such a manner that a gap cannot be palpated, although sutures are still present. In fact, even after normal fontanelle closure, significant head growth continues throughout childhood. As long as appropriate head growth is occurring along the normal head growth curve and the head shape is normal, there should not be concern for craniosynostosis. However, other medical conditions can be associated with premature fontanelle closure, including hyperthyroidism, hyperparathyroidism, hypophosphatasia, and rickets.

Microcephaly is defined as a head circumference below the fifth percentile for age. There are numerous causes for microcephaly, some of which are listed in Table 3. Primary microcephaly may be genetic; multiple pathogenic variants with both autosomal-dominant and recessive inheritance patterns have been described. Other conditions are usually identified by history, physical examination, and/or neuroimaging. Important considerations include a family history of microcephaly, the presence or absence of developmental delays or cognitive impairment, and a past history of pre- or postnatal brain injury. Infants with normal developmental milestones, no past history of brain injury, and a normal head shape most often have constitutional microcephaly. Single-suture craniosynostosis virtually never causes significant microcephaly, although multisutural synostosis can. Craniosynostosis is rarely a cause of microcephaly in infants whose head circumferences, although low, are running parallel to the normal curve and who have both a normal head shape and no family history of craniosynostosis.[86]

TABLE 3 Conditions Causing Microcephaly

Primary microcephaly
Chromosomal disorders
Anencephaly
Encephalocele
Holoprosencephaly
Agenesis of the corpus callosum
Neuronal migration disorders
Microcephaly vera
Secondary microcephaly
Intrauterine infections
Intrauterine toxins
Intrauterine vascular insufficiency
Hypoxic-ischemic brain injury
Intracranial hemorrhage
Neonatal infections (meningitis and encephalitis)
Neonatal stroke
Chronic cardiopulmonary or renal disease
Malnutrition
Craniosynostosis

Adapted from Pina-Garza J. *Fenichel's Clinical Pediatric Neurology.* 2nd ed. Amsterdam, Netherlands: Elsevier; 2013:359.

CONCLUSIONS

Single-suture craniosynostosis produces consistent head shape abnormalities that should be readily identifiable by the pediatric health care provider. Sagittal synostosis produces an elongated head (scaphocephaly), and metopic synostosis produces a triangular-shaped forehead (sometimes with hypotelorism). Unilateral coronal and lambdoid synostosis as well as occipital DP all produce an asymmetric head shape (plagiocephaly) but are readily differentiated by the shape of the head (parallelogram versus trapezoid or rhombus), the position of the ears (anterior or posterior), and secondary features such as nasal deviation, orbital asymmetry, or bulging of the retromastoid region. Bilateral coronal and lambdoid synostosis produce a short head (brachycephaly) and are differentiated by the presence or absence of associated midface hypoplasia or bilateral retromastoid bulging.

DP and DB are the most common head shape abnormalities encountered by primary care physicians; they are readily identified by conducting a history and clinical examination and do not usually require adjunctive imaging. Early detection and positional changes (with physical therapy for those with torticollis) suffice for most infants; referral at 5 to 6 months of age is considered for helmet therapy for those who have moderate or severe deformities that have not responded to treatment.[87]

Because both single-suture craniosynostosis and DP/DB can usually be diagnosed on clinical examination, routine imaging for the initial evaluation of infant head shape is not recommended to avoid exposing the child to unnecessary radiation. Instead, timely referral of infants with craniosynostosis and those with moderate or severe DP/DB to an experienced craniofacial team (including both a pediatric neurosurgeon and craniofacial surgeon) will allow sufficient time for the team to help the family cope with the diagnosis, obtain any necessary imaging for surgical planning, discuss treatment options, and plan a timely correction.

Anticipatory guidance for parents of children with craniosynostosis should include monitoring for symptoms of elevated ICP or developmental delays, especially for those with multisutural synostosis, and a discussion about the importance of early and timely referral to specialists. Parents of children with DP or DB should be encouraged to initiate positional changes early and, for those with torticollis, should be taught neck stretching exercises and/or referred to a physical therapist. For those with moderate or severe deformities, consider a referral to craniofacial specialists to discuss molding helmets.

KEY POINTS

Children with craniosynostosis most commonly present with stereotypically shaped heads, each associated with particular sutural fusions:

long (scaphocephaly: sagittal);

short (brachycephaly: bicoronal or bilambdoid);

anteriorly pointed (trigonocephaly: metopic); and

asymmetric (plagiocephaly: unilateral coronal or lambdoid).

DP and DB are the most common head shape abnormalities, recognized by their parallelogram-shaped head, lack of retroauricular bulge, and, in 80%, absence of deformation at birth.

Syndromic craniosynostosis most commonly manifests with bicoronal synostosis, midface hypoplasia, and shallow orbits with exorbitism and strabismus.

Surgery is often performed within the first 8 to 10 weeks for sagittal synostosis repairs, endoscopic procedures, and raised ICP. Orbitofrontal advancements for coronal and metopic synostosis are most often performed between 6 and 10 months.

Early referrals to craniofacial teams are encouraged to allow early identification and repair.

LEAD AUTHORS

Mark S. Dias, MD, FAAP, FAANS
Thomas Samson, MD, FAAP
Elias B. Rizk, MD, FAAP, FAANS
Lance S. Governale, MD, FAAP, FAANS
Joan T. Richtsmeier, PhD

SECTION ON NEUROLOGIC SURGERY EXECUTIVE COMMITTEE, 2018–2019

Philip R. Aldana, MD, FAAP, Chairperson
Douglas L. Brockmeyer, MD, FAAP
Andrew H. Jea, MD, FAAP
John Ragheb, MDGregory W. Albert, MD, MPH, FAAP
Sandi K. Lam, MD, MBA, FAAP, FACS
Ann-Christine Duhaime, MD, FAANS

SECTION ON PLASTIC AND RECONSTRUCTIVE SURGERY EXECUTIVE COMMITTEE, 2018–2019

Jennifer Lynn Rhodes, MD, FAAP, FACS, Chairperson
Stephen B. Baker, MD, DDS, FAAP, FACS, Immediate Past Chairperson
Anand R. Kumar, MD, FAAP, FACS
Jugpal Arneja, MD, FAAP
Karl Bruckman, MD, DDS
Lorelei J. Grunwaldt, MD, FAAP, FACS
Timothy W. King, MD, PhD, FAAP, FACS
Arin K. Greene, MD, MMSc, FAAP
John A. Girotto, MD, FAAP, FACS

ABBREVIATIONS

AP: anterior-posterior
BMP: bone morphogenetic factor
CI: cranial index
CT: computed tomography
CVAI: cranial vault asymmetry index
DB: deformational brachycephaly
DP: deformational plagiocephaly
FGFR: fibroblast growth factor receptor
FGR: fibroblast growth factor
ICP: intercranial pressure

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Hall BK. Endoskeleton/exo (dermal) skeleton – mesoderm/neural crest: two pair of problems and a shifting paradigm. *J Appl Ichthyol*. 2014;30(4): 608–615
2. Kawasaki K, Richtsmeier JT. Association of the Chondrocranium and Dermatocranium in Early Skull Development. In: Percival CJ, Richtsmeier JT, eds. *Building Bones: Bone Development and Formation in Anthropology. Cambridge Studies in Biological and Evolutionary Anthropology*. Cambridge, United Kingdom: Cambridge University Press; 2017:52–78
3. Flaherty K, Singh N, Richtsmeier JT. Understanding craniosynostosis as a growth disorder. *Wiley Interdiscip Rev Dev Biol*. 2016;5(4):429–459
4. Nagata M, Nuckolls GH, Wang X, et al. The primary site of the acrocephalic feature in Apert Syndrome is a dwarf cranial base with accelerated chondrocytic differentiation due to aberrant activation of the FGFR2 signaling. *Bone*. 2011;48(4):847–856
5. Abramson DL, Janecka IP, Mulliken JB. Abnormalities of the cranial base in synostotic frontal plagiocephaly. *J Craniofac Surg*. 1996;7(6):426–428
6. Burdi AR, Kusnetz AB, Venes JL, Gebarski SS. The natural history and pathogenesis of the cranial coronal ring articulations: implications in understanding the pathogenesis of the Crouzon craniostenotic defects. *Cleft Palate J*. 1986;23(1):28–39
7. Kawasaki K, Richtsmeier JT. Spatial association of the dermatocranium with the chondrocranium in early skull formation. *Am J Phys Anthropol*. 2014; 153(S58):156
8. McBratney-Owen B, Iseki S, Bamforth SD, Olsen BR, Morriss-Kay GM. Development and tissue origins of the mammalian cranial base. *Dev Biol*. 2008;322(1):121–132
9. Jiang X, Iseki S, Maxson RE, Sucov HM, Morriss-Kay GM. Tissue origins and interactions in the mammalian skull vault. *Dev Biol*. 2002;241(1):106–116
10. Opperman LA. Cranial sutures as intramembranous bone growth sites. *Dev Dyn*. 2000;219(4):472–485
11. Beederman M, Farina EM, Reid RR. Molecular basis of cranial suture biology and disease: osteoblastic and osteoclastic perspectives. *Genes Dis*. 2014;1(1):120–125
12. Da Costa AC, Walters I, Savarirayan R, Anderson VA, Wrennall JA, Meara JG. Intellectual outcomes in children and adolescents with syndromic and nonsyndromic craniosynostosis. *Plast Reconstr Surg*. 2006;118(1): 175–181–183
13. Wilkie AOM, Byren JC, Hurst JA, et al. Prevalence and complications of single-gene and chromosomal disorders in craniosynostosis. *Pediatrics*. 2010; 126(2). Available at: www.pediatrics.org/cgi/content/full/126/2/e391
14. Cunningham ML, Seto ML, Ratisoontorn C, Heike CL, Hing AV. Syndromic craniosynostosis: from history to hydrogen bonds. *Orthod Craniofac Res*. 2007;10(2):67–81
15. Heuzé Y, Holmes G, Peter I, Richtsmeier JT, Jabs EW. Closing the gap: genetic and genomic continuum from syndromic to nonsyndromic craniosynostoses. *Curr Genet Med Rep*. 2014;2(3):135–145
16. Orr-Urtreger A, Bedford MT, Burakova T, et al. Developmental localization of the splicing alternatives of fibroblast growth factor receptor-2 (FGFR2). *Dev Biol*. 1993;158(2):475–486
17. Orr-Urtreger A, Givol D, Yayon A, Yarden Y, Lonai P. Developmental expression of two murine fibroblast growth factor receptors, flg and bek. *Development*. 1991;113(4):1419–1434
18. Rice DPC, Rice R, Thesleff I. Fgfr mRNA isoforms in craniofacial bone development. *Bone*. 2003;33(1):14–27
19. Delezoide AL, Benoist-Lasselin C, Legeai-Mallet L, et al. Spatio-temporal expression of FGFR 1, 2 and 3 genes during human embryo-fetal ossification. *Mech Dev*. 1998;77(1):19–30
20. Bansal R, Lakhina V, Remedios R, Tole S. Expression of FGF receptors 1, 2, 3 in the embryonic and postnatal mouse brain compared with Pdgfralpha, Olig2 and Plp/dm20: implications for oligodendrocyte development. *Dev Neurosci*. 2003;25(2–4):83–95
21. Ornitz DM, Marie PJ. FGF signaling pathways in endochondral and intramembranous bone development and human genetic disease. *Genes Dev*. 2002;16(12):1446–1465
22. Wang Y, Sun M, Uhlhorn VL, et al. Activation of p38 MAPK pathway in the skull abnormalities of Apert syndrome Fgfr2(+P253R) mice. *BMC Dev Biol*. 2010;10:22
23. Wang Y, Xiao R, Yang F, et al. Abnormalities in cartilage and bone development in the Apert syndrome FGFR2(+/S252W) mouse. *Development*. 2005;132(15):3537–3548
24. Wang Y, Zhou X, Oberoi K, et al. p38 Inhibition ameliorates skin and skull abnormalities in *Fgfr2* Beare-Stevenson mice. *J Clin Invest*. 2012;122(6): 2153–2164
25. Chen L, Li D, Li C, Engel A, Deng C-X. A Ser252Trp [corrected] substitution in mouse fibroblast growth factor receptor 2 (Fgfr2) results in craniosynostosis. [published correction appears in *Bone*. 2005;37(6):876]. *Bone*. 2003;33(2):169–178
26. Zhou YX, Xu X, Chen L, Li C, Brodie SG, Deng C-X. A Pro250Arg substitution in mouse Fgfr1 causes increased expression of Cbfa1 and premature fusion of calvarial sutures. *Hum Mol Genet*. 2000;9(13):2001–2008
27. Yin L, Du X, Li C, et al. A Pro253Arg mutation in fibroblast growth factor receptor 2 (Fgfr2) causes skeleton malformation mimicking human Apert syndrome by affecting both chondrogenesis and osteogenesis. *Bone*. 2008;42(4):631–643
28. Eswarakumar VP, Horowitz MC, Locklin R, Morriss-Kay GM, Lonai P. A gain-of-function mutation of Fgfr2c demonstrates the roles of this receptor variant in osteogenesis. *Proc Natl Acad Sci U S A*. 2004;101(34):12555–12560
29. Mai S, Wei K, Flenniken A, et al. The missense mutation W290R in Fgfr2 causes developmental defects from aberrant IIIb and IIIc signaling. *Dev Dyn*. 2010;239(6):1888–1900
30. Twigg SRF, Healy C, Babbs C, et al. Skeletal analysis of the Fgfr3(P244R) mouse, a genetic model for the Muenke

craniosynostosis syndrome. *Dev Dyn*. 2009;238(2):331–342

31. Holmes G, O'Rourke C, Motch Perrine SM, et al. Midface and upper airway dysgenesis in FGFR2-related craniosynostosis involves multiple tissue-specific and cell cycle effects. *Development*. 2018;145(19):dev166488
32. Ting M-C, Wu NL, Roybal PG, et al. EphA4 as an effector of Twist1 in the guidance of osteogenic precursor cells during calvarial bone growth and in craniosynostosis. *Development*. 2009; 136(5):855–864
33. Rice DP, Aberg T, Chan Y, et al. Integration of FGF and TWIST in calvarial bone and suture development. *Development*. 2000;127(9):1845–1855
34. Merrill AE, Bochukova EG, Brugger SM, et al. Cell mixing at a neural crest-mesoderm boundary and deficient ephrin-Eph signaling in the pathogenesis of craniosynostosis. *Hum Mol Genet*. 2006;15(8):1319–1328
35. Tischfield MA, Robson CD, Gilette NM, et al. Cerebral vein malformations result from loss of Twist1 expression and BMP signaling from skull progenitor cells and dura. *Dev Cell*. 2017;42(5):445.e5-461.e5
36. Holmes G. The role of vertebrate models in understanding craniosynostosis. *Childs Nerv Syst*. 2012;28(9):1471–1481
37. Martínez-Abadías N, Motch SM, Pankratz TL, et al. Tissue-specific responses to aberrant FGF signaling in complex head phenotypes. *Dev Dyn*. 2013;242(1):80–94
38. Starr JR, Collett BR, Gaither R, et al. Multicenter study of neurodevelopment in 3-year-old children with and without single-suture craniosynostosis. *Arch Pediatr Adolesc Med*. 2012;166(6): 536–542
39. Knight SJ, Anderson VA, Spencer-Smith MM, Da Costa AC. Neurodevelopmental outcomes in infants and children with single-suture craniosynostosis: a systematic review. *Dev Neuropsychol*. 2014;39(3):159–186
40. Renier D. Intracranial Pressure in Craniosynostosis: Pre- and Postoperative Recordings. Correlation with Function Results. In: Persing JA, Edgerton MT, Jane JA, eds. *Scientific Foundations and Surgical Treatment of Craniosynostosis*. Baltimore, MD: Williams & Wilkins; 1989:263–274
41. Gault DT, Renier D, Marchac D, Jones BM. Intracranial pressure and intracranial volume in children with craniosynostosis. *Plast Reconstr Surg*. 1992;90(3):377–381
42. Renier D, Sainte-Rose C, Marchac D, Hirsch JF. Intracranial pressure in craniostenosis. *J Neurosurg*. 1982; 57(3):370–377
43. Blount JP, Louis RG Jr., Tubbs RS, Grant JH. Pansynostosis: a review. *Childs Nerv Syst*. 2007;23(10):1103–1109
44. Judy BF, Swanson JW, Yang W, et al. Intraoperative intracranial pressure monitoring in the pediatric craniosynostosis population. *J Neurosurg Pediatr*. 2018;22(5): 475–480
45. Arnaud E, Renier D, Marchac D. Prognosis for mental function in scaphocephaly. *J Neurosurg*. 1995; 83(3):476–479
46. Gewalli F, da Silva Guimarães-Ferreira JP, Sahlin P, et al. Mental development after modified π procedure: dynamic cranioplasty for sagittal synostosis. *Ann Plast Surg*. 2001;46(4):415–420
47. Patel A, Yang JF, Hashim PW, et al. The impact of age at surgery on long-term neuropsychological outcomes in sagittal craniosynostosis. *Plast Reconstr Surg*. 2014;134(4):608e–617e
48. Toth K, Collett B, Kapp-Simon KA, et al. Memory and response inhibition in young children with single-suture craniosynostosis. *Child Neuropsychol*. 2008;14(4):339–352
49. Starr JR, Kapp-Simon KA, Cloonan YK, et al. Presurgical and postsurgical assessment of the neurodevelopment of infants with single-suture craniosynostosis: comparison with controls. *J Neurosurg*. 2007;107(2 Suppl):103–110
50. Mathijssen I, Arnaud E, Lajeunie E, Marchac D, Renier D. Postoperative cognitive outcome for synostotic frontal plagiocephaly. *J Neurosurg*. 2006;105(1 Suppl):16–20
51. Melville H, Wang Y, Taub PJ, Jabs EW. Genetic basis of potential therapeutic strategies for craniosynostosis. *Am J Med Genet A*. 2010;152A(12): 3007–3015
52. Persing J, Jane JA, Edgerton MT. Surgical Treatment of Craniosynostosis. In: Persing J, Edgerton MT, Jane JA, eds. *Scientific Foundations and Surgical Treatment of Craniosynostosis*. Baltimore, MD: Williams & Wilkins; 1989: 117–238
53. Boulet SL, Rasmussen SA, Honein MA. A population-based study of craniosynostosis in metropolitan Atlanta, 1989-2003. *Am J Med Genet A*. 2008;146A(8):984–991
54. van der Meulen J, van der Hulst R, van Adrichem L, et al. The increase of metopic synostosis: a pan-European observation. *J Craniofac Surg*. 2009; 20(2):283–286
55. Kolar JC. An epidemiological study of nonsyndromal craniosynostoses. *J Craniofac Surg*. 2011;22(1):47–49
56. Lajeunie E, Le Merrer M, Bonaïti-Pellie C, Marchac D, Renier D. Genetic study of scaphocephaly. *Am J Med Genet*. 1996; 62(3):282–285
57. Cornelissen M, Ottelander B, Rizopoulos D, et al. Increase of prevalence of craniosynostosis. *J Craniomaxillofac Surg*. 2016;44(9):1273–1279
58. Gallagher ER, Evans KN, Hing AV, Cunningham ML. Bathrocephaly: a head shape associated with a persistent mendosal suture. *Cleft Palate Craniofac J*. 2013;50(1):104–108
59. Shah MN, Kane AA, Petersen JD, Woo AS, Naidoo SD, Smyth MD. Endoscopically assisted versus open repair of sagittal craniosynostosis: the St. Louis Children's Hospital experience. *J Neurosurg Pediatr*. 2011;8(2):165–170
60. Jimenez DF, Barone CM. Endoscopic technique for sagittal synostosis. *Childs Nerv Syst*. 2012;28(9):1333–1339
61. Vu HL, Panchal J, Parker EE, Levine NS, Francel P. The timing of physiologic closure of the metopic suture: a review of 159 patients using reconstructed 3D CT scans of the craniofacial region. *J Craniofac Surg*. 2001;12(6):527–532
62. Sauerhammer TM, Oh AK, Boyajian M, et al. Isolated frontosphenoidal synostosis: a rare cause of synostotic frontal plagiocephaly. *J Neurosurg Pediatr*. 2014;13(5):553–558

63. Plooij JM, Verhamme Y, Bergé SJ, van Lindert EJ, Borstlap-Engels VMF, Borstlap WA. Unilateral craniosynostosis of the frontosphenoidal suture: a case report and a review of literature. *J Craniomaxillofac Surg*. 2009;37(3): 162–166

64. Tay T, Martin F, Rowe N, et al. Prevalence and causes of visual impairment in craniosynostotic syndromes. *Clin Exp Ophthalmol*. 2006;34(5):434–440

65. Khan SH, Nischal KK, Dean F, Hayward RD, Walker J. Visual outcomes and amblyogenic risk factors in craniosynostotic syndromes: a review of 141 cases. *Br J Ophthalmol*. 2003; 87(8):999–1003

66. Wilkie AOM, Johnson D, Wall SA. Clinical genetics of craniosynostosis. *Curr Opin Pediatr*. 2017;29(6):622–628

67. Wang JC, Nagy L, Demke JC. Syndromic craniosynostosis. *Facial Plast Surg Clin North Am*. 2016;24(4):531–543

68. Reddy K, Hoffman H, Armstrong D. Delayed and progressive multiple suture craniosynostosis. *Neurosurgery*. 1990;26(3):442–448

69. Kreiborg S, Cohen MM Jr.. The oral manifestations of Apert syndrome. *J Craniofac Genet Dev Biol*. 1992;12(1): 41–48

70. Thompson DN, Slaney SF, Hall CM, Shaw D, Jones BM, Hayward RD. Congenital cervical spinal fusion: a study in Apert syndrome. *Pediatr Neurosurg*. 1996; 25(1):20–27

71. Cohen MM Jr.. Pfeiffer syndrome update, clinical subtypes, and guidelines for differential diagnosis. *Am J Med Genet*. 1993;45(3):300–307

72. National Center for Advancing Translational Sciences. Muenke syndrome. Available at: https://rarediseases.info.nih.gov/diseases/7097/muenke-syndrome. Accessed September 15, 2018

73. Rozovsky K, Udjus K, Wilson N, Barrowman NJ, Simanovsky N, Miller E. Cranial ultrasound as a first-line imaging examination for craniosynostosis. *Pediatrics*. 2016; 137(2):e20152230

74. Roby BB, Finkelstein M, Tibesar RJ, Sidman JD. Prevalence of positional plagiocephaly in teens born after the "Back to Sleep" campaign. *Otolaryngol Head Neck Surg*. 2012;146(5):823–828

75. Robinson S, Proctor M. Diagnosis and management of deformational plagiocephaly. *J Neurosurg Pediatr*. 2009;3(4):284–295

76. Volpe JJ. *Neurology of the Newborn*. Philadelphia, PA: W.B. Saunders Company; 1995

77. Dvoracek LA, Skolnick GB, Nguyen DC, et al. Comparison of traditional versus normative cephalic index in patients with sagittal synostosis: measure of scaphocephaly and post-operative outcome. *Plast Reconstr Surg*. 2015; 136(3):541–548

78. Collett BR, Wallace ER, Kartin D, Cunningham ML, Speltz ML. Cognitive outcomes and positional plagiocephaly. *Pediatrics*. 2019;143(2):e20182373

79. Baird LC, Klimo P Jr., Flannery AM, et al. Congress of Neurological Surgeons systematic review and evidence-based guideline for the management of patients with positional plagiocephaly: the role of physical therapy. *Neurosurgery*. 2016;79(5):E630–E631

80. Flannery AM, Tamber MS, Mazzola C, et al. Congress of Neurological Surgeons systematic review and evidence-based guidelines for the management of patients with positional plagiocephaly: executive summary. *Neurosurgery*. 2016;79(5):623–624

81. Klimo P Jr., Lingo PR, Baird LC, et al. Congress of Neurological Surgeons systematic review and evidence-based guideline on the management of patients with positional plagiocephaly: the role of repositioning. *Neurosurgery*. 2016;79(5):E627–E629

82. Mazzola C, Baird LC, Bauer DF, et al. Congress of Neurological Surgeons systematic review and evidence-based guideline for the diagnosis of patients with positional plagiocephaly: the role of imaging. *Neurosurgery*. 2016;79(5): E625–E626

83. Tamber MS, Nikas D, Beier A, et al. Congress of Neurological Surgeons systematic review and evidence-based guideline on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly. *Neurosurgery*. 2016;79(5):E632–E633

84. Tamber MS, Nikas D, Beier A, et al. Congress of Neurological Surgeons systematic review and evidence-based guideline on the role of cranial molding orthosis (helmet) therapy for patients with positional plagiocephaly. *Neurosurgery*. 2016;79(5):E632–E633

85. Aisenson MR. Closing of the anterior fontanelle. *Pediatrics*. 1950;6(2): 223–226

86. Hoffman HJ, Reddy KV. Progressive cranial suture stenosis in craniosynostosis. *Neurosurg Clin N Am*. 1991;2(3):555–564

87. Flannery AM, Tamber MS, Mazzola C, et al Summary: evidence based guidelines for the treatment of pediatric positional plagiocephaly. Available at: https://www.cns.org/Assets/2a42b91b-2146-464e-9b5c-c6a7c01202e2/636985419035000000/summary-with-recommendations-final-12-1-16-pdf Accessed September 15, 2018

Long-Acting Reversible Contraception: Specific Issues for Adolescents

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Long-Acting Reversible Contraception: Specific Issues for Adolescents

Seema Menon, MD, COMMITTEE ON ADOLESCENCE

Long-acting reversible contraceptives are the most effective methods to prevent pregnancy and also offer noncontraceptive benefits such as reducing menstrual blood flow and dysmenorrhea. The safety and efficacy of long-acting reversible contraception are well established for adolescents, but the rate of use remains low for this population. The pediatrician can play a key role in increasing access to long-acting reversible contraception for adolescents by providing accurate patient-centered contraception counseling and by understanding and addressing the barriers to use.

INTRODUCTION

The safety, efficacy, and long-term cost-benefit factors of long-acting reversible contraception (LARC) use in the adolescent population have been well established.[1–4] The noncontraceptive benefits, especially treatment of heavy uterine bleeding and dysmenorrhea, are also well accepted.[5–7] Available LARC methods include 1 progestin subdermal implant and 5 intrauterine devices (IUDs) and are all appropriate for use in the adolescent population.[4] The progestin subdermal implant works by suppressing ovulation, whereas the copper intrauterine device (Cu-IUD) and the progestin-releasing levonorgestrel intrauterine devices (LNG-IUDs) prevent fertilization.[2] LARC methods are the most effective forms of contraception, with less than 1% of users becoming pregnant during the first year of use.[3] The availability of effective contraception has been associated with declines in unplanned pregnancy, yet rates of LARC use among sexually active adolescents remain low at 2% to 3%.[8–10] Limitations in patient knowledge, availability of trained providers, and concerns over cost and confidentiality have been recognized as barriers contributing to the relatively low rate of use.[11–18] The American Academy of Pediatrics (AAP) previously published a policy statement and technical report on contraception for adolescents summarizing the full range of available methods.[1] This clinical report serves to improve the pediatrician's comfort level when providing LARC services and highlights specific adolescent populations that may especially benefit from the

abstract

Department of Obstetrics and Gynecology, Medical College of Wisconsin, Milwaukee, Wisconsin

Clinical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, clinical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Dr Menon was responsible for writing the draft and revising it on the basis of the input of reviewers and the Board of Directors and approved the final manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-007252

Address correspondence to Seema Menon, MD. E-mail: smenon@mcw.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The author has indicated she has no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The author has indicated she has no potential conflicts of interest to disclose.

To cite: Menon S, AAP COMMITTEE ON ADOLESCENCE. Long-Acting Reversible Contraception: Specific Issues for Adolescents. *Pediatrics*. 2020;146(2):e2020007252

noncontraceptive medical therapy provided by LARC methods.

LARC AWARENESS AND ACCEPTABILITY

A wealth of easily accessible online resources including evidence-based guidelines from the Centers for Disease Control and Prevention (CDC), US Medical Eligibility Criteria for Contraceptive Use (US MEC), and statements from the AAP, American College of Obstetricians and Gynecologists (ACOG), and Society for Adolescent Health and Medicine, all endorse the safety of LARC methods in the adolescent population.[1,3,4,19] This information has not effectively reached the adolescent population, with only 20% to 50% of this age group able to recognize LARCs as birth control methods.[12–15] Among adolescents aware of LARC methods, unsubstantiated safety concerns related to permanent loss of fertility, misconceptions about the insertion process, and general fears of pain and of having a foreign object in the body contribute heavily to the low use of these methods.[11,12,14,15] Counseling from a health care provider has been found to effectively improve knowledge in the adolescent population and can significantly impact LARC use.[13,15,17] Many pediatricians working with adolescents approach contraceptive counseling with the predetermination that this population is neither interested in LARC nor will they tolerate the irregular bleeding pattern that can be associated with these methods.[13,18] Data have suggested otherwise, as results from the 2011 Contraceptive CHOICE Project reported that 70% of the adolescents surveyed chose LARC when cost was removed as a barrier and accurate counseling was provided.[20] In this study, the authors also found continuation rates of LARC to be higher than those of other contraceptive methods at 12 and 24 months of use among adolescents and young adults, suggesting relatively high acceptability.[20–22]

LARC SAFETY

The US MEC provides an evidence-based summary assigning a level of safety to each contraceptive method when used in women with various medical conditions (Table 1). The CDC classifies the contraceptive subdermal implant as category 1 regardless of age group or parity status.[4] Although safe, IUD use in younger and nulliparous women still requires more caution (category 2) than does use in their adult counterparts (category 1) because of concerns related to higher expulsion risk and sexually transmitted infection (STI) rates.[4] Newer, well-conducted studies have refuted previous concerns associating IUD use and infertility.[4] A few absolute contraindications to LARC use have been defined but are uncommonly encountered in the adolescent population (Table 2). All LARC methods may be safely used at any point in the postpartum period, although IUD expulsion rates vary depending on the timing of placement relative to delivery.[2,4,23] Observational studies suggest that LARC does not interfere with lactation, although long-term data used to evaluate the effects on lactation are limited.[2,23] Given the dearth of evidence, ACOG recommends patients be counseled that hormonal LARC products may theoretically affect breastfeeding, acknowledging there is a lack of supporting data.[2] The Cu-IUD, LNG-IUD, and subdermal implant are all safe for immediate placement in a woman who is breastfeeding, with the Cu-IUD classified as a US MEC category 1 and the latter 2 classified as US MEC category 2.[4,23] There are free resources and tools available online from the CDC and other professional societies to assist in counseling adolescents on the safety of LARC use (Table 3).[24]

Adolescents with chronic medical conditions have a particular need for in-depth contraception counseling. The importance of providing safe and effective contraception to those with medical comorbidities associated with higher morbidity and mortality rates during pregnancy cannot be overstated. In a 2010 survey of 536 women with congenital heart disease, researchers found that 20% of participants were using a contraindicated contraceptive method and 28% of participants were not using any form of contraception despite stating pregnancy was not desired.[25] Although data used to guide contraceptive options are limited for adolescents with significant congenital heart defects, the safety of LARC use has been established in those with cardiomyopathy as well as for those at increased risk for a venous thromboembolic event (either from a known thrombophilia or underlying medical condition).[4] In a study of 30 adolescents with significant cardiovascular dysfunction, the authors found no complications related to LARC use.[26] Drug interactions are also an important

TABLE 1 Medical Eligibility Criteria

Category	Description
1	A condition for which there is no restriction for the use of the contraceptive method
2	A condition for which the advantages of using the method generally outweigh the theoretical or proven risks
3	A condition for which the theoretical or proven risk usually outweighs the advantages of using the method
4	A condition that represents an unacceptable health risk if the contraceptive method is used

Adapted from Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. medical eligibility criteria for contraceptive use, 2016. *MMWR Recomm Rep.* 2016;65(3):3.

TABLE 2 Conditions Presenting an Absolute Contraindication to LARC Use

	LNG-IUD	Cu-IUD	Subdermal Implant
Distorted uterine cavity	Placement and continuation contraindicated	Placement and continuation contraindicated	Not contraindicated
Current breast cancer	Placement and continuation contraindicated	Not contraindicated	Placement and continuation contraindicated
Untreated cervix cancer	Placement only contraindicated	Placement only contraindicated	Not contraindicated
Endometrial cancer	Placement only contraindicated	Placement only contraindicated	Not contraindicated
Malignant gestational trophoblastic neoplasia with intrauterine disease	Placement only contraindicated	Placement only contraindicated	Not contraindicated
Unexplained vaginal bleeding before evaluation	Placement only contraindicated	Placement only contraindicated	Not contraindicated
Active pelvic infection (pelvic inflammatory disease, current purulent cervicitis, pelvic tuberculosis, or active gonorrhea and/or *Chlamydia* infection)	Placement only contraindicated	Placement only contraindicated	Not contraindicated
Immediate postseptic abortion, puerperal sepsis	Placement and continuation contraindicated	Placement and continuation contraindicated	Not contraindicated

Adapted from Curtis KM, Tepper NK, Jatlaoui TC, et al. U.S. medical eligibility criteria for contraceptive use, 2016. *MMWR Recomm Rep.* 2016;65(3):5

consideration when providing contraception counseling to adolescents with complex medical conditions. Again, the US MEC provides guidance with virtually no significant drug interaction concerns associated with IUD use.[4]

Safety concerns related to the relationship between the relatively high prevalence of STIs, IUD use, and upper genital tract infection (pelvic inflammatory disease) have historically limited use of this method in adolescents. With new data reflected in the CDC recommendations, researchers have found that the IUD is not significantly associated with upper genital tract infection.[4] Therefore, screening tests for STIs are not required before placement of an IUD in a woman without risk factors.[4,27] Testing for STIs can be performed at the time of placement for adolescents requiring screening.[4] Delaying IUD placement is only recommended if purulent cervicitis is noted on examination or if a known gonorrhea or *Chlamydia* infection has not been treated (US MEC category 4).[4] If an STI is diagnosed after placement, the IUD may be left in place while initiating antibiotic treatment.[4]

The relationship between LARC and condom use has also generated interest. Using data from the Youth Risk Behavior Surveillance System, researchers found that condom use was significantly lower in adolescents using a LARC method (16.4%) compared with those using combination oral contraceptive pills (37.3%).[28] Theories as to why condom use may differ when using LARC include adolescents feeling more secure about the efficacy of these methods and pediatricians not routinely recommending condom use to adolescents using LARC.[28] Condom use is a complex behavior that changes over time in a relationship. The use of a particular contraceptive method is only one factor that may influence current condom use. Regardless of the reason, it is important to note the trend of reduced condom use among LARC users when providing contraception counseling to adolescents.

TABLE 3 Resources for Determining LARC Safety

http://www.acog.org/About-ACOG/ACOG-Departments/Long-Acting-Reversible-Contraception
http://fpntc.org
www.astho.org
http://larcprogram.ucsf.edu
https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html
https://guttmacher.org/united-states/contraception

TIMING OF LARC PLACEMENT

Offering same-day LARC placement to adolescents has been shown to increase the use of these contraceptives.[2,29] Despite this benefit, it is common practice to have multiple unnecessary visits for counseling and testing before LARC placement.[29–31] The 2 major considerations determining if LARC placement can be performed safely are pregnancy and infection. As mentioned previously, delaying IUD placement is recommended if there is an active, untreated infection.[4] It is also recommended that LARC placement be delayed if pregnancy cannot be excluded with reasonable certainty (Table 4).[4] Urine pregnancy tests have been shown to detect

TABLE 4 How To Be Reasonably Certain That a Woman Is Not Pregnant

A Health Care Provider Can Be Reasonably Certain That a Woman Is Not Pregnant If She Has No Symptoms or Signs of Pregnancy and Meets Any 1 of the Following Criteria
Is ≤7 d after the start of normal menses
Has not had sexual intercourse since the start of the last normal menses
Has been correctly and consistently using a reliable method of contraception
Is ≤7 d after spontaneous or induced abortion
Is within 4 wk postpartum
Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 mo postpartum

Centers for Disease Control and Prevention. How to be reasonably certain that a woman is not pregnant. When to start using specific contraceptive methods. Available at: https://www.cdc.gov/reproductivehealth/contraception/pdf/When-To-Start_508Tagged.pdf. Accessed September 24, 2019.

100% of pregnancies when performed 11 days after expected menses.[24] Determining the date of the last menstrual period is important for pregnancy evaluation and to guide whether back-up contraception is needed after LARC placement (Table 5). A short-term contraception method can also be used before LARC placement if pregnancy cannot be reliably ruled out. This is particularly important when an adolescent selects an IUD. In the case of the subdermal implant, same-day placement is possible even when pregnancy cannot be excluded because the benefits of starting the subdermal implant likely exceed any risk. In this case, the chance of pregnancy and need for pregnancy testing in the next few weeks are important points to discuss.[32] Regardless of the timing of LARC placement, review of the patient's medical history is fundamental to selecting the appropriate and safe contraception method. Similarly, providing expedited LARC services does not preclude the importance of discussing healthy relationships, providing education and screening for intimate partner violence, and facilitating use of resources if a coercive sexual relationship or sex trafficking activity is suspected.

NONCONTRACEPTIVE USES OF LARC

Using contraception to treat menstrual cycle concerns is well established in clinical practice. An estimated 82% of adolescents use the combination oral contraceptive pill for noncontraceptive reasons.[5] The LNG-IUD is particularly important in the treatment of heavy menstrual bleeding.[5,7] Studies involving adolescents have revealed promising results but are limited by small size.[5,33] In studies that are focused on adult women, researchers have found a reduction in menstrual blood loss of up to 80% using the LNG-IUD.[5,33]

Adolescents with physical and/or cognitive disabilities and their primary caregivers often seek options to reduce menstrual blood flow.[34] Policies surrounding consent and confidentiality often require review when working with this population of adolescents. Although confidential contraception counseling is often not feasible in this special population, including the adolescent in the discussion when possible is important. Medical therapy has greatly replaced surgical options to treat menstrual concerns in this population because of ethical questions related to consent as well as significantly higher morbidity and mortality risks compared to those of the general populaiton.[34,35] Depot medroxyprogesterone acetate is a commonly used therapy for menstrual suppression in adolescents with physical and/or cognitive disabilities. However, concerns surrounding weight gain and bone mineral density loss have likely contributed to the increased use of the LNG-IUD in this population.[6,36,37] Data regarding LNG-IUD use among young women with physical and/or cognitive disabilities are growing and are overall positive. Authors of a 2013 cohort study reported that 26 adolescents with disabilities (95% with cognitive impairment and 5% with physical impairment) undergoing LNG-IUD placement had an amenorrhea rate of 100% after 1 year of use.[38] The acceptability of LNG-IUD use in this population is also supported by limited data as authors of another study involving 56 adolescents with developmental disability reported a premature IUD removal rate of 7.4% secondary to pain and irregular bleeding comparable to adults.[37]

Adolescents with severe anemia attributable to heavy menstrual bleeding often require hormone therapy to limit menstrual blood loss. Although options have been traditionally focused on combination oral contraceptives and depot medroxyprogesterone acetate, the

TABLE 5 Back-up Contraception After LARC Placement

Type of LARC and Timing of Placement	Need for Contraception Backup for 7 d After LARC Placement
LNG-IUD inserted after 7 d of the start of menses	Yes
LNG-IUD inserted within 7 d of the start of menses	No
Subdermal implant inserted after 5 d of the start of menses	Yes
Subdermal implant inserted within 5 d of the start of menses	No
Cu-IUD insertion (anytime)	No

Adapted from Centers for Disease Control and Prevention. Appendix B: When to Start Using Specific Contraceptive Methods. Available at: https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/appendixb.html. Accessed September 24, 2019.

efficacy of using the LNG-IUD to treat heavy menstrual bleeding has been recognized.[3] Acceptance of this method is growing, with the National Hemophilia Foundation now recognizing this as a treatment option.[39] In a small study of adolescent girls with known bleeding disorders, the authors found that 100% experienced an improvement in heavy menstrual bleeding and 60% experienced amenorrhea after LNG-IUD placement.[33] These findings are consistent with studies conducted in the adult population with reported LNG-IUD associated bleeding pattern satisfaction rates ranging from of 68% to 100%.[40–43] The role of the subdermal implant as a treatment option for adolescents with bleeding disorders is unclear given the higher rate of prolonged irregular bleeding and lower rate of amenorrhea as compared to the LNG-IUD. No studies investigating the efficacy of using the subdermal implant in this population have been reported.

Dysmenorrhea is the most common gynecologic complaint during adolescence and is associated with a relatively high rate (12%) of monthly school absenteeism.[44] Dysmenorrhea is classified as primary or secondary; the latter is associated with a wide range of anatomic abnormalities. Treatment of dysmenorrhea in the adolescent population is primarily medical, with either nonsteroidal antiinflammatory drugs (NSAIDs) or hormonal contraceptive methods as initial agents.[44,45] The LNG-IUD and the subdermal implant have been shown to provide effective treatment.[44,45] Evaluation for causes requiring surgical treatment such as obstructive Müllerian anomalies or ovarian cysts is warranted if medical management is suboptimal, risk factors for congenital anomalies are present, or pain is acyclic.[44] Even in cases of secondary dysmenorrhea attributable to endometriosis, fibroids, or adenomyosis, the LNG-IUD and subdermal implant have been found to be effective treatment options.[44–46]

UNDERSTANDING LARC SIDE EFFECTS

Regardless of the reason for use, pediatricians report discomfort counseling adolescents on expected side effects and answering the multitude of questions surrounding LARC.[19] This discomfort improves after attending formal LARC training sessions.[18] Reviews of US Food and Drug Administration package insert information for the LNG-IUDs reveal that the absolute risk for an adverse event is low: ectopic pregnancy (1 in 1000), upper genital tract infection (0.5%–0.6%), uterine perforation (up to 0.1%), expulsion (3.5%–4.5%), and symptomatic ovarian cysts (3.5%). A large study including 4592 adolescents between 15 and 19 years of age found irregular bleeding to be the only significant side effect of LARC use.[47] Of note, there was no association with weight gain or mood changes.[47] Counseling about potential changes in bleeding patterns has been associated with higher LARC continuation when done prior to insertion.[48] Unscheduled spotting or light bleeding is expected during the first 3 to 6 months of LNG-IUD use and is common with subdermal implant use; this bleeding is not harmful and decreases over time.[49] Review of LARC package information provides detailed information related to expected bleeding patterns. A total of 35% of LNG-IUD (Mirena) users report 4 or more bleeding episodes or 1 episode lasting more than 10 days within the first 3 months of use. These patterns persist in only 4% of users after 1 year of use. Approximately 50% of women using the Mirena IUD report amenorrhea after 2 years of use. Amenorrhea rates after 2 years of Liletta use, another LNG-IUD with similar dosing as Mirena, is reported to be 26%. Review of packaging information for the lower-dose LNG-IUDs (Kyleena and Skyla) report prolonged or irregular bleeding patterns in 14% to 20% of users at the 90-day mark; this pattern persists in 6% to 18% of users by 1 year of use. Early discontinuation rates for unacceptable bleeding associated with the LNG-IUDs ranges from approximately 1.5% to 5%. Unlike the LNG-IUDs, heavier bleeding may persist after Cu-IUD placement. A discontinuation rate of approximately 12% is reported to be attributable to bleeding or pain concerns. Among subdermal implant users, 17.7% report prolonged bleeding and 6.7% report frequent bleeding, but 75% of women using the implant report fewer days of bleeding and spotting compared to their bleeding pattern before placement.

Bothersome irregular bleeding associated with LARC can be effectively treated with a short course of NSAIDs or oral hormonal therapy.[24,49,50] Smaller studies suggest that tranexamic acid is associated with reduced blood loss after placement of either the Cu-IUDs or LNG-IUDs.[50] Because of its ability to suppress metalloprotease activity, doxycycline may also be an effective option for irregular bleeding treatment.[50] Using this method to treat unscheduled bleeding has been associated with lower LARC discontinuation rates.[50] The CDC Selective Practice Recommendations for Contraceptive Use provides guidance to providers managing irregular bleeding associated with LARC (Fig 1).[3] It is important to consider that persistent bleeding may be attributable to pregnancy, infection, IUD displacement, or new pelvic organ pathology in LARC users.

INCREASING THE NUMBER OF TRAINED PROVIDERS

Although LARC placement is increasing in pediatric primary care clinics, adolescent medicine clinics, and school-based clinics, the lack of trained pediatricians is still a major

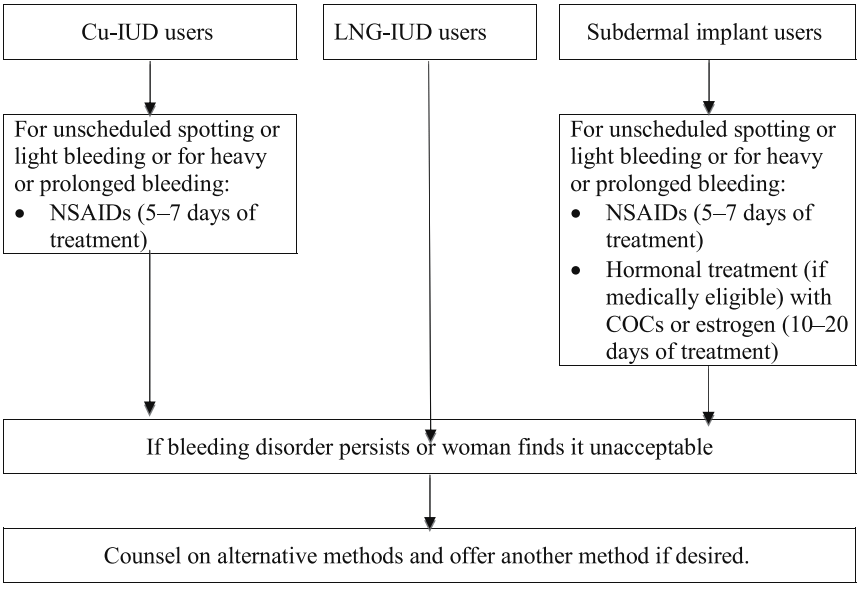


FIGURE 1
Management of women with bleeding irregularities while using LARC. COC, combined oral contraceptive. Adapted from Centers for Disease Control and Prevention. CDC contraceptive guidance for health care providers. US selected practice recommendations for contraceptive use, 2016: implants. Available at: https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/implants.html. Accessed September 24, 2019.

barrier to LARC availability within the adolescent population.[17,18,51] Physicians not trained in LARC placement have concerns that IUD placement may cause emotional or physical trauma to the adolescent.[18,52] These concerns significantly wane after training and successful placement of these devices.[18] The first attempt of IUD placement in nulliparous adolescents reveals success rates (96%) similar to their parous counterparts.[53] Similarly, the duration of the IUD placement procedure does not vary between adolescents and adults.[54] Methods used to improve pain and ease of insertion have been investigated and include preprocedure administration of misoprostol, NSAIDs, paracervical block by using lidocaine, and anxiolytic medication including nitrous oxide.[55–57] Although a few studies have found some benefit in pain reduction associated with paracervical block with lidocaine use, general review of current data do not support the routine use of these strategies during IUD placement.[24,55,57,58] In special circumstances, IUD placement under sedation is appropriate, most commonly in adolescents with physical limitations or cognitive challenges, and can be combined with other procedures requiring sedation, such as dental care.

Placement and removal of the subdermal implant requires a free in-person training session sponsored by the manufacturer of the product.[59] Frequency of these training sessions varies geographically, and for some clinicians, training can be difficult to access. To improve access, training sessions are often incorporated into clinical meetings held by professional societies that are focused on adolescent and reproductive health. The contraceptive subdermal implant may only be ordered by a licensed physician after completion of the manufacturer-sponsored training.[59]

IUD training is less formalized than that for the subdermal implant. Unlike the subdermal implant, insertion and removal of IUDs does not require the completion of a specific training program. Although this skill has historically fallen under the domain of the gynecologist or family physician, increased acceptance by both individual pediatricians and professional societies has led to more training opportunities ranging from training sessions at annual clinical meetings to on-site support from pharmaceutical representatives. Access to LARC training for a pediatrician remains a challenge despite the increase in opportunities. Both the ACOG-initiated LARC program (https://www.acog.org/programs/long-acting-reversible-contraception-larc/activities-initiatives) and the National Clinical Training Center for Family Planning (http://www.ctcfp.org/larc/) provide a list of training opportunities open to all physicians regardless of specialty and professional society affiliation.

COST, CONSENT, AND CONFIDENTIALITY CONCERNS

Adolescents and pediatricians express concerns over cost and confidentiality related to LARC. Adolescents also report uncertainty about how to obtain LARC services.[13,16] Specific concerns from pediatricians over accurate billing and in-office stocking of LARC and the supplies required for both insertion and removal have had a negative impact on LARC availability.[13,17,18] Billing for LARC services is complex and multilayered, requiring a *Current Procedural Terminology* code for the placement or removal procedure charge, a Healthcare Common Procedure Coding System code for the actual LARC device charge, and an *International Classification of Diseases, 10th Revision* code for the diagnosis (Table 6). Importantly, there are codes for failed placement that can help with device replacement from pharmaceutical companies if malfunction occurs. Resources to guide LARC billing practices have been compiled by

TABLE 6 Common Billing Codes for LARC Services

Procedure Code (CPT)	Medication Code (HCPCS)	Diagnosis Code (ICD-10)
11981 insertion of implant	J7307 etonogestrel implant	Z30.018 encounter for other contraception (implant insertion)
11982 removal of implant	J7298 LNG-IUD (Mirena)	Z30.49 check, reinsert, or removal of implant
5300 IUD insertion	J7297 LNG-IUD (Liletta)	Z30.430 IUD insertion
53801 IUD removal	J7301 LNG-IUD (Skyla)	Z30.432 IUD removal
	J7296 LNG-IUD (Kyleena)	Z30.433 IUD removal and reinsertion
	J7300 Cu-IUD (Paragard)	Z30.431 IUD routine check

CPT, *Current Procedural Terminology*; HCPCS, Healthcare Common Procedure Coding System; ICD-10, *International Classification of Diseases, 10th Revision.*

multiple agencies and are widely available (Table 7).

Although the Patient Protection and Affordable Care Act contains provisions designed to expand coverage of LARC and other contraceptives, gaps in access still exist. The Title X Family Planning Program is important and may help fill these gaps. This program, established in the 1970s, provides family planning for anyone desiring services, with priority given to individuals from low-income families. State government public health programs (eg, the New York State Family Planning Benefit Program and the California Department of Health Care Services Family Planning, Access, Care, and Treatment [PACT] program) and cost-assistance programs administered by pharmaceutical companies may also help cover costs.[60] Potential cuts to the Title X Family Planning Program and the uncertainty of the Patient Protection and Affordable Care Act make it difficult to forecast future coverage of LARC.

An adolescent's ability to provide consent for LARC services is dependent on state law. A minimum age of consent for reproductive health services, which includes LARC placement and removal, is explicitly defined by some states. Other states follow the mature minor principle, by which an adolescent under the age of majority and still dependent on parents or guardians can independently consent to reproductive health care services if cognitive maturity is demonstrated.[61] The Guttmacher Institute provides a helpful online resource for issues of consent.[62]

The right to consent does not guarantee confidentiality. The goal upheld by various professional societies such as the AAP, Society for Adolescent Health and Medicine, and ACOG is to consider the medical record as confidential when caring for minors able to consent for reproductive health care services, including LARC.[1,61] Breaches in confidentiality often stem from standard practices surrounding electronic health records. The electronic health record has posed multiple challenges that have yet to be adequately addressed, ranging from inability to limit sensitive health information when parents or guardians request medical records to the automated creation of discharge summaries, appointment notifications, and medication lists, which include contraception.[63] These concerns may affect the ability to provide LARC services confidentially even when state laws allow for confidential reproductive health care for adolescents.

The complexity of consent and confidentiality is amplified when working with adolescents in the child welfare and justice systems. These adolescents experience unplanned pregnancies at a higher rate than their peers, suggesting that these are special populations with higher rates of unmet reproductive health care needs.[64,65] The AAP and the National Commission on Correctional Health Care recommend that these groups of adolescents have access to appropriate reproductive health care services including contraception.[65,66] Disclosing reproductive health information is inevitable when obtaining consent for LARC services for adolescents who are unable to provide independent consent. Pediatricians may find themselves navigating between a state law that allows an adolescent to provide independent consent and a welfare agency regulation that restricts this.[64] In addition to questions of consent, incarcerated adolescents may also face an additional cost barrier because state-funded health insurance may be suspended during incarceration.[65]

Billing for LARC services also limits the ability to provide confidentiality. Groups advocating for better confidential care practices have suggested a more generic insurance bill be generated when adolescents are using parent or guardian insurance to cover reproductive

TABLE 7 Resources for Determining IUD Coverage

	Resource Link
University of California, San Francisco	http://larcprogram.ucsf.edu
National Women's Law Center CoverHer project	https://nwlc.org/coverher/
Kaiser Family Foundation	http://kff.org/womens-health-policy/report/medicaid-coverage-of-family-planning-benefits-results-from-a-state-survey/
Department of Health and Human Services	https://www.medicaid.gov/federal-policy-guidance/downloads/cib040816.pdf
ACOG	https://www.acog.org/programs/long-acting-reversible-contraception-larc/activities-initiatives

health care services.[63] The Title X Family Planning Program is unique in that a detailed bill of services is not generated and sent to the parent or guardian. The Title X Family Planning Program improves confidential care by allowing the adolescent to provide consent for reproductive health care independent of a parent or guardian. However, consent policies for procedures set by an individual health care facility may still need to be considered in some cases.[67]

TABLE 8 Steps for Patient-Centered Approach to Contraception Counseling

Patient-Centered Contraception Counseling
Review the patient's general thoughts, fears, and questions related to birth control methods
Understand the patient goals for contraception: when pregnancy is desired, whether reduction of menstrual bleeding or cramping is desired
Present all birth control options with information on efficacy, mechanism of action, safety of use, administration details, and side-effect profile
Review medical eligibility criteria and clearly discuss whether there is a contraindication to a specific birth control method
If the patient is ready to make a selection, encourage questions on the safety, efficacy, administration details, and side effect profile to ensure comfort with all aspects of the chosen method
Counsel on expected changes in bleeding
Assess need for back-up contraception and provide STI prevention education

PATIENT-CENTERED LARC COUNSELING

Pediatricians may unintentionally engage in directive counseling leading patients to select LARC methods when providing contraception care because of the overwhelmingly favorable attention these methods have received from multiple professional societies.[1–3,19] Resisting coercive counseling practice is essential when providing reproductive health care. The reproductive justice movement is focused on the human right to maintain bodily autonomy, to have and not have children, and to raise children in safe and sustainable communities.[68] Although this report endorses the demonstrable safety of LARC and supports providers caring for adolescents to incorporate LARC counseling, placement, or referral services into practice, the importance of counseling within the framework of reproductive justice is clear. Focusing contraception counseling on the priorities of the adolescent patient helps keep the discussion patient centered and the decision-making shared (Table 8). Efficacy of pregnancy prevention may not be the sole factor, or even the most important factor, influencing a patient's choice of contraception.[69,70] Cultural beliefs surrounding future fertility or bleeding patterns and side-effect profile may heavily influence the patient's contraceptive choice.[69,70] Just as cultural beliefs held by patients may impact LARC use, cultural beliefs held by providers may impact LARC availability to adolescents. The AAP and ACOG support conscientious objection by the provider as long patients receive complete information of all services (even those the health care provider is not willing to deliver) and a timely referral to another provider.[71,72]

Proponents of setting LARC within a reproductive justice framework do not discourage use of these methods. Rather, this framework advocates for active prevention of reproductive right abuses. Programs involving the previously available subdermal implant (Norplant) reflected aggressive marketing to poor women, women of color, and young urban women, and in some cases, offered cash incentive programs.[69,73] A recent survey of 100 LARC leading experts found that 77% of participants opposed incentive programs surrounding LARC. The majority of participants commented that incentive-based programming is coercive and described this type of policy as "wrong" and "very disturbing."[51]

The disparity of pregnancy incidence between adolescents from different socioeconomic and racial groups is clear. Pediatricians working with adolescents may feel compelled to deliver clear, directive counseling especially with the growing acceptance of LARC.[74,75] When pediatricians acknowledge that women in particular socioeconomic and racial groups have been the target of unethical contraceptive marketing or campaigns in the past, there is a natural recognition of the critical importance that patients choose their contraception free of coercion.[69,74] LARC counseling within the reproductive justice framework enables women to have equal access to LARC methods and allows for the removal of these devices when desired. Structuring LARC counseling within this framework focuses providers on enhancing the well-being of adolescent patients by increasing LARC availability and not on simply increasing LARC use.

RECOMMENDATIONS

In an effort to increase access to LARC by adolescents, pediatricians should do the following:

1. Recognize LARCs as safe options for adolescents. The US MEC can help clarify questions related to safety of use in a variety of complex medical conditions.
2. Have a clear discussion of expected side effects with their adolescent patients, including expected changes in bleeding patterns, as part of LARC counseling. Providing this type of information and understanding the short-term options to control abnormal uterine bleeding are associated with higher LARC continuation.
3. Recognize LNG-IUD as a promising option for reducing menses, particularly in those

with cognitive or physical disabilities or those with a diagnosis of anemia attributable to heavy menstrual bleeding.

4. Seek and obtain the required training for placement and removal of LARCs.
5. Understand that LARC placement does not need to be delayed for STI screening. IUD placement should be delayed if purulent cervicitis is noted or if an untreated gonorrhea or *Chlamydia* infection is present.
6. Emphasize dual therapy with condoms in LARC users to prevent STIs.
7. Be aware that confidentiality can be compromised when delivering LARC services during the consent process and inadvertently by insurance billing and various automated features of the electronic health record. Understand state laws surrounding reproductive health and the financial options available to cover LARC services.
8. When providing same-day LARC services, care must be taken to ensure all available contraceptive methods are reviewed, medical eligibility is considered, side effects are discussed, and personal safety related to intimate partner violence and coerced sexual activity is assessed.
9. Provide LARC counseling within the reproductive justice framework to prevent directive and potentially coercive counseling.
10. Focus on an end goal of improving the availability of LARC services to adolescents and not on increasing adolescent use of LARC methods.

LEAD AUTHOR

Seema Menon, MD

COMMITTEE ON ADOLESCENCE, 2019–2020

Elizabeth M. Alderman, MD, FSAHM, FAAP, Chairperson
Richard J. Chung, MD, FAAP
Laura K. Grubb, MD, MPH, FAAP
Janet Lee, MD, FAAP
Makia E. Powers, MD, MPH, FAAP
Krishna K. Upadhya, MD, FAAP
Stephenie B. Wallace, MD, MSPH, FAAP

PAST COMMITTEE MEMBER

Cora C. Breuner, MD, MPH, FAAP, Former Chairperson

LIAISONS

Liwei L. Hua, MD, PhD – *American Academy of Child and Adolescent Psychiatry*
Ellie Vyver, MD – *Canadian Paediatric Society*
Anne-Maria Amies, MD – *American College of Obstetricians and Gynecologists*
Seema Menon, MD – *North American Society for Pediatric and Adolescent Gynecology*
Lauren B. Zapata, PhD, MSPH – *Centers for Disease Control and Prevention*

STAFF

Karen Smith
James Baumberger, MPP

ABBREVIATIONS

AAP: American Academy of Pediatrics
ACOG: American College of Obstetricians and Gynecologists
CDC: Centers for Disease Control and Prevention
Cu-IUD: copper intrauterine device
IUD: intrauterine device
LARC: long-acting reversible contraception
LNG-IUD: levonorgestrel intrauterine device
NSAID: nonsteroidal antiinflammatory drug
STI: sexually transmitted infection
US MEC: US Medical Eligibility Criteria for Contraceptive Use

REFERENCES

1. Committee on Adolescence. Contraception for adolescents. *Pediatrics*. 2014;134(4). Available at: www.pediatrics.org/cgi/content/full/134/4/e1244
2. Committee on Practice Bulletins-Gynecology, Long-Acting Reversible Contraception Work Group. Practice Bulletin No. 186: long-acting reversible contraception: implants and intrauterine devices. *Obstet Gynecol*. 2017;130(5):e251–e269
3. Committee on Adolescent Health Care Long-Acting Reversible Contraception Work Group. ACOG Committee Opinion No. 735: adolescents and long-acting reversible contraception: implants and intrauterine devices. *Obstet Gynecol*. 2018;131(5):e130–e139
4. Curtis KM, Tepper NK, Jatlaoui TC, et al. US medical eligibility criteria for contraceptive use, 2016. *MMWR Recomm Rep*. 2016;65(3):1–103
5. Bayer LL, Hillard PJA. Use of levonorgestrel intrauterine system for medical indications in adolescents. *J Adolesc Health*. 2013;52(suppl 4): S54–S58
6. Kantartzis KL, Sucato GS. Menstrual suppression in the adolescent. *J Pediatr Adolesc Gynecol*. 2013;26(3):132–137
7. Hubacher D, Grimes DA. Noncontraceptive health benefits of intrauterine devices: a systematic review. *Obstet Gynecol Surv*. 2002;57(2): 120–128
8. Lindberg L, Santelli J, Desai S. Understanding the decline in adolescent fertility in the United States, 2007–2012. *J Adolesc Health*. 2016; 59(5):577–583
9. Martinez GM, Abma JC. Sexual activity, contraceptive use, and childbearing of teenagers aged 15–19 in the United States. *NCHS Data Brief*. 2015; (209):1–8
10. Santelli JS, Lindberg LD, Finer LB, Singh S. Explaining recent declines in adolescent pregnancy in the United States: the contribution of abstinence and improved contraceptive use. *Am J Public Health*. 2007;97(1): 150–156
11. Parks C, Peipert JF. Eliminating health disparities in unintended pregnancy with long-acting reversible contraception (LARC). *Am J Obstet Gynecol*. 2016;214(6):681–688

12. Barrett M, Soon R, Whitaker AK, Takekawa S, Kaneshiro B. Awareness and knowledge of the intrauterine device in adolescents. *J Pediatr Adolesc Gynecol*. 2012;25(1):39–42

13. Kumar N, Brown JD. Access barriers to long-acting reversible contraceptives for adolescents. *J Adolesc Health*. 2016; 59(3):248–253

14. Teal SB, Romer SE. Awareness of long-acting reversible contraception among teens and young adults. *J Adolesc Health*. 2013;52(suppl 4):S35–S39

15. Russo JA, Miller E, Gold MA. Myths and misconceptions about long-acting reversible contraception (LARC). *J Adolesc Health*. 2013;52(suppl 4): S14–S21

16. Potter J, Rubin SE, Sherman P. Fear of intrauterine contraception among adolescents in New York City. *Contraception*. 2014;89(5):446–450

17. Pritt NM, Norris AH, Berlan ED. Barriers and facilitators to adolescents' use of long-acting reversible contraceptives. *J Pediatr Adolesc Gynecol*. 2017;30(1): 18–22

18. Murphy MK, Stoffel C, Nolan M, Haider S. Interdependent barriers to providing adolescents with long-acting reversible contraception: qualitative insights from providers. *J Pediatr Adolesc Gynecol*. 2016;29(5):436–442

19. Society for Adolescent Health and Medicine. Improving knowledge about, access to, and utilization of long-acting reversible contraception among adolescents and young adults. *J Adolesc Health*. 2017;60(4): 472–474

20. Mestad R, Secura G, Allsworth JE, Madden T, Zhao Q, Peipert JF. Acceptance of long-acting reversible contraceptive methods by adolescent participants in the Contraceptive CHOICE Project. *Contraception*. 2011; 84(5):493–498

21. Usinger KM, Gola SB, Weis M, Smaldone A. Intrauterine contraception continuation in adolescents and young women: a systematic review. *J Pediatr Adolesc Gynecol*. 2016;29(6):659–667

22. O'neil-Callahan M, Peipert JF, Zhao Q, Madden T, Secura G. Twenty-four-month continuation of reversible contraception. *Obstet Gynecol*. 2013; 122(5):1083–1091

23. American College of Obstetricians and Gynecologists' Committee on Obstetric Practice. Committee Opinion No. 670: immediate postpartum long-acting reversible contraception. *Obstet Gynecol*. 2016;128(2):e32–e37

24. Curtis KM, Jatlaoui TC, Tepper NK, et al. US selected practice recommendations for contraceptive use, 2016. *MMWR Recomm Rep*. 2016;65(4):1–66

25. Vigl M, Kaemmerer M, Seifert-Klauss V, et al. Contraception in women with congenital heart disease. *Am J Cardiol*. 2010;106(9):1317–1321

26. Amies Oelschlager A-M, Micks EA, Debiec KE, Nizamic T, Mantrala MD, Prager SW. Long acting reversible contraception in adolescents with cardiovascular conditions. *J Pediatr Adolesc Gynecol*. 2014;27(6):353–355

27. Sufrin CB, Postlethwaite D, Armstrong MA, Merchant M, Wendt JM, Steinauer JE. *Neisseria gonorrhea* and *Chlamydia trachomatis* screening at intrauterine device insertion and pelvic inflammatory disease. *Obstet Gynecol*. 2012;120(6):1314–1321

28. Steiner RJ, Liddon N, Swartzendruber AL, Rasberry CN, Sales JM. Long-acting reversible contraception and condom use among female US high school students: implications for sexually transmitted infection prevention. *JAMA Pediatr*. 2016;170(5):428–434

29. Biggs MA, Arons A, Turner R, Brindis CD. Same-day LARC insertion attitudes and practices. *Contraception*. 2013;88(5): 629–635

30. Biggs MA, Harper CC, Brindis CD. California family planning health care providers' challenges to same-day long-acting reversible contraception provision. *Obstet Gynecol*. 2015;126(2): 338–345

31. Luchowski AT, Anderson BL, Power ML, Raglan GB, Espey E, Schulkin J. Obstetrician-gynecologists and contraception: long-acting reversible contraception practices and education. *Contraception*. 2014;89(6):578–583

32. Centers for Disease Control and Prevention. CDC contraceptive guidance for health care providers. US selected practice recommendations for contraceptive use, 2016: implants. Available at: https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/implants.html. Accessed September 24, 2019

33. Adeyemi-Fowode OA, Santos XM, Dietrich JE, Srivaths L. Levonorgestrel-releasing intrauterine device use in female adolescents with heavy menstrual bleeding and bleeding disorders: single institution review. *J Pediatr Adolesc Gynecol*. 2017;30(4): 479–483

34. Quint EH, O'Brien RF; Committee on Adolescence; North American Society for Pediatric and Adolescent Gynecology. Menstrual management for adolescents with disabilities. *Pediatrics*. 2016;137(4):e21060295

35. Rivera Drew JA. Hysterectomy and disability among US women. *Perspect Sex Reprod Health*. 2013; 45(3):157–163

36. Albanese A, Hopper NW. Suppression of menstruation in adolescents with severe learning disabilities. *Arch Dis Child*. 2007;92(7):629–632

37. Savasi I, Jayasinghe K, Moore P, Jayasinghe Y, Grover SR. Complication rates associated with levonorgestrel intrauterine system use in adolescents with developmental disabilities. *J Pediatr Adolesc Gynecol*. 2014;27(1): 25–28

38. Kirkham YA, Allen L, Kives S, Caccia N, Spitzer RF, Ornstein MP. Trends in menstrual concerns and suppression in adolescents with developmental disabilities. *J Adolesc Health*. 2013; 53(3):407–412

39. Hayes P. Contraceptive helps decrease bleeding in women. 2009. Available at: https://hemaware.org/story/contraceptive-helps-decrease-bleeding-women. Accessed September 24, 2019

40. Kadir RA, Chi C. Levonorgestrel intrauterine system: bleeding disorders and anticoagulant therapy. *Contraception*. 2007;75(suppl 6): S123–S129

41. Kingman CEC, Kadir RA, Lee CA, Economides DL. The use of levonorgestrel-releasing intrauterine system for treatment of menorrhagia in women with inherited bleeding

disorders. *BJOG*. 2004;111(12):1425–1428

42. Lukes AS, Reardon B, Arepally G. Use of the levonorgestrel-releasing intrauterine system in women with hemostatic disorders. *Fertil Steril*. 2008;90(3):673–677
43. Schaedel ZE, Dolan G, Powell MC. The use of the levonorgestrel-releasing intrauterine system in the management of menorrhagia in women with hemostatic disorders. *Am J Obstet Gynecol*. 2005;193(4):1361–1363
44. Committee on Adolescent Health Care. ACOG Committee Opinion No. 760: dysmenorrhea and endometriosis in the adolescent. *Obstet Gynecol*. 2018;132(6):e249–e258
45. Ryan SA. The treatment of dysmenorrhea. *Pediatr Clin North Am*. 2017;64(2):331–342
46. Nelson AL, Massoudi N. New developments in intrauterine device use: focus on the US. *Open Access J Contracept*. 2016;7:127–141
47. Berenson AB, Tan A, Hirth JM. Complications and continuation rates associated with 2 types of long-acting contraception. *Am J Obstet Gynecol*. 2015;212(6):761.e1
48. Villavicencio J, Allen RH. Unscheduled bleeding and contraceptive choice: increasing satisfaction and continuation rates. *Open Access J Contracept*. 2016;7:43–52
49. Casey PM, Long ME, Drozdowicz LB, Marnach ML, Weaver AL. Management of etonogestrel subdermal implant-related bleeding. *J Reprod Med*. 2014;59(5–6):306–312
50. Friedlander E, Kaneshiro B. Therapeutic options for unscheduled bleeding associated with long-acting reversible contraception. *Obstet Gynecol Clin North Am*. 2015;42(4):593–603
51. Foster DG, Barar R, Gould H, Gomez I, Nguyen D, Biggs MA. Projections and opinions from 100 experts in long-acting reversible contraception. *Contraception*. 2015;92(6):543–552
52. Berlan ED, Pritt NM, Norris AH. Pediatricians' attitudes and beliefs about long-acting reversible contraceptives influence counseling. *J Pediatr Adolesc Gynecol*. 2017;30(1):47–52
53. Teal SB, Romer SE, Goldthwaite LM, Peters MG, Kaplan DW, Sheeder J. Insertion characteristics of intrauterine devices in adolescents and young women: success, ancillary measures, and complications. *Am J Obstet Gynecol*. 2015;213(4):515.e1
54. O'Flynn O'Brien KL, Akers AY, Perriera LK, Schreiber CA, Garcia-Espana JF, Sonalkar S. Intrauterine device insertion procedure duration in adolescent and young adult women. *J Pediatr Adolesc Gynecol*. 2019;32(3):312–315
55. Zapata LB, Jatlaoui TC, Marchbanks PA, Curtis KM. Medications to ease intrauterine device insertion: a systematic review. *Contraception*. 2016;94(6):739–759
56. Singh RH, Thaxton L, Carr S, Leeman L, Schneider E, Espey E. A randomized controlled trial of nitrous oxide for intrauterine device insertion in nulliparous women. *Int J Gynaecol Obstet*. 2016;135(2):145–148
57. Akers AY, Steinway C, Sonalkar S, et al. Reducing pain during intrauterine device insertion: a randomized controlled trial in adolescents and young women. *Obstet Gynecol*. 2017;130(4):795–802
58. Lopez LM, Bernholc A, Zeng Y, et al. Interventions for pain with intrauterine device insertion. *Cochrane Database Syst Rev*. 2015;(7):CD007373
59. Merck Sharp and Dohme Corporation. Nexplanon: dosing and administration. Available at: https://www.merckconnect.com/nexplanon/dosing-administration/. Accessed September 24, 2019
60. Angelini K. A lower-cost option for intrauterine contraception. *Nurs Womens Health*. 2016;20(2):197–202
61. Committee on Adolescent Health Care. ACOG Committee Opinion No. 599: Committee on adolescent health care: Adolescent confidentiality and electronic health records. *Obstet Gynecol*. 2014;123(5):1148–1159
62. Guttmacher Institute. An overview of consent to reproductive health services by young people. 2019. Available at: https://www.guttmacher.org/state-policy/explore/overview-minors-consent-law. Accessed September 24, 2019
63. Anoshiravani A, Gaskin GL, Groshek MR, Kuelbs C, Longhurst CA. Special requirements for electronic medical records in adolescent medicine. *J Adolesc Health*. 2012;51(5):409–414
64. Council on Foster Care, Adoption, and Kinship Care; Committee on Adolescence; Council on Early Childhood. Health care issues for children and adolescents in foster care and kinship care. *Pediatrics*. 2015;136(4). Available at: www.pediatrics.org/cgi/content/full/136/4/e1131
65. Barnert ES, Perry R, Morris RE. Juvenile incarceration and health. *Acad Pediatr*. 2016;16(2):99–109
66. Committee on Adolescence. Health care for youth in the juvenile justice system. *Pediatrics*. 2011;128(6):1219–1235
67. US Department of Health and Human Services; Office of Population Affairs. Program requirements for Title X funded family planning projects. Available at: https://www.hhs.gov/opa/guidelines/program-guidelines/program-requirements/index.html. Accessed June 13, 2018
68. SisterSong. Reproductive justice. Available at: https://www.sistersong.net/reproductive-justice. Accessed March 9, 2020
69. Higgins JA. Celebration meets caution: LARC's boons, potential busts, and the benefits of a reproductive justice approach. *Contraception*. 2014;89(4):237–241
70. Gomez AM, Fuentes L, Allina A. Women or LARC first? Reproductive autonomy and the promotion of long-acting reversible contraceptive methods. *Perspect Sex Reprod Health*. 2014;46(3):171–175
71. American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 385 November 2007: the limits of conscientious refusal in reproductive medicine. *Obstet Gynecol*. 2007;110(5):1203–1208
72. Committee on Bioethics. Policy statement--Physician refusal to provide information or treatment on the basis of claims of conscience.

Pediatrics. 2009;124(6):1689–1693

73. Gold RB. Guarding against coercion while ensuring access: a delicate balance. *Guttmacher Policy Review*. 2014;17(3):8–14

74. Higgins JA, Kramer RD, Ryder KM. Provider bias in long-acting reversible contraception (LARC) promotion and removal: perceptions of young adult women. *Am J Public Health*. 2016;106(11):1932–1937

75. Gubrium AC, Mann ES, Borrero S, et al. Realizing reproductive health equity needs more than long-acting reversible contraception (LARC). *Am J Public Health*. 2016;106(1):18–19

Neonatal Opioid Withdrawal Syndrome

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Neonatal Opioid Withdrawal Syndrome

Stephen W. Patrick, MD, MPH, MS, FAAP,[a] Wanda D. Barfield, MD, MPH, FAAP,[b] Brenda B. Poindexter, MD, MS, FAAP,[c] COMMITTEE ON FETUS AND NEWBORN, COMMITTEE ON SUBSTANCE USE AND PREVENTION

The opioid crisis has grown to affect pregnant women and infants across the United States, as evidenced by rising rates of opioid use disorder among pregnant women and neonatal opioid withdrawal syndrome among infants. Across the country, pregnant women lack access to evidence-based therapies, including medications for opioid use disorder, and infants with opioid exposure frequently receive variable care. In addition, public systems, such as child welfare and early intervention, are increasingly stretched by increasing numbers of children affected by the crisis. Systematic, enduring, coordinated, and holistic approaches are needed to improve care for the mother-infant dyad. In this statement, we provide an overview of the effect of the opioid crisis on the mother-infant dyad and provide recommendations for management of the infant with opioid exposure, including clinical presentation, assessment, treatment, and discharge.

INTRODUCTION

The United States has experienced a surge in opioid use and opioid-related complications. From 1999 to 2009, there was a quadrupling of opioid pain reliever prescription sales nationwide.[1] By 2015, 3 times as many prescriptions for opioid pain relievers were filled than in 1999,[2] reaching >37% of US adults using opioid pain relievers in 2015.[3] The rapid increase in opioid pain reliever use in the early 2000s was associated with a parallel increase in opioid pain reliever–related treatment facility admissions and overdose deaths.[1] Since 2011, however, deaths from opioid pain relievers have plateaued, whereas deaths from heroin and fentanyl have grown exponentially.[4] In 2017, >47 600 Americans died of opioid-related overdoses (including opioid pain relievers, heroin, and fentanyl), outnumbering deaths from car crashes and firearms.[5]

As the opioid crisis grew in scope and complexity in the population at large, opioid use[6] and opioid use disorder (OUD)[7–9] among pregnant women also increased. Opioid use in pregnancy can lead to a withdrawal syndrome in the newborn shortly after birth. The syndrome has been traditionally called neonatal abstinence syndrome but more recently has been called neonatal opioid withdrawal syndrome (NOWS) by federal

abstract

[a]Division of Neonatology, Department of Pediatrics and Health Policy, School of Medicine, Vanderbilt University and Vanderbilt Center for Child Health Policy, Vanderbilt University Medical Center, Nashville, Tennessee; [b]Centers for Disease Control and Prevention, Atlanta, Georgia; and [c]Department of Pediatrics, College of Medicine, University of Cincinnati and Cincinnati Children's Medical Hospital Center, Cincinnati, Ohio

Drs Patrick, Barfield, and Poindexter were directly involved in the planning, researching, and writing of this report and approved the final manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the US Centers for Disease Control and Prevention.

DOI: https://doi.org/10.1542/peds.2020-029074

Address correspondence to Stephen W. Patrick, MD, MPH, MS, FAAP. E-mail: stephen.patrick@vanderbilt.edu

To cite: Patrick SW, Barfield WD, Poindexter BB, AAP COMMITTEE ON FETUS AND NEWBORN, COMMITTEE ON SUBSTANCE USE AND PREVENTION. Neonatal Opioid Withdrawal Syndrome. *Pediatrics*. 2020;146(5):e2020029074

agencies, including the US Food and Drug Administration.[10] Although neonatal abstinence syndrome is a more general term for neonatal withdrawal that, in the literature, may include nonopioid exposures (eg, benzodiazepines),[11] evidence suggests that the recent growth of neonatal drug withdrawal has been primarily from in utero opioid exposure either in isolation or in combination with other substances.[8]

The recent increase in OUD in pregnancy and NOWS reveals deficiencies in the continuum of care for the maternal-infant dyad in clinical and public systems. The child welfare system, for example, reported an increase of >10 000 infants in foster care from 2011 to 2017, most because of parental substance use.[12,13] Systematic, enduring, coordinated, and holistic approaches are needed to improve care for the mother-infant dyad. Optimizing the health and well-being of a pregnant woman gives her infant the highest likelihood of an ideal outcome. Care for the mother-infant dyad should be comprehensive and should consider the needs of both the mother and infant, as is outlined in the American Academy of Pediatrics (AAP) policy statement "A Public Health Response to Opioid Use in Pregnancy."[14] This statement builds on previous AAP-released clinical recommendations, including "Recommendations to the Indian Health Service on Neonatal Opioid Withdrawal Syndrome,"[15] and focuses primarily on the clinical presentation, assessment, and treatment of infants with opioid exposure and those with NOWS. The statement also discusses how the discharge process can be used to connect infants to important postdischarge services.

OUD IN PREGNANCY AND NOWS

Use of opioids, even as directed, can heighten risk of developing OUD, defined as a problematic pattern of opioid use that leads to clinically significant impairment or distress.[16] Rates of OUD in pregnancy grew substantially from 1999 to 2014,[7] with disproportionally higher rates in rural areas of the country.[9] Untreated OUD in pregnant women can result in dire consequences for the mother-infant dyad, including overdose death, fetal loss, and preterm birth. As highlighted by the recent report from the National Academies of Sciences, Engineering, and Medicine, "Medications for Opioid Use Disorder Save Lives,"[17] optimal care for pregnant women with OUD includes treatment with methadone or buprenorphine. Methadone is a full μ-opioid receptor agonist, which is dispensed from federally licensed opioid treatment programs. In contrast, buprenorphine is a partial μ-opioid receptor agonist and partial κ-opioid receptor antagonist that can be obtained from an opioid treatment program or from a provider who has obtained a waiver to prescribe through the Drug Addiction Treatment Act of 2000. Despite literature to support the use of medications for OUD in pregnancy, there remain substantial barriers in obtaining medications for OUD among pregnant women.[18,19] These barriers may, in part, be why the majority of pregnant women who are able to obtain treatment of OUD do not receive medications for OUD, despite evidence of their benefit.[18,20]

Opioid use typically does not occur in isolation and frequently involves other substances. In a recent study, using data from the National Survey of Drug Use and Health from 2005 to 2014, authors found that 5.1% of US pregnant women reported nonmedical use of an opioid pain reliever in the last year. Compared with pregnant women who did not report nonmedical use of an opioid pain reliever in the last 30 days, pregnant women who reported nonmedical use of an opioid pain reliever were more likely ($P < .001$) to also report last-30-day use of alcohol (49.2% vs 8.6%), tobacco (59.3% vs 15.6%), and marijuana (41.6% vs 3.3%).[21] Importantly, use of other substances (eg, tobacco)[22] or prescription sedatives (eg, benzodiazepines)[23] along with an opioid may increase risk and/or severity of NOWS. In addition, alcohol use in pregnancy is particularly problematic because alcohol, a teratogen, can cause fetal alcohol spectrum disorders and is the leading cause of preventable intellectual disability in the United States.[24] It is difficult for clinicians to disentangle the short- and long-term effects of exposure to opioids from other substances. Finally, social and economic factors,[25] systemic racism,[26] maternal physical and mental health, genetic and/or epigenetic, nutritional, and environmental factors may adversely affect infant development independent of maternal substance use disorder.[27]

Increases in maternal opioid use were accompanied by a parallel increase in NOWS.[8,9] From 2000 to 2016, the incidence of NOWS increased from 1.2 to 8.8 per 1000 hospital births.[8,28–30] These increases have been steeper in rural and tribal areas[9] and among infants enrolled in the Medicaid program.[29] In addition, there is remarkable state-to-state variation in NOWS. For example, West Virginia has the highest reported rate of NOWS at 33.4 per 1000 hospital births, compared with Hawaii at 0.7 per 1000 hospital births.[31] American Indian and Alaskan native populations have been disproportionately affected by NOWS. In 2016, American Indian and Alaskan native infants had the highest rate of NOWS at 15.9 per 1000 hospital births, compared with white infants at 10.5 per 1000 hospital births, Black infants at 3.4 per 1000 hospital births, and Hispanic infants at 2.5 per 1000 hospital births.[32]

ASSESSMENT AND CLINICAL PRESENTATION

Assessment of infants with opioid exposure by the health care team should include a thorough maternal history, including information gathered on substance use, additional medication use (prescribed and unprescribed), adversities experienced in childhood, cultural beliefs, trauma and violence exposures past and present, mental health disorders, and infectious diseases (including HIV and hepatitis C virus [HCV] infections). Ideally, clinicians should also assess the needs of the family, including the status of significant others and children as well as food and housing insecurity. When evaluating an infant with clinical signs consistent with NOWS, it is also important to consider other diagnoses that present similarly (eg, sepsis, hypoglycemia, hypocalcemia, and neurologic injury).

CLINICAL PRESENTATION OF NOWS IN NEONATES

NOWS occurs after chronic exposure to opioids (Table 1); therefore, exposure to opioids around the time of delivery, including opioids in an epidural or intravenous agonist and/or antagonist therapies (eg, nalbuphine, butorphanol), does not cause NOWS. The clinical presentation or risk of NOWS varies by opioid type (eg, immediate release, sustained release, maintenance),[22] the maternal drug history (including timing of the most recent use of drugs before delivery), maternal metabolism, net transfer of drugs across the placenta, placental metabolism, infant metabolism and excretion, and other factors.[11] In addition, maternal use of other substances, such as cigarettes, benzodiazepines, and gabapentin, may influence the onset, severity, or duration of the withdrawal syndrome.[22,23,33] Higher cumulative opioid exposure may increase the risk of NOWS among infants exposed to immediate-release prescription opioids[22]; however, studies of the relationship between maternal methadone[34,35] and buprenorphine[22,36] dosage and risk or severity of NOWS have generally found no relationship.

Because opioid receptors are concentrated in the central nervous system and the gastrointestinal tract, the predominant clinical signs reflect these systems (eg, tremors, loose stools; Table 2). Onset of clinical signs of withdrawal tend to reflect the half-life of the opioid involved. For example, withdrawal from heroin often begins within 24 hours of birth, whereas withdrawal from methadone usually begins at ~24 to 72 hours of age.[11] Withdrawal, however, may be delayed until 5 to 7 days of age, which is typically after hospital discharge for uncomplicated term infants.[11] Subacute signs of opioid withdrawal may last up to 6 months.[11,37]

SCREENING

Screening for substance use is distinct from testing for substance use. Screening generally refers to the use of a validated instrument to assess substance use, whereas testing refers to the use of a diagnostic test (eg, urine toxicology). Ideally, screening for substance use occurs in the first trimester by a prenatal provider (eg, family medicine, obstetrician, midwife) using a validated screening tool, as endorsed by the American College of Obstetricians and Gynecologists (ACOG). The ACOG recommends early universal screening for substance use at the time of the first prenatal visit.[38] During this time, other risks should be assessed, including HIV, HCV, and syphilis infection, and, if identified, appropriate planning for treatment (eg, HIV antiviral therapy) should occur in the perinatal period. An ACOG committee opinion mentions that screening tools include the "4 P's" for adults and the "CRAFFT" tool for adolescents (Table 3).[38] Clinical guidance from the AAP for screening

TABLE 1 Common Immediate-Release, Sustained-Release, and Maintenance Opioids

Drug	Immediate Release	Sustained Release	Maintenance
Buprenorphine	—	—	X
Codeine	X	—	—
Dihydrocodeine	X	—	—
Fentanyl	X	X	—
Hydrocodone	X	—	—
Hydromorphone	X	X	—
Levorphanol	X	—	—
Meperidine	X	—	—
Methadone	—	—	X
Morphine	X	X	—
Oxycodone	X	X	—
Oxymorphone	X	X	—
Tramadol	X	—	—

Adapted from Argoff CE, Silvershein DI. A comparison of long- and short-acting opioids for the treatment of chronic noncancer pain: tailoring therapy to meet patient needs. *Mayo Clin Proc.* 2009;84(7):602–612. —, not applicable.

TABLE 2 Signs of NOWS

Signs of NOWS
Central nervous system irritability
High-pitched, continuous crying
Decreased sleep
Tremors
Increased muscle tone
Hyperactive Moro reflex
Seizures
Gastrointestinal dysfunction
Feeding difficulties
Vomiting
Loose or watery stools
Autonomic nervous system activation
Sweating
Fever
Frequent yawning and sneezing
Increased respiratory rate
Nasal stuffiness and flaring

Adapted from Ko JY, Wolicki S, Barfield WD, et al. CDC Grand Rounds: public health strategies to prevent neonatal abstinence syndrome. *MMWR Morb Mortal Wkly Rep.* 2017;66(9):242–245.

adolescents for substance use can be found in the clinical report on substance use screening, brief intervention, and referral to treatment.[39] Prenatal clinicians can also use their state's prescription drug monitoring program as a resource for filled prescriptions because it may capture some high-risk patient behaviors, such as patients seeking controlled substances from different clinicians.[40] A complete summary of ACOG-recommended screening is beyond the scope of this statement but can be found online (https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Opioid-Use-and-Opioid-Use-Disorder-in-Pregnancy). Ideally, pediatric clinicians should work collaboratively with obstetric colleagues to obtain relevant clinical information (eg, screening results) to minimize care duplication. Pregnant women with OUD should also receive antenatal counseling by a pediatric health care provider to assess infant risks of NOWS and provide education on the clinical signs of withdrawal and need for nonpharmacologic and pharmacologic interventions.

SCREENING AND TESTING: MOTHER AND INFANT

Given the challenges in identifying infants at risk for NOWS with maternal screening, some have advocated for universal urine toxicology testing of mothers at the time of delivery. In a recent cohort study from a single center, the efficacy of a universal testing protocol for all mothers was assessed in a community hospital setting. In this study, 5.4% of pregnant women had a positive drug test result at the time of admission (3.2% were positive for opioids). Of the pregnant women with a positive urine drug test result for opioids, 20% had a negative risk-based screen result.[41] However, screening and testing processes are complex and have potential legal ramifications, and the AAP endorses informed consent for toxicology testing of pregnant women.[14] Notably universal testing has resulted in disproportionately higher child protective services referrals for Black women compared with white women[42,43] Pediatricians should be aware of and reduce institutional biases in implementing universal toxicology testing for infants, which could result in unequal consequences for mothers and infants on the basis of race, ethnicity, and/or socioeconomic status.

Toxicology testing for an infant can occur from multiple modalities, including urine, meconium, and umbilical cord tissue.[11] A urine sample should be collected as soon as possible after birth if the clinician is concerned because many drugs are rapidly metabolized and eliminated.[44–46] For example, after in utero exposure, opioids and their metabolites may no longer be detectable in an infant's urine after the first few days of life. Similarly, a positive urine screening result may only reflect recent exposure for most substances and may not reflect previous, more remote in utero exposure. Drugs that are excreted in the hepatobiliary system as well as drugs excreted by the fetal kidneys into the amniotic fluid are concentrated in meconium. Meconium testing provides a longer window of time throughout the pregnancy, beginning as early as 20 weeks' gestation, and is generally considered the gold standard for infant toxicology testing.[47–49] Meconium collection, however, can be labor intensive, requiring collection for several days, and does not reflect periods of abstinence close to delivery. Meconium must be collected before it is contaminated by nonmeconium stools (ie, after the infant receives colostrum or transitional milk, mature human milk, or formula). More recently, umbilical cord tissue testing has emerged as an alternative to meconium collection; given that umbilical cord tissue is readily available at the time of birth, it has logistic advantages to meconium collection.[49–53] Although some studies have suggested equivalence between meconium and umbilical cord tissue testing,[53] others studies have found the paired testing of meconium and umbilical cord tissue to be discordant.[54] Clinicians should be mindful of the differences in testing modalities when considering their needs for testing and work with their laboratories to determine the best testing modality in their setting.

Infant toxicology testing should be completed when it will inform clinical management. In some instances, testing of the infant provides no additional clinical information and would not be recommended. For example, for women in treatment for OUD who are closely monitored with frequent toxicology testing, meconium and/or umbilical cord tissue testing would not likely provide any additional clinical information if this information is readily available to the pediatrician. Testing can be helpful, however, when clinical details are lacking (eg, late or

TABLE 3 Screening for Substance Use

Screening for Substance Use
4 P's[a]
Parents: Did any of your parents have a problem with alcohol or other drug use?
Partner: Does your partner have a problem with alcohol or drug use?
Past: In the past, have you had difficulties in your life because of alcohol or other drugs, including prescription medications?
Present: In the past month, did you drink any alcohol or use any other drugs?
Any "yes" answer indicates that additional assessment is needed.
CRAFFT[b,c]
C: Have you ever ridden in a car driven by someone (including yourself) who was high or had been using alcohol or drugs?
R: Do you ever use alcohol or drugs to relax, feel better about yourself, or fit in?
A: Do you ever use alcohol or drugs while you are by yourself or alone?
F: Do you ever forget things you did while using alcohol or drugs?
F: Does your family or friends ever tell you that you should cut down on your drinking or drug use?
T: Have you ever gotten in trouble while you were using alcohol or drugs?
Two or more "yes" answers indicate that additional assessment is needed.

[a] Ewing H. A practical guide to intervention in health and social services with pregnant and postpartum addicts and alcoholics: theoretical framework, brief screening tool, key interview questions, and strategies for referral to recovery resources. Martinez, CA: The Born Free Project, Contra Costa County Department of Health Services; 1990.

[b] Notice to clinic staff and medical records: The information on this page is protected by special federal confidentiality rules (42 CFR §2), which prohibit disclosure of this information unless authorized by specific written consent. A general authorization for release of medical information is not sufficient.

[c] Copyright John R. Knight, MD, Boston Children's Hospital, 2018. All rights reserved. Reproduced with permission. For more information, contact crafft@childrens.harvard.edu.

no prenatal care, placental abruption) and should be considered.

DIAGNOSIS, ASSESSMENT, AND TREATMENT

In the 1970s, several scoring systems were developed to guide the diagnosis and treatment of neonatal abstinence syndrome.[55,56] Still today, however, there is not one agreed-on scoring tool, and each scoring tool is prone to challenges of interrater reliability because each contains clinical signs that can be subjective or related to infant adaptation to extrauterine life.

The most commonly used scoring tool in the United States today is a modification of the original Finnegan score, developed in the early 1970s by Dr Loretta Finnegan.[55,57] Another commonly used score is a Finnegan scale modification created from the Maternal Opioid Treatment: Human Experimental Research (MOTHER) Neonatal Abstinence Measure trial (Fig 1).[58] Similar to other tools, the MOTHER modification includes common central nervous system, gastrointestinal tract, and autonomic clinical signs. Clinical signs are weighted to reflect severity; for example, sleeping <1 hour after feeding reflects a score of 3, whereas sleeping <3 hours after feeding reflects a score of 1. The score is used for initiation, advancement, and weaning of pharmacotherapy for NOWS on the basis of severity. The MOTHER modification suggests initiating pharmacotherapy if there is a consistent score of 9 to 12 or a single score of 13.

More recently, a new scoring tool has emerged, called Eat, Sleep, Console (ESC), which aims to guide treatment of NOWS.[59] The tool is guided by the infant's clinical signs of withdrawal through evaluation of an infant's ability to eat ≥ 1 oz or breastfeed well, sleep undisturbed ≥ 1 hour, and be consoled. If these criteria are not met, the medical team meets, assesses the environment and nonpharmacologic approaches, and considers initiating or escalating pharmacotherapy. ESC is appealing because of its ease of use and simplicity but has not been studied outside of quality improvement initiatives. It remains somewhat unclear, for example, if improvements in length of hospital stay are attributable to the ESC approach itself or to better adherence to nonpharmacologic approaches, which can also reduce length of stay.[59]

Despite challenges presented by scoring tools, data suggest that standardizing institutional scoring processes (ie, by using the same tool the same way with each patient) and training to improve interrater reliability improves clinical outcomes, including decreasing length of hospital stay.[60] For example, during the 2-year Vermont Oxford Neonatal Abstinence Syndrome Collaborative, standardized scoring processes were associated with a shorter length of stay (–3.3 days; 95% confidence interval [CI], –4.9 to –1.4).[60] The AAP does not endorse one scoring system over another because there is not significant evidence to support one tool's superiority. However, given evidence to suggest that establishing a consistent protocol and approach to scoring improves outcomes, every hospital should have a written protocol and optimize provider adherence. More research to support the optimal assessment of an infant with opioid exposure is needed.

CLINICAL MANAGEMENT OF NOWS

Observation

All infants with chronic opioid exposure should be observed for at least 72 hours to monitor for the development of withdrawal. Although

Appendix Figure 2. Maternal Opioid Treatment: Human Experimental Research (MOTHER) Neonatal Abstinence Measure

PATIENT ID#_____

Dose given q 3-4 hrs with feeds; do not exceed 4 hrs between doses

SCORE Morphine (0.04mg/0.1ml) DOSE FOR INITIATION

0-8	0	
9-12	0.04	mg/dose
13-16	0.08	mg/dose
17-20	0.12	mg/dose
21-24	0.16	mg/dose

25 or above 0.20mg/dose

Morphine Initiation:

- If neonate scores 9-12 re-score after feeding or within the hour and if re-score is 9-12 start treatment based on highest score. If re-score is 0-8, do not initiate treatment.
- If initial score is 13 or greater, start treatment immediately without reassessment.

Morphine Maintenance

- Maintain dose if score 0-8
- Increase dose by 0.02 if score is 9-12 (rescore before dosing)
- Increase dose by 0.04 if score 13-16
- Increase score by 0.06 if score 17-20

Weaning Instructions:

- Maintain on dose 48 hrs before starting weaning
- Wean 0.02 mg morphine every day for a score is 0-8
- Defer wean for score e 9-12

Re-escalation

- If neonate scores 9-12 re-score as described for initiation .
- If second score is in 9-12 increase morphine 0.01 mg q3-4 hrs
- If 2 consecutive scores 13-16, increase 0.02 mg q3-4 hrs
- If 2 consecutive scores in 17-20, increase 0.04 mg q3-4 hrs etc

Timing of Scoring: Hospitalized infants scored every 3-4 hrs **before** feeds. Reassessment Occurs immediately **after feeds** or within 1 hour.
Discharged (e.g., in GCRC) infants scored twice a day scores must be separated by 8 hrs)
NOTE: Discharged infants are to be admitted to hospital if the infant receives a single score of 9 or more

SIGNS AND SYMPTOMS Please note **presence (pr) or absence (ab)** of items where indicated. Include observations for the past 4 hour period.	Score	Date/time	Date/time	Date/time	Date/time	Date/time	Date/time	Date/time	Date/time
Crying: excessive high pitched Crying: Continuous high pitched	2 3								
Sleeps < 1 hour after feeding Sleeps < 2 hours after feeding Sleeps < 3 hours after feeding	3 2 1								
Hyperactive Moro Reflex Markedly Hyperactive Moro Reflex	1 2								
Mild Tremors: Disturbed Moderate-Severe Tremors: Disturbed	1 2								
Mild Tremors: Undisturbed Moderate-Severe Tremors: Undisturbed	1 2								
Myoclonic jerks	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Increased Muscle Tone	1-2								
Excoriation (indicate specific area):	1 - 2								
Mottling	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Generalized Seizure (or convulsion)	8								
Convulsions	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Fever ≥ 37.3 C (99.2 F)	1								
Fever >38.4 (101.2 F)	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Frequent Yawning (4 or more successive times)	1								
Sweating	1								
Nasal Stuffiness	1								
Sneezing (4 or more successive times)	1								
Tachypnea (Respiratory Rate> 60/min)	2								
Retractions	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Nasal flaring	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Poor Feeding	2								
Excessive sucking	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Vomiting (or regurgitation)	2								
Projectile vomiting	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Loose Stools	2								
Watery Stools	present/absent	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab	☐pr ☐ab
Failure to Thrive (Current weight ≥ 10% below birth weight) 90% BWT=_____	2 (record weight in score box 1 x day)								
Excessive Irritability	1 - 3								
TOTAL SCORE									
CURRENT MORPHINE DOSE	Dose in mg Time Given								
STATUS OF TREATMENT*	N, I, M, W, R								
INITIALS of SCORER									

Note: Code Status of Treatment as follows: N="No treatment", I="Initiation", M="Maintenance", W="Weaning", R=" Re-Escalation"

FIGURE 1

MOTHER Trial Modification of the Finnegan Score. (Reprinted with permission from Jones HE, Kaltenbach K, Heil SH, et al. Neonatal abstinence syndrome after methadone or buprenorphine exposure. *N Engl J Med.* 2010;363(24):2320–2331.)

there is increasing evidence that multiple factors may increase an opioid-exposed infant's risk of withdrawal (eg, gestational age, specific genotypes, cigarette use, benzodiazepine and gabapentin use), there remains insufficient evidence of how to use these exposures to tailor an infant's postnatal observation period. Institutions should consider observing infants exposed to immediate-release opioids for at least 3 days, infants exposed to buprenorphine and sustained-release opioids for 4 to 7 days, and infants exposed to methadone for 5 to 7 days. Notably, however, there remains limited evidence to inform observation periods, and excess observation could result in separation of the mother-infant dyad. Additional research is needed to inform appropriate hospital observation periods for infants with opioid exposure.

Setting

Traditionally, NOWS in the United States has been managed in the NICU[61]; however, many infants at risk for or with NOWS do not need NICU-level care. Depending on the physical design of the unit, care in a NICU may result in separation of the mother-infant dyad, which can further exacerbate infant clinical signs of withdrawal and can be traumatic for mothers during this vulnerable postpartum period. In addition, for infants going through withdrawal, the NICU environment, which can be loud and overly stimulating, may not be optimal. Recently, models of care have emerged that are focused on enabling the new mother to "room-in" with her newborn (in many cases, outside the NICU environment).[62] In a recent meta-analysis, it was found that rooming-in was associated with lower rates of pharmacotherapy for withdrawal (relative risk, 0.37; 95% CI, 0.19 to 0.71; I^2, 85%) and shorter lengths of hospital stay (weighted mean difference, –10.41 days; 95% CI, –16.84 to –3.98 days; I^2, 91%).[63] Keeping the mother-infant dyad together may promote bonding and facilitate breastfeeding, and rooming-in should be considered the preferred model, including in the NICU, for infants with opioid exposure. In addition, the environment and infant handling should be modified so that it is not overly stimulating, which can exacerbate clinical signs of withdrawal (eg, loud noises, bright lights). In addition, it is important that care clinicians (eg, nurses, nurse practitioners, physicians) cluster care interventions together temporally so as not to unnecessarily disturb the infant, which may also aggravate signs of withdrawal.

Nonpharmacologic Care

The literature to support specific nonpharmacologic approaches is sparse; however, evolving evidence suggests that effective nonpharmacologic care that engages the mother is an essential foundation to the care of an infant with opioid exposure. Nonpharmacologic care that is individualized should be applied beginning at birth for all infants with substance exposure and continued throughout hospitalization and beyond, regardless of the need for pharmacotherapeutic intervention. Engaging and coaching caregivers in nonpharmacologic care promotes bonding and may improve outcomes, beginning with education about the infant-specific signs of NOWS and helping the family to interpret what triggers the clinical signs the infant is experiencing and education about how to support his or her regulation. Clinical features of NOWS, such as irritability, uncontrolled movements, and fragmented sleep, can be challenging for the new mother. Providing support to the mother as she responds to these clinical features is important. Mothers frequently experience overwhelming feelings of guilt and anxiety in response to the dysregulated neurobehaviors associated with NOWS, and pediatricians are uniquely positioned to support mothers to manage their emotions while supporting the healing and development of their infants.[64] Nonpharmacologic care should also include a thorough assessment of the hospital environment and infant handling and adaptations by the infant to each to minimize NOWS expression.

Nonpharmacologic treatment may include a variety of supportive care approaches. As described by Velez and Jansson,[64] approaches to nonpharmacologic care should be tailored to the clinical behavioral and physiologic signs the infant is experiencing. Velez and Jansson[64] note 4 specific domains: (1) reactivity to sensory stimulation and regulatory issues, (2) behavioral states and state control, (3) motor and tone control, and (4) autonomic signs of stress. For example, an infant experiencing overreactivity to visual stimulation may benefit from a dimly lit environment, whereas an infant with hypertonia may benefit from swaddling (Fig 2).

Breastfeeding

Perhaps the most studied nonpharmacologic intervention is breastfeeding.[65] In general, breastfeeding is safe for mothers who take methadone or buprenorphine and may reduce clinical signs of NOWS and length of hospital stay; thus, in many settings, breastfeeding has become a critical foundation in care for the mother-infant dyad. Methadone and buprenorphine are excreted into human milk at low concentrations. The Academy of Breastfeeding Medicine has published consensus breastfeeding guidelines that suggest that breastfeeding should be encouraged if the mother has not had a relapse in >90 days but discouraged if there has been a relapse in the last 30 days.[66] Being HIV-positive is a contraindication to breastfeeding in high-income

countries, such as the United States, and HCV-positive mothers with bleeding or cracked nipples should also consider abstaining from breastfeeding.[67] Clinicians and patients should be cautious with sudden discontinuation of breastfeeding because some have reported signs of infant withdrawal.[68]

In a recent survey of women in treatment of OUD, it was found that although most mothers desire and attempt to establish breastfeeding, they encounter significant challenges (eg, long NICU stays, lack of support and education) that compromise their success. For these reasons, rates of breastfeeding initiation, exclusivity, and duration remain low among mothers with OUD. In addition, some mother-infant dyads may have difficulty with latching because of withdrawal and may require fortification of milk because of infant weight loss, which can lead to fewer breastfeeding attempts and lower sustainment of breastfeeding. Lastly, breastfeeding counseling and support should be trauma informed because mothers with OUD report high rates of trauma, including sexual trauma, which may influence their desire to breastfeed.[69–71]

PHARMACOTHERAPY

For infants with severe NOWS, use of a medication in addition to nonpharmacologic measures is necessary to improve clinical signs of withdrawal and minimize complications from withdrawal (eg, severe weight loss). Ideally, pharmacotherapy minimizes clinical signs of withdrawal, and then the infant is weaned off the medication using a standardized protocol to minimize total medication exposure.[72] Pharmacologic therapy should be considered for severe opioid withdrawal despite nonpharmacologic interventions. Vomiting and loose stools are associated with dehydration and poor weight gain and are relative indications for treatment. Naloxone should never be administered to an infant with NOWS because it will exacerbate the underlying withdrawal syndrome.

The literature supports the use of an opioid for opioid withdrawal as a first-line agent.[73] In the United States, the most common first-line therapy for NOWS is morphine.[61] In several recently published studies, it was found that longer-acting opioids may reduce length of stay when compared with morphine. Kraft et al[74] found that when compared with morphine, buprenorphine used for NOWS resulted in a shorter median duration of treatment (15 vs 18 days; $P < .001$) and length of hospital stay (21 vs 33 days; $P < .001$). Similarly, Davis et al[75] found that when compared with morphine, methadone resulted in a shorter duration of treatment (11.5 vs 15 days; $P = .009$) and length of stay (16 vs 20 days; $P = .005$). Importantly, both clinical trials occurred in the context of rigorous study protocols and included only women in treatment of OUD to test the efficacy of these medications; therefore, one limitation of these clinical trials may be generalizability to other populations (ie, infants of mothers not in treatment of OUD).

There is evidence to support the use of secondary medications for NOWS, either when initiating pharmacotherapy[76] or, more commonly, as an additional medication when clinical signs continue to escalate despite

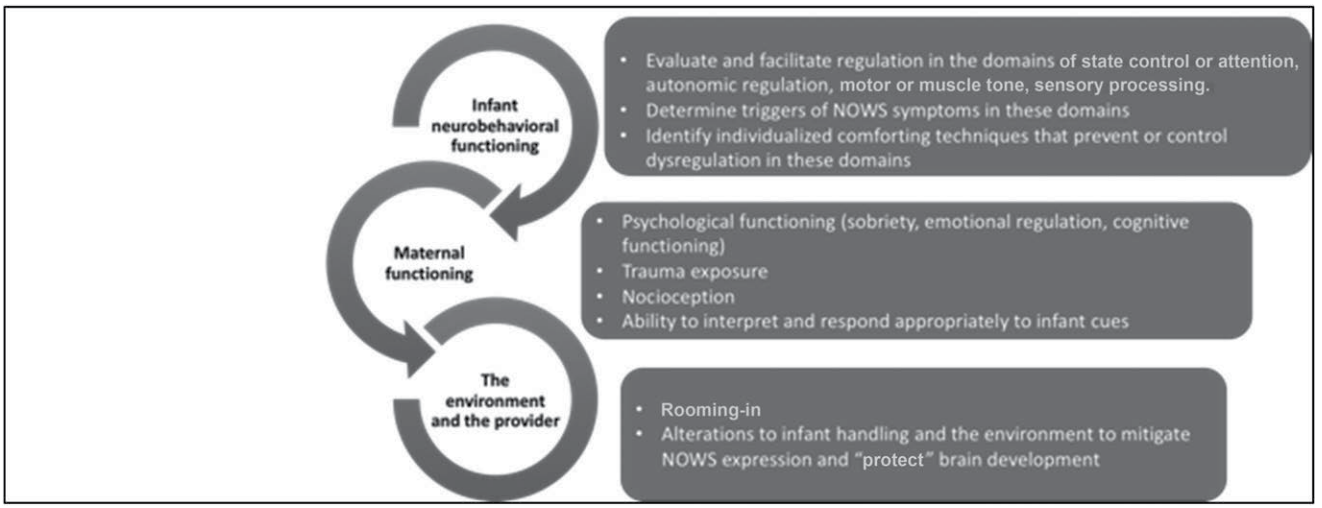


FIGURE 2
Nonpharmacologic approaches to NOWS. Adapted from Velez M, Jansson LM. The opioid dependent mother and newborn dyad: non-pharmacologic care. *J Addict Med.* 2008;2(3):113–120.

pharmacotherapy with an opioid. The most common medications used after initiation of an opioid for NOWS are clonidine and phenobarbital. The majority of practitioners use phenobarbital as a second drug if the opioid does not adequately control withdrawal signs.[77,78] In recent years, clonidine has increased in the United States as a therapy for NOWS.[61] Clonidine is an α-2-adrenergic receptor agonist that has been used in combination with an opioid or other drug in older children and adults to reduce withdrawal symptoms.[79,80] There is not sufficient evidence to suggest greater efficacy of clonidine over phenobarbital; however, phenobarbital has been shown to have neurotoxicity in animal studies,[81,82] and its use has been associated with adverse developmental outcomes.[83] Therefore, clinicians should consider use of clonidine as a second-line agent over phenobarbital, and additional study is needed to test the effects of both agents on infants' long-term development.

Clinicians should be mindful that some drug preparations may include a high alcohol content (eg, buprenorphine), and choosing preparations of low alcohol content is preferred. In addition, consistent with previous AAP statements, camphorated tincture of opium (paregoric) and/or deodorized tincture of opioid (laudanum) should not be used for NOWS.

PREPARING FOR DISCHARGE

It is important to plan effectively for a safe transition from the hospital to home after birth for the mother-infant dyad. Families of infants with opioid exposure are disproportionately impoverished,[28] may face multiple economic and social challenges,[12,25,84] and are frequently involved in the child welfare system. Adequate preparation for hospital discharge cannot be the pediatrician's responsibility alone; it requires hospital supports (eg, social work) to appropriately assess and assist families in this critical transition.

The immediate postnatal period is a time of high risk for mothers with OUD, especially if they lose access to medications for OUD. Recent data suggest that loss of access to medications for OUD after delivery is associated with overdose death.[85] In addition, a key support to give mothers the best chance of remission of OUD and improved dyadic relational health is partnering with mental health clinicians to provide comprehensive treatment. For example, maternal screening for treatable problems, such as traumatic stress and depression, could be addressed by referral to evidence-based, dyadic-focused interventions, such as child-parent psychotherapy.[86]

Infants with opioid exposure are also at risk for adverse outcomes, including hospital readmission.[87,88] Women may have to manage their own medical follow-up needs (eg, obstetrics, addiction medicine), their infant's medical follow-up needs (eg, general pediatrician, pediatric infectious disease, lactation support), and additional services (eg, the Special Supplemental Nutrition Program for Women, Infants, and Children, early intervention, child welfare). The task of coordinating these multiple stakeholders, combined with the risk of adverse postdischarge outcomes (such as readmission),[88] makes formalizing the discharge process for infants with opioid exposure critical. Use of simplified electronic or print checklists can be helpful in improving discharge processes (Table 4).[89] When possible, postdischarge care for the mother-infant dyad should be coordinated and comprehensive. Lastly, hospitals should ensure adequate handoffs and information transfer to postdischarge care providers, including, pediatricians, early intervention providers, and home-nurse visitation programs.

Discharge Education

In addition to routine newborn education, emphasis should be placed on the needs of the opioid-exposed dyad. Ideally, the infant caregiver has been engaged in care during the pregnancy and is familiar with common clinical signs and scoring processes. The caregiver should know when and how to seek help if signs of infant withdrawal become unmanageable or if additional challenges present (eg, maternal depression, relapse). Infants with substance exposure are at an increased risk of sleep-related deaths[90]; therefore, additional emphasis on safe sleep and safe sleep environments is recommended. Similar to all infant discharges, parents of infants with opioid exposure should be provided education on how to deal with challenging infant behaviors (eg, subacute withdrawal signs) that may increase the risk of nonaccidental trauma.

Medical Follow-up

Infants should be observed for 24 to 48 hours after finishing any medication taper. Ideally, an infant with opioid exposure would be seen by his or her pediatrician within 48 hours of discharge from the hospital to monitor for adequate weight gain and to monitor for any continued signs of withdrawal. The frequency of pediatrician visits may need to be higher than that for uncomplicated term infants. Although there are no data to inform the most optimal pediatrician visit schedule for infants with opioid exposure, the infant should be seen within 48 hours of discharge, with a 1-week follow-up. Additional visits should be tailored to the needs of the dyad. Ideally, breastfed infants should also have outpatient lactation support

TABLE 4 Discharge Checklist for Infants With Opioid Exposure

Completed (Check Yes)
Task
No significant clinical signs of withdrawal for 24–48 h
Parent education about NOWS and routine newborn care, emphasizing safe sleep
Pediatrician or primary care provider follow-up visit scheduled within 48 h of discharge
Early intervention services referral
Home-nurse visitation referral
Hepatitis C testing follow-up, including referral to pediatric infectious disease when appropriate
Plan of safe care, coordinating with child welfare as appropriate
Developmental-behavioral pediatrician referral as appropriate

and be assessed in the first 48 hours of life.

Outpatient Pharmacotherapy

With increasing focus on reducing length of hospital stay for infants with NOWS, many institutions began discharging infants from the hospital on medications. Among infants treated in the nearly 200 centers participating in the Vermont Oxford Network collaboration focused on improving care for NOWS, >25% were discharged from the hospital on medications at the end of the 2-year collaborative.[60] Consistently, the literature suggests that discharging infants from the hospital on pharmacotherapy reduces length of hospital stay[91–94]; however, comparative outcomes, in particular duration of total treatment and development outcomes, are scant. In a recent study, of nearly 1000 infants with NOWS enrolled in the Tennessee Medicaid program, infants discharged from the hospital on medications had a shorter median length of hospital stay (11 vs 23 days; $P < .001$) but longer median lengths of treatment (60 vs 19 days; $P < .001$).[87] Given the lack of long-term follow-up data, clinicians should avoid outpatient tapers when possible. If outpatient tapers are used, a structured weaning plan with comprehensive follow-up should be implemented to minimize total medication time.

Hepatitis C

HCV screening among pregnant women is not universal in the United States, potentially missing a window of opportunity to identify HCV in the mother-infant dyad. Even without universal screening, data suggest that as the opioid crisis grew, rates of HCV infection among pregnant women increased.[95] From 2009 to 2014, the rate of HCV infection among US pregnant women doubled to 3.4 per 1000 live births and as high as 1 in 50 births in West Virginia.[96] Given this rising risk to maternal and infant health, hospitals should consider universally screening pregnant women for HCV and creating processes to connect the dyad to treatment postnatally.

Because vertical transmission occurs in 6% of infants exposed to HCV (11% if HIV coinfection), infants must be tested after discharge to determine if they seroconvert. Maternal antibodies can persist for 18 months; thus, antibody testing must occur after 18 months; however, RNA polymerase chain reaction testing may occur earlier. Data suggest, however, that only a minority of exposed infants are tested.[97,98] Because infants with opioid exposure are at risk for HCV exposure, it is imperative that (1) all infants with opioid exposure are evaluated for HCV exposure and (2) all infants with HCV exposure are adequately managed to determine if they acquire the virus. All infants HCV exposure should be evaluated and should be tested for seroconversion by using RNA polymerase chain reaction or antibody testing.

Postdischarge Services

Infants with opioid exposure, regardless of the need for pharmacotherapy for NOWS, are at increased risk for developmental alterations.[99] In addition to developmental, behavioral, and mental health[100] screenings by the primary care pediatrician, all infants with substance exposure should be referred to early intervention services, and developmental screenings in a NICU developmental assessment clinic or equivalent should be considered. Early intervention services are available in all areas of the United States as part C of the Individuals with Disabilities Education Act. Strong consideration should also be given to referral to home-nurse visitation programs (eg, the Maternal, Infant, and Early Childhood Home Visiting Program) as a resource to families.

Early Head Start programs are similar to Head Start but are targeted to pregnant women and infants until age 3 years. These programs support parental and infant development and can further enable family success, promoting housing and financial stability. Pediatricians should consider referrals to Early Head Start programs for opioid-exposed infants. Early Head Start programs can be identified by using the Center Locator (https://eclkc.ohs.acf.hhs.gov/center-locator).

In addition, the AAP has several resources to aid pediatricians in connecting children to developmental resources that are free and available online, including the National Center on Early Childhood Health and Wellness (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/NCECHW/Pages/National-Center-on-Early-Childhood-Health-and-Wellness.aspx) and publications such as *Caring for Our Children* (https://nrckids.org/CFOC/). Similar resources, such as HealthySteps (https://www.healthysteps.org/),

may also serve pediatricians in developing models of care to meet the needs of infants with opioid exposure.

The Child Welfare System and Plans of Safe Care

The opioid crisis resulted in greater demands on the US child welfare system.[12,13] Although evidence suggests that keeping the family intact improves outcomes for parents and infants, child safety must still be paramount.[12] A report to child protective services should be considered when the mother has not received or been adherent to treatment of OUD, when there is concern or evidence of polysubstance use during pregnancy, or when there is a concern for infant safety. In cases in which a child cannot be safely cared for by his or her parents, appropriately trained kinship or foster care placement may be necessary. Referral to child protective services is not a substitute for referral to treatment of the pregnant or parenting woman.

Recently, there have been numerous changes to the child welfare system to provide parental supports and connection to treatment. In 2016, the Comprehensive Addiction and Recovery Act amended the Child Abuse Prevention and Treatment Act to ensure that "plans of safe care" are created for infants "being affected by substance abuse or withdrawal symptoms, or a fetal alcohol spectrum disorder." Importantly, these plans should address the "health and substance use disorder treatment needs of the infant and affected family or caregiver."[101] Ideally, plans of safe care are well coordinated within state child welfare agencies, and planning begins before birth. States may interpret and implement legislation related to plans of safe care differently; therefore, it is important for pediatricians to be aware of their local requirements. The creation of plans of safe care are actively being developed, and there is evidence that many states are struggling with implementation.[13] Pediatricians should consider involvement in the development of plans of safe care in their communities. Because of their expansive nature of supporting the mother-infant dyad, some states have elected to call their plans of safe care "plans of supportive care." Such partnerships between pediatricians and child welfare professionals can help fill education gaps, foster positive partnerships, and promote understanding, with the ultimate goal of improving outcomes for the mother-infant dyad.[102]

Public Health Considerations

NOWS reflects the downstream implications of a complex public health crisis. To prevent NOWS, pregnant women, women and men of reproductive age, and the communities they live in need effective access to prevention, treatment, and services (eg, access to comprehensive treatment of substance use disorder, access to highly effective contraception) (Fig 3).[103,104] As public health and surveillance efforts continue to evolve, involvement of pediatricians at the local, state, and national level will continue to be important to ensure that the unique needs of children are addressed.

A federal prevention strategy outlined in the 2015 Protecting our Infants Act[105] provides several mandates for the US Department of Health and Human Services (HHS) to address problems related to prenatal opioid exposure. The strategy requires HHS agencies to plan, review, and coordinate activities related to prenatal opioid exposure and NOWS to (1) develop recommendations for prevention; (2) treat OUD in pregnant women and infants with NOWS; (3) identify pregnant women and infants in need of services to treat OUD in pregnancy and NOWS, including any long-term consequences; and (4) develop a coordinated strategy to address gaps in research. In fall 2018, the HHS held a summit to improve coordination of national surveillance, research, and prevention efforts.[106]

Currently, there is considerable variation in reporting of NOWS by state or jurisdiction. Improvement in reporting of NOWS to public health officials can help to identify communities in critical need of intervention. Currently, only a handful of states have mandatory reporting of NOWS,[107] and states vary in case definitions for state reporting. In a study of 6 states with case reporting for NOWS during 2013–2017, considerable variability was found in how states defined and used surveillance.[107] Nevertheless, for states and other jurisdictions to improve reporting, a consistent definition is needed. In an attempt to provide a more universal definition for public health surveillance, the Council on State and Territorial Epidemiologists, in collaboration with the Centers for Disease Control and Prevention, met with state health officials to improve reporting in all states on the basis of maternal opioid use reported in prenatal and delivery records as well as newborn hospitalization records.[108] With more consistent reporting, states may be able to better and more rapidly identify needs among and between localities.

State and regional collaborations are developing strategies to improve access to maternal medications for OUD, improve the quality of care for newborn infants with NOWS, and reduce hospital length of stay and associated costs. Ohio's Perinatal Quality Collaborative initiated a statewide approach to the care of infants with NOWS that included standardized assessment and treatment, including both pharmacologic and nonpharmacologic interventions.

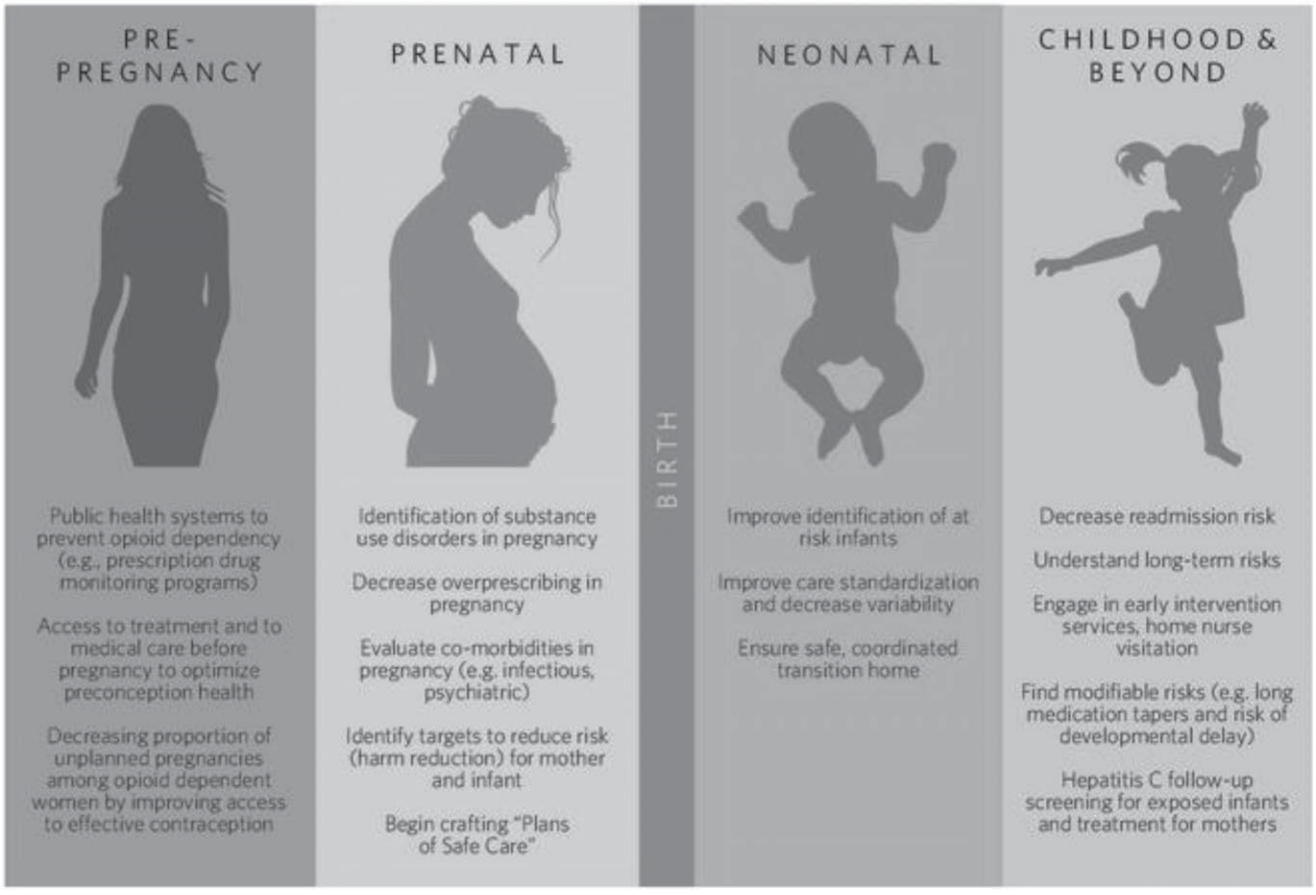


FIGURE 3
Public health approaches to opioid use in pregnancy and in infants with opioid exposure. (Reprinted with permission from Patrick SW. Improving public health systems for substance-affected pregnancies. *Am J Public Health.* 2019;109(1):22–23.)

Among 52 of the state's 54 neonatal care facilities, standardized pharmacologic treatment and increased use of nonpharmacologic treatment reduced both the length of treatment and the length of hospital stay from 13.4 to 12 days and from 18.3 to 17 days, respectively.[109] Among a multistate, multicenter quality improvement collaborative, participating hospitals were able to reduce the median length of pharmacologic treatment from 16 to 15 days and the infant length of hospital stay from 21 to 19 days through a standardized scoring process for NOWS. Albeit noteworthy, these reductions in length of stay and costs are modest. Additional quality improvement approaches and measures are needed to improve care to the mother-infant dyad.

CONCLUSIONS

The opioid crisis has had a profound effect on pregnant women and their infants. Despite improvements in the identification, assessment, and treatment of NOWS, substantial knowledge gaps remain. Pediatricians are well positioned to improve outcomes for the mother-infant dyad through evidence-based practice and connection of families to public resources.

RECOMMENDATIONS

NOWS is a major consequence of the opioid crisis, with dramatic increases over the last decade. Pediatric care clinicians can help reduce newborn morbidity, hospitalization, and costs and help improve maternal screening, referral, and follow-up for the mother-infant dyad. We present the following recommendations for care.

Access to Treatment

1. All pregnant women should have access to medications for OUD because they have been shown to reduce risk of overdose death and improve pregnancy outcomes.
2. Pediatricians should partner with state and local child welfare agencies to advocate for funding to improve access to quality treatment of OUD.

Antenatal Counseling and Screening

1. Pregnant women with OUD should receive antenatal counseling to provide education on the clinical signs of withdrawal and enhance maternal understanding of postnatal treatment (eg,

nonpharmacologic treatment, including breastfeeding and pharmacotherapy). When possible, maternal antenatal counseling should be provided by a pediatric provider.

2. Multiple modalities of testing should be considered for the infant, including, infant urine, meconium, and umbilical cord tissue testing.
3. For women in treatment of OUD who receive frequent toxicology testing, infant meconium and/or umbilical cord tissue testing may not be necessary.
4. For many substances, urine toxicology only captures a short window of substance use for some systems.
5. Pediatricians should assess additional social risks, including, but not limited to, food and housing insecurity, and connect to community resources.

Observation

1. All infants with chronic opioid exposure should be observed for at least 72 hours to monitor for the development of withdrawal. Although there is increasing evidence that multiple factors may increase an opioid-exposed infant's risk of withdrawal (eg, gestational age, specific genotypes, tobacco use, benzodiazepine, and gabapentin), there remains insufficient evidence of how to use these exposures to tailor an infant's postnatal observation period. Institutions may use the following approach for observation of infants with opioid exposure:
2. immediate-release opioids: 3 days;
3. buprenorphine and sustained-release opioids: 4 to 7 days; and
4. methadone: 5 to 7 days.

Diagnosis

1. For all infants at risk for NOWS, a standardized assessment approach by using a commonly used tool (eg, modified Finnegan score) should be employed to measure the presence and severity of withdrawal symptoms as well as the response to treatment (Fig 1).
2. Comorbidities should also be considered, including infectious and neurologic conditions. If no clear in utero exposure is identified through maternal history, screening, or testing, NOWS is a diagnosis that should be used only if other potential causes of an infant's symptoms have been evaluated fully and no other cause has been identified.

Treatment

1. Hospitals should prioritize keeping the mother-infant dyad intact throughout observation and treatment of an infant with opioid exposure. Rooming-in is the preferred model of care.
2. Hospitals should have a written protocol for the nonpharmacologic and pharmacologic treatment of an infant with opioid exposure.
3. Admission to a NICU only for opioid exposure or NOWS is not required.
4. All hospitals should have a written protocol for initiating nonpharmacologic and pharmacologic treatment of an infant with opioid exposure.
5. Nonpharmacologic interventions should be used for all infants with opioid exposure and should be considered the foundation of care.
6. Nonpharmacologic treatment should be tailored to the clinical signs of the infant.
7. All hospitals should have a protocol for breastfeeding an infant with substance exposure.
8. For infants of mothers in treatment of OUD with buprenorphine or methadone who have not had relapse for $\geq$90 days, breastfeeding should be supported if there are no other contraindications.
9. For infants of women with active substance use or with relapses within the last 30 days, breastfeeding should be discouraged.
10. For infants of women in treatment between 30 and 90 days without relapse, breastfeeding should be considered.
11. HIV is a contraindication to breastfeeding in high-income countries, such as the United States. HCV-positive mothers with cracked or bleeding nipples should consider abstaining from breastfeeding.
12. Lactation support should be provided in the inpatient setting and after discharge.
13. Pharmacologic therapy should be considered for severe opioid withdrawal (eg, MOTHER score $>8 \times 2$ or $>12 \times 1$) in addition to nonpharmacologic interventions. Vomiting and loose stools are associated with dehydration and poor weight gain and are relative indications for treatment.
14. Opioids should be used as a first-line therapy for severe NOWS.
15. Infants who require pharmacologic treatment should be monitored (eg, pulse oximetry).
16. Recent data suggest that opioids with a longer half-life, such as buprenorphine and methadone, may reduce length of treatment. However, caution should be considered if the preparation has a high alcohol content.
17. Paregoric and deodorized tincture of opium should not be used.
18. If a second agent is needed for severe opioid withdrawal, the use of clonidine should be considered over phenobarbital.

19. Naloxone should never be used in the treatment of an infant with chronic opioid exposure because it may precipitate rapid withdrawal and seizure.

Discharge

1. Discharge of infants from the hospital on pharmacotherapy should be avoided and should only occur if there is a structured, close outpatient follow-up plan for the mother-infant dyad.
2. A discharge checklist should be completed (Table 3):
3. no significant clinical signs of withdrawal for 24 to 48 hours after treatment;
4. parent education about NOWS and routine newborn care, emphasizing safe sleep;
5. pediatrician or primary care provider follow-up visit with 48 hours of discharge;
6. early intervention services referral;
7. consideration of home-nurse visitation and Early Head Start;
8. hepatitis C and HIV testing referral, including referral to pediatric infectious disease when appropriate;
9. plan of safe care, coordinating with child welfare;
10. developmental-behavioral pediatrician referral, as appropriate; and
11. consideration of behavioral and/or mental health system referrals to address dyadic relational health.

LEAD AUTHORS

Stephen W. Patrick, MD, MPH, MS, FAAP
Wanda D. Barfield, MD, MPH, FAAP
Brenda B. Poindexter, MD, MS, FAAP

COMMITTEE ON FETUS AND NEWBORN, 2019–2020

James Cummings, MD, FAAP, Chairperson
Ivan Hand, MD, FAAP
Ira Adams-Chapman, MD, MPH, FAAP
Susan W. Aucott, MD, FAAP
Karen M. Puopolo, MD, FAAP
Jay P. Goldsmith, MD, FAAP
David Kaufman, MD, FAAP
Camilia Martin, MD, FAAP
Meredith Mowitz, MD, FAAP

LIAISONS

Timothy Jancelewicz, MD, FAAP – *American Academy of Pediatrics Section on Surgery*
Michael Narvey, MD – *Canadian Paediatric Society*
Russell Miller, MD – *American College of Obstetricians and Gynecologists*
RADM Wanda Barfield, MD, MPH, FAAP – *Centers for Disease Control and Prevention*
Lisa Grisham, APRN, NNP-BC – *National Association of Neonatal Nurses*

STAFF

Jim Couto, MA

COMMITTEE ON SUBSTANCE USE AND PREVENTION, 2019–2020

Lucien Gonzalez, MD, MS, FAAP, Chairperson
Deepa R. Camenga, MD, MHS, FAAP
Stephen W. Patrick, MD, MPH, MS, FAAP
Joanna Quigley, MD, FAAP
Sheryl A. Ryan, MD, FAAP
Leslie Walker-Harding, MD, FAAP

LIAISON

Rebecca Ba'Gah, MD – *American Academy of Child and Adolescent Psychiatry*

STAFF

Renee Jarrett, MPH

ABBREVIATIONS

AAP: American Academy of Pediatrics
ACOG: American College of Obstetricians and Gynecologists
CI: confidence interval
ESC: Eat, Sleep, Console
HCV: hepatitis C virus
HHS: US Department of Health and Human Services
MOTHER: Maternal Opioid Treatment: Human Experimental Research
NOWS: neonatal opioid withdrawal syndrome
OUD: opioid use disorder

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. *MMWR Morb Mortal Wkly Rep.* 2011;60(43):1487–1492
2. Guy GP Jr., Zhang K, Bohm MK, et al. Vital signs: changes in opioid prescribing in the United States, 2006–2015. *MMWR Morb Mortal Wkly Rep.* 2017;66(26):697–704
3. Han B, Compton WM, Blanco C, Crane E, Lee J, Jones CM. Prescription opioid use, misuse, and use disorders in US adults: 2015 National Survey on Drug Use and Health. *Ann Intern Med.* 2017;167(5):293–301

4. Rudd RA, Seth P, David F, Scholl L. Increases in drug and opioid-involved overdose deaths - United States, 2010–2015. *MMWR Morb Mortal Wkly Rep*. 2016;65(50–51):1445–1452
5. Hedegaard H, Miniño AM, Warner M. Drug overdose deaths in the United States, 1999–2017. *NCHS Data Brief*. 2018;(329):1–8
6. Desai RJ, Hernandez-Diaz S, Bateman BT, Huybrechts KF. Increase in prescription opioid use during pregnancy among Medicaid-enrolled women. *Obstet Gynecol*. 2014;123(5): 997–1002
7. Haight SC, Ko JY, Tong VT, Bohm MK, Callaghan WM. Opioid use disorder documented at delivery hospitalization - United States, 1999–2014. *MMWR Morb Mortal Wkly Rep*. 2018;67(31): 845–849
8. Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. Neonatal abstinence syndrome and associated health care expenditures: United States, 2000–2009. *JAMA*. 2012;307(18): 1934–1940
9. Villapiano NLG, Winkelman TNA, Kozhimannil KB, Davis MM, Patrick SW. Rural and urban differences in neonatal abstinence syndrome and maternal opioid use, 2004 to 2013. *JAMA Pediatr*. 2017;171(2):194–196
10. US Food and Drug Administration. Neonatal opioid withdrawal syndrome and medication-assisted treatment with methadone and buprenorphine. 2016. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm503630.htm. Accessed January 21, 2020
11. Hudak ML, Tan RC; Committee on Drugs; Committee on Fetus and Newborn; American Academy of Pediatrics. Neonatal drug withdrawal. *Pediatrics*. 2012;129(2). Available at: www.pediatrics.org/cgi/content/full/129/2/e540
12. Waite D, Greiner MV, Laris Z; American Academy of Pediatrics Council on Foster Care, Adoption, and Kinship Care. Putting families first: how the opioid epidemic is affecting children and families, and the child welfare policy options to address it. *J Appl Res Child*. 2018;9(1):4
13. Patrick SW, Frank RG, McNeer E, Stein BD. Improving the child welfare system to respond to the needs of substance-exposed infants. *Hosp Pediatr*. 2019; 9(8):651–654
14. Patrick SW, Schiff DM; Committee on Substance Use and Prevention. A public health response to opioid use in pregnancy. *Pediatrics*. 2017;139(3): e20164070
15. American Academy of Pediatrics, Committee on Native American Child Health. Recommendations to the Indian Health Service on Neonatal Opioid Withdrawal Syndrome. Available at: https://www.ihs.gov/sites/opioids/themes/responsive2017/display_objects/documents/aapnowsrecommendationstoihs.pdf. Accessed September 28, 2020
16. National Institute on Drug Abuse. The science of drug use and addiction: the basics. Available at: https://www.drugabuse.gov/publications/media-guide/science-drug-use-addiction-basics. Accessed June 21, 2019
17. National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on Medication-Assisted Treatment for Opioid Use Disorder. In: Mancher M, Leshner AI, eds. *Medications for Opioid Use Disorder Save Lives*. Washington, DC: National Academies Press; 2019
18. Patrick SW, Buntin MB, Martin PR, et al. Barriers to accessing treatment for pregnant women with opioid use disorder in Appalachian states. *Subst Abus*. 2019;40(3):356–362
19. Patrick SW, Richards MR, Dupont WD, et al. Association of Pregnancy and Insurance Status With Treatment Access for Opioid Use Disorder. *JAMA network open*. 2020;3(8):e2013456
20. Martin CE, Longinaker N, Terplan M. Recent trends in treatment admissions for prescription opioid abuse during pregnancy. *J Subst Abuse Treat*. 2015; 48(1):37–42
21. Kozhimannil KB, Graves AJ, Levy R, Patrick SW. Nonmedical use of prescription opioids among pregnant U.S. women. *Womens Health Issues*. 2017;27(3):308–315
22. Patrick SW, Dudley J, Martin PR, et al. Prescription opioid epidemic and infant outcomes. *Pediatrics*. 2015;135(5): 842–850
23. Huybrechts KF, Bateman BT, Desai RJ, et al. Risk of neonatal drug withdrawal after intrauterine co-exposure to opioids and psychotropic medications: cohort study. *BMJ*. 2017;358:j3326
24. Popova S, Lange S, Shield K, et al. Comorbidity of fetal alcohol spectrum disorder: a systematic review and meta-analysis. *Lancet*. 2016;387(10022): 978–987
25. Patrick SW, Faherty LJ, Dick AW, Scott TA, Dudley J, Stein BD. Association among county-level economic factors, clinician supply, metropolitan or rural location, and neonatal abstinence syndrome. *JAMA*. 2019;321(4):385–393
26. Beck AF, Edwards EM, Horbar JD, Howell EA, McCormick MC, Pursley DM. The color of health: how racism, segregation, and inequality affect the health and well-being of preterm infants and their families. *Pediatr Res*. 2020;87(2):227–234
27. Ackerman JP, Riggins T, Black MM. A review of the effects of prenatal cocaine exposure among school-aged children. *Pediatrics*. 2010;125(3): 554–565
28. Patrick SW, Davis MM, Lehmann CU, Cooper WO. Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012. [published correction appears in *J Perinatol*. 2015;35(8):667]. *J Perinatol*. 2015;35(8):650–655
29. Winkelman TNA, Villapiano N, Kozhimannil KB, Davis MM, Patrick SW. Incidence and costs of neonatal abstinence syndrome among infants with Medicaid: 2004–2014. *Pediatrics*. 2018;141(4):e20173520
30. Leech AA, Cooper WO, McNeer E, Scott TA, Patrick SW. Neonatal abstinence syndrome in the United States, 2004–16. *Health Aff (Millwood)*. 2020;39(5): 764–767
31. Ko JY, Patrick SW, Tong VT, Patel R, Lind JN, Barfield WD. Incidence of neonatal abstinence syndrome - 28 states, 1999–2013. *MMWR Morb Mortal Wkly Rep*. 2016;65(31):799–802

32. Strahan AE, Guy GP Jr., Bohm M, Frey M, Ko JY. Neonatal abstinence syndrome incidence and health care costs in the United States, 2016. *JAMA Pediatr*. 2019; 174(2):200–202

33. Sanlorenzo LA, Cooper WO, Dudley JA, Stratton S, Maalouf FI, Patrick SW. Increased severity of neonatal abstinence syndrome associated with concomitant antenatal opioid and benzodiazepine exposure. *Hosp Pediatr*. 2019;9(8):569–575

34. Cleary BJ, Donnelly J, Strawbridge J, et al. Methadone dose and neonatal abstinence syndrome-systematic review and meta-analysis. *Addiction*. 2010; 105(12):2071–2084

35. Cleary BJ, Reynolds K, Eogan M, et al. Methadone dosing and prescribed medication use in a prospective cohort of opioid-dependent pregnant women. *Addiction*. 2013;108(4):762–770

36. Jones HE, Dengler E, Garrison A, et al. Neonatal outcomes and their relationship to maternal buprenorphine dose during pregnancy. *Drug Alcohol Depend*. 2014;134:414–417

37. Desmond MM, Wilson GS. Neonatal abstinence syndrome: recognition and diagnosis. *Addict Dis*. 1975;2(1–2): 113–121

38. Committee on Obstetric Practice. Committee opinion No. 711: opioid use and opioid use disorder in pregnancy. *Obstet Gynecol*. 2017;130(2):e81–e94

39. Levy SJL, Williams JF; Committee on Substance Use and Prevention. Substance use screening, brief intervention, and referral to treatment. *Pediatrics*. 2016;138(1):e20161211

40. Peirce GL, Smith MJ, Abate MA, Halverson J. Doctor and pharmacy shopping for controlled substances. *Med Care*. 2012;50(6):494–500

41. Wexelblatt SL, Ward LP, Torok K, Tisdale E, Meinzen-Derr JK, Greenberg JM. Universal maternal drug testing in a high-prevalence region of prescription opiate abuse. *J Pediatr*. 2015;166(3):582–586

42. Chasnoff IJ, Landress HJ, Barrett ME. The prevalence of illicit-drug or alcohol use during pregnancy and discrepancies in mandatory reporting in Pinellas County, Florida. *N Engl J Med*. 1990;322(17):1202–1206

43. Roberts SCM, Nuru-Jeter A. Universal screening for alcohol and drug use and racial disparities in child protective services reporting. *J Behav Health Serv Res*. 2012;39(1):3–16

44. Beauman SS. Identification and management of neonatal abstinence syndrome. *J Infus Nurs*. 2005;28(3): 159–167

45. Chan D, Klein J, Koren G. New methods for neonatal drug screening. *NeoReviews*. 2003;4(9):e236–e244

46. Chasnoff IJ. Prenatal substance exposure: maternal screening and neonatal identification and management. *NeoReviews*. 2003;4(9): e228–e235

47. Concheiro M, Lendoiro E, de Castro A, et al. Bioanalysis for cocaine, opiates, methadone, and amphetamines exposure detection during pregnancy. *Drug Test Anal*. 2017;9(6):898–904

48. Gray T, Huestis M. Bioanalytical procedures for monitoring in utero drug exposure. *Anal Bioanal Chem*. 2007;388(7):1455–1465

49. Wabuyele SL, Colby JM, McMillin GA. Detection of drug-exposed newborns. *Ther Drug Monit*. 2018;40(2):166–185

50. Labardee RM, Swartzwelder JR, Gebhardt KE, et al. Method performance and clinical workflow outcomes associated with meconium and umbilical cord toxicology testing. *Clin Biochem*. 2017;50(18):1093–1097

51. Montgomery D, Plate C, Alder SC, Jones M, Jones J, Christensen RD. Testing for fetal exposure to illicit drugs using umbilical cord tissue vs meconium. *J Perinatol*. 2006;26(1):11–14

52. Montgomery DP, Plate CA, Jones M, et al. Using umbilical cord tissue to detect fetal exposure to illicit drugs: a multicentered study in Utah and New Jersey. *J Perinatol*. 2008;28(11):750–753

53. Palmer KL, Wood KE, Krasowski MD. Evaluating a switch from meconium to umbilical cord tissue for newborn drug testing: a retrospective study at an academic medical center. *Clin Biochem*. 2017;50(6):255–261

54. Colby JM, Adams BC, Morad A, Presley LD, Patrick SW. Umbilical cord tissue and meconium may not be equivalent for confirming in utero substance exposure. *J Pediatr*. 2019;205:277–280

55. Finnegan LP, Connaughton JF Jr., Kron RE, Emich JP. Neonatal abstinence syndrome: assessment and management. *Addict Dis*. 1975;2(1–2): 141–158

56. Lipsitz PJ. A proposed narcotic withdrawal score for use with newborn infants. A pragmatic evaluation of its efficacy. *Clin Pediatr (Phila)*. 1975;14(6): 592–594

57. Finnegan LP, Kron RE, Connaughton JF, Emich JP. Assessment and treatment of abstinence in the infant of the drug-dependent mother. *Int J Clin Pharmacol Biopharm*. 1975;12(1–2):19–32

58. Jones HE, Kaltenbach K, Heil SH, et al. Neonatal abstinence syndrome after methadone or buprenorphine exposure. *The New England Journal of Medicine*. 2010;363(24):2320–2331

59. Grossman MR, Lipshaw MJ, Osborn RR, Berkwitt AK. A novel approach to assessing infants with neonatal abstinence syndrome. *Hosp Pediatr*. 2018;8(1):1–6

60. Patrick SW, Schumacher RE, Horbar JD, et al. Improving care for neonatal abstinence syndrome. *Pediatrics*. 2016; 137(5):e20153835

61. Tolia VN, Patrick SW, Bennett MM, et al. Increasing incidence of the neonatal abstinence syndrome in U.S. neonatal ICUs. *N Engl J Med*. 2015;372(22): 2118–2126

62. Holmes AV, Atwood EC, Whalen B, et al. Rooming-in to treat neonatal abstinence syndrome: improved family-centered care at lower cost. *Pediatrics*. 2016;137(6):e20152929

63. MacMillan KDL, Rendon CP, Verma K, Riblet N, Washer DB, Volpe Holmes A. Association of rooming-in with outcomes for neonatal abstinence syndrome: a systematic review and meta-analysis. *JAMA Pediatr*. 2018; 172(4):345–351

64. Velez M, Jansson LM. The opioid dependent mother and newborn dyad: non-pharmacologic care. *J Addict Med*. 2008;2(3):113–120

65. Wachman EM, Schiff DM, Silverstein M. Neonatal abstinence syndrome:

advances in diagnosis and treatment. *JAMA*. 2018;319(13):1362–1374

66. Jansson LM; Academy of Breastfeeding Medicine Protocol Committee. ABM clinical protocol #21: guidelines for breastfeeding and the drug-dependent woman. *Breastfeed Med*. 2009;4(4): 225–228

67. American Academy of Pediatrics. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*, 31st ed. Itasca, IL: American Academy of Pediatrics; 2018

68. Isemann B, Meinzen-Derr J, Akinbi H. Maternal and neonatal factors impacting response to methadone therapy in infants treated for neonatal abstinence syndrome. *J Perinatol*. 2011; 31(1):25–29

69. Hicks J, Morse E, Wyant DK. Barriers and facilitators of breastfeeding reported by postpartum women in methadone maintenance therapy. *Breastfeed Med*. 2018;13(4):259–265

70. Yonke N, Maston R, Weitzen S, Leeman L. Breastfeeding intention compared with breastfeeding postpartum among women receiving medication-assisted treatment. *J Hum Lact*. 2019;35(1):71–79

71. Meyer MC, Johnston AM, Crocker AM, Heil SH. Methadone and buprenorphine for opioid dependence during pregnancy: a retrospective cohort study. *J Addict Med*. 2015;9(2):81–86

72. Hall ES, Wexelblatt SL, Crowley M, et al.; OCHNAS Consortium. A multicenter cohort study of treatments and hospital outcomes in neonatal abstinence syndrome. *Pediatrics*. 2014;134(2). Available at: www.pediatrics.org/cgi/content/full/134/2/e527

73. Osborn DA, Jeffery HE, Cole MJ. Opiate treatment for opiate withdrawal in newborn infants. *Cochrane Database Syst Rev*. 2010;(10):CD002059

74. Kraft WK, Adeniyi-Jones SC, Chervoneva I, et al. Buprenorphine for the treatment of the neonatal abstinence syndrome. *N Engl J Med*. 2017;376(24): 2341–2348

75. Davis JM, Shenberger J, Terrin N, et al. Comparison of safety and efficacy of methadone vs morphine for treatment of neonatal abstinence syndrome: a randomized clinical trial. *JAMA Pediatr*. 2018;172(8):741–748

76. Agthe AG, Kim GR, Mathias KB, et al. Clonidine as an adjunct therapy to opioids for neonatal abstinence syndrome: a randomized, controlled trial. *Pediatrics*. 2009;123(5). Available at: www.pediatrics.org/cgi/content/full/123/5/e849

77. Sarkar S, Donn SM. Management of neonatal abstinence syndrome in neonatal intensive care units: a national survey. *J Perinatol*. 2006; 26(1):15–17

78. O'Grady MJ, Hopewell J, White MJ. Management of neonatal abstinence syndrome: a national survey and review of practice. *Arch Dis Child Fetal Neonatal Ed*. 2009;94(4): F249–F252

79. Gold MS, Redmond DE Jr., Kleber HD. Clonidine blocks acute opiate-withdrawal symptoms. *Lancet*. 1978; 2(8090):599–602

80. Yaster M, Kost-Byerly S, Berde C, Billet C. The management of opioid and benzodiazepine dependence in infants, children, and adolescents. *Pediatrics*. 1996;98(1):135–140

81. Bittigau P, Sifringer M, Genz K, et al. Antiepileptic drugs and apoptotic neurodegeneration in the developing brain. *Proc Natl Acad Sci U S A*. 2002; 99(23):15089–15094

82. Gutherz SB, Kulick CV, Soper C, Kondratyev A, Gale K, Forcelli PA. Brief postnatal exposure to phenobarbital impairs passive avoidance learning and sensorimotor gating in rats. *Epilepsy Behav*. 2014;37:265–269

83. Farwell JR, Lee YJ, Hirtz DG, Sulzbacher SI, Ellenberg JH, Nelson KB. Phenobarbital for febrile seizures–effects on intelligence and on seizure recurrence. *N Engl J Med*. 1990; 322(6):364–369

84. Case A, Deaton A. Mortality and morbidity in the 21st century. *Brookings Pap Econ Act*. 2017;2017:397–476

85. Schiff DM, Nielsen T, Terplan M, et al. Fatal and nonfatal overdose among pregnant and postpartum women in Massachusetts. *Obstet Gynecol*. 2018; 132(2):466–474

86. Gleason MM, Goldson E, Yogman MW; Council on Early Childhood; Committee on Psychosocial Aspects of Child and Family Health; Section on Developmental and Behavioral Pediatrics. Addressing early childhood emotional and behavioral problems. *Pediatrics*. 2016;138(6):e20163025

87. Maalouf FI, Cooper WO, Slaughter JC, Dudley J, Patrick SW. Outpatient pharmacotherapy for neonatal abstinence syndrome. *J Pediatr*. 2018; 199:151–157.e1

88. Patrick SW, Burke JF, Biel TJ, Auger KA, Goyal NK, Cooper WO. Risk of hospital readmission among infants with neonatal abstinence syndrome. *Hosp Pediatr*. 2015;5(10):513–519

89. Crook TW, Munn EK, Scott TA, et al. Improving the discharge process for opioid-exposed neonates. *Hosp Pediatr*. 2019;9(8):643–648

90. Garstang JJ, Sidebotham P. Qualitative analysis of serious case reviews into unexpected infant deaths. *Arch Dis Child*. 2019;104(1):30–36

91. Backes CH, Backes CR, Gardner D, Nankervis CA, Giannone PJ, Cordero L. Neonatal abstinence syndrome: transitioning methadone-treated infants from an inpatient to an outpatient setting. *J Perinatol*. 2012; 32(6):425–430

92. Lee J, Hulman S, Musci M Jr., Stang E. Neonatal abstinence syndrome: influence of a combined inpatient/outpatient methadone treatment regimen on the average length of stay of a Medicaid NICU population. *Popul Health Manag*. 2015;18(5):392–397

93. Oei J, Feller JM, Lui K. Coordinated outpatient care of the narcotic-dependent infant. *J Paediatr Child Health*. 2001;37(3):266–270

94. Smirk CL, Bowman E, Doyle LW, Kamlin O. Home-based detoxification for neonatal abstinence syndrome reduces length of hospital admission without prolonging treatment. *Acta Paediatr*. 2014;103(6):601–604

95. Ko JY, Haight SC, Schillie SF, Bohm MK, Dietz PM. National trends in hepatitis C infection by opioid use disorder status among pregnant women at delivery hospitalization - United States,

2000–2015. *MMWR Morb Mortal Wkly Rep*. 2019;68(39):833–838

96. Patrick SW, Bauer AM, Warren MD, Jones TF, Wester C. Hepatitis C virus infection among women giving birth — Tennessee and United States, 2009–2014. *MMWR Morb Mortal Wkly Rep*. 2017;66(18):470–473
97. Lopata SM, McNeer E, Dudley JA, et al. Hepatitis C testing among perinatally exposed infants. *Pediatrics*. 2020;145(3): e20192482
98. Chappell CA, Hillier SL, Crowe D, Meyn LA, Bogen DL, Krans EE. Hepatitis C virus screening among children exposed during pregnancy. *Pediatrics*. 2018; 141(6):e20173273
99. Behnke M, Smith VC; Committee on Substance Abuse; Committee on Fetus and Newborn. Prenatal substance abuse: short- and long-term effects on the exposed fetus. *Pediatrics*. 2013; 131(3). Available at: www.pediatrics.org/cgi/content/full/131/3/e1009
100. Weitzman C, Wegner L; Section on Developmental and Behavioral Pediatrics; Committee on Psychosocial Aspects of Child and Family Health; Council on Early Childhood; Society for Developmental and Behavioral Pediatrics; American Academy of Pediatrics. Promoting optimal development: screening for behavioral and emotional problems. *Pediatrics*. 2015;135(2):384–395
101. Comprehensive Addiction and Recovery Act. Pub L No. 114-198, 130 Stat 695 (2016)
102. Bryant RA, Creamer M, O'Donnell M, et al. Separation from parents during childhood trauma predicts adult attachment security and post-traumatic stress disorder. *Psychol Med*. 2017; 47(11):2028–2035
103. Patrick SW. Improving public health systems for substance-affected pregnancies. *Am J Public Health*. 2019; 109(1):22–23
104. Ko JY, Wolicki S, Barfield WD, et al. CDC Grand Rounds: public health strategies to prevent neonatal abstinence syndrome. *MMWR Morb Mortal Wkly Rep*. 2017;66(9):242–245
105. Protecting our Infants Act, Pub L No. 114-91, 129 Stat 723 (2015)
106. Jilani SM, Giroir BP. Neonatal abstinence syndrome: leveraging health information technology to develop a data-driven national policy approach. *Public Health Rep*. 2020;135(2):173–176
107. Jilani SM, Frey MT, Pepin D, et al. Evaluation of state-mandated reporting of neonatal abstinence syndrome - six states, 2013–2017. *MMWR Morb Mortal Wkly Rep*. 2019;68(1):6–10
108. Binkin N; Council of State and Territorial Epidemiologists. Neonatal abstinence syndrome (NAS): environmental scan and key informant interview analysis report. Available at: https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/NAS_Environmental_Scan_Repor.pdf. Accessed June 25, 2020
109. Walsh MC, Crowley M, Wexelblatt S, et al.; Ohio Perinatal Quality Collaborative. Ohio perinatal quality collaborative improves care of neonatal narcotic abstinence syndrome. *Pediatrics*. 2018;141(4):e20170900

Nickel Allergic Contact Dermatitis: Identification, Treatment, and Prevention

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Nickel Allergic Contact Dermatitis: Identification, Treatment, and Prevention

Nanette B. Silverberg, MD, FAAP, FAAD,[a] Janice L. Pelletier, MD, FAAP,[b,c] Sharon E. Jacob, MD, FAAP, FAAD,[d,e] Lynda C. Schneider, MD, FAAP,[f] SECTION ON DERMATOLOGY, SECTION ON ALLERGY AND IMMUNOLOGY

Nickel is a ubiquitous metal added to jewelry and metallic substances for its hardening properties and because it is inexpensive. Estimates suggest that at least 1.1 million children in the United States are sensitized to nickel. Nickel allergic contact dermatitis (Ni-ACD) is the most common cutaneous delayed-type hypersensitivity reaction worldwide. The incidence among children tested has almost quadrupled over the past 3 decades. The associated morbidities include itch, discomfort, school absence, and reduced quality of life. In adulthood, individuals with Ni-ACD may have severe disabling hand eczema. The increasing rate of Ni-ACD in children has been postulated to result from early and frequent exposure to metals with high amounts of nickel release (eg, as occurs with ear piercing or with products used daily in childhood such as toys, belt buckles, and electronics).

To reduce exposure to metal sources with high nickel release by prolonged and direct contact with human skin, Denmark and the European Union legislated a directive several decades ago with the goal of reducing high nickel release and the incidence of Ni-ACD. Since then, there has been a global reduction in incidence of Ni-ACD in population-based studies of adults and studies of children and young adults being tested for allergic contact dermatitis. These data point to nickel exposure as a trigger for elicitation of Ni-ACD and, further, provide evidence that legislation can have a favorable effect on the economic and medical health of a population.

This policy statement reviews the epidemiology, history, and appearances of Ni-ACD. Examples of sources of high nickel release are discussed to highlight how difficult it is to avoid this metal in modern daily lives. Treatments are outlined, and avoidance strategies are presented. Long-term epidemiological interventions are addressed. Advocacy for smarter nickel use is reviewed. The American Academy of Pediatrics supports US legislation that advances safety standards (as modeled by the European Union) that protect children from early and prolonged skin exposure to high–nickel-releasing items. Our final aim for this article is to aid the pediatric community in developing nickel-avoidance strategies on both individual and global levels.

abstract

[a]Departments of Dermatology and Pediatrics, Mt Sinai Hospital and Icahn School of Medicine at Mt Sinai, New York, New York; [b]Northern Light Health, Bangor, Maine; [c]College of Medicine, University of New England, Biddeford, Maine; [d]Department of Dermatology, Loma Linda University, Loma Linda, California; [e]Departments of Medicine and Pediatrics, University of California, Riverside, California; and [f]Department of Pediatrics, Boston Children's Hospital and Harvard Medical School, Boston, Massachusetts

Drs Silverberg, Pelletier, Jacob, and Schneider fully participated in the conceptualization, drafting, and revision of this manuscript, and all authors approved the final manuscript as submitted.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-0628

To cite: Silverberg NB, Pelletier JL, Jacob SE, et al. AAP SECTION ON DERMATOLOGY, SECTION ON ALLERGY AND IMMUNOLOGY. Nickel Allergic Contact Dermatitis: Identification, Treatment, and Prevention. *Pediatrics.* 2020;145(5):e20200628

INTRODUCTION

Nickel Is a Common Cutaneous Allergen

Recent estimates suggest that 1.1 million children in the United States are potentially sensitized to nickel[1]; however, this may be a gross underestimate given that nickel allergic contact dermatitis (Ni-ACD) is found in approximately one-quarter of children who undergo patch testing. Nickel is present in metallic items that are common in children's environments, including earrings, watches, toys, and fasteners on clothing and belts. Chronic exposure to nickel increases risk for Ni-ACD. Nickel has become the most common metallic cause of allergic dermatitis and was named the "Contact Allergen of the Year" in 2008 by the American Contact Dermatitis Society. Determining the presence of Ni-ACD in those with allergic dermatitis can be difficult and elusive, with patch testing being a crucial tool used to help differentiate Ni-ACD from other forms of dermatitis.[2] The risk of Ni-ACD increases when ears are pierced.[3]

Nickel Exposures Are Common

Nickel is a ubiquitous metal, being the fifth most common element in the world. Worldwide use of nickel in the production of hardened metal items has been increasing since World War II.[4] The process by which nickel use shifted from coins and military purposes to daily use products, such as clothes and electronics, was strongly influenced by metal use in the post–World War II era. Among adults who were screened in Massachusetts General Hospital from 1996 to 2006, Ni-ACD was found in 22.1% of those 20 to 40 years of age but in only 10.1% of those older than 60 years, suggesting that Ni-ACD is a problem of younger individuals (those raised or those who had their ears pierced after World War II).[5] Today, nickel has continued to be a leading production metal in home and personal goods. Over time, Ni-ACD evolved from an occupational eczema of electroplaters to a common form of allergic contact dermatitis (ACD) among both adults and children, currently affecting as many as 20% of Americans. Historically, Ni-ACD has been linked to a wide range of exposures, including suspenders in the 1950s–1960s; zippers, buttons, and rivets in the 1970s; and ear piercing in the 1980s.[4] Environmental nickel present in oxides and sulfides is not as allergenic as the free nickel present in metal fittings found in industry.[4,6]

Nickel Allergy Has Significant Symptomatology

Virtually any site of the body can be affected by Ni-ACD, but some of the more commonly affected areas are the eyelids (transfer from hands), face, neck, wrists, fingers and hands, periumbilical area, and thighs.[7] Symptoms and signs of Ni-ACD range from mild dermatitis with pruritus, to deep erythema with oozing and papulation, to a systemic reaction with generalized idiopathic hypersensitivity.[6,7] Although Ni-ACD is a delayed-type hypersensitivity, symptoms can occur within the first 30 minutes of exposure through a complex cascade of inflammatory mediators generated after sensitization.[8]

KEY POINTS IN THE EVOLUTION OF NICKEL ALLERGY AS A SERIOUS ALLERGEN

Introduction of Nickel Into the Manufacturing of Metals

Nickel was first identified as an element in 1751 by a Swiss chemist named Axel Cronstedt. In the 1800s, nickel was introduced into the manufacturing of metal alloys with copper and zinc. As an alloy, its high value is related to many inherent qualities: high strength, lengthy life, anticorrosion, heat resistance, low cost, and minimal maintenance. In the mid-1800s, coins in the United States were alloyed with copper. In the late 1800s, steel production accelerated because of the strength of steel products. During the 20th century, nickel gained a solid place in industry as part of manufactured stainless steel alloy (along with chromate and iron). Today, two-thirds of nickel production in the world is devoted to the manufacture of stainless steel, 20% is for other specialized steel alloys (for military and aerospace), 9% is for plating, and the remainder is for various uses, including batteries, coins, and electronics.[9,10]

Early Reporting of Nickel Allergy

Weston et al[11] first reported Ni-ACD in young pediatric patients in 1984. Until that point, it was unclear whether cutaneous immune function in infants was mature enough to mount such responses. After the report of this phenomenon by Weston et al,[11] more attention to allergic reactions in infants and young children made it clear that contact allergy to nickel can begin in infancy, with some authors indicating increasing incidence after the age of 5 years.[12–16] Nickel's place as a cause of contact dermatitis in pediatrics was solidified by these early reports.

Ni-ACD can cause systemic hypersensitivity in children, and this was elucidated in 2 articles in 2002. Silverberg et al[16] reported a group of 30 children with clinical features of Ni-ACD manifested by persistent umbilical or wrist dermatitis. In that cohort, all children had positive results on patch testing for nickel; furthermore, 50% had an idiopathic hypersensitivity reaction, a hypersensitivity response characterized by the presence of inflammatory papules on the extensor surfaces of the extremities in sites not exposed to nickel.[17] A similar article from Sharma et al[17] reviewed 38 children with periumbilical papules consistent with Ni-ACD, all of whom demonstrated an idiopathic reaction.[18] Systemic contact

dermatitis has been defined as "a generalized ACD rash from systemic administration of a drug, chemical, or food to which the patient previously experienced ACD." There is no known general population-based prevalence of systemic nickel hypersensitivity, neither for kids nor for adults. Strongly positive (≥3 papular) nickel patch test results in these patients suggest that severe reactions correlate with systemic disease.[17]

Pathophysiology and Genetics of Nickel Allergic Sensitization

Nickel-contact allergy is a delayed-type (type IV) cutaneous hypersensitivity reaction that develops through a biphasic process: an induction phase is followed by an elicitation phase. In the induction phase, there are repeat exposures to free nickel that are beyond a minimal threshold. During this initial phase, an antigen is presented by the skin's dendritic cells to T cells (T helper 1 and T helper 17 cells), which causes the skin to develop a set of memory T cells that specifically recognize nickel. During the elicitation phase, there is amplification of the allergy through subsequent repetitive exposures that result in the manifestations of ACD.[4,6,18]

Ni-ACD is influenced by a combination of genetic and environmental factors, the latter being more important, according to leading experts.[4] Filaggrin mutations are associated with increased Ni-ACD risk. Another genetic determinant that may increase risk for Ni-ACD is HLA antigen expression.[19,20] Staphylococcal biofilms may promote the development of Ni-ACD in the setting of atopic dermatitis.[21]

Menné and Holm[22] showed a twin concordance rate of 29% in patients with Ni-ACD, confirmed from a population-based survey. Half of the pediatric patients with severe Ni-ACD with additional idiopathic reactions had a parent with Ni-ACD in the Silverberg et al[16] cohort, a statistic that is higher than that in the general population.

Product Properties That Contribute to Allergenicity

The amount of nickel released to the skin from contact with a metal object (not the presence of nickel) determines the potential for causing Ni-ACD. The development of Ni-ACD from contact with a nickel-containing object is promoted in a 3-step process: "1) the nickel in the material must be corroded, 2) the resulting nickel compounds must be solubilized, and 3) the nickel ions must be absorbed by the skin to cause a reaction."[23,24] Other contributory factors include the use of products under occlusion (eg, piercing holes) or prolonged contact with the skin such that sweat may erode or release nickel (eg, underside of the thighs against a chair).

Rising Prevalence of Nickel Allergy

The prevalence of nickel allergy in North America has increased significantly since the 1980s in both adults and children. Data on prevalence in the United States are derived from patch testing, that is, epicutaneous allergy testing, which reveals contact sensitization but not relevance of the allergy, outcomes, and/or associated disabilities. The North American Contact Dermatitis Group (NACDG) reported that nickel sensitization rates increased steadily between 1970 and 2002 in a mixed group of adults and children from 11% to 16.9%.[25] Pediatric-specific data from Peltonen[26] revealed a prevalence of Ni-ACD of 2.5% in 1981, and the NACDG series from 2001 to 2004 demonstrated 28.3% of children with positive patch test results were nickel allergic, showing an increase even more substantial in childhood than in adulthood.[27] One series revealed that although not all children with Ni-ACD have disabling symptoms, for those who undergo a patch test series, Ni-ACD represents a common relevant allergen, being detected in as many as 36.8% of children and adolescents tested and having an 80.4% relevance (ie, being identified as contributing to dermatitis activity).[28]

Population-based screening on individuals (including adults) referred for patch testing have highlighted the pervasive issue of Ni-ACD in the United States. In 1978, a population-based study of 1158 people identified 9% of individuals with Ni-ACD,[1] and approximately 50% of those who were nickel allergic had never sought medical care.[26] In a recent meta-analysis of 5 ACD studies representing 1507 pediatric subjects, 22.9% had Ni-ACD.[29] The current estimate of Ni-ACD in children with suspected ACD who are patch tested is 28.3% according to the NACDG.[27]

Data from Denmark are the most revealing when evaluating European Union (EU) nickel directives because Denmark introduced the directives in 1990, 14 years before widespread EU adoption. The Nickel Directive states that "consumer items intended to be in direct and prolonged contact with the skin were not allowed to release more than 0.5 mcg nickel/cm^2/week." This legislation was intended to reduce Ni-ACD but not eliminate disease. The venture has been successful in reducing Ni-ACD in young women with ear piercings who are patch tested. One particular outcome has been reduced severity of reaction on epicutaneous patch testing to nickel, which suggests less severity of disease. On the other hand, because the sale of nickel-laden agents is not criminalized, sales of items with nickel release persist in Europe, especially in outdoor flea markets.[3,30]

Before EU legislation, the percentage of female first-year college students in Finland in 1995 with Ni-ACD was 39%, suggesting that the rate may continue to increase further in the United States if no population-based

restrictions are enacted.[29,31,32] Population-based data on true nickel allergy in adolescents derived from survey data in Sweden reported in 2008, 7 years after EU legislation was put into action, revealed that 14.8% of 6095 adolescents polled believed they had Ni-ACD, with confirmation in 9.9%, revealing how EU nickel directives may be benefiting adolescents.[33] Data from a Danish pediatric contact dermatology database reveal ongoing reduction in nickel sensitization, with ACD rates of 9.7% in those tested (252 of 2587) from 2003 to 2011 and 7% (107 of 1540) from 2012 to 2016 (adjusted odds ratio, 0.69; 95% confidence interval, 0.55–0.88). Predominance of girls in the Ni-ACD group persisted in this study, as with previous studies.[33,34]

Piercings and Jewelry Are Leading Sources of Nickel Sensitization

Piercings, costume jewelry, watches, belt buckles, and clothing fasteners (grommets, buttons, studs, and toggles) are leading sources of epicutaneous nickel sensitization in countries without legislation controlling nickel release.[6] The same 1995 Finnish study of first-year college students revealed that piercings in female students were associated with a rate of 42% nickel allergy, compared withs 14% for female students without piercings.[31] A study of 960 girls 8 to 15 years of age in Sweden (published in 1985) with piercings revealed that 13% were nickel allergic, compared with 1% of girls without piercings.[23] In patch testing of school-aged girls for Ni-ACD from 1999 to 2000, older girls who had piercings before Danish regulations were implemented were 4 to 5 times as likely as those who had piercings after regulations to be allergic to nickel (17.1% vs 3.9%, respectively). A Norwegian pediatric contact allergy study of 7- to 12-year-old schoolchildren, published in 1994, identified a rate of 30.8% nickel allergy in children with piercings, compared with 16.3% in children without piercings.[35,36] Nickel allergy in girls with pierced ears has dramatically decreased in Denmark over the last 3 decades since strict nickel-release legislation was enacted.[14] Although piercings have been linked to nickel sensitization, occurrence of Ni-ACD is also common in children without piercings; therefore, reduction of nickel release is needed across all costume jewelry types.[6] A recent review of NACDG data revealed that of 1894 pediatric patients who were patch tested, 23.7% had nickel contact dermatitis and 36.4% had a pattern of skin disease consistent with all types of jewelry as the source of the nickel.[37]

The High Cost of Nickel Allergy in the United States

The 2004 estimates in the United States suggest that contact dermatitis, which includes nickel sensitization, accounted for $1.918 billion in health care costs (including direct medical costs and lost productivity costs) and affected 72.29 million people. Given that nickel-contact sensitization is noted in approximately one-quarter of patients, it is likely that nickel allergy contributes heavily to this burden.[24] Recent data from the American Academy of Dermatology reveal that contact allergy costs more than $1.5 billion in 2013.[38] Given that nickel allergy is the number one allergen nationwide in all age groups, nickel allergy is costly.

Other Sources of Nickel-Contact Sensitization

Contact with commonplace nickel alloy metallic products, such as toys, can lead to nickel release that deposits on a child's skin.[39,40] In a recent radiograph fluorescence spectroscopy study of US jewelry, 79 of 96 samples released nickel.[41] In a case series of children and adolescents from Brazil, the source of nickel exposure in the setting of Ni-ACD included jewelry piercings; metal clothing appliques on garments, accessories, and shoes; nail clippers; razor blades; and cosmetics.[1] Newer nickel sources reported to cause dermatitis include devices such as metallic cell phone cases (a persistent plaque on the hollow of the cheek), laptop cases and handheld device cases (fingertip, hand, lap, and periocular dermatitis), makeup applicators and ferrules (site of application), eye makeup, dog tag necklaces, and lip balm containers (lip and perioral).[42–48] Table 1 contains a brief compendium of items of daily use linked to nickel exposure and allergy.[4,6] Many of these newer nickel sources are more difficult to diagnose because the site of allergy can be areas not in direct contact, for example, the eyes.[43] The timing and type of nickel exposures throughout life are important. Ni-ACD was shown to be much less common when ear piercing occurred after placement of metal dental braces, compared with when piercing occurred before exposure to braces. So, less nickel sensitization may occur if placement of braces occurs first and piercing later.[44] This phenomenon may be analogous to the enteral tolerance that develops to lessen peanut allergy and may be akin to reasoning forwarded by the Learning Early About Peanut Allergy study.[49]

THE CLINICAL APPEARANCE OF NICKEL CONTACT DERMATITIS IS PROTEAN

Ni-ACD commonly is diagnosed on the basis of the appearance of itchy, persistent, erythematous, and/or lichenified papules and plaques that appear to conform to the area matching the exposure pattern of the metal object with the skin, for example, a circular erythematous plaque on the extensor wrist at the site of exposure to the backside of the wristwatch. Ni-ACD can also be caused by a child playing with a nickel-releasing object and then transferring the nickel to other sites.[1,45,46] Ni-ACD has also been described with nail polish from

TABLE 1 Sources of Nickel Exposure in Children

Sources
Artwork
White metal statues
Cleaners and detergents
Steel wool
Coins
Cooking
Pans
Pots
Stainless steel cookware used to cook acidic foods
Utensils (eg, silverware, spatula, and tongs)
Electronics
Batteries
Cell phone cases and electric shavers[a]
Mobile phones[a]
Laptops[a]
Tablets[a]
Foods (Mislankar and Zirwas[50] and Sharma[51])
Especially canned food
Seafood
Beans
Chocolate
Furniture
Brushed-metal furniture
Metal fittings and studs
Grooming
Nail clippers
Razors
Hair clips
Bobby pins
Metal brushes
Curling irons
Implants
Cardiac
Dental
Orthopedic
Keys
Makeup
Eyelash curlers
Ferrules
Lip balm containers
Musical instruments
Horns
Wind instrument mouthpieces
Occupational
Metal workers
Miners
Hospital cleaning staff
Ornamentation
Accessories
Ball and chain necklaces[a]
Belt buckles and/or belts[a]
Button flies[a]
Glasses
Grommets
Jewelry (costume, white gold, and low-karat gold)[a]
Earrings[a]
Necklaces[a]
Rings[a]
Watches[a]
Overalls
Rivets
Snaps
Zippers
Scissors
Tools
Toys

Adapted from Jacob SE, Goldenberg A, Pelletier JL, Fonacier LS, Usatine R, Silverberg N. Nickel allergy and our children's health: a review of indexed cases and a view of future prevention. *Pediatr Dermatol.* 2015;32(6): 779–78 and Tuchman M, Silverberg JI, Jacob SE, Silverberg N. Nickel contact dermatitis in children. *Clin Dermatol.* 2015;33(3):320–326.

[a] The most commonly identified nickel-allergy sources in clinical practice.

a bottle with nickel metal balls included.[47] This itchy rash is often diffuse and can occur on other less common areas, such as the scalp and eyelids.

Other jewelry-related patterns of appearance include a plaque over the upper back at the site of a necklace clasp pressed against the skin, periumbilical plaques at the site of belt buckle or button fly skin contact, midback plaques where bra hooks press against the skin, and earring plaques and/or nodules at the site of piercing because of exposure to high–nickel-releasing earring posts.[16,17,48] Dental amalgams are rarely high nickel releasing, but they still can cause oral lesions such as persistent oral lichenoid reactions near the amalgam, anesthetic sensation, and/or systemic lesions.[52]

When the source of nickel shifts against the skin, (eg, chair nail heads, belt buckles, and coins in the pocket), the contact dermatitis may be more papular and/or diffuse, making the source less obvious. Furthermore, patients with atopic dermatitis may have background disease activity that prevents the margins of the Ni-ACD from being clearly distinguished.[4,16,17,53] In adults, nickel has been identified as a contact allergen that can worsen palmoplantar or scalp psoriasis.[54]

Idiopathic reactions, or diffuse hypersensitivity reactions, to nickel can occur. These may be associated with dietary or complementary supplements as the source of nickel ingestion,[55] creating generalized pruritus and exacerbating pruritus at the site of cutaneous nickel exposure, or they may come from a generalized idiopathic hypersensitivity reaction triggered by ongoing cutaneous exposures (a type of systemic contact dermatitis), the latter of which is manifested by extensor papules and lichenoid (flat-topped) papules and plaques over extensor surfaces. Idiopathic reactions (also called dermatophytid) are similar to those seen in some patients with tinea capitis when starting oral griseofulvin therapy.[4,6]

Dental amalgams, caps, and braces that contain or release nickel in higher concentration are associated with perioral Ni-ACD as well as Ni-ACD in eccentric sites such as ears, the waist, and wrists. Ni-ACD may precede or be caused by dental devices containing nickel. Furthermore, such Ni-ACD can be associated with lip swelling and a burning oral sensation.[52,56–58]

Although most allergic reactions to nickel are of a type IV delayed-type hypersensitivity, rare reports have appeared in the literature of individuals with systemic nickel hypersensitivity of a type I or immediate-type hypersensitivity. Other types of allergic reactions to nickel may occur after oral nickel exposure, causing symptoms as minor as flares of earlier nickel-allergic eczema sites, to a generalized maculopapular or vasculitislike rash, to more severe symptoms, including urticaria, headache malaise, diarrhea, fever, and arthralgia.[59,60] Skin prick testing has been performed in rare cases but remains controversial.[52,59,60] It is still most likely, even in such settings, that the reaction to nickel is a delayed-type hypersensitivity because rapid

reactions as fast as 10 to 30 minutes can be described in Ni-ACD delayed type.[61] The data on these cases are extremely limited, and no recommendation can be made until additional broad-based population data become available for testing.

OVERLAP WITH ATOPIC DERMATITIS

The NACDG demonstrated that 34% of children with a positive contact allergy result on testing had concurrent atopic dermatitis.[62] In children with atopic dermatitis, Ni-ACD can trigger severe exacerbations of pruritus.[6] In the setting of atopic dermatitis, Ni-ACD overlap is associated with more extensive atopic dermatitis and greater difficulty in diagnosing Ni-ACD.[7] Because the background population data on nickel allergy does not differ in prevalence, Ni-ACD can only be viewed as an aggravating or obscuring factor and not necessarily as a cause of disease.

MANAGEMENT OF NI-ACD

The broad goals of medical therapy in Ni-ACD are as follows:

1. identification and avoidance of nickel;
2. treatment of skin inflammation; and
3. restoration of the skin barrier and skin protection.

Identification and Avoidance of Nickel

Identifying sources of nickel requires investigation of personal adornments, hobbies (eg, instruments played), and jobs (eg, leisure-time activities and review of everyday device usage). Patients should be asked about garments or uniforms worn at work or school. Avoidance of nickel can be enhanced through testing objects for nickel content (see Avoidance of Nickel Exposure in Childhood section). Using Table 1 as a guide, pediatricians can ask patients targeted questions to determine nickel sources hidden in daily activities.

TABLE 2 Handout for Patients

Nickel is a metal that is added to many metal objects to harden them. Nickel can be found in almost all costume jewelry (including earrings, necklaces, watch backs, rings, and bracelets), some belt buckles, and such jewelry as ball and chain necklaces, dog tags, metal tabs, grommets, and button flies.

When you sweat, the nickel is released from the metal, even if it is only a small amount or percentage of the metal. Stainless steel is a stronger white metal and does not release nickel as easily.

If you are allergic to nickel, your rash will keep returning until you avoid nickel completely. There are many steps required to avoid nickel completely. It is not easy, but it is necessary to make you feel better.

1. Remove all nonessential metal from your clothing; replace button flies with plastic buttons and wear a belt that ties or has a plastic buckle.
2. For metal that you cannot remove, such as grommets on the side pockets of your jeans or the back of your watch, coat with 2 coats of clear nail polish every week or after washings.
3. Avoid sitting in shorts on metal chairs or plastic chairs with metal tabs.
4. Do not cook acidic foods in stainless steel cookware. Avoid stainless steel cookware if you can.
5. Tucking in your shirt does not prevent you from reacting to the nickel in your belt buckle or button fly.
6. Avoid ear piercing, especially if dental work, such as braces, is expected.
7. Sources of nickel in jewelry include costume jewelry, including earring posts that are not stainless steel, white gold, and all low-karat gold jewelry. Sterling silver and high-karat yellow gold jewelry are expected to have a low content of nickel but are not generally nickel free.
8. Tests to look for nickel released from household metals can be found at the following Web sites: https://nonickel.com/collections/nickel-test-kit-for-jewelry-and-meteorites and https://www.delasco.com/spot-test-for-nickel/. More information can be found at https://athenaallergy.com/pages/how-to-test-for-nickel-using-nickel-alert-dimethylglyoxime-test.

One of the hallmarks of good clinical care in ACD is education on how to avoid allergen-laden goods. Such is the case in Ni-ACD. Patients with Ni-ACD can be counseled to recognize objects that may be high-release nickel, to test such objects, and to protect the skin from prolonged and direct contact with the objects. Table 2 is a handout that can be used to help educate parents and children and adolescents about nickel avoidance. In general, piercing with nickel-free earrings can minimize risk of Ni-ACD, as can use of low-release nickel, but the latter still results in some release of nickel. Sterling silver (which is 92.5% pure silver), 18-karat yellow gold (which is 75% gold) or more-pure gold, platinum, titanium, and plastic earrings are alternatives that have low or no nickel content. Silver that is not sterling, such as nickel silver, 800 silver (80% silver), and German silver (which contains no silver at all; an alloy of nickel and zinc), are not ideal for the patient with Ni-ACD.

Treatment of Skin Inflammation

Inflammatory symptoms, including eczematous changes and pruritus, are the main symptoms of Ni-ACD–induced inflammation. There is no US Food and Drug Administration–approved therapy for Ni-ACD; however, Ni-ACD is a steroid-responsive dermatosis, and therefore topical corticosteroids may be helpful in conjunction with prevention of retriggering of dermatitis through avoidance of suspected sources of nickel exposure and with therapeutics to aid in pruritus or itch reduction. Although no specific regimen of topical corticosteroids has been endorsed by any organization for Ni-ACD, the American Academy of Pediatrics recommends choosing the corticosteroid class on the basis of the site of application and severity. Like in atopic dermatitis, off-label use of topical calcineurin inhibitors (eg, pimecrolimus and tacrolimus) can be effective in steroid-resistant Ni-ACD cases.[63,64] These topical therapies are used in combination with nickel avoidance, which is the cornerstone of treatment of Ni-ACD. Prevention is

paramount because there is no cure for Ni-ACD and because the disease is lifelong.[65] In recalcitrant cases or in the setting of severe Ni-ACD and severe pruritus or for those with widespread lesions, oral steroids for several days and then tapered, together with antihistamines for pruritus, can aid in symptomatic resolution.[66]

Restoration of the Skin Barrier and Skin Protection

Emollients can be used to enhance the skin barrier in children with atopic dermatitis and may benefit children with Ni-ACD and concurrent dermatitis symptoms. Skin protection can be achieved through thick physical blockage of nickel-containing metal objects, for example, cell phone cases, backing button flies in denim, or replacing metal buttons with plastic buttons. Thin fabrics and strategies such as tucking in one's shirt may not be fully protective.[4,53]

Confirmation of Suspected Ni-ACD

When a typical pattern of Ni-ACD appears on the wrist or periumbilical region, no confirmatory testing is needed.[16,17,67] In some cases in which suspicion is harder to confirm, patch testing, otherwise known as epicutaneous skin testing, is a form of testing in which a dilute version of the allergen is placed in a hypoallergenic well (sometimes called a Finn chamber) and applied to the back. Contact time with the skin of the upper back or inner upper arms is up to 48 hours. After this period, the patches are removed, and the test results are read. The patches are read again at a delayed point between 72 and 120 hours after placement. Interpretation of results is based on the appearance of redness and/or papules and/or a plaque in the shape of the chamber. Papular ($\geq$3 severity) reactions at the site of testing are common in nickel allergy in children, and they can be associated with idiopathic systemic hypersensitivity. If the testing result is negative but clinical history supports Ni-ACD, a late reading should be considered 7 to 10 days after the patch test application. There is a US Food and Drug Administration–approved series of 36 patches (T.R.U.E. Test; SmartPractice, Phoenix, AZ) that contains nickel at 200 $\mu g/cm^2$ nickel sulfate, which corresponds to 160 μg of nickel per patch. In pediatrics, standardized comprehensive patch testing is often custom tailored by history, and testing is performed with nickel sulfate hexahydrate 2.5% in petrolatum, as would be found in the American Contact Dermatitis Society Core series.[4,53] Broad-metal contact allergy screening should be performed when multiple metals are suspected as the potential source of contact dermatitis. This screening can be accomplished by using an epicutaneous metal contact allergy panel containing nickel, gold, titanium, copper, cobalt, zinc, and more than a dozen other metals.

Although children with obvious nickel allergy usually do not need confirmatory patch testing for nickel, they may need testing for other metal allergens when metal appliances for dental work or implants are needed.[68,69] In particular, the Nuss procedure, which is a placement of metal rods for the repair of pectus excavatum, has been associated with complications in patients with metal allergy, especially to nickel. Consequences include extensive granulation tissue formation, localized edema, dermatitis, lymphadenopathy, pleural effusion, and inflammation and/or infection, which may require removal of stainless steel rods in some cases.[70,71] Because of the potential consequences of undiagnosed Ni-ACD in such patients, surgeons performing the procedure often refer patients for patch testing to nickel and other metals before the procedure.[72] Stainless steel discs provided by the manufacturer are suboptimal to screen for metal allergy and Ni-ACD in this setting; it is more prudent to proceed with patch testing by using the extended metal series.[73] Titanium bars can be used safely in patients with Ni-ACD if they are identified before surgery as having no previously reported allergic events.[70]

PREVENTION OF NI-ACD

Avoidance of Nickel Exposure in Childhood

Ni-ACD is a threat to pediatric public health that persists as a problematic skin disease into adulthood. Ni-ACD is the most common cutaneous allergy and involves lifelong hazards that can affect people's lives both personally and professionally.[74] Common cutaneous nickel-containing items include earring posts, belt buckles, jewelry, zippers, snaps, clasps, grommets, electronics, coins, keys, paper clips, chairs, braces, and implants.[2,24,45,75–77] To reduce the risk and severity of Ni-ACD, avoidance of skin contact with nickel is critical. According to European reports, earrings appear to be the most common source of elicitation of Ni-ACD, providing credence to take preventive and economic measures. The United States should heed the European lead to reduce nickel release from common contacts in children to serve and protect population health. Using the handout in Table 2, parents can identify sources of high-release nickel in their children's lives. The purchase of items with no nickel or with a low release of nickel can be guided by the use of the dimethylglyoxime test, which indicates a pink or red color on exposure to a nickel-releasing metallic item. Currently, because of the lack of labeling of low–nickel-release or nickel-free metal items, parents can screen metal objects for nickel release using such test kits, which can be purchased on medical Web sites (eg, https://www.delasco.com/spot-test-for-nickel/ and

https://athenaallergy.com/pages/how-to-test-for-nickel-using-nickel-alert-dimethylglyoxime-test).[78] However, it would be more ideal if labeling of low–nickel-release or nickel-free items was available for parents.

Reduction in Dietary Nickel Exposure

Withdrawal diets in children cannot be recommended because of inadequate pediatric data and risk of malnutrition with a limited diet.[50,79,80] Data on the use of low-nickel diets in children are lacking.[51,81,82]

Advocacy

Ni-ACD represents a significant and preventable pediatric public health burden. Regulation of nickel release in materials that comes in contact with skin can decrease both the high pediatric prevalence and treatment costs of the disease. There is a call in the United States for such regulation[2] given the high number of children affected by this disease. The American Academy of Dermatology has recently accepted a proposal in support of reduced nickel release in manufacturing.[82] Adoption of legislation similar to that in the EU by the US Congress would represent a promise for prevention by starting to reduce the nickel-related health burden.

A REVIEW OF EU POLICY

Nickel is ubiquitous, and people are exposed to it primarily via metal objects throughout their lifetimes. Preventive models of safer exposures, or those less likely to trigger Ni-ACD, have been demonstrated by other countries to be medically and economically beneficial. The EU Nickel Directive of 1994 (approved June 30, 1994, and in full effect June 2001) regulated the method for measuring nickel release onto human skin and established regulations for nickel allowed to be released onto exposed skin over time, including for watches, buttons, zippers, and now mobile phone cases.[83] The EU directive was born from the original work in Denmark, where the Nickel Directive was designed to limit the maximum release of nickel in contact with human skin to an amount less than 0.2 $\mu g/cm^2$ per week for posts inserted into pierced skin and not more than 0.5 $\mu g/cm^2$ per week for products with prolonged and direct skin contact.[83,84] The European standard EN 1811:2011+A1:2015 is a standardized testing system that is approved by the EU to measure the potential amount of nickel release under the conditions of direct and prolonged contact with the skin. Articles, such as those used for earrings in children, should not release nickel more than 0.2 $\mu g/cm^2$ per week (by EN 1811 testing) to prevent children from becoming allergic to nickel or having a dermatitis reaction if they are already allergic to nickel. This nickel-release rate is for the parts of earrings that are in contact with the skin and within the pierced part of the ear.[4,83] Germany and Sweden joined in the legislation and eventually Korea and China did as well.[83]

Because the rate of release of nickel (and not nickel content itself) is important and relevant in determining whether there is a risk for Ni-ACD, articles may contain nickel but not cause a dermatitis reaction. For example, surgical stainless steel (grade 316L), which contains 10% to 15% nickel and does not release nickel more than 0.2 $\mu g/cm^2$ per week (by using EN 1811 testing), is therefore regarded as appropriate for use in articles in direct and prolonged contact with the skin. The American Section of the International Association for Testing Materials Standard Consumer Safety Specification for Adult Jewelry (designation: F2999-13) lists surgical stainless steel (typically containing 10%–15% nickel) as one of the "approved materials for adult body-piercing jewelry."[4,84,85]

The effect of the Danish decree was a drastic decrease in pediatric nickel sensitization from 24.8% to 9.2%.[85] Reduction in Ni-ACD after Denmark's Nickel Directive resulted in cost savings that grew to more than $2 billion (US dollars) over the 2 decades after implementation.[4] The EU followed the commanding lead of the Danish dermatologists who worked with the Danish ministry to advance this innovative health directive. In 2006, the Nickel Directive was incorporated into the EU regulation of toxins, which is called Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH).[84] After this regulation, there was a significant reduction of Ni-ACD in patients younger than 30 years studied in European countries.[83] National databases involving 180 390 patients with suspected ACD reveal an approximately 10% reduction in Ni-ACD in young women, specifically from the following 4 countries, in the years 1985–2010: Denmark, Germany, Italy, and the United Kingdom (2004–2010 only).

REACH is a complex bill that outlines industry obligations regarding 30 000 chemicals. REACH is far more "reaching" than is the US counterpart, the Toxic Substances Control Act (TSCA) of 1975,[86] which regulates chemicals but does not differentiate toxic from nontoxic chemicals. The TSCA was supplanted by the Chemical Safety for the 21st Century Act, introduced in the Senate in 2015 and passed in the House of Representatives in May 2016. Although the TSCA required the Environmental Protection Agency (EPA) to consider least burdensome chemical regulations for industry, the Chemical Safety for the 21st Century Act tasks the EPA to focus on unreasonable risk to human health and the environment; however, unfortunately, this may not apply to

jewelry and cosmetics.[86–88] Although the EPA acknowledges the hazards of nickel as a cause of ACD, no current ruling restricts nickel exposures in childhood; however, this regulatory foundation has room to act to reduce risk for Ni-ACD in children.[86–89] The United States stands to improve collective health status and lower related medical costs if it were to follow Denmark's lead and the EU model in protecting the public from the hazards of high nickel exposure.

Stakeholders may note that the nonprofit organization Nickel Producers Environmental Research Association does support the elimination of high-release nickel alloys and plating used in products with dermal contact such as jewelry and electronics.[7,90] US legislators should advance evidenced-based policies to adopt a twofold guideline: (1) adoption of the EU guidelines on nickel release in manufacturing and (2) adoption of a policy to avoid usage of nickel in plating in household electronic devices. If the United States can incorporate safety directives and sound recommendations regarding nickel production and usage, as has been done in the EU, then the population can achieve significant reductions in Ni-ACD in the next 2 to 3 decades.

RECOMMENDATIONS

The following are recommended to reduce the US pediatric burden of Ni-ACD:

1. To minimize nickel-induced ACD in children, use of nickel in the manufacture of items that have direct or prolonged contact with the skin (eg, jewelry, electronic devices, toys, etc) should be limited. Regulations similar to the EU Nickel Directive that limit the weekly allowable release of nickel to less than 0.5 $\mu g/cm^2$/week should be adopted.
2. Additional safety and toxicity studies are needed to better understand the complex relationship between nickel exposure and population health.
3. Companies and industries using metal in products should voluntarily create labeling for low–nickel-release products and Web-based resources to identify those items in the United States that follow EU legislation guidelines, allowing individuals who are nickel allergic to shop more wisely. Ideally, the development of trustable resources for those with Ni-ACD can be met through physician and industry partnership to develop educational resources about nickel allergy that can be easily understood and accessed by children, parents, and teachers.
4. Physicians and other health care providers can support the reduction of Ni-ACD by encouraging parents to request that posts for piercings in their children's ears be made of surgical-grade steel with low nickel release, per EU standards. It is recommended that all individuals who perform piercing services mention Ni-ACD as a potential complication of piercing.
5. Nickel allergy can be genetic; therefore, physicians and other providers should consider educating at-risk groups to avoid nickel-based body piercings. There is further genetic reason to believe that children from families with a history of Ni-ACD would benefit from reduced exposure in childhood through the universal use of low–nickel-releasing jewelry.
6. It is likely that most children would benefit from lower exposure to such contact, even in the absence of family history of Ni-ACD, because such family history is only present in approximately half of cases of documented disease.
7. If orthodontic metal braces are anticipated, families should consider delaying ear piercing until after dental work is completed.
8. Until such legislation can be passed, voluntary manufacturer reduction of nickel-releasing metal in children's clothing and close contacts, including grommets, button flies, belt buckles, school chairs, and tables, aimed for use by children would reduce Ni-ACD disease burden. Reporting of voluntary reduction on labels and on public Web sites would help parents of children and adolescents with Ni-ACD identify hypoallergenic metal objects, further enhancing reduction of disease symptomatology and burden.

CONCLUSIONS

Ni-ACD is a common chronic dermatitis with detrimental effects on children now and as they progress into adulthood. The burden of symptoms and cost is high. The United States can act on EU data revealing that legislation to limit exposures in childhood, especially with earrings, can impact the prevalence and potentially the severity of disease. Until and even if legislation is available, pediatricians can help patients by identifying the allergy early and intervening with a plan of prevention and care of disease.

LEAD AUTHORS

Nanette B. Silverberg, MD, FAAP, FAAD
Janice L. Pelletier, MD, FAAP
Sharon E. Jacob, MD, FAAP, FAAD
Lynda C. Schneider, MD, FAAP

SECTION ON DERMATOLOGY EXECUTIVE COMMITTEE, 2018–2019

Bernard Cohen, MD, FAAP
Kimberly A. Horii, MD, FAAP, Chairperson
Leonard Kristal, MD, FAAP
Sheilagh M. Maguiness, MD, FAAP
Megha Mathakia Tollefson, MD, FAAP

ABBREVIATIONS

ACD: allergic contact dermatitis
EPA: Environmental Protection Agency
EU: European Union
NACDG: North American Contact Dermatitis Group
Ni-ACD: nickel allergic contact dermatitis
REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals
TSCA: Toxic Substances Control Act

Address correspondence to Nanette B. Silverberg, MD. E-mail: nanette.silverberg@mountsinai.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Dr Jacob has indicated she is the Past President and is serving her last year on the Executive Director Board of the American Contact Dermatitis Society.

REFERENCES

1. Rietschel RL, Fowler JF, Warshaw EM, et al. Detection of nickel sensitivity has increased in North American patch-test patients. *Dermatitis*. 2008;19(1):16–19
2. Jacob SE, Moennich JN, McKean BA, Zirwas MJ, Taylor JS. Nickel allergy in the United States: a public health issue in need of a "nickel directive". *J Am Acad Dermatol*. 2009;60(6):1067–1069
3. Thyssen JP. Nickel and cobalt allergy before and after nickel regulation–evaluation of a public health intervention. *Contact Dermatitis*. 2011; 65(suppl 1):1–68
4. Tuchman M, Silverberg JI, Jacob SE, Silverberg N. Nickel contact dermatitis in children. *Clin Dermatol*. 2015;33(3): 320–326
5. Landeck L, Gonzalez E, Baden LA, Neumann K, Schalock PC. Contact sensitization by age group in adults: patch-test data from the Massachusetts General Hospital, 1996 to 2006. *Dermatitis*. 2009;20(5):287–291
6. Brod BA, Treat JR, Rothe MJ, Jacob SE. Allergic contact dermatitis: kids are not just little people. *Clin Dermatol*. 2015; 33(6):605–612
7. Nickel Institute. Nickel and nickel allergic contact dermatitis. Available at: https://www.nickelinstitute.org/policy/nickel-and-product-policy/nickel-and-nickel-allergic-contact-dermatitis/. Accessed July 29, 2019
8. Saito M, Arakaki R, Yamada A, Tsunematsu T, Kudo Y, Ishimaru N. Molecular mechanisms of nickel allergy. *Int J Mol Sci*. 2016;17(2):E202
9. Wikipedia. Stainless steel. Available at: https://en.wikipedia.org/wiki/Stainless_steel. Accessed July 29, 2019
10. Weston WL, Weston JA. Allergic contact dermatitis in children. *Am J Dis Child*. 1984;138(10):932–936
11. Weston WL, Weston JA, Kinoshita J, et al. Prevalence of positive epicutaneous tests among infants, children, and adolescents. *Pediatrics*. 1986;78(6): 1070–1074
12. Kuiters GR, Smitt JHS, Cohen EB, Bos JD. Allergic contact dermatitis in children and young adults. *Arch Dermatol*. 1989; 125(11):1531–1533
13. Fisher AA. Patch testing in children including early infancy. *Cutis*. 1994; 54(6):387–388
14. Mortz CG, Andersen KE. Allergic contact dermatitis in children and adolescents. *Contact Dermatitis*. 1999;41(3):121–130
15. Giordano-Labadie F, Rancé F, Pellegrin F, Bazex J, Dutau G, Schwarze HP. Frequency of contact allergy in children with atopic dermatitis: results of a prospective study of 137 cases. *Contact Dermatitis*. 1999;40(4):192–195
16. Silverberg NB, Licht J, Friedler S, Sethi S, Laude TA. Nickel contact hypersensitivity in children. *Pediatr Dermatol*. 2002;19(2):110–113
17. Sharma V, Beyer DJ, Paruthi S, Nopper AJ. Prominent pruritic periumbilical papules: allergic contact dermatitis to nickel. *Pediatr Dermatol*. 2002;19(2): 106–109
18. Toebak MJ, Moed H, von Blomberg MB, et al. Intrinsic characteristics of contact

and respiratory allergens influence production of polarizing cytokines by dendritic cells. *Contact Dermatitis*. 2006;55(4):238–245

19. Schram SE, Warshaw EM. Genetics of nickel allergic contact dermatitis. *Dermatitis*. 2007;18(3):125–133
20. Ross-Hansen K, Johansen JD, Vølund A, Menné T, Thyssen JP. The nickel dose-response relationship by filaggrin genotype (FLG). *Contact Dermatitis*. 2014;71(1):49–53
21. Rundle CW, Bergman D, Goldenberg A, Jacob SE. Contact dermatitis considerations in atopic dermatitis. *Clin Dermatol*. 2017;35(4):367–374
22. Menné T, Holm NV. Nickel allergy in a female twin population. *Int J Dermatol*. 1983;22(1):22–28
23. Larsson-Stymne B, Widström L. Ear piercing–a cause of nickel allergy in schoolgirls? *Contact Dermatitis*. 1985; 13(5):289–293
24. Bickers DR, Lim HW, Margolis D, et al; American Academy of Dermatology Association; Society for Investigative Dermatology. The burden of skin diseases: 2004 a joint project of the American Academy of Dermatology Association and the Society for Investigative Dermatology. *J Am Acad Dermatol*. 2006;55(3):490–500
25. Nguyen SH, Dang TP, MacPherson C, Maibach H, Maibach HI. Prevalence of patch test results from 1970 to 2002 in a multi-centre population in North America (NACDG). *Contact Dermatitis*. 2008;58(2):101–106
26. Peltonen L. Nickel sensitivity. An actual problem. *Int J Dermatol*. 1981;20(5): 352–353
27. Zug KA, Pham AK, Belsito DV, et al. Patch testing in children from 2005 to 2012: results from the North American contact dermatitis group. *Dermatitis*. 2014;25(6):345–355
28. Rodrigues DF, Goulart EM. Patch test results in children and adolescents. Study from the Santa Casa de Belo Horizonte Dermatology Clinic, Brazil, from 2003 to 2010. *An Bras Dermatol*. 2015;90(5):671–683
29. Prystowsky SD, Allen AM, Smith RW, Nonomura JH, Odom RB, Akers WA. Allergic contact hypersensitivity to nickel, neomycin, ethylenediamine, and benzocaine. Relationships between age, sex, history of exposure, and reactivity to standard patch tests and use tests in a general population. *Arch Dermatol*. 1979;115(8):959–962
30. Thyssen JP, Uter W, McFadden J, et al. The EU Nickel Directive revisited--future steps towards better protection against nickel allergy. *Contact Dermatitis*. 2011; 64(3):121–125
31. Mattila L, Kilpeläinen M, Terho EO, Koskenvuo M, Helenius H, Kalimo K. Prevalence of nickel allergy among Finnish university students in 1995. *Contact Dermatitis*. 2001;44(4):218–223
32. Admani S, Matiz C, Jacob SE. Nickel allergy–a potential cause of razor dermatitis. *Pediatr Dermatol*. 2014; 31(3):392–393
33. Simonsen AB, Foss-Skiftesvik MH, Thyssen JP, et al. Contact allergy in Danish children: current trends. *Contact Dermatitis*. 2018;79(5):295–302
34. Fors R, Persson M, Bergström E, Stenlund H, Stymne B, Stenberg B. Nickel allergy–prevalence in a population of Swedish youths from patch test and questionnaire data. *Contact Dermatitis*. 2008;58(2):80–87
35. Dotterud LK, Falk ES. Metal allergy in north Norwegian schoolchildren and its relationship with ear piercing and atopy. *Contact Dermatitis*. 1994;31(5): 308–313
36. Jensen CS, Lisby S, Baadsgaard O, Vølund A, Menné T. Decrease in nickel sensitization in a Danish schoolgirl population with ears pierced after implementation of a nickel-exposure regulation. *Br J Dermatol*. 2002;146(4): 636–642
37. Warshaw EM, Aschenbeck KA, DeKoven JG, et al. Epidemiology of pediatric nickel sensitivity: retrospective review of North American Contact Dermatitis Group (NACDG) data 1994-2014. *J Am Acad Dermatol*. 2018;79(4):664–671
38. Lim HW, Collins SAB, Resneck JS Jr., et al. The burden of skin disease in the United States. *J Am Acad Dermatol*. 2017;76(5):958–972.e2
39. Jensen P, Hamann D, Hamann CR, Jellesen MS, Jacob SE, Thyssen JP. Nickel and cobalt release from children's toys purchased in Denmark and the United States. *Dermatitis*. 2014; 25(6):356–365
40. Overgaard LE, Engebretsen KA, Jensen P, Johansen JD, Thyssen JP. Nickel released from children's toys is deposited on the skin. *Contact Dermatitis*. 2016;74(6):380–381
41. Hamann D, Thyssen JP, Hamann CR, et al. Jewellery: alloy composition and release of nickel, cobalt and lead assessed with the EU synthetic sweat method. *Contact Dermatitis*. 2015;73(4): 231–238
42. Oh JE, Lee HJ, Choi YW, Choi HY, Byun JY. Metal allergy in eyelid dermatitis and the evaluation of metal contents in eye shadows. *J Eur Acad Dermatol Venereol*. 2016;30(9):1518–1521
43. Usatine RP, Jacob SE. Rash on eyebrows and periumbilical region. *J Fam Pract*. 2017;66(1):45–47
44. Mortz CG, Lauritsen JM, Bindslev-Jensen C, Andersen KE. Nickel sensitization in adolescents and association with ear piercing, use of dental braces and hand eczema. The Odense Adolescence Cohort Study on Atopic Diseases and Dermatitis (TOACS). *Acta Derm Venereol*. 2002;82(5):359–364
45. Goldenberg A, Admani S, Pelletier JL, Jacob SE. Belt buckles-increasing awareness of nickel exposure in children: a case report. *Pediatrics*. 2015;136(3). Available at: www.pediatrics.org/cgi/content/full/136/3/e691
46. Jacob SE, Admani S. iPad–increasing nickel exposure in children. *Pediatrics*. 2014;134(2). Available at: www.pediatrics.org/cgi/content/full/134/2/e580
47. Ozkaya E, Ekinci A. Metal contact sites: a hidden localization for nail varnish allergy? *Clin Exp Dermatol*. 2010;35(4): e137–e140
48. Silverberg NB. The "jewelry addict": allergic contact dermatitis from repetitive multiple children's jewelry exposures. *Pediatr Dermatol*. 2016; 33(2):e103–e105
49. Du Toit G, Roberts G, Sayre PH, et al; Learning Early About Peanut Allergy (LEAP) Study Team. Identifying infants at high risk of peanut allergy: the Learning Early About Peanut Allergy

(LEAP) screening study. *J Allergy Clin Immunol*. 2013;131(1):135–143.e12

50. Mislankar M, Zirwas MJ. Low-nickel diet scoring system for systemic nickel allergy. *Dermatitis*. 2013;24(4):190–195
51. Sharma AD. Relationship between nickel allergy and diet. *Indian J Dermatol Venereol Leprol*. 2007;73(5): 307–312
52. Syed M, Chopra R, Sachdev V. Allergic reactions to dental materials- a systematic review. *J Clin Diagn Res*. 2015;9(10):ZE04-ZE09
53. Jacob SE, Goldenberg A, Pelletier JL, Fonacier LS, Usatine R, Silverberg N. Nickel allergy and our children's health: a review of indexed cases and a view of future prevention. *Pediatr Dermatol*. 2015;32(6):779–785
54. Rasool F, Akhtar S, Hassan I, Zeerak S, Mubashir S, Sheikh G. Common contact allergens in patients with palmoplantar and scalp psoriasis and impact of their avoidance on dermatology life quality index: a hospital-based study. *Indian J Dermatol*. 2018;63(2):160–164
55. de Medeiros LM, Fransway AF, Taylor JS, et al. Complementary and alternative remedies: an additional source of potential systemic nickel exposure. *Contact Dermatitis*. 2008;58(2):97–100
56. Schultz JC, Connelly E, Glesne L, Warshaw EM. Cutaneous and oral eruption from oral exposure to nickel in dental braces. *Dermatitis*. 2004;15(3): 154–157
57. Pantuzo MC, Zenóbio EG, de Andrade Marigo H, Zenóbio MA. Hypersensitivity to conventional and to nickel-free orthodontic brackets. *Braz Oral Res*. 2007;21(4):298–302
58. Johnson EF, Lau EG, Smidt AC. Picture of the month. Allergic contact dermatitis to nickel-containing dental work. *JAMA Pediatr*. 2013;167(6):581–582
59. Büyüköztürk S, Gelincik A, Ünal D, et al. Oral nickel exposure may induce type I hypersensitivity reaction in nickel-sensitized subjects. *Int Immunopharmacol*. 2015;26(1):92–96
60. Tosti A, Melino M, Labanca M, Ragazzi R. Immediate hypersensitivity to nickel. *Contact Dermatitis*. 1986;15(2):95
61. Ahlström MG, Menné T, Thyssen JP, Johansen JD. Nickel allergy in a Danish population 25 years after the first nickel regulation. *Contact Dermatitis*. 2017;76(6):325–332
62. Zug KA, McGinley-Smith D, Warshaw EM, et al. Contact allergy in children referred for patch testing: North American Contact Dermatitis Group data, 2001-2004. *Arch Dermatol*. 2008; 144(10):1329–1336
63. Alomar A, Puig L, Gallardo CM, Valenzuela N. Topical tacrolimus 0.1% ointment (protopic) reverses nickel contact dermatitis elicited by allergen challenge to a similar degree to mometasone furoate 0.1% with greater suppression of late erythema. *Contact Dermatitis*. 2003;49(4):185–188
64. Pacor ML, Di Lorenzo G, Martinelli N, et al. Tacrolimus ointment in nickel sulphate-induced steroid-resistant allergic contact dermatitis. *Allergy Asthma Proc*. 2006;27(6):527–531
65. Bourke J, Coulson I, English J; British Association of Dermatologists Therapy Guidelines and Audit Subcommittee. Guidelines for the management of contact dermatitis: an update. *Br J Dermatol*. 2009;160(5):946–954
66. Bruckner AL, Weston WL. Allergic contact dermatitis in children: a practical approach to management. *Skin Therapy Lett*. 2002;7(8):3–5
67. Hill H, Goldenberg A, Golkar L, Beck K, Williams J, Jacob SE. Pre-Emptive Avoidance Strategy (P.E.A.S.) - addressing allergic contact dermatitis in pediatric populations. *Expert Rev Clin Immunol*. 2016;12(5):551–561
68. Belloni Fortina A, Fontana E, Peserico A. Contact sensitization in children: a retrospective study of 2,614 children from a single center. *Pediatr Dermatol*. 2016;33(4):399–404
69. Smith VM, Clark SM, Wilkinson M. Allergic contact dermatitis in children: trends in allergens, 10 years on. A retrospective study of 500 children tested between 2005 and 2014 in one UK centre. *Contact Dermatitis*. 2016; 74(1):37–43
70. Rushing GD, Goretsky MJ, Gustin T, Morales M, Kelly RE Jr., Nuss D. When it is not an infection: metal allergy after the Nuss procedure for repair of pectus excavatum. *J Pediatr Surg*. 2007;42(1): 93–97
71. Aneja S, Taylor JS, Soldes O, DiFiore J. Dermatitis in patients undergoing the Nuss procedure for correction of pectus excavatum. *Contact Dermatitis*. 2011;65(6):317–321
72. Shah B, Cohee A, Deyerle A, et al. High rates of metal allergy amongst Nuss procedure patients dictate broader pre-operative testing. *J Pediatr Surg*. 2014; 49(3):451–454
73. Heitmiller K, French A, Alaish SM, Goldner R, Gaspari AA. Patch testing for metal allergy with manufacturer-supplied materials before Nuss bar insertion. *Dermatitis*. 2015;26(6): 271–275
74. Peiser M, Tralau T, Heidler J, et al. Allergic contact dermatitis: epidemiology, molecular mechanisms, in vitro methods and regulatory aspects. Current knowledge assembled at an international workshop at BfR, Germany. *Cell Mol Life Sci*. 2012;69(5): 763–781
75. Schachner LA, Hansen RC, eds. *Pediatric Dermatology*, 4th ed. Philadelphia, PA: Mosby Elsevier; 2011
76. Hunt RD, Feldstein SI, Krakowski AC. Itching to learn: school chair allergic contact dermatitis on the posterior thighs. *J Clin Aesthet Dermatol*. 2014; 7(4):48–49
77. Ko LN, Schalock PC. Hypersensitivity to Hip and Knee Implants. In: Chen JK, Thyssen JP, eds. *Metal Allergy: From Dermatitis to Implant and Device Failure*. Cham, Switzerland: Springer International Publishing; 2018:249–262
78. Minster JT. The determination of nickel by precipitation with dimethylglyoxime. *Analyst*. 1946;71(846):424–428
79. Veien NK, Hattel T, Laurberg G. Low nickel diet: an open, prospective trial. *J Am Acad Dermatol*. 1993;29(6): 1002–1007
80. Matiz C, Jacob SE. Systemic contact dermatitis in children: how an avoidance diet can make a difference. *Pediatr Dermatol*. 2011;28(4):368–374
81. Ojekunle OZ, Ojekunle OV, Adeyemi AA, et al. Evaluation of surface water quality indices and ecological risk assessment for heavy metals in scrap yard neighbourhood. *Springerplus*. 2016;5:560

82. American Academy of Dermatology. Position statement on nickel sensitivity. 2015. Available at: https://www.aad.org/Forms/Policies/Uploads/PS/PS-Nickel%20Sensitivity.pdf. Accessed July 29, 2019

83. Garg S, Thyssen JP, Uter W, et al. Nickel allergy following European Union regulation in Denmark, Germany, Italy and the U.K. *Br J Dermatol*. 2013;169(4):854–858

84. Council of the European Union, European Parliament. European Parliament and Council Directive 94/27/EC, of 30 June 1994 amending for the 12th time Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the member states relating to restrictions on the marketing and use of certain dangerous substances and preparations. *Official Journal of the European Communities*. 1994;L 188:1–2

85. Johansen J, Menné T, Christophersen J, Kaaber K, Veien N. Changes in the pattern of sensitization to common contact allergens in Denmark between 1985-86 and 1997-98, with a special view to the effect of preventive strategies. *Br J Dermatol*. 2000;142(3):490–495

86. Toxic Substances Control Act, 15 USC §2601–2692 (2003).

87. Chemical Safety Improvement Act, S 1009, 113th Cong (2013). Available at: https://www.govtrack.us/congress/bills/113/s1009/text. Accessed July 29, 2019

88. Institute of Medicine Panel on Micronutrients. Arsenic, Boron, Nickel, Silicon, and Vanadium. In: *Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc*. Washington, DC: National Academies Press; 2001:502–553. Available at: www.nap.edu/read/10026/chapter/15#522. Accessed July 29, 2019

89. US Environmental Protection Agency. Nickel compounds. Available at: https://www.epa.gov/sites/production/files/2016-09/documents/nickle-compounds.pdf. Accessed March 11, 2020

90. Nickel Institute. The life of Ni. Available at: https://www.nickelinstitute.org/en/MediaCentre/News/CurrentYear/20160426-LifeofNi.aspx. Accessed May 30, 2016

Optimizing Resources in Children's Surgical Care: An Update on the American College of Surgeons' Verification Program

- *Technical Report*

TECHNICAL REPORT

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Optimizing Resources in Children's Surgical Care: An Update on the American College of Surgeons' Verification Program

Kasper S. Wang, MD, FAAP,[a] James Cummings, MD, FAAP,[b] Ann Stark, MD, FAAP,[c] Constance Houck, MD, MPH, FAAP,[d] Keith Oldham, MD, FAAP,[e] Catherine Grant, BSN, RN,[f] Mary Fallat, MD, FAAP,[g] SECTION ON SURGERY, COMMITTEE ON FETUS AND NEWBORN, SECTION ON ANESTHESIOLOGY AND PAIN MEDICINE

abstract

Surgical procedures are performed in the United States in a wide variety of clinical settings and with variation in clinical outcomes. In May 2012, the Task Force for Children's Surgical Care, an ad hoc multidisciplinary group comprising physicians representing specialties relevant to pediatric perioperative care, was convened to generate recommendations to optimize the delivery of children's surgical care. This group generated a white paper detailing the consensus opinions of the involved experts. Following these initial recommendations, the American College of Surgeons (ACS), Children's Hospital Association, and Task Force for Children's Surgical Care, with input from all related perioperative specialties, developed and published specific and detailed resource and quality standards designed to improve children's surgical care (https://www.facs.org/quality-programs/childrens-surgery/childrens-surgery-verification). In 2015, with the endorsement of the American Academy of Pediatrics (https://pediatrics.aappublications.org/content/135/6/e1538), the ACS established a pilot verification program. In January 2017, after completion of the pilot program, the ACS Children's Surgery Verification Quality Improvement Program was officially launched. Verified sites are listed on the program Web site at https://www.facs.org/quality-programs/childrens-surgery/childrens-surgery-verification/centers, and more than 150 are interested in verification. This report provides an update on the ACS Children's Surgery Verification Quality Improvement Program as it continues to evolve.

[a]Division of Pediatric Surgery, Department of Surgery, Keck School of Medicine, University of Southern California and Children's Hospital Los Angeles, Los Angeles, California; [b]Albany Medical Center, Albany, New York; [c]Department of Neonatology, Beth Israel Deaconess Medical Center, Boston, Massachusetts; [d]Division of Perioperative Anesthesia, Department of Anesthesiology, Perioperative and Pain Medicine, Boston Children's Hospital, Boston, Massachusetts; [e]Children's Hospital of Wisconsin, Milwaukee, Wisconsin; [f]American College of Surgeons, Chicago, Illinois; and [g]Department of Surgery, University of Louisville, Louisville, Kentucky

Technical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, technical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Dr Wang wrote the main manuscript; Drs Houck, Oldham, Stark, Fallat, and Cummings provided guidance and extensive editing of the manuscript; Ms Grant provided input on the guidelines from the American College of Surgeons as well as editing assistance for the document; and all authors approved the final manuscript as submitted.

To cite: Wang KS, Cummings J, Stark A, et al. AAP SECTION ON SURGERY, COMMITTEE ON FETUS AND NEWBORN, SECTION ON ANESTHESIOLOGY AND PAIN MEDICINE. Optimizing Resources in Children's Surgical Care: An Update on the American College of Surgeons' Verification Program. *Pediatrics.* 2020;145(5):e20200708

INTRODUCTION

An estimated 5 million ambulatory and inpatient operations are performed on infants and children annually at thousands of sites in the

United States.[1,2] Evidence suggests that some operations are performed in environments lacking the optimal levels of expertise and/or resources.[3]

Studies since the early 1960s comparing outcomes at different ages have consistently demonstrated increased perioperative morbidity and mortality in infants younger than 1 year, with infants younger than 1 month demonstrating the highest risk.[4,5] Both the incidence of perioperative cardiac arrest and death were more than 20-fold higher in infants younger than 30 days compared with children older than 10 years.[6] Pediatric-specific anesthesiology training was subsequently associated with reductions in anesthesia-related morbidity.[7,8] In one survey in which respondents self-reported pediatric anesthesia-related complications such as inadequate ventilation, overdose of anesthetic, cardiac arrest, pulmonary aspiration, complications attributable to regional anesthesia, and acute pulmonary edema, anesthesiologist-specific annual pediatric anesthesia case volume was inversely correlated with the incidence of complications, with the best-achieving practitioners performing >250 pediatric anesthesia cases annually.[9]

In 1999, given concerns that many pediatric patients were undergoing surgery in environments without pediatric-specific expertise and equipment available, the American Academy of Pediatrics (AAP) Section on Anesthesiology and Pain Medicine published guidelines for the pediatric perioperative anesthesia environment.[10] These guidelines were subsequently updated in 2015 and specifically aligned with the American College of Surgeons (ACS) Children's Surgery Verification (CSV) standards.[3] The updated guidelines included recommendations that younger children and children with significant comorbidities should be cared for by board-certified or -eligible pediatric anesthesiologists. In 2012, the American Board of Anesthesiology established board certification standards for pediatric anesthesia in the form of a certificate of added qualifications in pediatric anesthesiology (Table 1). As of 2015, more than 4000 pediatric anesthesiologists in the United States have obtained this certification, and 191 pediatric anesthesia fellowship training positions are available (up 162% from 2002 to 2015).[11] Projections based on current trends suggest that more than 7000 pediatric anesthesiologists will be practicing in the United States by 2035.[11]

Compelling evidence exists that some degree of regionalization of complex children's surgical care improves outcomes. Using statewide hospital discharge databases for the states of California in 1988 and Massachusetts in 1989, Jenkins et al[13] demonstrated that children undergoing surgery for a congenital heart defect were at much lower risk of dying in the hospital if the surgery was performed at a high-volume institution (>300 cases annually).[13] Using discharge data for the state of California from 1995 to 1997, Chang and Klitzner[14] modeled a statewide system in which cases from low- and medium-volume centers were transferred to a small number of high-volume and high-performing centers and demonstrated a significant theoretical decrease in deaths associated with surgery for a congenital heart defect.[14] Similarly, using data from the California Perinatal Quality Care Collaborative from 2005 to 2011, Kastenberg et al[15] showed lower risk-adjusted mortality in very low birth weight infants with necrotizing enterocolitis in high-volume level III NICUs compared with low-volume level III NICUs. Using data from the 2010 National Trauma Data Bank, Webman et al[16] showed that the risk-adjusted mortality rate for injured adolescents was lower when treated at pediatric trauma centers compared to adult trauma centers. These data again indicate that mortality outcomes are improved when care is delivered in centers with

TABLE 1 Verification and Quality Improvement Programs

Program	Year Established	Description
ACS Committee on Trauma	1950	The committee develops and implements programs that support injury prevention and ensure optimal patient outcomes across the continuum of care incorporating advocacy, education, trauma center and trauma system resources, best practice creation, outcome assessment, and continuous quality improvement.
ACS NSQIP-Pediatric	2008	Participating hospitals collect clinical data and compare their surgical outcomes with the outcomes of other participants in the program.
American Board of Anesthesiology Pediatric Anesthesiology Certification	2012	The American Board of Anesthesiology establishes initial pediatric subspecialty certification as well as maintenance of certification to ensure quality anesthetic management of infants and children.
ACS CSV Quality Improvement Program	2015	To ensure pediatric surgical patients have access to high-quality care, the program verifies that resources required to achieve optimal patient outcomes for children receiving surgical care at health care facilities are met.
AAP NICU Verification Program	2016	The program reviews NICUs to verify whether standards for a specific level of care as established by the policy statement "Levels of Neonatal Care"[12] are met.

appropriately matched expertise and resources.

Children who receive care for less complex surgical problems at hospitals with more robust pediatric resources also have better clinical outcomes than those treated at less well-resourced facilities. For instance, although patients had more severe disease related to intussusception, the rate of bowel resection was lower in pediatric facilities compared to nonpediatric facilities in the state of Washington.[17] Similarly, risk of complications related to surgical treatment of appendicitis and pyloric stenosis was lower for children at pediatric hospitals compared with nonpediatric hospitals.[18] These studies demonstrate that management of children with certain surgical conditions at centers with greater expertise and/or resources generally results in fewer adverse outcomes.

Programs have been developed on national and state levels to promote regionalization and establish criteria for a range of care levels with the goal of optimizing disease-specific outcomes. In 1976, the ACS established criteria for categorizing hospitals on the basis of availability of resources for the care of traumatic injuries. In 1987, in an effort to regionalize systems care for trauma patients, the ACS Committee on Trauma established the trauma site verification program (https://www.facs.org/quality-programs/trauma) (Table 1). After the regionalization of trauma care,[19] MacKenzie et al[20] demonstrated that mortality risk for similarly injured adults was significantly lower in trauma centers compared with nontrauma centers.

In 2004, an AAP policy statement proposed a classification system that was based on the functional capabilities of NICUs with the goal of matching the acuity and complexity of a neonate with the expertise and resources of the treating unit.[21] The AAP proposed that regionalized systems should be organized on the basis of defined capabilities of the various units to optimize the care of newborn infants. This policy has been reaffirmed twice since the original statement, most recently in 2012, at which time levels of care were restratified as I through IV (level IV being the highest).[12] In the latest policy statement, additional literature was cited demonstrating superior survival outcomes for very low birth weight (<1500 g) and extremely low birth weight (<1000 g) infants in level III NICUs compared to level I and II NICUs as well as superior survival outcomes in higher-volume centers of equivalent level. In 2016, the AAP initiated a NICU Verification Program (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/nicuverification) (Table 1). This program initially was developed to verify adherence to the Texas regulations regarding NICU levels of care (https://dshs.texas.gov/emstraumasystems/neonatal.aspx), which were developed on the basis of attributes of each level, as described in the AAP policy statement "Levels of Neonatal Care."[12]

ESTABLISHING CHILDREN'S SURGICAL VERIFICATION

The ad hoc Task Force for Children's Surgical Care was established in 2012 to address the potential mismatch of resources and an individual child's surgical needs in the United States. This multidisciplinary group comprising children's general and specialty surgeons, pediatric anesthesiologists, and others relevant to comprehensive perioperative care of infants and children met on 4 occasions and worked continuously between 2012 and 2015 to develop a consensus approach to matching resources with children's surgical needs and prepare an initial report.[22] This report included components of optimal resources for basic, advanced, and comprehensive children's surgical centers. Participants in the task force included representatives from the AAP, ACS, the American Pediatric Surgical Association, Children's Hospital Association, the Committee on Pediatric Anesthesia of the American Society of Anesthesiologists, and the Society for Pediatric Anesthesia.

Given the task force's white paper, the ACS CSV Quality Improvement Program was modeled after the well-established ACS verification programs that support a quality portfolio including trauma, colorectal cancer, breast cancer, and bariatric surgery. In 2015, the ACS released final standards for the CSV Quality Improvement Program as its fifth quality improvement program (Table 1). ACS CSV–verified programs are stratified from I through III (level I is the highest) on the basis of available resources and demonstrable commitment to pediatric surgical care (Table 2).

The main principles that form the foundation for the ACS CSV Program include the development of standards based on research, definition of infrastructure, a robust performance improvement process, rigorous data collection, and an external peer review verification process. Level I verification requires the presence of a wide range of pediatric subspecialists along with a level IV NICU and a PICU. In addition to pediatric general and specialty surgeons, pediatric proceduralists, including gastroenterology, pulmonary medicine, and interventional radiology, are also required in this multidisciplinary effort. A level III NICU is the minimum requirement for level II ACS CSV status. Institutional membership in the ACS National Surgical Quality Improvement Program Pediatric (NSQIP-Pediatric) (https://www.facs.org/quality-programs/pediatric) is required for standardized data collection for level I and level II ACS CSV centers; although this is not a requirement for level III ACS CSV status, institutional data collection is still

TABLE 2 Criteria for Children's Surgical Centers by Level

Criteria	Level I	Level II	Level III
Graduate medical education (any type)	Desired	No	No
Freestanding children's hospital or comprehensive pediatric care unit within general hospital organization	Yes	Yes	No
Children's surgical services	Yes	Yes	Yes
Pediatric surgeons	≥2	≥1	Pediatric expertise[a]
Pediatric anesthesiologists	≥2	≥1	Pediatric expertise[b]
Pediatric emergency medicine physicians	Yes	Desired	Pediatric expertise[c]
Pediatric radiologists	≥2	≥1	Pediatric expertise[d]
Other children's surgical specialists	Mandatory	Within scope	Variable
Pediatric rapid response team[e]	Yes	Yes	Yes
Surgery-specific children's CME for children's surgery medical director and liaisons	Yes	Yes	Yes
NICU	AAP level IV	AAP level III or greater	No
Neonatologists	Yes	Yes	No
Pediatric emergency department	Yes	Yes	"Expertise" facility
PICU	Yes	Desired	No
Pediatric critical care medicine physicians	Yes	Yes, within scope	No
Pediatric acute care unit[f]	Yes	Yes	No
Pediatric resuscitation equipment in all appropriate patient-care areas	Yes	Yes	Yes
Children's surgical program manager or coordinator	Yes	Yes	Yes
Surgical data collection	Yes	Yes	Yes, limited
Child-life and family-support programs	Yes	Yes	No
Pediatric social work and/or child protective services	Yes	Yes	Yes
Community outreach programs	Yes	Yes	Yes
Children's education programs	Yes	Yes	Yes
Surgical research	Yes	Desired	No
Minimum number of annual surgical procedures for children younger than 18 y	1000	—	—
Children's surgical performance improvement and patient safety program	Yes	Yes	Yes

CME, continuing medical education; —, not applicable.

[a] A general surgeon with pediatric expertise is defined as a surgeon either eligible for certification or certified by the American Board of Surgery or an equivalent body in general surgery. All surgeons who care for children will demonstrate ongoing clinical engagement and expertise in children's surgery, as evidenced by the performance of 25 or more procedures annually in patients younger than 18 years, as well as completion of 10 or more pediatric category 1 CME credit hours annually.[23]

[b] An anesthesiologist with pediatric expertise is defined as an anesthesiologist either eligible to certify with, or with a current certificate from, the American Board of Anesthesiology or equivalent. He or she will demonstrate continuous experience with children younger than 24 months, defined as 25 patients per anesthesiologist per year. In addition, this individual will demonstrate ongoing pediatric clinical engagement with patients younger than 18 years and will complete 10 or more pediatric category 1 CME credit hours annually.[23]

[c] An emergency medicine physician with pediatric expertise is defined as an individual certified by the American Board of Emergency Medicine, the American Board of Pediatrics, or equivalent and who has demonstrable pediatric experience and training to support the actual scope of emergency medicine practice, as well as 10 h annually of pediatric category 1 CME.[23]

[d] A radiologist with pediatric expertise is defined as a radiologist with certification by the American Board of Radiology or equivalent with demonstrable pediatric experience to support the scope of actual practice and 10 or more pediatric category 1 CME credit hours annually.[23]

[e] A pediatric rapid response and/or resuscitation team is required for level I verification (CD 2–35). There must be a 24/7 physical presence of a pediatric physician or surgeon who has current pediatric advanced life support certification (CD 2–36). The NICU should have a neonatal rapid response and/or resuscitation team with a 24/7 presence of a pediatric provider who has current Neonatal Resuscitation Program certification.[23]

[f] Staffed by pediatricians and/or pediatric hospitalists.

required. ACS NSQIP-Pediatric is a nationally validated, risk-adjusted outcomes assessment program used to measure and improve the quality of children's surgical care among more than 100 participating centers by reporting of institution's adverse events rates compared with those of peer institutions. As with all ACS verification programs, a dedicated administrative team, comprising a surgeon (NSQIP-Pediatric champion) and support staff, is vital to the success of the program. The current annual fees to participate in CSV and ACS NSQIP-Pediatric are listed at https://www.facs.org/quality-programs/childrens-surgery/fees. Reverification is performed every 3 years.

An up-to-date list of all verified centers is listed on the program Web site at https://www.facs.org/quality-programs/childrens-surgery/childrens-surgery-verification/centers. An additional 150 centers have expressed interest in verification. After receipt of a CSV application and submission of the prereview questionnaire, a reviewer team is selected. The team is a combination of 3 reviewers. The team always includes a specialty-qualified children's surgeon(s) and a pediatric anesthesiologist. The team may also include a pediatric nurse. The reviewers are selected by the ACS CSV Program staff. The review team is provided relevant documents and an organized agenda in advance of the site visit. Guidelines ensure consistent and appropriate conduct of the review. After the site visit, a standardized report is generated and reviewed by the ACS CSV Committee, which makes the final decision regarding verification.

Lessons learned from completed verification visits include the importance of developing institution-wide, multidisciplinary process improvement structures, and the need for robust resource commitments that prioritize pediatric patient safety and encourage quality improvement initiatives. In addition, establishing and maintaining pediatric-specific resources (nursing, operating rooms, etc) and

focused attention on pediatric provider training and availability are essential.

ACS CSV is a voluntary program that, if implemented uniformly, would enable all hospitals to identify and advocate for shortfalls in important resources for optimizing children's surgical care. Without augmentation of resources, Baxter et al,[24] using the 2009 Kids' Inpatient Database, estimated conservatively that more than one-third of all neonates with complex surgical conditions would need to be relocated from level II or III hospitals to a level I hospital.[24] Using propensity score-adjusted logistic regression, the authors further estimated 1 life saved for every 32 neonates relocated, with a median distance traveled of 6.6 miles (range up to >200 miles). The authors did not analyze the implications on morbidity and its associated costs. Although access to care is important, the goal of ACS CSV is ensuring the best care possible for each child requiring surgery, and site review can be used to advocate for pediatric perioperative resources important to achieving this goal.

Going forward, the ACS CSV Program actively collaborates with the AAP NICU Verification Program in Texas. The program also collaborates with Wake Up Safe, an anesthesia quality improvement program supported by the Society for Pediatric Anesthesia. As more hospitals undergo children's surgical verification, outcomes will be assessed to ascertain whether the process results in demonstrable improvements in children's health, as has been documented with trauma program verification.

CONCLUSIONS

The goal of the ACS CSV Program is to improve the quality of care for children requiring surgery by matching individual patient needs (including surgical complexity and comorbidities) with appropriate and optimal perioperative resources (including equipment and personnel). The ACS CSV Program is actively collaborating with the AAP NICU Verification Program. The program, which has been endorsed by the AAP, has already verified several programs, and it is projected that at least 20 additional pediatric perioperative programs will be verified by 2020. Ensuring that hospital resources are matched with children's surgical needs is expected to optimize clinical outcomes.

LEAD AUTHORS

Kasper S. Wang, MD, FAAP – *Section on Surgery*
James Cummings, MD, FAAP – *Committee on Fetus and Newborn*
Ann Stark, MD, FAAP – *NICU Verification Program*
Constance Houck, MD, MPH, FAAP – *Surgical Advisory Panel*

COAUTHORS

Keith Oldham, MD, FAAP
Catherine Grant, BSN, RN
Mary Fallat, MD, FAAP – *American College of Surgeons Children's Surgery Verification Committee*

SECTION ON SURGERY EXECUTIVE COMMITTEE, 2019–2020

Gail Ellen Besner, MD, Chairperson
Mary Fallat, MD, FAAP, Immediate Past Chairperson
Marybeth Browne, MD
Andrew Davidoff, MD, Incoming Chairperson
Cynthia D. Downard, MD
Kenneth William Gow, MD
Saleem Islam, MD

STAFF

Vivian B. Thorne

COMMITTEE ON FETUS AND NEWBORN, 2019–2020

James Cummings, MD, FAAP, Chairperson
Kristi Watterberg, MD, Immediate Past Chairperson
Ira S. Adams-Chapman, MD
Susan Aucott, MD
Jay P. Goldsmith, MD
Ivan Hand, MD
David Kaufman, MD
Camilia Martin, MD
Karen Puopolo, MD, PhD

LIAISONS

Michael Narvey, MD – *Canadian Paediatric Society*
Russell Miller, MD – *American College of Obstetricians and Gynecologists*
RADM Wanda Barfield, MD, MPH – *Centers for Disease Control and Prevention*
Erin Keels, DNP, APRN, NNP-BC – *National Association of Neonatal Nurses*
Timothy Jancelewicz, MD – *American Academy of Pediatrics Section on Surgery*
Meredith Mowitz, MD, MS – *American Academy of Pediatrics Section on Neonatal and Perinatal Medicine*

STAFF

Jim Couto, MA

SECTION ON ANESTHESIOLOGY AND PAIN MEDICINE EXECUTIVE COMMITTEE, 2019–2020

Anita Honkanen, MD, Chairperson
Mary Landrigan-Ossar, MD, PhD, Chair-Elect
Raeford Brown, MD, Immediate Past Chairperson
Christina D. Diaz, MD
Lisa Wise-Faberowski, MD
Stephen Hays, MD
Debnath Chatterjee, MD

LIAISONS

Rita Agarwal, MD – *Society for Pediatric Pain Medicine*
Kirk Lawani, MD – *Society for Pediatric Anesthesia*
Constance Houck, MD, MPH, FAAP – *American Academy of Pediatrics Committee on Drugs*
Sulpicio Soriano II, MD – *American Society of Anesthesiologists Committee on Pediatric Anesthesia*

STAFF

Jennifer Riefe

ABBREVIATIONS

AAP: American Academy of Pediatrics
ACS: American College of Surgeons
CSV: Children's Surgery Verification
NSQIP-Pediatric: National Surgical Quality Improvement Program Pediatric

DOI: https://doi.org/10.1542/peds.2020-0708

Address correspondence to Kasper S. Wang, MD, FAAP. E-mail: kwang@chla.usc.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Rabbitts JA, Groenewald CB, Moriarty JP, Flick R. Epidemiology of ambulatory anesthesia for children in the United States: 2006 and 1996. *Anesth Analg*. 2010;111(4):1011–1015
2. Tzong KYS, Han S, Roh A, Ing C. Epidemiology of pediatric surgical admissions in US children: data from the HCUP Kids Inpatient Database. *J Neurosurg Anesthesiol*. 2012;24(4): 391–395
3. Polaner DM, Houck CS; Section on Anesthesiology and Pain Medicine; American Academy of Pediatrics. Critical elements for the pediatric perioperative anesthesia environment. *Pediatrics*. 2015;136(6):1200–1205
4. Rackow H, Salanitre E, Green LT. Frequency of cardiac arrest associated with anesthesia in infants and children. *Pediatrics*. 1961;28:697–704
5. van der Griend BF, Lister NA, McKenzie IM, et al. Postoperative mortality in children after 101,885 anesthetics at a tertiary pediatric hospital. *Anesth Analg*. 2011;112(6):1440–1447
6. Flick RP, Sprung J, Harrison TE, et al. Perioperative cardiac arrests in children between 1988 and 2005 at a tertiary referral center: a study of 92,881 patients. *Anesthesiology*. 2007; 106(2):226–237–414
7. Keenan RL, Boyan CP. Cardiac arrest due to anesthesia. A study of incidence and causes. *JAMA*. 1985;253(16): 2373–2377
8. Mamie C, Habre W, Delhumeau C, Argiroffo CB, Morabia A. Incidence and risk factors of perioperative respiratory adverse events in children undergoing elective surgery. *Paediatr Anaesth*. 2004;14(3):218–224
9. Auroy Y, Ecoffey C, Messiah A, Rouvier B. Relationship between complications of pediatric anesthesia and volume of pediatric anesthetics. *Anesth Analg*. 1997;84(1):234–235
10. Hackel A, Badgwell JM, Binding RR, et al; Section on Anesthesiology; American Academy of Pediatrics. Guidelines for the pediatric perioperative anesthesia environment. *Pediatrics*. 1999;103(2):512–515
11. Muffly MK, Singleton M, Agarwal R, et al. The pediatric anesthesiology workforce: projecting supply and trends 2015-2035. *Anesth Analg*. 2018;126(2):568–578
12. American Academy of Pediatrics Committee on Fetus and Newborn. Levels of neonatal care. *Pediatrics*. 2012;130(3):587–597
13. Jenkins KJ, Newburger JW, Lock JE, Davis RB, Coffman GA, Iezzoni LI. In-hospital mortality for surgical repair of congenital heart defects: preliminary observations of variation by hospital caseload. *Pediatrics*. 1995;95(3): 323–330
14. Chang R-KR, Klitzner TS. Can regionalization decrease the number of deaths for children who undergo cardiac surgery? A theoretical analysis. *Pediatrics*. 2002;109(2):173–181
15. Kastenberg ZJ, Lee HC, Profit J, Gould JB, Sylvester KG. Effect of deregionalized care on mortality in very low-birth-weight infants with necrotizing enterocolitis. *JAMA Pediatr*. 2015;169(1):26–32
16. Webman RB, Carter EA, Mittal S, et al. Association between trauma center type and mortality among injured adolescent patients. *JAMA Pediatr*. 2016; 170(8):780–786
17. McAteer JP, Kwon S, LaRiviere CA, Oldham KT, Goldin AB. Pediatric specialist care is associated with a lower risk of bowel resection in children with intussusception: a population-based analysis. *J Am Coll Surg*. 2013;217(2):226–232.e3
18. McAteer JP, LaRiviere CA, Oldham KT, Goldin AB. Shifts towards pediatric specialists in the treatment of appendicitis and pyloric stenosis: trends and outcomes. *J Pediatr Surg*. 2014;49(1):123–127–128
19. Sampalis JS, Denis R, Lavoie A, et al. Trauma care regionalization: a process-outcome evaluation. *J Trauma*. 1999; 46(4):565–579–581
20. MacKenzie EJ, Rivara FP, Jurkovich GJ, et al. A national evaluation of the effect of trauma-center care on mortality. *N Engl J Med*. 2006;354(4):366–378
21. Stark AR; American Academy of Pediatrics Committee on Fetus and Newborn. Levels of neonatal care [published correction appears in *Pediatrics*. 2005;115(4):118]. *Pediatrics*. 2004;114(5):1341–1347
22. Task Force for Children's Surgical Care. Optimal resources for children's

surgical care in the United States. *J Am Coll Surg.* 2014;218(3):479–487.e4

23. American College of Surgeons. Optimal resources for children's surgical care: children's surgical verification quality improvement program v.1. Available at: https://www.facs.org/-/media/files/quality-programs/csv/acs-csv_standardsmanual.ashx. Accessed November 11, 2019

24. Baxter KJ, Gale BF, Travers CD, Heiss KF, Raval MV. Ramifications of the Children's Surgery Verification program for patients and hospitals. *J Am Coll Surg.* 2018;226(5):917–924.e1

Participation of Children and Adolescents in Live Crisis Drills and Exercises

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Participation of Children and Adolescents in Live Crisis Drills and Exercises

David J. Schonfeld, MD, FAAP,[a] Marlene Melzer-Lange, MD, FAAP,[b] Andrew N. Hashikawa, MD, MS, FAAP,[c] Peter A. Gorski, MD, MPA, FAAP,[d,e] COUNCIL ON CHILDREN AND DISASTERS, COUNCIL ON INJURY, VIOLENCE, AND POISON PREVENTION, COUNCIL ON SCHOOL HEALTH

Children and adolescents should be included in exercises and drills to the extent that their involvement advances readiness to meet their unique needs in the event of a crisis and/or furthers their own preparedness or resiliency. However, there is also a need to be cautious about the potential psychological risks and other unintended consequences of directly involving children in live exercises and drills. These risks and consequences are especially a concern when children are deceived and led to believe there is an actual attack and not a drill and/or for high-intensity active shooter drills. High-intensity active shooter drills may involve the use of real weapons, gunfire or blanks, theatrical makeup to give a realistic image of blood or gunshot wounds, predatory and aggressive acting by the individual posing to be the shooter, or other means to simulate an actual attack, even when participants are aware that it is a drill. This policy statement outlines some of the considerations regarding the prevalent practice of live active shooter drills in schools, including the recommendations to eliminate children's involvement in high-intensity drills and exercises (with the possible exception of adolescent volunteers), prohibit deception in drills and exercises, and ensure appropriate accommodations during drills and exercises based on children's unique vulnerabilities.

BACKGROUND

Historically, children of all ages have generally not been included in crisis preparedness efforts in the United States, including participation in live drills and exercises, and certainly not to the extent that children are represented in the general population. This lack of planning and practice for the needs of children represents a significant oversight that increases the vulnerability of children in the event of a crisis.[1] However, increasing concerns about the risk of mass casualty events in schools throughout the United States have given rise to crisis preparedness efforts that now include

abstract

[a]National Center for School Crisis and Bereavement, Children's Hospital Los Angeles and Department of Clinical Pediatrics, Keck School of Medicine, University of Southern California, Los Angeles, California; [b]Division of Emergency Medicine, Department of Pediatrics, Medical College of Wisconsin and Children's Wisconsin, Milwaukee, Wisconsin; [c]Departments of Emergency Medicine and Pediatrics, Michigan Medicine, University of Michigan, Ann Arbor, Michigan; [d]Departments of Pediatrics and Humanities, Health, and Society, Herbert Wertheim College of Medicine, Florida International University, Miami, Florida; and [e]Department of Public Health Sciences, Miller School of Medicine, University of Miami, Miami, Florida

Drs Schonfeld, Melzer-Lange, Hashikawa, and Gorski all contributed to the manuscript concept and design, critically reviewed and revised the manuscript and earlier drafts, and approved the final manuscript as submitted.

To cite: Schonfeld DJ, Hashikawa AN, et al. AAP COUNCIL ON CHILDREN AND DISASTERS, COUNCIL ON INJURY, VIOLENCE, AND POISON PREVENTION, COUNCIL ON SCHOOL HEALTH. Participation of Children and Adolescents in Live Crisis Drills and Exercises. *Pediatrics.* 2020;146(3):e2020015503

children in high-intensity live crisis exercises such as active shooter drills, which are increasingly held in schools and involving children of all ages, including early elementary school- and preschool-aged children as well as college students. For the purpose of this policy statement, "children" will be used to refer to children and youth of all ages (ie, 0–21 years of age), unless stated otherwise. The American Academy of Pediatrics (AAP) recommends that children be included in exercises and drills only to the extent that their involvement advances adult readiness to meet the unique needs of children in the event of a crisis and/or furthers their own preparedness or resiliency. However, there is also a need to be cautious about the potential psychological risks of directly involving children in live exercises and drills. These risks are especially a concern when children are deceived so that they believe there is an actual attack and not a drill and/or for high-intensity active shooter drills.

A lockdown is an emergency procedure to minimize risk of harm to students and staff when a significant threat of violence within (or near) the school is present. A lockdown generally involves the immediate movement of students and staff into rooms in which doors are locked and students remain quiet. Other security measures are often followed, including darkened lights, shades on exterior windows, and covered doors, and children moving to an area that is not visible from hallways. Lockdown drills are when lockdown procedures are practiced in the absence of a threat, including as a form of preparation for a possible armed assailant (in which case, some people may refer to this as an active shooter drill). High-intensity active shooter drills may involve the use of real weapons, gunfire or blanks, theatrical makeup to give a realistic image of blood or gunshot wounds, predatory and aggressive acting by the individual posing to be the shooter, or other means to simulate an actual attack, even when participants are aware that it is a drill.[2]

STATEMENT OF PROBLEM

The majority of school districts currently require active shooter drills, among other emergency drills and exercises within schools and other community settings.[3] If planned and conducted thoughtfully with sufficient attention to the potential emotional impact of participation and conducted in a manner that is developmentally appropriate, exercises such as lockdown drills may be completed without a major negative impact to most children.[4] However, in practice, active shooter drills are often planned and conducted without guidance from those familiar with the unique needs and vulnerabilities of individual or groups of children, which is critical to inform best practices. The unique needs of young children (eg, those in early care and education settings), children who suffered traumatic events in the past, and those with physical, intellectual, and neurodevelopmental disabilities are rarely considered and addressed in live exercise planning. Preparedness initiatives and approaches need to be evaluated to ensure that they are effective, and research is needed to demonstrate that these initiatives do not cause untoward distress or other unintended consequences for individual or groups of children and school staff or other adult participants.

EVIDENCE BASE

Although there is general agreement that the direct involvement of children should be based on the value of including them in crisis drills and exercises, their age and developmental capabilities, and their personal vulnerabilities, there is a limited evidence base on how to make these assessments. Mass shootings in schools, although highly visible in the media and social consciousness, are rare events. These events, therefore, provide limited opportunities to test the efficacy of interventions in real-life situations. School safety, especially related to school shootings, has generated opportunities for products and services that together represent major financial investments, without much or any evidence of efficacy.[5] Products promoted for purchase by schools now include bulletproof barriers or shelters intended to accommodate the full class and teacher that can be used as panic rooms in the event of a school shooting.[6] These types of training and interventions proposed have rarely been evaluated, despite an escalating demand for both.

Recently, researchers have begun to question the efficacy of some popular training approaches. For example, Dorn[7] conducted more than 8000 one-on-one controlled video and audio simulations and, in the study, found that school personnel who completed active shooter training designed to train people to make decisions among various crisis response options (eg, whether to run, hide, or physically attack a shooter) were almost twice as likely to misjudge many critical action steps in simulations compared with untrained school staff who relied on common-sense actions. For example, adults who completed the training were more likely to attack a child who was holding a gun and threatening suicide or run from a classroom when staying within the room was the safer alternative.

It is possible, and even likely, that other well-intentioned preparedness efforts may inadvertently cause children and adults to place themselves in additional danger in a crisis situation. Children (and adults) might be taught to fight a heavily armed intruder, when fleeing or hiding would be a more appropriate response. Children taught to provide first aid to a bleeding peer or remain near an injured person to comfort them may remain in harm's way in an

active shooter event and place themselves at increased risk of becoming a casualty.

Some students and school personnel may feel empowered by being able to actively participate in live exercises because they may feel that it better prepares them for possible events. These individuals may, however, underestimate how others with different personalities, coping styles, personal histories, and individual vulnerabilities may respond. Children and adults who receive training to respond to a crisis may feel comforted because it provides them an illusion of control. However, such efforts could result in increased guilt if the individual is not able to respond in the idealized fashion in a real event. For example, children taught to fight back against an armed intruder or adult staff who are armed with a weapon to shoot a potential attacker may feel substantial guilt if they end up fleeing (appropriately) or are unable to save the life of a child or peer in an actual attack. These and other unintended consequences need to be carefully considered, and programs need to be evaluated more strategically for efficacy before being widely implemented. Even initiatives with good intentions may cause serious harm.

Unfortunately, there is not much evidence to guide best practices. Survivors or family members of individuals who died in crisis events may be powerful advocates for preparedness efforts and feel passionately about the need to take active steps to protect students and staff from school crisis events. Parents and other community members may simply be unwilling to wait until preparedness approaches are adequately evaluated. Pediatricians and other pediatric health care providers can provide important insights into the developmental needs and vulnerabilities of children of all ages that can help inform best practices.

Law enforcement personnel who place their own lives in jeopardy have the unenviable responsibility of protecting children from such acts of violence and may understandably suggest taking virtually any action that may save a child's life, thereby leading them to recommend involving children in high-intensity drills. Their passion may need to be balanced with concerns of unintended mental and physical consequences and/or the lack of evidence about the efficacy of certain approaches.

Law enforcement personnel benefit from regular and realistic opportunities to practice critical skills, much as physicians do. It, therefore, stands to reason that these professionals would seek opportunities to identify and then practice how best to respond to active shooter scenarios in schools and other settings. The question is whether and in which situations children and adolescents should be actively engaged in such live exercises and how the exercises should be conducted to minimize the negative impacts on students. Guidelines developed by the National Association of School Psychologists and National Association of School Resource Officers recommend that schools follow a hierarchy of preparedness strategies, beginning with simple discussion-based exercises, before even considering complex (in-person or live) operations-based drills. These organizations also recommend the inclusion of school mental health professionals in both the planning and implementation of drills so that careful consideration can be given to the appropriate involvement of children and potential means to minimize distress for all participants.[8,9]

In contrast, some schools have conducted active shooter exercises without advance notice and misled students and/or staff members that it was an actual shooting event, complete with a police response and, in at least one situation, armed weapons pointed at school-aged children. This is based on the belief that simulations that evoke the same level of distress as real events better prepare participants to act appropriately at a time of true crisis.[2] During one recent live exercise in which high school students were deceived to believe it was a real event, children sobbed hysterically, vomited, or fainted, and some children sent farewell notes to parents. Children risked physical harm when a stampede ensued, and students jumped over fences to escape.[10] In one situation, staff were intentionally shot at close range with pellets as part of the training.[11]

High-intensity crisis preparedness efforts may contribute to a distorted sense of risk in children and perspective that adults and peers need to be viewed as potential killers. More broadly, these activities can increase children's anxiety and fear that the world is a threatening place.[12] This atmosphere of a continuous threat of violent death is likely to increase anxiety further among children when frequent threats directed at the school or present in the community lead to lockdown procedures. It should not be a surprise that there are reports of young children writing frantic notes while in lockdown, including one 7-year-old who wrote "Love mom and dad" with marker on her arm and later explained to her mother that it was "In case the bad guy got to us and I got killed, you and daddy would know that I love you" after her body was discovered.[10,13] Even infants and toddlers in early child care settings, who will have little understanding of the implications of gun violence, may nonetheless react negatively with increased anxiety, stress, and helplessness to the stressful context, loud noises, and disruptive environment of active shooter drills, especially when the adults are themselves distressed. Stakeholders can instead be focused on equipping children with the skills

needed and expectations of peaceful coexistence rather than an expectation for and preparation to recover from mass violence. Resources directed to prevention efforts are more cost-effective and have wider benefits to potential victims, survivors, and society.

The December 2018 report of the Federal Commission on School Safety[14] included the following statement: "While there is some disagreement over whether it is appropriate to subject students to active shooter training, as school shootings become more prevalent, more schools are opting to drill their students on how to respond to an active shooter situation. According to a 2016 US Government Accountability Office report, an estimated 67% of school districts conduct active shooter drills involving their students. Whether to conduct active shooter drills with the student population is something each community must determine for itself. For those that do elect to conduct active shooter drills with students, they should ensure that the training is age-appropriate and designed in a manner not to unduly traumatize any of the participants."

The determination of what is generally age-appropriate and/or likely to be traumatizing to children when conducting a live crisis exercise or drill is something that can be determined at a national level. There is a general lack of national recommendations on whether to include children in active shooter exercises and other crisis drills. This policy statement aims to provide those recommendations.

CONCLUSIONS

The AAP supports advocacy efforts at the national and state levels to ensure that the unique needs of children are fully considered in crisis preparedness efforts, including, when appropriate, the involvement of children in live exercises and drills. However, the AAP also recognizes the importance of ensuring that preparedness efforts are effective but do not cause children untoward psychological distress or lead to other unintended consequences.

RECOMMENDATIONS

1. Eliminate children's routine involvement in high-intensity drills and exercises. Children should generally only be involved in crisis exercises when their involvement is of direct benefit to them and/or other children, rather than only of benefit to adult professionals. If the goal of a high-intensity drill or exercise is for adult responders to practice their roles (eg, to train law enforcement and/or medical personnel), then alternatives such as manikins or adults playing the roles of children should be sufficient, or the activity can occur outside of the hours when students are present in schools or preschools. First responders may need to practice being in a high-stress situation involving active shooters, but the same is not true for school-aged children. Therefore, only adolescents who have a personal desire to participate (eg, volunteers from a drama club or teenagers who plan a career in law enforcement or as an emergency medical technician) should have the option to be included in high-intensity drills and exercises until evidence is gathered that such drills or exercises are of sufficient benefit to warrant the likely distress of other participants.
2. Obtain active consent/assent of adolescent volunteer participants. If adolescents volunteer to be involved in high-intensity live exercises, they should be carefully briefed on what will be involved and the feelings that the experience may engender (including for those with undisclosed personal vulnerabilities, such as anxiety or past traumatic experiences) and told that they are under no pressure to volunteer. For this reason, active consent (for those youth able to provide consent) or active consent from a legal guardian and assent from the adolescent should generally be required for live high-intensity exercises, rather than the use of passive consent procedures. Children who are of an age and developmental ability to provide consent/assent for procedures that may cause modest physical discomfort or modest emotional distress to an average child (eg, donating blood in a blood drive for example) may be permitted to provide consent/assent to participate in such exercises; younger children should not be allowed to participate. Even adolescents who have been appropriately briefed and are capable of providing consent/assent may still not disclose personal vulnerabilities and/or may underestimate the distress that participation may ultimately cause.
3. School personnel or other adults present during drills should remain vigilant for psychological distress. It is critical to minimize the distress children may experience throughout any exercise. Simulations involving real weapons, gunfire or blanks, theatrical makeup to give a realistic image of blood or gunshot wounds, predatory and aggressive acting by the individual posing to be the shooter, or other means to accurately simulate an actual attack are likely to still be traumatic to some and should require careful justification. Even if children have agreed to participate in an exercise, they ought to be instructed to discontinue participation if it is causing any physical or emotional

distress and explicitly given permission to take a break from the exercise for any reason. Adult monitors should be observing children's reactions and checking on them periodically throughout the exercise. Even when exercises or drills do not include any elements that may be felt likely to engender distress, some children and adults may nevertheless experience distress. For this reason, adults should carefully monitor the reactions of children and adults to any exercises and drills, with oversight by an experienced member of the team planning the exercise or drill, and provide supportive services as indicated.

4. Eliminate deception in drills and exercises. Notice of drills should be provided to parents, students, and staff members. Students, staff, and families of students should not be led to believe that an exercise is a real event or misled about the injury to or death of others. Such a practice is harmful and unethical and is not justified by a theoretical benefit of evaluating people's response under extreme levels of stress. State AAP chapters can advocate that schools and emergency response agencies prohibit the use of deception in live drills and exercises and any related simulations (eg, mock death notifications and funerals). Instead, it should be mandatory to notify parents, students, and staff members of planned live crisis drills and exercises. Pediatricians can review the policies of local school districts, inquire about their current practices related to drills and exercises, and offer guidance as described in this policy.
5. Focus on teaching skills rather than simulating distressing crisis events. The goal of live exercises and drills is to teach skills before actively testing them in a more pressured context that may degrade performance, thereby helping to promote and demonstrate competence rather than overwhelming people by their failures. Stakeholders planning drills and exercises should articulate that the learning objectives for adult and child participants are different and ensure that the drills and exercises highlight or teach specific behaviors that promote safety rather than simply being used to highlight potential dangers or convey the seriousness of a crisis event. Feedback from all stakeholder groups, including students and staff, should be obtained after exercises and drills to identify any remaining gaps in knowledge and skills and ascertain if participation caused any distress or other unintended consequences.
6. Make accommodations that are based on children's unique vulnerabilities. In most situations, active shooter drills should be conducted as fire drills are generally conducted (without simulation of there being an active fire) using a well-discussed, calm approach to the safe movement of students and staff in the school building. In general, adults should avoid referencing these drills with names that may engender further distress, such as calling them "active shooter drills"; instead, terms such as "lockdown," "shelter in place," or "safety drills" are preferable. Children with a high level of personal vulnerability (eg, students with an anxiety disorder, previous traumatic experience, or physical disability) may require particular accommodations, including being excused from certain drills or exercises when such participation may be overwhelming.[15,16] Parents and/or guardians can be notified at the start of a school year about the likely drills that will be held and invited to bring any concerns about their child's participation to the school's attention. Pediatricians who become aware of such concerns should encourage and assist parents to communicate them directly to school authorities. In some situations, the accommodations may be part of a 504 Plan or incorporated into a student's Individualized Education Program. School personnel must be conscious of the unique needs of early childhood, child care, Head Start and Early Head Start, or preschool programs located on campus and consider ways to exclude or mitigate the impact on this vulnerable population.
7. Seek and incorporate student input. School personnel can give thought as to how to incorporate the input of students into safety discussions and planning for exercises and drills. Students can provide important insight into the risks that students may face in the event of a crisis, vulnerabilities that adults may not anticipate, and how best to prepare peers for exercises and drills and minimize their distress while participating. It is important, though, to remember that some students and staff may feel empowered by opportunities to engage actively in exercises and underestimate the distress it may cause other students with different personalities, coping styles, or preexisting vulnerabilities. Adults can talk with students after conducting drills and exercises to obtain their feedback about the experience and suggestions on how to optimize future exercises and drills.
8. Obtain multidisciplinary input into exercise and/or drill planning. To give careful consideration to the needs of all children in drills and

exercises, planning teams should be multidisciplinary and include pediatricians or other professionals with expertise in child development and behavioral health, such as school mental health providers (eg, school counselors, psychologists, and social workers). Such planning teams should also explore how best to incorporate the input of students, school and/or preschool staff of different professions, parents, and other community partners. Teachers and other school professionals care deeply about protecting children and may, therefore, have more emotional reactions to such exercises and drills than planners anticipate, even in the absence of any personal vulnerabilities such as preexisting trauma or loss. The impact of drills and exercises on adults should be given careful consideration as well.

9. Emphasize the role of prevention. Sufficient emphasis should be placed on the prevention of violence, including the necessary financial resources and professional efforts. These efforts include, among others, efforts in social-emotional learning, positive school climate and culture, early identification and effective and readily accessible treatment of behavioral health concerns and mental illness, educator and school administration training, deployment of sufficient mental health and support personnel in schools, and interdisciplinary threat assessment.[5] The AAP and its members can work with others nationally to balance the rights of gun ownership with the need to protect the safety of children in a way that does not allow society to view mass shootings involving children as inevitable or as a "new normal" in society.
10. Promote legislative advocacy. All legislation requiring active shooter drills in schools should be required to follow best-practice guidelines, such as those from the National Association of School Psychologists and the National Association of School Resource Officers.[8] Among other recommendations, these guidelines recommend that schools begin with simple discussion-based exercises (ie, tabletop exercises) before considering complex live drills.
11. Conduct research on the impact of exercises and drills. Funding for research is needed to evaluate the goals, efficacy, and potential unintended consequences of crisis preparedness activities involving children. Strategies that are likely to cause significant distress or other unintended consequences, such as high-intensity live exercises, should be evaluated before they are implemented, especially in the absence of evidence of their efficacy.

LEAD AUTHORS

David J. Schonfeld, MD, FAAP
Marlene Melzer-Lange, MD, FAAP
Andrew N. Hashikawa, MD, MS, FAAP
Peter A. Gorski, MD, MPA, FAAP

COUNCIL ON CHILDREN AND DISASTERS EXECUTIVE COMMITTEE, 2019–2020

Steven Krug, MD, FAAP, Chairperson
Carl Baum, MD, FACMT, FAAP
Sarita Chung, MD, FAAP
Deanna Dahl-Grove, MD, FAAP
H. Dele Davies, MD, MS, MHCM, FAAP
Eric Dziuban, MD, DTM, CPH, FAAP
Aaron Gardner, MD, MS, FAAP
Stephanie Griese, MD, MPH, FAAP
Scott Needle, MD, FAAP
David J. Schonfeld, MD, FAAP
Joelle Simpson, MD, MPH, FAAP

STAFF

Laura Aird, MS

COUNCIL ON INJURY, VIOLENCE, AND POISON PREVENTION EXECUTIVE COMMITTEE, 2019–2020

Benjamin D. Hoffman, MD, FAAP, Chairperson
Phyllis F. Agran, MD, MA, MPH, FAAP
Michael Peter Hirsh, MD, FAAP
Brian Duncan Johnston, MD, MPH, FAAP
Sadiqa Kendi, MD, CPST, FAAP
Lois Kaye Lee, MD, MPH, FAAP
Kathy Wingo Monroe, MD, FAAP
Judy Schaechter, MD, MBA, FAAP
Milton Tenenbein, MD, FAAP
Mark R. Zonfrillo, MD, MSCE, FAAP

LIAISONS

Suzanne Marie Beno, MD – *Canadian Paediatric Society*
Jonathan D. Midgett, PhD – *Consumer Product Safety Commission*
Bethany Miller, LCSW-C, MEd – *Health Resources and Services Administration*
Alexander "Sandy" Sinclair – *National Highway Traffic Safety Administration*

STAFF

Bonnie Kozial

COUNCIL ON SCHOOL HEALTH EXECUTIVE COMMITTEE, 2019–2020

Cheryl L. De Pinto, MD, MPH, FAAP, Chairperson
Marti Baum, MD, FAAP
Nathaniel Brittingham Savio Beers, MD, MPA, FAAP
Sara Moran Bode, MD, FAAP
Erica J. Gibson, MD, FAAP
Peter A. Gorski, MD, MPA, FAAP
Viju Jacob, MD, FAAP
Marian Larkin, MD, FAAP
Sonja C. O'Leary, MD, FAAP
Ryan Christopher Padrez, MD, FAAP
Heidi Kristen Schumacher, MD, FAAP

LIAISONS

Shashank Vishnuprasad Joshi, MD – *American Academy of Child and Adolescent Psychiatry*
Linda Mendonca, RN, MSN, PHNA-BC, NCSN, FNASN – *National Association of School Nurses*

STAFF

Stephanie Domain, MS

ABBREVIATION

AAP: American Academy of Pediatrics

DOI: https://doi.org/10.1542/peds.2020-015503

Address correspondence to David J. Schonfeld, MD, FAAP. E-mail: schonfel@usc.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

This document is copyrighted and is property of the American Academy of Pediatrics and its Board of Directors. All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors. The American Academy of Pediatrics has neither solicited nor accepted any commercial involvement in the development of the content of this publication.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Needle S, Wright J; Disaster Preparedness Advisory Council; Committee on Pediatric Emergency Medicine. Ensuring the health of children in disasters. *Pediatrics*. 2015; 136(5). Available at: www.pediatrics.org/cgi/content/full/136/5/e1407
2. Schonfeld DJ, Rossen E, Woodard D. Deception in schools-when crisis preparedness efforts go too far. *JAMA Pediatr*. 2017;171(11):1033–1034
3. US Government Accountability Office. *Emergency Management: Improved Federal Coordination Could Better Assist K–12 Schools Prepare for Emergencies*. Washington, DC: US Government Accountability Office; 2016
4. Zhe EJ, Nickerson AB. Effects of an intruder crisis drill on children's knowledge, anxiety, and perceptions of school safety. *School Psych Rev*. 2007; 36(3):501–508
5. Cornell DG. Threat assessment as a school violence prevention strategy. *Criminol Public Policy*. 2020;19(1): 235–252
6. Osborne M. Oklahoma elementary school installs bulletproof shelters in classrooms. 2018. Available at: https://abcnews.go.com/US/oklahoma-elementary-school-installs-bulletproof-shelters-classrooms/story?id=53409001. Accessed April 6, 2020
7. Dorn M. Safety & security: dangers of active shooter training programs. 2018. Available at: https://www.netassets.org/blogs/net-assets/2018/10/04/safety-security-dangers-of-active-shooter-training. Accessed April 6, 2020
8. National Association of School Psychologists. Best practice considerations for schools in active shooter and other armed assailant drills. Available at: https://www.nasponline.org/resources-and-publications/resources-and-podcasts/school-climate-safety-and-crisis/systems-level-prevention/best-practice-considerations-for-schools-in-active-shooter-and-other-armed-assailant-drills. Accessed April 6, 2020
9. Chung S, Foltin G, Schonfeld DJ, et al; American Academy of Pediatrics. *Pediatric Disaster Preparedness and Response Topical Collection*. Itasca, IL: American Academy of Pediatrics; 2019. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Children-and-Disasters/Pages/Pediatric-Terrorism-And-Disaster-Preparedness-Resource.aspx. Accessed April 6, 2020
10. Christakis E. Active-shooter drills are tragically misguided. *The Atlantic*. March 2019. Available at: www.theatlantic.com/magazine/archive/2019/03/active-shooter-drills-erika-christakis/580426/. Accessed April 6, 2020
11. Zraick K. Indiana teachers were shot with pellets during active-shooter drill, union says. *The New York Times*. March 22, 2019. Available at: https://www.nytimes.com/2019/03/22/us/indiana-teachers-shot.html. Accessed April 6, 2020
12. Woesner ME. The return of duck and cover and the imminence of death—what it means for physicians. *JAMA Pediatr*. 2018;172(6): 511–512
13. Higgins M. 7-year-old writes love note to parents on her arm 'in case I got killed' during school lockdown. 2019. Available at: https://m.dailykos.com/stories/2019/2/13/1834418/-7-year-old-writes-love-note-to-parents-on-her-arm-in-case-I-got-killed-during-school-lockdown. Accessed April 6, 2020
14. Federal Commission on School Safety. Final report of the Federal Commission on School Safety. 2018. Available at: https://www2.ed.gov/documents/school-safety/school-safety-report.pdf. Accessed April 6, 2020
15. Schonfeld DJ, Demaria T; Committee on Psychosocial Aspects of Child and Family Health, Disaster Preparedness Advisory Council. Supporting the grieving child and family. *Pediatrics*. 2016;138(3):e20162147
16. Schonfeld DJ, Demaria T; Disaster Preparedness Advisory Council and Committee on Psychosocial Aspects of Child and Family Health. Providing psychosocial support to children and families in the aftermath of disasters and crises. *Pediatrics*. 2015;136(4). Available at: www.pediatrics.org/cgi/content/full/136/4/e1120

Pediatric Readiness in Emergency Medical Services Systems

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Pediatric Readiness in Emergency Medical Services Systems

Brian Moore, MD, FAAP,[a] Manish I. Shah, MD, MS, FAAP,[b] Sylvia Owusu-Ansah, MD, MPH, FAAP,[c] Toni Gross, MD, MPH, FAAP,[d] Kathleen Brown, MD, FAAP,[e,f] Marianne Gausche-Hill, MD, FACEP, FAAP, FAEMS,[g] Katherine Remick, MD, FACEP, FAAP, FAEMS,[h,i,j] Kathleen Adelgais, MD, MPH, FAAP,[k] John Lyng, MD, FAEMS, FACEP, NRP,[l] Lara Rappaport, MD, MPH, FAAP,[m] Sally Snow, RN, BSN, CPEN, FAEN,[n] Cynthia Wright-Johnson, MSN, RNC,[o] Julie C. Leonard, MD, MPH, FAAP,[p] and the AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE AND SECTION ON EMERGENCY MEDICINE EMS SUBCOMMITTEE, AMERICAN COLLEGE OF EMERGENCY PHYSICIANS EMERGENCY MEDICAL SERVICES COMMITTEE, EMERGENCY NURSES ASSOCIATION PEDIATRIC COMMITTEE, NATIONAL ASSOCIATION OF EMERGENCY MEDICAL SERVICES PHYSICIANS STANDARDS AND CLINICAL PRACTICE COMMITTEE, NATIONAL ASSOCIATION OF EMERGENCY MEDICAL TECHNICIANS EMERGENCY PEDIATRIC CARE COMMITTEE

This is a joint policy statement from the American Academy of Pediatrics, American College of Emergency Physicians, Emergency Nurses Association, National Association of Emergency Medical Services Physicians, and National Association of Emergency Medical Technicians on pediatric readiness in emergency medical services systems.

abstract

[a]Department of Emergency Medicine, University of New Mexico Health Sciences Center, Albuquerque, New Mexico; [b]Section of Emergency Medicine, Department of Pediatrics, Baylor College of Medicine and Texas Children's Hospital, Houston, Texas; [c]Division of Emergency Medical Services, Department of Pediatrics and Emergency Department, University of Pittsburgh Medical Center Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania; [d]Department of Emergency Medicine, Children's HospitalNew Orleans and Louisiana State University Health New Orleans, New Orleans, Louisiana; [e]Departments of Pediatrics and Emergency Medicine, School of Medicine and Health Sciences, The George Washington University, Washington, District of Columbia; [f]Division of Emergency Medicine, Children's National Medical Center, Washington, District of Columbia; [g]Departments of Emergency Medicine and Pediatrics, David Geffen School of Medicine, University of California, Los Angeles and Harbor–University of California, Los Angeles Medical Center, Los Angeles, California; [h]San Marcos Hays County Emergency Medical Services, San Marcos, Texas; [i]Austin-Travis County Emergency Medical Services System, Austin, Texas;

To cite: Moore B, Shah MI, Owusu-Ansah S, et al. AAP and the AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE AND SECTION ON EMERGENCY MEDICINE EMS SUBCOMMITTEE, AAP AMERICAN COLLEGE OF EMERGENCY PHYSICIANS EMERGENCY MEDICAL SERVICES COMMITTEE, AAP EMERGENCY NURSES ASSOCIATION PEDIATRIC COMMITTEE, AAP NATIONAL ASSOCIATION OF EMERGENCY MEDICAL SERVICES PHYSICIANS STANDARDS AND CLINICAL PRACTICE COMMITTEE, AAP NATIONAL ASSOCIATION OF EMERGENCY MEDICAL TECHNICIANS EMERGENCY PEDIATRIC CARE COMMITTEE. Pediatric Readiness in Emergency Medical Services Systems. *Pediatrics.* 2020;145(1): e20193307

Prehospital emergency care typically involves emergency medical technicians, paramedics, and other licensed medical providers who work in emergency medical services (EMS) systems in ground ambulances and fixed- or rotor-wing aircraft that are dispatched to an emergency when either a bystander calls 9-1-1 or when a patient requires interfacility transport for a medical illness or traumatic injury. Because prehospital emergency care of children plays a critical role in the continuum of health care, which also involves primary prevention, hospital-based acute care, rehabilitation, and return to the medical home, the unique needs of children must be addressed by EMS systems.[1–5] Pediatric readiness encompasses the presence of equipment and medications, usage of guidelines and policies, availability of education and training, incorporation of performance-improvement practices, and integration of EMS physician medical oversight to equip EMS systems to deliver optimal care to children.[6–8] It has been shown that emergency departments are more prepared to care for children when a pediatric emergency care coordinator is responsible for championing and making recommendations for policies, training, and resources pertinent to the emergency care of children.[9,10] The specialty of EMS medicine has the potential to derive similar benefits when members of the EMS community are personally

invested in pediatric patient care. Although a critical aspect of pediatric readiness in EMS involves strong EMS physician oversight of these investments, a discussion of physician oversight of pediatric care in EMS is outside the scope of this article. This topic is, however, well addressed in the National Association of Emergency Medical Services Physicians position statement "Physician Oversight of Pediatric Care in Emergency Medical Services."[1] This policy statement is accompanied by a technical report published simultaneously in this issue of *Pediatrics*.[11]

RECOMMENDATIONS

To provide infrastructure designed to support the prehospital emergency care of children, the American Academy of Pediatrics, American College of Emergency Physicians, Emergency Nurses Association, National Association of Emergency Medical Services Physicians, and National Association of Emergency Medical Technicians believe that EMS systems and agencies should do the following:

- Include pediatric considerations in EMS planning and the development of pediatric EMS dispatch protocols, operations, and physician oversight (for example, as outlined in the National Association of Emergency Medical Services Physicians position statement "Physician Oversight of Pediatric Care in Emergency Medical Services").[1]
- Collaborate with medical professionals with significant experience or expertise in pediatric emergency care, public health experts, and family advocates for the development and improvement of EMS operations, treatment guidelines, and performance-improvement initiatives.[2]
- Integrate evidence-based, pediatric-specific elements into the direct and indirect medical oversight that constitute the global EMS oversight structure.[4]
- Have pediatric-specific equipment and supplies available, using national consensus recommendations as a guide, and verify that EMS providers are competent in using them.[3,4,12–15]
- Develop processes for delivering comprehensive, ongoing, pediatric-specific education and evaluating pediatric-specific psychomotor and cognitive competencies of EMS providers.[13,14,16–18]
- Promote education and awareness among EMS providers about the unique physical characteristics, physiologic responses, and psychosocial needs of children with an illness or injury.[19–21]
- Implement practices to reduce pediatric medication errors.[22,23]
- Include pediatric-specific measures in periodic performance-improvement practices that address morbidity and mortality.[4]
- Submit data to a statewide database that is compliant with the most recent version of the National Emergency Medical Services Information System and work with hospitals to which it transports patients to track pediatric patient-centered outcomes across the continuum of care.[4]
- Develop, maintain, and locally enforce policies for the safe transport of children in emergency vehicles.[4]
- Develop protocols for the destination of pediatric patients, with consideration of regional resources and weighing of the risks and benefits of keeping children in their own communities.[4]
- Collaborate, along with receiving emergency departments, to provide pediatric readiness across the care continuum.[4–10]
- Include provisions for caring for children and families in emergency preparedness planning and exercises, including the care and tracking of unaccompanied children and timely family reunification in the event of disasters.[3,4,24]
- Promote overall patient- and family-centered care, which includes using lay terms to communicate with patients and families, having methods for accessing language services to communicate with non–English-speaking patients and family members, narrating actions, and alerting patients and caregivers before interventions are performed. In addition, allow family members to remain close to their children during resuscitation activities and to practice cultural or religious customs as long as they are not interfering with patient care.[19]
- Have policies and procedures in place to allow a family member or guardian to accompany a pediatric patient during transport when appropriate and feasible.[19]
- Consider using resources compiled by the Emergency Medical Services for Children program when implementing the recommendations noted here.[25]

CONCLUSIONS

Ill and injured children and their families have unique needs that can be magnified when the child's ailment is serious or life-threatening. Resource availability and pediatric readiness across EMS agencies are variable. Providing high-quality EMS care to children requires an infrastructure that is designed to support the care of pediatric patients and their families. Therefore, it is important that EMS physicians, administrators, and personnel collaborate with pediatric acute care experts to optimize EMS care through the development of care models to minimize morbidity and mortality in children as a result of illness and injuries.

LEAD AUTHORS

Brian Moore, MD, FAAP
Manish I. Shah, MD, MS, FAAP
Sylvia Owusu-Ansah, MD, MPH, FAAP
Toni Gross, MD, MPH, FAAP
Kathleen Brown, MD, FAAP
Marianne Gausche-Hill, MD, FACEP, FAAP, FAEMS
Katherine Remick, MD, FACEP, FAAP, FAEMS
Kathleen Adelgais, MD, MPH, FAAP
John Lyng, MD, FAEMS, FACEP, NRP (Paramedic)
Lara Rappaport, MD, MPH, FAAP
Sally Snow, RN, BSN, CPEN, FAEN
Cynthia Wright-Johnson, MSN, RNC
Julie C. Leonard, MD, MPH, FAAP

AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE, 2017–2018

Joseph Wright, MD, MPH, FAAP, Chairperson
Terry Adirim, MD, MPH, FAAP
Michael S.D. Agus, MD, FAAP
James Callahan, MD, FAAP
Toni Gross, MD, MPH, FAAP
Natalie Lane, MD, FAAP
Lois Lee, MD, MPH, FAAP
Suzan Mazor, MD, FAAP
Prashant Mahajan, MD, MPH, MBA, FAAP
Nathan Timm, MD, FAAP

LIAISONS

Andrew Eisenberg, MD – *American Academy of Family Physicians*
Cynthia Wright-Johnson, MSN, RNC – *National Association of State EMS Officials*
Cynthiana Lightfoot, BFA, NRP – *American Academy of Pediatrics Family Partnerships Network*
Charles Macias, MD, MPH, FAAP – *Emergency Medical Services for Children Innovation and Improvement Center*
Brian Moore, MD, FAAP – *National Association of EMS Physicians*
Diane Pilkey, RN, MPH – *Maternal and Child Health Bureau*
Katherine Remick, MD, FACEP, FAAP, FAEMS – *National Association of Emergency Medical Technicians*
Mohsen Saidinejad, MD, MBA, FAAP, FACEP – *American College of Emergency Physicians*
Sally Snow, RN, BSN, CPEN, FAEN – *Emergency Nurses Association*
Mary Fallat, MD, FAAP – *American College of Surgeons*

FORMER AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE MEMBERS, 2012–2018

Alice Ackerman, MD, MBA, FAAP
Thomas Chun, MD, MPH, FAAP
Gregory Conners, MD, MPH, MBA, FAAP
Edward Conway Jr, MD, MS, FAAP
Nanette Dudley, MD, FAAP
Joel Fein, MD, FAAP
Susan Fuchs, MD, FAAP
Marc Gorelick, MD, MSCE, FAAP
Natalie Lane, MD, FAAP
Brian Moore, MD, FAAP
Steven Selbst, MD, FAAP
Kathy Shaw, MD, MSCE, FAAP, Chair (2008–2012)
Joan Shook, MD, MBA, FAAP, Chair (2012–2016)

STAFF

Sue Tellez

AMERICAN COLLEGE OF EMERGENCY PHYSICIANS EMERGENCY MEDICAL SERVICES COMMITTEE, 2017–2018

Jeffrey Goodloe, MD, FACEP, FAEMS, Chairperson
Kathleen Brown, MD, FACEP, FAAP, Workgroup Leader
Becky Abell, MD, FACEP
Roy Alson, MD, PhD, FACEP
Kerry Bachista, MD, FACEP
Lynthia Bowman, DO, FACEP
Heather Boynton, MD
Sara Ann Brown, MD, FACEP
Allen Chang, MD
Darby Copeland, EdD, RN, NRP
Robert De Lorenzo, MD, FACEP
Derek Douglas
Raymond Fowler, MD, FACEP
John Gallagher, MD, FACEP
Sheaffer Gilliam, MD
Frank Guyette, MD, FACEP
Dustin Holland, MD
Jeffrey Jarvis, MD, FACEP, EMT-P
Clinton Kalan, PA-C
Jacob Keeperman, MD, FACEP
Douglas Kupas, MD, FACEP
Julio Lairet, DO, FACEP
Michael Levy, MD, FACEP
Kristopher Lyon, MD, FACEP
Craig Manifold, DO, FACEP
Kristin McCabe-Kline, MD, FACEP
Howard Mell, MD, FACEP
Brian Miller, MD
Michael Millin, MD, MPH, FACEP
Brett Rosen, MD
Jared Ross, MD
Kevin Ryan, MD
Stephen Sanko, MD
Shira Schlesinger, MD, MPH
Charles Sheppard, MD, FACEP
Harry Sibold, MD, FACEP
Sullivan Smith, MD, FACEP
Michael Spigner, MD
Vincent Stracuzzi, MD
Christopher Tanski, MD, MS, EMT
Joseph Tennyson, MD, FACEP
Chelsea White IV, MD, NREMT-P
David Wilcocks, MD
Allen Yee, MD, FACEP

STAFF

Rick Murray, EMT-P

BOARD LIAISON

Debra Perina, MD, FACEP

EMERGENCY NURSES ASSOCIATION PEDIATRIC COMMITTEE, 2016–2017

Tiffany Young, BSN, RN, CPNP, Chair (2016)
Joyce Foresman-Capuzzi, MSN, RN, CNS, Chair (2017)
Rose Johnson, RN
Heather Martin, DNP, MS. RN, PNP-BC
Justin Milici, MSN, RN
Cam Brandt, MS, RN
Nicholas Nelson, MS, RN, EMT-P

BOARD LIAISONS

Maureen Curtis-Cooper, BSN, RN, 2016 Board Liaison
Kathleen Carlson, MSN, RN, 2017 Board Liaison

STAFF

Catherine Olson, MSN, RN

NATIONAL ASSOCIATION OF EMS PHYSICIANS STANDARDS AND CLINICAL PRACTICE COMMITTEE, 2017–2018

John Lyng, MD, FAEMS, FACEP, NRP (Paramedic)

NATIONAL ASSOCIATION OF EMERGENCY MEDICAL TECHNICIANS EMERGENCY PEDIATRIC CARE COMMITTEE, 2017–2018

Shannon Watson, CCEMT-P, Chairperson
Katherine Remick, MD, Medical Director
Ann Dietrich, MD, Medical Director
Kyle Bates, MS, NREMT-P, CCEMT-P
Frank Flake, EMT-P
Gustavo Flores, MD, EMT-P

ABBREVIATION

EMS: emergency medical services

[j]*Department of Pediatrics, Dell Medical School, The University of Texas at Austin, Austin, Texas*; [k]*Department of Pediatrics, School of Medicine, University of Colorado, Aurora, Colorado*; [l]*Level I Adult Trauma Center and Level II Pediatric Trauma Center, North Memorial Health Hospital, Minneapolis, Minnesota*; [m]*Department of Pediatric Emergency Medicine and Urgent Care Center, Denver Health Medical Center, Denver, Colorado*; [n]*Pediatric Emergency and Trauma Nursing, Fort Worth, Texas*; [o]*Emergency Medical Services for Children, Maryland Institute for Emergency Medical Services Systems, Baltimore, Maryland; and* [p]*Division of Emergency Medicine, Department of Pediatrics, Nationwide Children's Hospital and College of Medicine, The Ohio State University, Columbus, Ohio*

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Drs Moore and Shah were the 2 primary authors, but all of the listed authors contributed sections of the manuscript and reviewed and revised subsequent drafts; this was done in conjunction with the American Academy of Pediatrics staff and Board of Directors as well as the boards of directors of the American College of Emergency Physicians, the Emergency Nurses Association, the National Association of EMS Physicians, and the National Association of Emergency Medical Technicians; and all of these organizations have approved the final manuscript as submitted.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

Published simultaneously in December 2019 in *Annals of Emergency Medicine* and *Prehospital Emergency Care*.

DOI: https://doi.org/10.1542/peds.2019-3307

Address correspondence to Brian Moore, MD, FAAP. Email: brmoore@salud.unm.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Dr Shah has disclosed the following: Health Resources and Services Administration, EMSC Program. Relationship: Pediatric Prehospital Readiness Steering Committee member. Amount: $2000 per year maximum for travel reimbursement only. All other authors indicated they have no financial relationships relevant to this article to disclose.

COMPANION PAPER: A companion to this article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2019-3308.

REFERENCES

1. National Association of EMS Physicians. Physician oversight of pediatric care in emergency medical services. *Prehosp Emerg Care*. 2017;21(1):88
2. Remick K, Gross T, Adelgais K, Shah MI, Leonard JC, Gausche-Hill M. Resource document: coordination of pediatric emergency care in EMS systems. *Prehosp Emerg Care*. 2017;21(3): 399–407
3. Institute of Medicine, Committee of the Future of Emergency Care in the U.S. Health System. *Emergency Medical Services at the Crossroads*. Washington, DC: National Academies Press; 2006
4. Institute of Medicine, Committee of the Future of Emergency Care in the U.S. Health System. *Emergency Care for Children: Growing Pains*. Washington, DC: National Academies Press; 2006
5. Gausche-Hill M, Johnson RW, Warden CR, Brennan JA; American College of Emergency Physicians' Pediatric Emergency Committee. The role of the emergency physician in emergency medical services for children. *Ann Emerg Med*. 2003;42(2):206–215
6. Gausche-Hill M, Wiebe RA. Guidelines for preparedness of emergency departments that care for children: a call to action. *Ann Emerg Med*. 2001; 37(4):389–391
7. American Academy of Pediatrics; Committee on Pediatric Emergency Medicine; American College of Emergency Physicians; Pediatric Committee; Emergency Nurses Association Pediatric Committee. Joint policy statement–guidelines for care of children in the emergency department. *Pediatrics*. 2009;124(4):1233–1243
8. Gausche-Hill M. Integrating children into our emergency care system: achieving the vision. *Ann Emerg Med*. 2006;48(2):131–134
9. Gausche-Hill M, Ely M, Schmuhl P, et al. A national assessment of pediatric readiness of emergency departments. *JAMA Pediatr*. 2015;169(6):527–534
10. Remick K, Kaji AH, Olson L, et al. Pediatric readiness and facility verification. *Ann Emerg Med*. 2016;67(3): 320–328.e1
11. Owusu-Ansah S, Moore B, Shah MI, et al; American Academy of Pediatrics, Committee on Pediatric Emergency

Medicine, Section on Emergency Medicine, Subcommittee on EMS, Section on Surgery. Technical report: pediatric readiness in emergency medical services systems. *Pediatrics*. 2020;145(1):e20193308

12. Glaeser PW, Linzer J, Tunik MG, Henderson DP, Ball J. Survey of nationally registered emergency medical services providers: pediatric education. *Ann Emerg Med*. 2000;36(1): 33–38
13. Hansen M, Meckler G, Dickinson C, et al. Children's safety initiative: a national assessment of pediatric educational needs among emergency medical services providers. *Prehosp Emerg Care*. 2015;19(2):287–291
14. Gausche-Hill M. Pediatric continuing education for out-of-hospital providers: is it time to mandate review of pediatric knowledge and skills? *Ann Emerg Med*. 2000;36(1):72–74
15. American Academy of Pediatrics; American College of Emergency Physicians; American College of Surgeons Committee on Trauma; Emergency Medical Services for Children; Emergency Nurses Association; National Association of EMS Physicians; National Association of State EMS Officials. Equipment for ground ambulances. *Prehosp Emerg Care*. 2014;18(1):92–97
16. Su E, Schmidt TA, Mann NC, Zechnich AD. A randomized controlled trial to assess decay in acquired knowledge among paramedics completing a pediatric resuscitation course. *Acad Emerg Med*. 2000;7(7):779–786
17. Henderson DP, Gausche M, Goodrich SM, Poore PD, Michael WB, Lewis RJ. Education of paramedics in pediatric airway management: effects of different retraining methods on self-efficacy and skill retention. *Acad Emerg Med*. 1998; 5(5):429
18. Gausche M, Henderson DP, Brownstein D, et al; Pediatric Education Task Force Members. Education of out-of-hospital emergency medical personnel in pediatrics: report of a national task force. *Ann Emerg Med*. 1998;31(1):58–64
19. Ayub EM, Sampayo EM, Shah MI, Doughty CB. Prehospital providers' perceptions on providing patient and family centered care. *Prehosp Emerg Care*. 2017;21(2):233–241
20. Schonfeld DJ, Demaria T; Disaster Preparedness Advisory Council and Committee on Psychosocial Aspects of Child and Family Health. Providing psychosocial support to children and families in the aftermath of disasters and crises. *Pediatrics*. 2015;136(4). Available at: www.pediatrics.org/cgi/content/full/136/4/e1120
21. Schonfeld DJ, Demaria T; Committee on Psychosocial Aspects of Child and Family Health, Disaster Preparedness Advisory Council. Supporting the grieving child and family. *Pediatrics*. 2016;138(3):e20162147
22. Kaji A, Gausche-Hill M, Conrad H, et al. Emergency medical services system changes reduce pediatric epinephrine dosing errors in the prehospital setting. *Pediatrics*. 2006;118(4): 1493–1500
23. Lammers R, Byrwa M, Fales W. Root causes of errors in a simulated prehospital pediatric emergency. *Acad Emerg Med*. 2012;19(1):37–47
24. Disaster Preparedness Advisory Council. Medical countermeasures for children in public health emergencies, disasters, or terrorism. *Pediatrics*. 2016;137(2):e20154273
25. Emergency Medical Services for Children Innovation and Improvement Center. Prehospital based care. Available at: https://emscimprovement.center/domains/prehospital-care/. Accessed November 19, 2019

Pediatric Readiness in Emergency Medical Services Systems (Technical Report)

- *Technical Report*

TECHNICAL REPORT

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Pediatric Readiness in Emergency Medical Services Systems

Sylvia Owusu-Ansah, MD, MPH, FAAP,[a] Brian Moore, MD, FAAP,[b] Manish I. Shah, MD, MS, FAAP,[c] Toni Gross, MD, MPH, FAAP,[d] Kathleen Brown, MD, FAAP,[e,f] Marianne Gausche-Hill, MD, FACEP, FAAP, FAEMS,[g] Katherine Remick, MD, FACEP, FAAP, FAEMS,[h,i,j] Kathleen Adelgais, MD, MPH, FAAP,[k] Lara Rappaport, MD, MPH, FAAP,[l] Sally Snow, RN, BSN, CPEN, FAEN,[m] Cynthia Wright-Johnson, MSN, RNC,[n] Julie C. Leonard, MD, MPH, FAAP,[o] John Lyng, MD, FAEMS, FACEP, NRP,[p] Mary Fallat, MD, FACS, FAAP,[q] COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE, SECTION ON EMERGENCY MEDICINE, EMS SUBCOMMITTEE, SECTION ON SURGERY

Ill and injured children have unique needs that can be magnified when the child's ailment is serious or life-threatening. This is especially true in the out-of-hospital environment. Providing high-quality out-of-hospital care to children requires an emergency medical services (EMS) system infrastructure designed to support the care of pediatric patients. As in the emergency department setting, it is important that all EMS agencies have the appropriate resources, including physician oversight, trained and competent staff, education, policies, medications, equipment, and supplies, to provide effective emergency care for children. Resource availability across EMS agencies is variable, making it essential that EMS medical directors, administrators, and personnel collaborate with outpatient and hospital-based pediatric experts, especially those in emergency departments, to optimize prehospital emergency care for children. The principles in the policy statement "Pediatric Readiness in Emergency Medical Services Systems" and this accompanying technical report establish a foundation on which to build optimal pediatric care within EMS systems and serve as a resource for clinical and administrative EMS leaders.

DEFINITIONS

- Emergency medical services (EMS): An intricate and comprehensive system, which in a coordinated response, provides the arrangements of personnel, facilities, and equipment for the effective, coordinated, and timely delivery of health and safety services to provide emergency care.[1,2]
- Out of hospital: A term used in emergency medicine to mean "in the field," "in the community," "at the patient's home or workplace," or "prehospital." Assessments performed and treatments given out of

abstract

[a]Division of Emergency Medical Services, Department of Pediatrics and Emergency Department, University of Pittsburgh Medical Center Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania; [b]Department of Emergency Medicine, University of New Mexico Health Sciences Center, Albuquerque, New Mexico; [c]Section of Emergency Medicine, Department of Pediatrics, Baylor College of Medicine and Texas Children's Hospital, Houston, Texas; [d]Department of Emergency Medicine, Children's Hospital New Orleans and Louisiana State University Health New Orleans, New Orleans, Louisiana; [e]Departments of Pediatrics and Emergency Medicine, School of Medicine and Health Sciences, The George Washington University, Washington, District of Columbia; [f]Division of Emergency Medicine, Children's National Medical Center, Washington, District of Columbia; [g]Departments of Emergency Medicine and Pediatrics, David Geffen School of Medicine, University of California, Los Angeles and Harbor–University of California, Los Angeles Medical Center, Los Angeles, California; [h]San Marcos Hays County Emergency Medical Services, San Marcos, Texas; [i]Austin-Travis County Emergency Medical Services System, Austin, Texas; [j]Department of Pediatrics, Dell Medical School, The University of Texas at Austin, Austin, Texas; [k]Department of Pediatrics, School of Medicine, University of Colorado, Aurora, Colorado; [l]Department of Pediatric Emergency Medicine and Urgent Care Center, Denver Health Medical Center, Denver, Colorado; [m]Pediatric Emergency and Trauma Nursing, Fort Worth, Texas; [n]Emergency Medical Services for Children, Maryland Institute for Emergency Medical Services Systems, Baltimore, Maryland; [o]Division of Emergency Medicine, Department of Pediatrics, Nationwide Children's Hospital and College of Medicine, The Ohio State University, Columbus, Ohio; [p]Level I Adult Trauma Center and Level II Pediatric Trauma Center, North Memorial Health Hospital, Minneapolis, Minnesota; and [q]Division of Pediatric Surgery, University of Louisville and Norton Children's Hospital, Louisville, Kentucky

To cite: Owusu-Ansah S, Moore B, Shah MI, et al. AAP COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE, SECTION ON EMERGENCY MEDICINE, AAP EMS SUBCOMMITTEE, SECTION ON SURGERY. Pediatric Readiness in Emergency Medical Services Systems. *Pediatrics*. 2020;145(1): e20193308

hospital often stabilize a patient or initiate critically needed care.[3]

INTRODUCTION

Emergency care for children occurs along a continuum from primary prevention to prehospital, hospital-based acute care, and rehabilitation services. In 2009, the American Academy of Pediatrics (AAP), the American College of Emergency Physicians (ACEP), and the Emergency Nurses Association collaborated to produce a document focused on the emergency department (ED), "Guidelines for Care of Children in the Emergency Department,"[4] recently revised and published as "Pediatric Readiness in the Emergency Department."[5] Alongside the ED policy statement, the National Association of EMS Physicians (NAEMSP) and National Association of Emergency Medical Technicians (NAEMT) joined those organizations in authoring a policy statement[6] on pediatric readiness in EMS systems. This technical report supports these policies with evidence for the need for pediatric services to be embedded into the EMS segment of the continuum of emergency care for children. This report identifies areas where improvements can be made in EMS systems and provides resources and references for clinical and administrative EMS leaders to use to transform health care for pediatric patients. Recommendations for integrating pediatric-specific components into EMS systems are noted in Table 1.

BACKGROUND

In 2011, the National Association of State EMS Officials (NASEMSO) published the results of the National EMS Assessment. At the time, 826 111 credentialed EMS professionals in 19 971 licensed EMS agencies cared for more than 35 million patients annually in the United States.[7] Children represented only 10% of EMS encounters,[8] raising concerns that even well-trained EMS providers can face challenges in the maintenance of their cognitive knowledge and psychomotor skills given the range of acuity in pediatric patients they encounter.[8–19] These challenges underscore the importance of establishing activities in EMS agencies and systems to ensure pediatric readiness in the EMS environment.[19–24]

Pediatric Readiness

In 2006, the Institute of Medicine (IOM), now called the National Academies of Sciences, Engineering, and Medicine, published a report titled, "Emergency Care for Children: Growing Pains," which described multiple deficiencies and gaps in the ability of our emergency care system to meet the needs of children.[25] For example, the IOM noted that the workforce providing emergency care must have the knowledge and skills to take care of children to minimize devastating health consequences. As evidence of deficiencies in this necessary knowledge and skill, the authors noted significant gaps in both clinical and administrative areas as well as a paucity of research on best practices, clinical outcomes, and patient safety for the prehospital care of children. The report had several recommendations including the need for the EMS industry to establish defined pediatric emergency care competencies and provide initial and continuing pediatric-specific education for providers.[4–25]

The 2013 National Pediatric Readiness Project assessment evaluated various foundational elements based on the joint policy statement "Guidelines for Care of Children in the ED." The fundamental elements of readiness included administration and coordination; physicians, nurses, and other health care providers; quality improvement (QI); patient safety; policies, procedures, and protocols; support services; and equipment, supplies, and medications.[4,26] This study demonstrated that although pediatric readiness had improved in EDs, 80% still reported some barriers to implementing the recommendations in the guidelines. Studies examining pediatric readiness and a pediatric facility verification program found that activities in EDs that achieve higher scores of pediatric readiness are linked to improved outcomes such as a decreased pediatric mortality rate, timeliness of pain management and reduced radiation for fractures, and improved simulation care for pediatric sepsis.[4,26–30]

Evidence from the National Pediatric Readiness Project supports that EDs are more prepared to care for children when guidelines are adhered to for the care of children in EDs.[26,27] Several of the elements of pediatric readiness assessed recommended a pediatric liaison in the EMS environment. EMS medicine has the potential to see similar benefits in readiness to care for children with established guidelines for the care of children in EMS systems.[5,24]

The Impact of Population-Specific Oversight Practices on Improving Care

Attention to sufficient cognitive and psychomotor training, provider experience, and physician oversight aids EMS success. An example of success for a condition-specific population is advanced airway management, in which focused oversight has been shown to improve performance.[31,32] Researchers in Rochester, New York, studied the effect of a redesigned rapid sequence intubation program that was consistent with recommendations published by the NAEMSP.[33] They were able to demonstrate significant gains in cognitive performance, most notably proper

TABLE 1 Integration of Pediatric Components Into EMS Systems

Medical oversight
Ensure pediatric representation in EMS planning, operations, and oversight as outlined in the NAEMSP position statement "Physician Oversight of Pediatric Care in EMS"
Provide direct and indirect medical oversight that integrates pediatric-specific elements into the global EMS system
Operations
Include pediatric-specific guidance and expertise in the development and improvement of EMS operations
Have pediatric-specific equipment and supplies available and ensure that prehospital providers are competent in their use
Develop processes for evaluating pediatric-specific psychomotor and cognitive competencies of prehospital providers
Have policies that ensure the safe transport of children and families in emergency vehicles
Collaborate with outpatient and hospital-based pediatric experts, especially those in EDs
Facilitate destination determination of patients by weighing the risks and benefits of transport to a higher level of care
Collaborate with local EDs to promote basic pediatric readiness of all facilities
Include considerations for care of children and families in emergency preparedness planning and exercises, including family repatriation, in time of disasters
Provide situational awareness to caregivers by encouraging providers to designate a person to narrate and preempt actions to the bystander on the scene, using lay terms to communicate with patients and families, and allowing bystanders to maintain a line of sight with the child as long as they are not interfering with patient care
Education
Ensure that prehospital providers receive periodic pediatric-specific education
Ensure pediatric assessment and recognition of respiratory distress or failure, cardiac failure, and shock
Competency in neonatal and pediatric resuscitation
Ensure updated psychomotor skills and practice in pediatric airway management (focusing on basic airway management) and venous and intraosseous placement and access
Provide education tools to improve proper pain and wt assessment and pain management
Research, data management, and QI
Implement practices to reduce pediatric medication errors
Include pediatric-specific measures in QI and quality assurance processes
Submit data to a statewide database that is compliant with the most recent version of the NEMSIS and work with local hospitals to track pediatric patient-centered outcomes across the continuum of care

Adapted from National Association of Emergency Medical Services Physicians. Physician oversight of pediatric care in emergency medical services. *Prehosp Emerg Care.* 2017;21(1):88 and Ayub EM, Sampayo EM, Shah MI, Doughty CB. Prehospital providers' perceptions on providing patient and family centered care. *Prehosp Emerg Care.* 2017;21(2):233–241.

patient selection.[33] This serves as an example of the effect that recommendations from professional organizations can have on increasing EMS agency attention toward special populations or conditions and how adding close physician oversight can improve provider performance.

ADMINISTRATION AND COORDINATION FOR THE CARE OF CHILDREN IN EMS SYSTEMS

Many publications have called for the coordination and integration of patient care throughout EMS systems. In 1993, the NASEMSO and NAEMSP published a position statement on physician oversight, emphasizing that quality patient care depends on a commitment to the development and operation of an integrated and comprehensive EMS system.[34] High-quality leadership is a critical element in developing such a high-functioning EMS agency or system, especially with regard to physician oversight of EMS. In 2017, the NAEMSP provided clear descriptions of the role and duties of the EMS medical director, which were intended to help system administrators integrate medical direction throughout EMS systems.[35] The NAEMSP has published a position statement specifically outlining the critical elements of "Physician Oversight of Pediatric Care in EMS."[36] In another policy statement that discussed the role of pediatricians in rural communities, the AAP described how pediatricians' expertise can help close gaps in pediatric care for EDs and EMS agencies that have limited resources.[37] In the EMS Agenda 2050 document, which is a collaborative effort to create a plan for the next several decades, there is an emphasis on patient-centered care, as follows: "EMS medical oversight for specific patients and populations includes close collaboration with the physicians who make up the patients' medical home," including input from various specialists such as pediatricians. Collaboration is an intrinsic component to system-wide EMS care tailored to the individual patient.[38]

Pediatric Leadership in EMS

As previously noted, the 2006 IOM report stated the importance of having a pediatric emergency care coordinator (PECC) designated at the EMS agency level to facilitate continued pediatric emergency education; ensure QI for pediatric patients; enhance the availability of pediatric medications, equipment, and supplies; represent the pediatric perspective in the development of EMS protocols; and participate in pediatric research.[25] The 2017 NAEMSP position statement on the importance and oversight of pediatric care in EMS also discussed how PECC oversight could be incorporated into existing roles (eg, an agency's EMS physician medical director) or established as a new role that is

collaborative within the EMS leadership team (eg, PECC or EMS system pediatric advisory committee).[36] The PECC could be incorporated into an EMS system as a single provider or team of providers. A person and/or team in this role would be expected to oversee the system-based care of pediatric patients and would promote the integration of pediatric elements into day-to-day services as well as local and/or regional disaster planning.[25,36] The PECC also can serve as a pediatric health care liaison among the EMS agency, community pediatricians, and medical home in addition to the local health care facilities. The recommended qualifications and responsibilities of an EMS PECC are noted in Table 2, which as previously noted, can be incorporated into an existing role already within the EMS agency or established as a stand-alone role.[5,25,36] The importance of a PECC within EMS agencies was further exemplified by the Emergency Medical Services for Children (EMSC) program adding this supportive role as a performance measure.[39] Analysis of pediatric readiness assessment data demonstrated that having a PECC in an ED increased the likelihood of a higher readiness score overall and improved pediatric QI processes.[40] A recent study showed interest among EMS agency administrators in integrating a PECC into their systems, and in addition, pediatric-specific psychomotor skills testing was more common in EMS agencies that respond to a higher pediatric call volume and have a PECC. The presence of a PECC can potentially increase provider confidence and safety for all pediatric prehospital patients regardless of volume and location.[41] Regardless of how this role is incorporated into the structure of EMS, it is important that each agency include pediatric-specific guidance and expertise in the development and improvement of their operations.

Pediatric Emergency Care Coordinator Learning Collaborative

There is currently an initiative to strategize integrations of PECCs within EMS agencies, known as the Pediatric Emergency Care Coordinator Learning Collaborative. This initiative is being led by the Emergency Medical Services for Children Innovation and Improvement Center (EIIC). The purpose of this project is to form a cohort of EMSC state partnership grant recipients to participate in a learning collaborative that will demonstrate effective and replicable strategies for local EMS agencies with a PECC. Results from this project will inform and advance efforts within all 58 EMSC state partnership recipient sites to increase the adoption of PECCs within local EMS agencies.[42]

COMPETENCIES FOR PROVIDERS

Considering the challenges associated with low patient volumes, a number of experts in the field have recommended mandated skills testing or ongoing education in pediatric emergency care programs such as Pediatric Advanced Life Support, Pediatric Education for Prehospital Professionals (PEPP), Advanced Pediatric Life Support, and the Emergency Nursing Pediatric Course.[9–19,43–46]

EMS Education

EMS agencies have an important role in integrating pediatric-specific elements into all aspects of prehospital care, including oversight, education, protocol development, and performance improvement. Only 10% of the EMS patient volume involves pediatric patients,[8] underscoring the recognition that additional methods of exposure are needed to help EMS providers maintain clinically relevant cognitive and psychomotor competencies. One of these alternatives includes an annual educational and skill assessment of provider competency in the following domains:

- pediatric assessment, including recognition of respiratory distress or failure, shock, and cardiac failure[43,47–49];
- neonatal and pediatric cardiopulmonary resuscitation[43–46];
- pediatric airway management with an emphasis on basic airway intervention skills[10–14,17];
- pediatric vascular access, including intravenous access and intraosseous access;
- pain assessment and management, using age-appropriate pain scales; and
- pediatric weight assessment, equipment sizing, and medication dosing.[48–51]

Pediatric Clinical Care Within EMS: Pediatric Assessment

Critical illness and injury do not always manifest in children in the same way as they do in adults. EMS agencies should ensure that providers have access to tools that can help them recognize critically ill or injured pediatric patients. Structured pediatric assessment tools, such as the Pediatric Assessment Triangle (PAT),[47–49] which is taught in the PEPP course,[44] allow EMS providers to develop a standardized approach to pediatric assessment. Evidence has shown that the PAT is a proven triage tool for EMS and has become a foundation for rapid pediatric assessment.[46,49–51] Such assessment tools have been incorporated into most standardized life support courses in the United States, including Pediatric Advanced Life Support, Advanced Pediatric Life Support, and the Emergency Nursing Pediatric Course.[43–46] The PAT includes an observational assessment of a child's respiratory status, circulatory status, and mental status and, when paired with measurement of a child's vital signs, can help

TABLE 2 Responsibilities of an EMS PECC

Recommended Qualifications	Responsibilities
A clinical provider (physician, nurse, physician assistant, or nurse practitioner) with experience in EMS medicine and who works in an ED with active clinical practice in pediatric emergency medicine or a paramedic with some experience in pediatric prehospital or pediatric emergency medicine	Education
Strong interest in and desire to improve pediatric emergency care within the EMS system	To enhance pediatric proficiency for all EMS providers by facilitating both initial and continuing pediatric education for all providers
Experience in emergency medical care of children as demonstrated by training, clinical experience, and/or focused continuing education	To verify and promote EMS provider competency in providing pediatric emergency care through periodic training and evaluation of both cognitive and psychomotor competencies
Maintenance of competency in pediatric emergency care	To provide resuscitation skills training that includes concepts related to both trauma and medical care for neonates through adolescents
Provider may already be working within the EMS system	To promote opportunities for additional pediatric emergency care education and advancement within the EMS organization including, where available, collaboration with academic institutions
	Clinical care
	To actively provide pediatric-based input in the development and revision of EMS protocols
	To assess compliance with pediatric emergency care protocols and policies
	To observe and measure the quality of pediatric emergency care
	To equip the EMS agency to care for all children through the availability of pediatric-sized equipment and supplies, including medications required to treat common conditions in children
	To integrate pediatric needs into EMS disaster and emergency preparedness plans
	To serve as a liaison between hospitals, the local community, and EMS to establish local destination determination guidelines that ensure that pediatric patients are transported to appropriate regional facilities on the basis of the patient's clinical needs
	Research and QI
	To oversee pediatric QI, patient safety, injury and illness prevention, and clinical care initiatives
	To identify potential sources of funding for pediatric EMS research at local, state, or federal levels
	To integrate pediatric-specific quality metrics into the EMS agency that are either based on the national EMS Compass Initiative or are evidence based
	To establish a mechanism for electronic data collection that captures pediatric-relevant information in accordance with the most recent version of the NEMSIS data dictionary
	To analyze system efficacy and cost-effectiveness with respect to pediatric patient outcomes
	To identify local pediatric public health and operational issues in need of scientific evaluation and provide leadership to develop pediatric EMS research

a provider rapidly identify a child with significant illness or injury.[47–49]

The PEPP course and textbook is an additional EMS resource for pediatric assessment of abnormal respiratory and circulatory status and includes evaluating a child's lung sounds and work of breathing, noting the oxygen concentration and route of delivery required to improve oxygenation, and signs of perfusion such as skin color and capillary refill time.[44] Assessment of mental status can be achieved by using the "alert-verbal-pain-unresponsive" (also known as AVPU) scale or the Glasgow Coma Scale.[44]

Age-related changes in ranges of normal pediatric vital signs can add to the challenges EMS providers face in recognition of critically ill or injured children.[15] Initial and ongoing assessment and documentation of pediatric vital signs include evaluation of respiratory rate, heart rate, blood pressure, temperature, pulse oximetry, mental status, weight, and pain.[43–49] Current weight assessment tools in EMS include length-based tape[52] and age-based weight applications standardized in kilograms.[45,50–52] Pain assessment with age-appropriate tools and documentation before and after medication administration is consistent with evidence-based guidelines and defined EMS Compass quality metrics.[53,54] Understanding and recognizing critical departures from normal values can guide providers in detecting unstable

children early.[15] Processes for identifying abnormal vital signs and reporting them to receiving facilities as part of prearrival notification can enhance patient care and should be incorporated into EMS-based policies and clinical protocols.

In addition to these vital assessment findings, pediatric readiness also includes developing processes to include training on the recognition of child sex trafficking and interventions in cases of suspected child physical and/or sexual abuse and/or neglect.[5,55] Such processes should be incorporated into each EMS agency's pediatric-specific policies and protocols.

QI AND PERFORMANCE IMPROVEMENT

In 2006, the federal EMSC program established performance measures to evaluate the status of pediatric emergency care capabilities in each state and territory. The performance measures included benchmarks for EMS access to direct and indirect pediatric-specific medical oversight and suggested pediatric equipment guidelines for ground ambulances. This document also recommended hospital benchmarks to establish standardized systems for identifying facilities that are equipped to stabilize and manage children with medical or traumatic emergencies and to establish interfacility transfer guidelines and agreements among hospitals.[39]

A 2013 assessment of the EMSC performance measures revealed that approximately 90% of basic life support (BLS) and Advanced Life Support (ALS) agencies have direct pediatric-specific medical oversight. Indirect medical oversight, provided as written pediatric protocols, was available to 72% of BLS and 94% of ALS EMS agencies. In addition, both BLS and ALS agencies carried more than 90% of the nationally recommended pediatric equipment.[39] After this assessment, the EMSC program worked with the National EMS for Children Data Analysis Resource Center to develop the next generation of "EMS for Children" performance measures, which were implemented for assessment in 2017[39]:

- submission of National Emergency Medical Services Information System (NEMSIS)–compliant version 3 data,
- pediatric emergency care coordination at the EMS agency level, and
- evaluation of psychomotor competencies using pediatric equipment.

PEDIATRIC-SPECIFIC ELEMENTS OF EMS QI

EMS QI involves the continuous monitoring of EMS system performance by using measures to identify opportunities for improving patient care. Such improvements can include changes in policies, addition or revision of clinical protocols, and ensuring access to appropriate resources and health care facilities.

Pediatric EMS QI includes several important elements, starting with the integration of pediatric-relevant content into prearrival dispatch instructions. Other components are the inclusion of pediatric data elements into prehospital patient care charts and data-reporting technology and collaboration with pediatric content-matter experts in off-line protocol development. Of critical importance are the development of relationships and a communication process between EMS and hospitals to facilitate the exchange of QI information including patient outcomes and case reviews and to include both EMS and hospitals in system data analysis.[5,56] The EIIC is spearheading a QI collaborative to assist state programs in accelerating their progress in improving the pediatric readiness of EDs through new interventions. The EIIC hopes to demonstrate how leveraging QI science and the expertise of multiple professional societies and federal organizations can improve and transform health care outcomes for children in the United States.[57] Evaluation of EMS as part of the trauma QI program is a requirement for trauma centers by state designation, the American College of Surgeons verification process, or both. Integration of prehospital care and children's hospital transport services in the QI process is also an essential component of the American College of Surgeons Optimal Resources for Children's Surgical Care Verification Program.[58]

Pediatric-specific EMS QI programs should consider the following clinical areas for inclusion in both concurrent reporting and peer review with medical oversight and in a written plan that incorporates quality metrics that use NEMSIS-based data elements:

- neonatal assessment, resuscitation, and transport;
- respiratory distress and failure, including airway management;
- cardiovascular assessment and management;
- trauma, including burns and head injury;
- child abuse and neglect;
- pain assessment and management;
- hypoglycemia and hyperglycemia assessment and management;
- seizure assessment and management;
- environmental exposure hypothermia and hyperthermia; and
- toxicology assessment and management.

In 2014, NASEMSO launched an initiative known as EMS Compass. This initiative was funded through a cooperative agreement with the National Highway Traffic Safety

Administration with the focused goal of helping EMS systems (local, regional, and state) measure EMS care delivery and improve the quality of care at all 3 levels.[54] The quality metrics proposed by this program are linked to NEMSIS data variables to allow individual EMS agencies to assess quality and benchmark their care against other EMS agencies. As pediatric-relevant quality metrics are developed through EMS Compass, it is important to integrate them into local QI processes at the EMS agency level. The first pediatric-specific quality metrics focus on pediatric respiratory assessment, the administration of β-agonists for asthma, and the documentation of weight in kilograms with the use of various methods and applications, such as length-based tape. To ensure sustainability of the initial work of the EMS Compass initiative, the Joint National Emergency Medical Services Leadership Forum is working with the National Highway Traffic Safety Administration to create the National EMS Quality Alliance.[59]

POLICIES, PROCEDURES, AND PROTOCOLS

Use of prehospital guidelines will assist EMS entities in achieving recommendations from the IOM that "EMS systems should implement evidence-based approaches to reduce errors in emergency and trauma care for children."[25] Integration of these guidelines into operational practice requires the involvement of EMS medical directors and administrators, EMS educators, state health entities, emergency physicians, pediatricians, and nurses who are involved in the prehospital care of children.[5,36,56]

Pediatric Refusals

Refusal of medical aid is a challenging element of EMS care for patients of any age and can be especially difficult when the refusal of aid involves pediatric patients. A NAEMSP and ACEP joint position statement recommends that each EMS agency and system include key elements in their policies surrounding refusal of medical aid and that such policies specifically address the issue of nontransport of minors. It also recommends that nontransport occur only in the presence of online medical direction or detailed off-line protocols.[60] These specific guidelines are useful tools to help EMS systems prepare for the special needs of their pediatric population.

Existing Guidelines for Policies, Procedures, and Protocols

Local or statewide EMS policies, procedures, and protocols lay the foundation for providing optimal care to ill and injured pediatric patients in the prehospital setting. The development of policies, procedures, and protocols that are evidence based, when possible, and inclusive of EMS system stakeholders at the local, regional, and state levels will make EMS care more effective for children.

Implementation of procedures that integrate QI activities and include education within the system has the potential to enhance care. Suggested prehospital pediatric policies, procedures, and protocols could include, but are not limited to, the following:

- appropriate level of care (BLS, ALS, or critical care);
- appropriate mode of transport (ground, rotor wing, or fixed wing);
- pediatric field triage and facility destination decision-making;
- refusal of medical aid (nontransport decision-making and documentation);
- prehospital determination of death and withholding of resuscitation;
- physician medical direction;
- dispatch prearrival instructions for children and families;
- children with special health care needs;
- child maltreatment, including recognition and criteria and processes for mandated reporting;
- evidence-based guidelines for clinical care and, when not available, vetted consensus-based guidelines, such as the NASEMSO Model EMS Clinical Guidelines[61];
- development of new guidelines based on the pediatric community's health care needs by using rigorous methods for guideline development;
- children and disaster management planning[62–67]; and
- key support services.

PATIENT AND MEDICATION SAFETY

Unlike adults, for whom a "one-dose-fits-most" approach can be an effective method of dosing medications, dosage of medications for pediatric patients requires an accurate assessment of a child's weight to avoid significant over- and underdosing.[45,50–52] Estimation of children's weight by using a specific pediatric validated tool for weight and documenting the weight in kilograms in the EMS record can enhance safety.[45,50–52] Medication dosages are based on weight in kilograms, and adjuncts, such as smartphone applications that provide decision support for precalculated doses, can minimize dosing errors.[50–52] Online medical direction from a physician with pediatric expertise can provide important guidance when EMS personnel have reached the limit of what is specified in their agency's protocols. A method to identify, prevent, and report medication errors, including a policy for timely reporting and tracking of adverse events, can enhance safety.[68] Including pediatric weight measurement tools, use of weight-based dosing tools, education in the use of those tools, and developing QI projects surrounding the accuracy of pediatric-based medication dosing

are necessary components of pediatric readiness that should be incorporated in the activities of each EMS agency.[45,50–52,68–70]

Patient- and Family-Centered Care in EMS

Policies and/or protocols that promote family presence, participation in care, and safe transport of children have been recommended by the NAEMT.[71] Methods for the identification of the child receiving treatment and transport during a disaster that includes contact information for a responsible adult can enhance the ability of EMS systems and/or hospitals to reunify children with adult caregivers. Planning for the reunification of children and families is often an overlooked element of disaster planning but is an important consideration in disaster response plans for both EMS and receiving facilities.[67,72]

Part of providing patient- and family-centered care also involves using effective communication strategies and technology. In a qualitative study of EMS providers who participated in simulated resuscitations of pediatric patients, providers identified several strategies to promote patient- and family-centered care. These included providing emotional support to caregivers, maintaining a calm demeanor, empowering families to feel involved, designating a person to narrate and preemptively describe interventions in lay terms, summarizing between interventions, allowing a line of sight between the caregiver and child, and allowing the bystander the opportunity to return if temporarily removed for interfering with patient care.[72]

The diversity of languages that EMS providers encounter continues to grow, and methods for accessing language services can enhance the ability of EMS personnel to communicate with non–English-speaking patients and family members. Organizations such as the NAEMT have recommended that EMS agencies adopt procedures to ensure effective communication in culturally diverse communities.[71]

Policies on advanced directives for withholding or terminating prehospital resuscitation efforts in children are also an important consideration for local protocols and should be considered as part of an EMS agency's pediatric readiness activities. State protocols for the declaration of death in the field and termination of resuscitation vary widely and often differ between adults and children. For childhood victims of out-of-hospital cardiac arrest attributable to blunt trauma, there is evidence that children and adults have similar outcomes, although the current recommendations for termination of resuscitation in children are more conservative, recommending at least 30 minutes of resuscitation efforts compared with 15 minutes in adults. The recommendations in children also advocate for a family-centered approach under guidance from medical control, especially in remote areas that are far from a hospital.[73–77]

Guidance for prehospital providers on how to disclose that a child is dead of any cause, next steps in the care of the family, and prevention of secondary trauma in themselves are all challenges of encountering pediatric death in the field.[75]

Pediatric Safe Transport

Safe transport for children has been a significant problem that is now being recognized. Given the unique features of children, including their smaller size and different anatomic proportions, the National Highway Traffic Safety Administration published guidelines for the safe transport of children in ground ambulances, including specific guidance regarding requirements for pediatric-passenger restraint.[78] Previously, there were no federal standards or protocols for the best method of pediatric transport in ambulances. It is estimated that up to 1000 ambulance crashes involve pediatric patients per year, with approximately 4 fatalities occurring per year.[79] In addition, in a collision at 35 mph, an unrestrained 15-kg child is exposed to the same forces as in falling from a fourth-story window.[79] The NASEMSO released interim guidance in 2017 on the safe transport of children by EMS, and this organization specifically highlighted the need for further research to establish a Society of Automotive Engineers standard for pediatric restraint recommendations through crash testing of different types of equipment.[80] The interim guidance emphasized that safe transport for children should be considered standard of care equivalent to EMS airway, breathing, and circulation maintenance. The guidance strongly states that all EMS agencies should have pediatric safe transport policies and procedures for evidence-based and appropriately sized and positioned child-restraint systems. Children should not be transported in ambulances unrestrained (eg, held in laps and/or arms).[80]

Children With Special Health Care Needs

Children with special health care needs are defined as "children who have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally."[81] Given that the number of children with special health care needs or dependence on health technologies has been steadily increasing, EMS systems have always

faced the need to provide quality prehospital care to children with special needs. A report from Utah found that these children were more likely to receive ALS and prehospital clinical interventions than children who are not technology dependent.[82] Up to 78% of ED encounters for children with special health care needs are also more likely to use EMS for interfacility transport.[83]

It is important to have access to key information to care for patients, especially those with special needs. Professional organizations such as the ACEP and AAP have recommended that families maintain an emergency information form (EIF).[84] Paper and electronic versions of the form are available from both organizations' Web sites. The development of electronic, remotely accessible health-information exchanges available to EMS providers in real time may someday reduce the need for paper copies of EIFs. Until then, EMS-applicable patient-specific care plans, EIFs, and off-line guidelines are each important elements of pediatric prehospital readiness programs. In addition to key information and medical history for this population, it is equally important to ensure specific training for pediatric technology such as ventilators, tracheostomies, and gastrostomy tubes.[84]

Health Disparities in Pediatric Prehospital Care

Significant health disparities exist in pediatric prehospital care. EMS personnel are often the initial contact for many children who do not have insurance or access to emergency care. EMS serves as a health care safety net for this population. Rural areas are a setting in which EMS can act as a primary source of health care. Rural EMS systems face operational and clinical challenges in meeting the prehospital needs of their communities and more specifically the vulnerable population of children. These challenges include geographic isolation, lack of qualified physicians to serve as medical directors, insufficient staffing of EMS providers, substandard road conditions, inadequate landing areas for air transport, and radio communication dead zones.[85–87]

In addition, the health disparity gap is widened for pediatric minority populations such as African American, American Indian, Alaskan native, and Hispanic children. Children of minority populations experience myriad disparities in prehospital care, medical care, access to health care, and use of health care services. Some of these health disparities include suboptimal health status; higher levels of obesity, asthma, and behavioral problems; lack of mental health services and medical insurance; transportation barriers to care; and increased frequency of ED visits. Language and cultural differences can lead to barriers to care in the prehospital environment. African American children and children in urban residences are more likely to arrive at the ED by EMS.[86,87] In a recently published abstract, pediatric patients with severe asthma who were transported by regional EMS agencies were predominantly older, of male sex, and African American.[88] In addition, in a recent study assessing statewide EMS management of pediatric asthma, 49% of the patients were African American, and there was a geographic disparity of EMS asthma encounters involving African American children living in rural areas.[89] American Indian and Alaskan native children are disproportionately burdened by injuries and diseases and often live in rural areas geographically far from hospitals.[90–92] A study focusing on prehospital care for rural American Indian children concluded that Indian Health Service EMS agencies do not have the infrastructure to treat pediatric patients during day-to-day operations as well as disaster situations. Indian Health Service agencies were markedly overwhelmed and unable to provide pediatric continued medical education.[93] Mobile integrated health (MIH) and community paramedicine is a way for EMS systems to provide patient-centered and integrated health care with social services, subsequently improving the overall health of the community. MIH programs improve and enhance care by sending EMS personnel to patients' home to aide in chronic disease management (eg, asthma) and education, follow-up, and rehabilitation care as well as preventive care.[94] A PECC can serve as a pediatric liaison within an EMS MIH system to provide much needed health care to children in minority and rural populations where they live. Integration of PECCs within EMS systems could help to overcome health care barriers and obstacles for these patients and serve as a possible solution to help coordinate pediatric emergency care for these particularly vulnerable populations.

Mental Health and Pediatric Prehospital Care

Mental health disorders are one of the most common diseases of childhood. Children with mental health disorders are at increased risk for substance use, residing in juvenile detention, and suicide and homicide. There continues to be an increasing number of children with mental health disorders seen in the ED and a decreasing number of available mental health facilities.[95] As a result, there is growing evidence revealing increased use of EMS services for children with mental health disorders to obtain care related to these disorders.[95] In a study of a statewide EMS system, a large proportion of pediatric patients with behavior-related disorders within mental health disorders was associated with an increase in EMS resource use because of limited behavioral

health infrastructure.[96] Interventions are key to training EMS providers on the recognition and management of pediatric mental health disorders.

INTERACTION WITH SYSTEMS OF CARE

Trauma

Trauma accounts for approximately 20% of pediatric EMS encounters.[97] The care of the pediatric trauma patient in the prehospital setting involves rapid assessment of hemodynamic status; focused and measured assessment and management of airway patency, oxygenation, and ventilation; evaluation of pain and provision of analgesia; consideration of cervical spine injury and provision of appropriate spinal motion restriction; and making appropriate destination determination decisions.[98–100] Verification or state designation of a trauma center does not mean that the facility has also achieved a high degree of overall pediatric readiness.[101] In regions where both trauma center and pediatric facility designation programs exist, a trauma center does not equate to pediatric readiness, further highlighting the potential benefits of regionalizing pediatric care.[101] Pediatric readiness in EMS systems will therefore need to include an assessment of appropriate destination facilities with respect to pediatric-focused protocols, equipment, and training to optimally manage the pediatric trauma patient.[5] Most children's hospitals that are also pediatric trauma centers will have the requisite resources for the care of the injured child, and EMS providers who use a destination determination triage tool such as the one developed by the Centers for Disease Control and Prevention will triage children to a pediatric trauma center if one is available.[102] Coordination with the regional trauma system as well as any pediatric facility verification program, where it exists, will be critical.[102,103]

Mass Casualties and Disasters

Few position statements regarding mass casualty events address infants and children. The NAEMSP has position statements on both the role of EMS in disaster response and mass gathering medical care,[64,65] with neither document specifically addressing children. In a survey of EMS agencies, only 13% had pediatric-specific mass casualty incident plans.[66] Several organizations have worked or are now working to develop resources for EMS agencies to incorporate children into their disaster preparedness plans, including educational resources.[67–69] These resources can be leveraged by EMS agencies to prepare for the care of children and families during disasters as part of their prehospital pediatric readiness activities.

EQUIPMENT, SUPPLIES, AND MEDICATIONS

Even with the best leadership and well-trained providers, without appropriate equipment, optimal care cannot be provided to pediatric patients in the field. The policy statement "Equipment for Ground Ambulances" addresses this issue and serves as a standard for the minimum equipment and supplies needed for both ALS and BLS ground ambulances in the United States.[104]

CONCLUSIONS

Numerous publications have indicated the need for improved integrated pediatric care within the prehospital setting.[4,5,25,26,36] EMS systems can adopt policies, practices, and procedures that guide provider prehospital pediatric emergency care. Pediatric-specific components that will aid in improving care include pediatric-specific education, equipment, QI, data collection and management, and research. Designation of a PECC, EMS provider access to pediatric direct and indirect medical direction, and safe transport of pediatric patients are particularly important components of a well-integrated pediatric prehospital care system.

LEAD AUTHORS

Sylvia Owusu-Ansah, MD, MPH, FAAP
Brian Moore, MD, FAAP
Manish Shah, MD, MS, FAAP
Toni Gross, MD, MPH, FAAP
Kathleen Brown, MD, FAAP
Marianne Gausche-Hill, MD, FACEP, FAAP, FAEMS
Katherine Remick, MD, FACEP, FAAP, FAEMS
Kathleen Adelgais, MD, MPH, MSPH, FAAP
Lara Rappaport, MD, PhD, MPH, FAAP
Sally Snow, RN, BSN, CPEN, FAEN
Cynthia Wright-Johnson, MSN, RNC
Julie C. Leonard, MD, MPH, FAAP
John Lyng, MD, FAEMS, FACEP, NRP (Paramedic)
Mary Fallat, MD, FACS, FAAP

AMERICAN ACADEMY OF PEDIATRICS COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE, 2018–2019

Joseph Wright, MD, MPH, FAAP, Chairperson
James Callahan, MD, FAAP
Javier Gonzalez del Rey, MD, MEd, FAAP
Toni Gross, MD, MPH, FAAP
Madeline Joseph, MD, FAAP
Natalie Lane, MD, FAAP
Lois Lee, MD, MPH, FAAP
Elizabeth Mack, MD, MS, FAAP
Jennifer Marin, MD, MSc, FAAP
Suzan Mazor, MD, FAAP
Nathan Timm, MD, FAAP

LIAISONS

Andrew Eisenberg, MD, MHA – *American Academy of Family Physicians*
Cynthia Wright-Johnson, MSN, RNC – *National Association of State EMS Officials*
Cynthiana Lightfoot, BFA, NRP – *American Academy of Pediatrics Family Partnerships Network*
Charles Macias, MD, MPH, FAAP – *Emergency Medical Services for Children Innovation and Improvement Center*
Brian Moore, MD, MPH, FAAP – *National Association of EMS Physicians*
Diane Pilkey, RN, MPH – *Maternal and Child Health Bureau*
Katherine Remick, MD, FACEP, FAAP, FAEMS – *National Association of Emergency Medical Technicians*
Mohsen Saidinejad, MD, MBA, FAAP, FACEP – *American College of Emergency Physicians*
Sally Snow, RN, BSN, CPEN, FAEN – *Emergency Nurses Association*
Mary Fallat, MD, FAAP – *American College of Surgeons*

ABBREVIATIONS

AAP: American Academy of Pediatrics
ACEP: American College of Emergency Physicians
ALS: Advanced Life Support
BLS: basic life support
ED: emergency department
EIF: emergency information form
EIIC: Emergency Medical Services for Children Innovation and Improvement Center
EMS: emergency medical services
EMSC: Emergency Medical Services for Children
IOM: Institute of Medicine
MIH: mobile integrated health
NAEMSP: National Association of EMS Physicians
NAEMT: National Association of Emergency Medical Technicians
NASEMSO: National Association of State EMS Officials
NEMSIS: National Emergency Medical Services Information System
PAT: Pediatric Assessment Triangle
PECC: pediatric emergency care coordinator
PEPP: Pediatric Education for Prehospital Professionals
QI: quality improvement

Dr Owusu-Ansah served as the lead author of the draft statement; Drs Moore and Shah collaborated on the draft statement; Drs Gross, Brown, Gausche-Hill, Remick, Adelgais, Rappaport, Leonard, Lyng, and Fallat, Ms Snow, and Ms Wright-Johnson provided input; members of the Committee on Pediatric Emergency Medicine, Section on Emergency Medicine Emergency Medical Services Subcommittee, and Section on Surgery provided guidance on content and key edits; and all authors reviewed and approved the final manuscript as submitted.

DOI: https://doi.org/10.1542/peds.2019-3308

Address correspondence to Sylvia Owusu-Ansah, MD, MPH, FAAP. E-mail: sylvia.owusuansah@chp.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: Dr Shah has disclosed the following: Health Resources and Services Administration, EMSC Program. Relationship: Pediatric Prehospital Readiness Steering Committee member. Amount: $2000 per year maximum for travel reimbursement only. All other authors indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

COMPANION PAPER: A companion to this article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds2019-3307.

REFERENCES

1. Moore L. Measuring quality and effectiveness of prehospital EMS. *Prehosp Emerg Care*. 1999;3(4):325–331
2. National Highway Traffic and Safety Administration Office of EMS. What is EMS? Available at: https://www.ems.gov/whatisems.html. Accessed May 14, 2019
3. Medical Dictionary. Out-of-hospital. Available at: https://medical-dictionary.thefreedictionary.com/out-of-hospital. August 29, 2018

4. American Academy of Pediatrics, Committee on Pediatric Emergency Medicine and Section on Surgery; American College of Emergency Physicians, Pediatric Emergency Medicine Committee; Emergency Nurses Association, Pediatric Emergency Medicine Committee. Joint policy statement guidelines for care of children in the emergency department. *Pediatrics*. 2009;124(4): 1233–1243. Reaffirmed February 2016

5. Remick K, Gausche-Hill M, Joseph MM, Brown K, Snow SK, Wright JL; American Academy of Pediatrics Committee on Pediatric Emergency Medicine and Section on Surgery; American College of Emergency Physicians Pediatric Emergency Medicine Committee; Emergency Nurses Association Pediatric Committee. Pediatric readiness in the emergency department [published correction appears in Pediatrics. 143(3):e20183894]. *Pediatrics*. 2018; 142(5):e20182459

6. American Academy of Pediatrics, Committee on Pediatric Emergency Medicine; American College of Emergency Physicians, Emergency Medical Services Committee; Emergency Nurses Association, Pediatric Committee; National Association of Emergency Medical Services Physicians, Standards and Clinical Practice Committee; National Association of Emergency Medical Technicians, Emergency Pediatric Care Committee. Policy statement: pediatric readiness in emergency medical services systems. *Pediatrics*. 2019; 145(1):e20193307

7. National Highway Traffic Safety Administration. *Federal Interagency Committee on Emergency Medical Services. 2011 National EMS Assessment. Publication No. D0T HS 811 723*. Washington, DC: US Department of Transportation, National Highway Traffic Safety Administration; 2012. Available at: https://www.nhtsa.gov/staticfiles/nti/ems/pdf/811723.pdf. Accessed May 14, 2019

8. Seidel JS, Hornbein M, Yoshiyama K, Kuznets D, Finklestein JZ, St Geme JW Jr.. Emergency medical services and the pediatric patient: are the needs being met? *Pediatrics*. 1984;73(6): 769–772

9. Hill MG, Fuchs S, Sirbaugh P. Prehospital emergencies. *Pediatr Emerg Care*. 2004;20(2):135–140

10. Garza AG, Algren DA, Gratton MC, Ma OJ. Populations at risk for intubation nonattempt and failure in the prehospital setting. *Prehosp Emerg Care*. 2005;9(2):163–166

11. Gausche M, Lewis RJ, Stratton SJ, et al. Effect of out-of-hospital pediatric endotracheal intubation on survival and neurological outcome: a controlled clinical trial. *JAMA*. 2000;283(6):783–790

12. Hubble MW, Brown L, Wilfong DA, Hertelendy A, Benner RW, Richards ME. A meta-analysis of prehospital airway control techniques part I: orotracheal and nasotracheal intubation success rates. *Prehosp Emerg Care*. 2010;14(3): 377–401

13. Youngquist ST, Henderson DP, Gausche-Hill M, Goodrich SM, Poore PD, Lewis RJ. Paramedic self-efficacy and skill retention in pediatric airway management. *Acad Emerg Med*. 2008; 15(12):1295–1303

14. Kovacs G, Bullock G, Ackroyd-Stolarz S, Cain E, Petrie D. A randomized controlled trial on the effect of educational interventions in promoting airway management skill maintenance. *Ann Emerg Med*. 2000;36(4):301–309

15. Su E, Mann NC, McCall M, Hedges JR. Use of resuscitation skills by paramedics caring for critically injured children in Oregon. *Prehosp Emerg Care*. 1997;1(3):123–127

16. Su E, Schmidt TA, Mann NC, Zechnich AD. A randomized controlled trial to assess decay in acquired knowledge among paramedics completing a pediatric resuscitation course. *Acad Emerg Med*. 2000;7(7):779–786

17. Henderson DP, Gausche-Hill M, Goodrich SM, Poore PD, Michael WB, Lewis RJ. Education of paramedics in pediatric airway management: effects of different retraining methods on self-efficacy and skill retention. *Acad Emerg Med*. 1998; 5(5):429

18. Gausche-Hill M, Henderson DP, Brownstein D, Foltin G. The education of out-of-hospital medical personnel in pediatrics: report of a national task force. *Ann Emerg Med*. 1998;31(1): 58–63

19. Baker TW, King W, Soto W, Asher C, Stolfi A, Rowin ME. The efficacy of pediatric advanced life support training in emergency medical service providers. *Pediatr Emerg Care*. 2009;25(8):508–512

20. Gausche-Hill M, Schmitz C, Lewis RJ. Pediatric preparedness of US emergency departments: a 2003 survey. *Pediatrics*. 2007;120(6):1229–1237

21. Gausche-Hill M. Integrating children into our emergency care system: achieving the vision. *Ann Emerg Med*. 2006;48(2):131–134

22. Hansen M, Meckler G, Dickinson C, et al. Children's safety initiative: a national assessment of pediatric educational needs among emergency medical services providers. *Prehosp Emerg Care*. 2015;19(2):287–291

23. Institute of Medicine, Committee on the Future of Emergency Care in the US Health System. *Hospital Based Emergency Care at the Breaking Point*. Washington, DC: National Academies Press; 2006

24. Institute of Medicine, Committee on the Future of Emergency Care in the US Health System. *Emergency Medical Services at the Crossroads*. Washington, DC: National Academies Press; 2006

25. Institute of Medicine, Committee on the Future of Emergency Care in the US Health System. *Emergency Care for Children: Growing Pains*. Washington, DC: National Academies Press; 2007

26. Gausche-Hill M, Ely M, Schmuhl P, et al. A national assessment of pediatric readiness of emergency departments. *JAMA Pediatr*. 2015;169(6):527–534

27. Remick K, Kaji AH, Olson L, et al. Pediatric readiness and facility verification. *Ann Emerg Med*. 2016;67(3): 320–328.e1

28. Ball JW, Sanddal ND, Mann NC, et al. Emergency department recognition program for pediatric services: does it make a difference? *Pediatr Emerg Care*. 2014;30(9):608–612

29. Kessler DO, Walsh B, Whitfill T, et al; INSPIRE ImPACTS Investigators. Disparities in adherence to pediatric sepsis guidelines across a spectrum of

emergency departments: a multicenter, cross-sectional observational in situ simulation study. *J Emerg Med*. 2016; 50(3):403–415–e3

30. Rice A, Dudek J, Gross T, St Mars T, Woolridge D. The impact of a pediatric emergency department facility verification system on pediatric mortality rates in Arizona. *J Emerg Med*. 2017;52(6):894–901
31. Wang HE, Davis DP, O'Connor RE, Domeier RM. Drug-assisted intubation in the prehospital setting (resource document to NAEMSP position statement). *Prehosp Emerg Care*. 2006; 10(2):261–271
32. National Association of EMS Physicians. Drug-assisted intubation in the prehospital setting position statement of the National Association of Emergency Physicians. *Prehosp Emerg Care*. 2006;10(2):260
33. Cushman JT, Zachary Hettinger A, Farney A, Shah MN. Effect of intensive physician oversight on a prehospital rapid-sequence intubation program. *Prehosp Emerg Care*. 2010;14(3): 310–316
34. National Association of State EMS Directors and National Association of EMS Physicians. Joint position statement on emergency medical services and emergency medical services systems. National Association of State EMS Directors and National Association of EMS Physicians. *Prehosp Disaster Med*. 1993;8(4):285, 288–289
35. National Association of Emergency Medical Services Physicians. Physician oversight of emergency medical services. *Prehosp Emerg Care*. 2017; 21(2):281–282
36. National Association of Emergency Medical Services Physicians. Physician oversight of pediatric care in emergency medical services. *Prehosp Emerg Care*. 2017;21(1):88
37. Moore B, Sapien R; American Academy of Pediatrics, Committee on Pediatric Emergency Medicine. Policy statement: the role of the pediatrician in rural emergency medical services for children. *Pediatrics*. 2012;130(5): 978–982. Reaffirmed September 2015
38. EMS Agenda. *2050, Technical Expert Panel. EMS Agenda 2050: A People-Centered Vision for the Future of Emergency Medical Services Report No. DOT HS 812 664*. Washington, DC: National Highway Traffic Safety Administration; 2019. Available at: https://www.ems.gov/pdf/EMS-Agenda-2050.pdf. Accessed May 14, 2019
39. Morrison-Quinata T, Edgerton EA. National EMS for Children Data Analysis Resource Center. EMSC performance measures: implementation manual for state partnership grantees. EMSC Natural Resource Center. 2017. Available at: www.nedarc.org/performanceMeasures/documents/EMS%20Perf%20Measures%20Manual%20Web_0217.pdf. Accessed May 14, 2019
40. National EMS for Children Data Analysis Resource Center. National pediatric readiness project. Available at: https://www.pedsready.org/. Accessed May 14, 2019
41. Hewes H, Ely M, Richards R, et al. Ready for children: assessing pediatric care coordination and psychomotor skills evaluation in the prehospital setting. *Prehosp Emerg Care*. 2019;23(4): 510–518
42. US Department of Health and Human Services. Health resources and services administration and maternal and child health services. Pediatric Emergency Care Coordinator (PECC) learning collaborative demonstration project. Available at: https://mchb.hrsa.gov/fundingopportunities/?id=e9870d04-acb5-4d5b-a85d-bdfd26d85132. Accessed May 14, 2019
43. de Caen AR, Berg MD, Chameides L, et al. Part 12: pediatric advanced life support: 2015 American heart association guidelines update for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2015;132(18, suppl 2): S526–S542
44. American Academy of Pediatrics. In: Gausche-Hill M, Brownstein D, Dieckmann R, eds., et al *Pediatric Education for Prehospital Professionals*, 3rd ed. Sudbury, MA: Jones and Bartlett Learning LLC; 2016
45. American Academy of Pediatrics, American College of Emergency Physicians. *Advanced Pediatric Life Support (APLS): The Pediatric Emergency Medicine Resource Book*, 5th ed. Sudbury, MA: Jones and Bartlett Learning LLC; 2011
46. Emergency Nursing Association. *Emergency Nursing Pediatric Course Book*, 4th ed. Schaumburg, IL: Emergency Nurses Association; 2012
47. Fuchs S, Terry M, Adelgais K, et al. Definitions and assessment approaches for emergency medical services for children. *Pediatrics*. 2016;138(6): e20161073
48. Dieckmann RA, Brownstein D, Gausche-Hill M. The pediatric assessment triangle: a novel approach for the rapid evaluation of children. *Pediatr Emerg Care*. 2010;26(4):312–315
49. Gausche-Hill M, Eckstein M, Horeczko T, et al. Paramedics accurately apply the Pediatric Assessment Triangle to drive management. *Prehosp Emerg Care*. 2014;18(4):520–530
50. Heyming T, Bosson N, Kurobe A, Kaji AH, Gausche-Hill M. Accuracy of paramedic Broselow tape use in the prehospital setting. *Prehosp Emerg Care*. 2012; 16(3):374–380
51. Graves L, Chayen G, Peat J, O'Leary F. A comparison of actual to estimated weights in Australian children attending a tertiary children's' hospital, using the original and updated APLS, Luscombe and Owens, Best Guess formulae and the Broselow tape. *Resuscitation*. 2014;85(3):392–396
52. Young KD, Korotzer NC. Weight estimation methods in children: a systematic review. *Ann Emerg Med*. 2016;68(4):441–451.e10
53. Gausche-Hill M, Brown KM, Oliver ZJ, et al. An Evidence-based Guideline for prehospital analgesia in trauma. *Prehosp Emerg Care*. 2014;18(suppl 1): 25–34
54. National Association of State EMS Officials. EMS compass-improving systems of care through meaningful measures. Available at: http://www.nemsqa.org/completed-quality-measures/. Accessed November 22, 2019
55. Greenbaum J, Bodrick N; Committee on Child Abuse and Neglect; Section on International Child Health. Global human trafficking and child victimization. *Pediatrics*. 2017;140(6): e20173138

56. American Academy of Pediatrics, Committee on Pediatric Emergency Medicine and American College of Emergency Physicians, and Pediatric Committee. Care of children in the emergency department: guidelines for preparedness. *Pediatrics*. 2001;107(4): 777–781

57. EMSC Improvement and Innovation Center. Pediatric readiness quality collaborative. Available at: https://emscimprovement.center/collaboratives/PRQuality-collaborative/. Accessed May 14, 2019

58. American College of Surgeons, Committee on Trauma. Resources for optimal care of the injured patient. 2014. Available at: https://www.facs.org/-/media/files/quality-programs/trauma/vrc-resources/resources-for-optimal-care.ashx. Accessed November 22, 2019

59. National EMS Quality Alliance. National EMS Quality Alliance. Available at: http://www.nemsqa.org/about/. Accessed November 22, 2019

60. American College of Emergency Physicians. Clinical practice and management joint position statement: refusal of medical aid. Available at: https://naemsp.org/resources/position-statements/joint-position-documents/. Accessed November 22, 2019

61. National Association of EMS State Officials. National Model EMS clinical guidelines. Version 2.2, January 2019. Available at: https://nasemso.org/wp-content/uploads/National-Model-EMS-Clinical-Guidelines-2017-PDF-Version-2.2.pdf. Accessed November 22, 2019

62. National Association Of Ems Physicians. Role of emergency medical services in disaster response. *Prehosp Emerg Care*. 2010;14(4):543

63. Schwartz B, Nafziger S, Milsten A, Luk J, Yancey A II. Mass gathering medical care: resource document for the National Association of EMS Physicians Position Statement. *Prehosp Emerg Care*. 2015;19(4):559–568

64. Shirm S, Liggin R, Dick R, Graham J. Prehospital preparedness for pediatric mass-casualty events. *Pediatrics*. 2007; 120(4). Available at: www.pediatrics.org/cgi/content/full/120/4/e756

65. US Department of Health and Human Services, Federal Emergency Management Agency. Ready Kids. Available at: https://www.fema.gov/children-and-disasters. Accessed May 14, 2019

66. US Department of Health and Human Services. Children in disasters and emergencies: health information guide. Available at: https://disasterinfo.nlm.nih.gov/dimrc/children.html. Accessed May 14, 2019

67. Chung S, Shannon M. Reuniting children with their families during disasters: a proposed plan for greater success. *Am J Disaster Med*. 2007;2(3):113–117

68. Krug SE, Frush K; Committee on Pediatric Emergency Medicine, American Academy of Pediatrics. Patient safety in the pediatric emergency care setting. *Pediatrics*. 2007;120(6):1367–1375

69. Hoyle JD Jr., Sleight D, Henry R, Chassee T, Fales B, Mavis B. Pediatric prehospital medication dosing errors: a mixed-methods study. *Prehosp Emerg Care*. 2016;20(1):117–124

70. Kaji AH, Gausche-Hill M, Conrad H, et al. Emergency medical services system changes reduce pediatric epinephrine dosing errors in the prehospital setting. *Pediatrics*. 2006;118(4): 1493–1500

71. National Association of Emergency Medicine Technicians. Emergency pediatric care. Available at: https://www.naemt.org/education/epc. Accessed May 14, 2019

72. Ayub EM, Sampayo EM, Shah MI, Doughty CB. Prehospital providers' perceptions on providing patient and family centered care. *Prehosp Emerg Care*. 2017;21(2):233–241

73. Fallat ME; American College of Surgeons Committee on Trauma; American College of Emergency Physicians Pediatric Emergency Medicine Committee; National Association of EMS Physicians; American Academy of Pediatrics Committee on Pediatric Emergency Medicine. Withholding or termination of resuscitation in pediatric out-of-hospital traumatic cardiopulmonary arrest. *Pediatrics*. 2014;133(4). Available at: www.pediatrics.org/cgi/content/full/133/4/e1104

74. Jordan KA, Fallat ME. Prehospital resuscitation decisions in cases of traumatic cardiopulmonary arrest: assessing the risk of legal liability & the impact of TOR guidelines. *J Leg Med*. 2015;36(2):159–213

75. Hopson LR, Hirsh E, Delgado J, Domeier RM, McSwain NE, Krohmer J. Guidelines for withholding or termination of resuscitation in prehospital traumatic cardiopulmonary arrest: joint position statement of the National Association of EMS Physicians and the American College of Surgeons Committee on Trauma. *J Am Coll Surg*. 2003;196(1): 106–112

76. Barbee AP, Fallat ME, Forest R, McClure ME, Henry K, Cunningham MR. EMS perspectives on coping with child death in an out of hospital setting. *J Loss Trauma*. 2016;21(6):455–470

77. Fallat ME, Barbee AP, Forest R, McClure ME, Henry K, Cunningham MR. Family centered practice during pediatric death in an out of hospital setting. *Prehosp Emerg Care*. 2016;20(6): 798–807

78. National Traffic Highway Safety Administration, Office of EMS. Working group best-practice recommendations for the safe transportation of children in emergency ground ambulances. 2012. Available at: www.ems.gov/pdf/811677.pdf. Accessed May 14, 2019

79. Pediatric Safety Net. Finally – a step towards safe transport for kids in ambulances. Available at: https://www.pediatricsafety.net/2012/09/finally-safe-transport-for-kids-in-ambulances-thanks-nhtsa/. Accessed May 14, 2019

80. National Association of State EMS Officials. Safe transport of children by EMS: interim guidance. 2017. Available at: https://nasemso.org/wp-content/uploads/Safe-Transport-of-Children-by-EMS-InterimGuidance-08Mar2017-FINAL.pdf. Accessed November 22, 2019

81. McPherson M, Arango P, Fox H, et al. A new definition of children with special health care needs. *Pediatrics*. 1998; 102(1, pt 1):137–140

82. Suruda A, Vernon DD, Diller E, Dean JM. Usage of emergency medical services by children with special health care needs. *Prehosp Emerg Care*. 2000;4(2): 131–135

83. Lerner CF, Kelly RB, Hamilton LJ, Klitzner TS. Medical transport of children with complex chronic conditions. *Emerg Med Int*. 2012;2012:837020

84. American Academy of Pediatrics; Committee on Pediatric Emergency Medicine and Council on Clinical Information Technology; American College of Emergency Physicians; Pediatric Emergency Medicine Committee. Policy statement–emergency information forms and emergency preparedness for children with special health care needs. *Pediatrics*. 2010;125(4):829–837. Reaffirmed October 2014

85. Freeman VA, Patterson D, Slifkin RT. *Issues in Staffing Emergency Medical Services: Results from a National Survey of Local Rural and Urban EMS Directors. Report No. 93*. Chapel Hill, NC: University of North Carolina at Chapel Hill, US Department of Health and Human Services; 2008

86. Flores G, Tomany-Korman SC. Racial and ethnic disparities in medical and dental health, access to care, and use of services in US children. *Pediatrics*. 2008;121(2). Available at: www.pediatrics.org/cgi/content/full/121/2/e286

87. Shah MN, Cushman JT, Davis CO, Bazarian JJ, Auinger P, Friedman B. The epidemiology of emergency medical services use by children: an analysis of the National Hospital Ambulatory Medical Care Survey. *Prehosp Emerg Care*. 2008;12(3):269–276

88. Owusu-Ansah S, Ramgopal S, Martin-Gill C. Prehospital management of pediatric asthma patients. Abstracts for the 2019 NAEMSP Scientific Assembly. *Prehosp Emerg Care*. 2019;23(1):133

89. Fishe JN, Palmer E, Finlay E, et al. A statewide study of the epidemiology of emergency medical services' management of pediatric asthma [published online ahead of print February 14, 2019]. *Pediatr Emerg Care*. doi:10.1097/PEC.0000000000000174

90. Mark D. Community-associated MRSA: disparities and implications for AI/AN communities. *IHS Prim Care Provid*. 2007;32(12):1–88

91. Indian Health Service. Chapter 17 - emergency medical services. Available at: https://www.ihs.gov/ihm/pc/part-3/p3c17/. Accessed November 22, 2019

92. McGinnis K. *Rural and Frontier. Emergency Medical Services. Agenda for the Future*. Kansas City, MO: National Rural Health Association; 2004

93. Genovesi AL, Hastings B, Edgerton EA, Olson LM. Pediatric emergency care capabilities of Indian Health Service emergency medical service agencies serving American Indians/Alaska Natives in rural and frontier areas. *Rural Remote Health*. 2014;14(2):2688

94. Goodwin J, Zavadsky M, Hagen T, et al. Mobile integrated healthcare and community paramedicine. National Association of Emergency Medical Technicians. Available at: https://www.naemt.org/docs/default-source/community-paramedicine/naemt-mih-cp-report.pdf?sfvrsn=df32c792_4. Accessed May 14, 2019

95. Perou R, Bitsko RH, Blumberg SJ, et al; Centers for Disease Control and Prevention (CDC). Mental health surveillance among children–United States, 2005-2011. *MMWR Suppl*. 2013;62(2):1–35

96. Fishe JN, Lynch S. Pediatric behavioral health-related EMS Encounters: a statewide analysis. *Prehosp Emerg Care*. 2019;23(5):654–662

97. Committee on Pediatric Emergency Medicine, Council on Injury; Violence, And Poison Prevention, Section on Critical Care, Section on Orthopaedics, Section on Surgery, Section on Transport Medicine, Pediatric Trauma Society, and Society of Trauma Nurses Pediatric Committee. Management of pediatric trauma. *Pediatrics*. 2016;138(2):e20161569

98. Nance ML, Carr BG, Branas CC. Access to pediatric trauma care in the United States. *Arch Pediatr Adolesc Med*. 2009;163(6):512–518

99. MacKenzie EJ, Rivara FP, Jurkovich GJ, et al. A national evaluation of the effect of trauma-center care on mortality. *N Engl J Med*. 2006;354(4):366–378

100. Fischer PE, Perina DG, Delbridge TR, et al. Spinal motion restriction in the trauma patient – a joint position statement. *Prehosp Emerg Care*. 2018;22(6):659–661

101. Walther AE, Falcone RA, Pritts TA, Hanseman DJ, Robinson BR. Pediatric and adult trauma centers differ in evaluation, treatment, and outcomes for severely injured adolescents. *J Pediatr Surg*. 2016;51(8):1346–1350

102. Centers for Disease Control and Prevention. Guidelines for field triage of injured patients: Recommendations of the national expert panel on field triage, 2011. *MMWR Morb Mortal Wkly Rep*. 2012;61(1):1–21

103. Lerner EB, Cushman JT, Drendel AL, et al. Effect of the 2011 revisions to the field triage guidelines on under- and over-triage rates for pediatric trauma patients. *Prehosp Emerg Care*. 2017;21(4):456–460

104. American Academy of Pediatrics; American College of Emergency Physicians; American College of Surgeons Committee on Trauma; Emergency Medical Services for Children; Emergency Nurses Association; National Association of EMS Physicians; National Association of State EMS Officials. Equipment for ground ambulances. *Prehosp Emerg Care*. 2014;18(1):92–97

Pediatrician Guidance in Supporting Families of Children Who Are Adopted, Fostered, or in Kinship Care

• *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Pediatrician Guidance in Supporting Families of Children Who Are Adopted, Fostered, or in Kinship Care

Veronnie F. Jones, MD, MSPH, FAAP,[a] Elaine E. Schulte, MD, MPH, FAAP,[b] Douglas Waite, MD, FAAP,[c] COUNCIL ON FOSTER CARE, ADOPTION, AND KINSHIP CARE

The child welfare system strives to provide children and adolescents in foster care with a safe, nurturing environment through kinship and nonkinship foster care placement with the goal of either reunification with birth parents or adoption. Pediatricians can support families who care for children and adolescents who are fostered and adopted while attending to children's medical needs and helping each child attain their developmental potential. Although this report primarily focuses on children in the US child welfare system, private and internationally adopted children often have similar needs.

THE FACES OF CHILD WELFARE IN THE UNITED STATES

The child welfare system strives to protect the safety of children while supporting families whose children are placed in foster care. In this document, the term "child" includes infants, children, adolescents, and young adults. The child welfare system also serves as a bridge to the primary goal of permanency through reunification or adoption. On September 30, 2018, the Adoption and Foster Care Analysis and Reporting System reported that 437 283 children and adolescents were in foster care.[1] Of these children, 262 956 entered foster care during the fiscal year of 2018, with 250 103 exiting foster care. The number of children served in the foster care system during 2018 was 687 345. There were 125 422 children waiting to be adopted, with 71 254 having parental rights terminated and 63 123 subsequently being adopted from care. Primary reasons for entering foster care include neglect (62%), parental substance use (36%), poor coping skills of the caregiver (14%), physical abuse (13%), and inadequate housing (10%). Other reasons that account for less than 10% in each category include child behavior problems, parental incarceration, parental alcoholism, abandonment, sexual abuse, child disability, relinquishment, parental death, and child alcohol and other substance use.[1] A growing number of children, estimated to be 5% to 10%

abstract

[a]*Department of Pediatrics, School of Medicine, University of Louisville, Louisville, Kentucky;* [b]*The Children's Hospital at Montefiore, Bronx, New York; and* [c]*Department of Pediatrics, Icahn School of Medicine at Mount Sinai, New York, New York*

All authors participated in the concept and design, analysis and interpretation of data, and drafting or revising of the manuscript; and all authors approved the final manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-034629

Address correspondence to V. Faye Jones, MD, PhD. E-mail: vfjone01@louisville.edu

To cite: Jones VF, Waite D, AAP COUNCIL ON FOSTER CARE, ADOPTION, AND KINSHIP CARE. Pediatrician Guidance in Supporting Families of Children Who Are Adopted, Fostered, or in Kinship Care. *Pediatrics*. 2020; 146(6):e2020034629

of the total foster care population, are specifically placed because of complex medical needs.[2] In many cases, a combination of these factors leads to foster care placement.

The 2018 Adoption and Foster Care Analysis and Reporting System reports the mean age of children in foster care is 8.3 years of age, with 42% of children 5 years or younger. Of note, adolescents 13 to 20 years of age account for 21% of the population in foster care.[1] Black or African American children account for 23% of the foster care population, and Hispanic and Latino children make up 21%. Children who identify as ≥2 races account for 8% of the foster care population, and children of American Indian or Alaskan native, Asian American, and Native Hawaiian or other Pacific or unknown ethnicity represent 4% of the population.[1] Forty-six percent of children are placed in nonrelative foster care, with another 32% placed in a relative or kinship foster home. Other placement categories include institutional (6%), group home (4%), trial home discharge (5%), preadoptive home placement (4%), supervised independent living (2%), and runaways (1%). Fifty-nine percent of children exiting foster care in 2018 returned to a parent or primary caregiver, and 25% were adopted, 7% were emancipated, 7% were living with other relatives, 11% were placed in guardianship care, and 1% transferred to another agency.[1] In 2017, a report by the National Council of Juvenile and Family Court Judges revealed Black and African American and American Indian and Alaska Native children constitute 27.5% and 2% of the population in care, respectively, although African American and American Indian and Alaska Native children represent approximately 14% and 1%, respectively, of the general population.[3] Although the data during the time period did not reveal overrepresentation for Hispanic and Latino children nationally, they did reveal disproportionate representations in several states.[3] These disproportionate rates of children in the child welfare system may result from social factors related to poverty, race, and class bias in initial reporting and subsequent processing of children in the child welfare system.[3–6] The effects of structural racism in the child welfare system also should be acknowledged and addressed in the disproportionate rates of minority children in the system.[7,8]

LEGISLATION SUPPORTING THE CARE OF CHILDREN IN FOSTER CARE AND ADOPTION

In 2018, the Family First Prevention Services Act was signed into law.[9–11] This law evolved in response to an increase in child welfare placements as a result of the opioid epidemic. The current increase in placements is similar to increases observed in 1999 at the height of the crack cocaine epidemic, when 567 000 children were in foster care.[12] The Family First Act allows reallocation of annual foster care funding to states, territories, and tribes to be redirected toward evidence-based preventive programs for mental health services, substance use treatment, and in-home parenting skill training with the goal of keeping children with their families, focusing especially on families affected by substance use and psychiatric illness.[9–11] The Family First Act also seeks to improve the well-being of children in foster care by placing children in the least restrictive environment within the child welfare system while setting standards of care for children with special needs placed in residential treatment programs, including timely assessments and periodic reviews to ensure continued need for a high level of care.[9–11,13] Summaries of the Family First Prevention Services Act and other significant federal legislation passed to protect children in foster care are highlighted in Table 1.[13–15]

KINSHIP CARE

Approximately 4% of all children in the general population are cared for by extended family members. Although the vast majority of these more than 2.7 million children in the United States live in extended family homes without involvement of the child welfare system, approximately 104 000 of these children have been formally placed in kinship care as part of the state-supervised foster care system.[23] One-quarter of all children who have been removed from their homes by the child welfare system are subsequently placed in a kinship home. Over the past decade, the number of children in kinship care has grown 6 times faster than the number of children in the general population (18% vs 3%, respectively). It is estimated that 1 in 11 children live in kinship care for at least 3 consecutive months at some point before the age of 18 years. The likelihood that African American children will experience kinship care is more than double that of the overall population, with 1 in 5 African American children spending time in kinship care at some point during their childhood.[23] The passage of the Adoption and Safe Families Act in 1997 promoted placement in kinship care as a means of shortening length of child placement in foster care while continuing a child's relationship with his or her birth parent.[20] Kinship care is relatively cost-effective and may keep children more connected with their families, communities, and cultures compared with nonkinship care.[24,25]

Multiple studies suggest specific advantages when children are placed with members of their birth family.[26–32] In a systematic review, authors found that children placed in kinship foster care experienced fewer behavioral problems, mental health

TABLE 1 Federal Mandates for Adopted and Foster Children

	Description
Family First Prevention Services Act of 2018 (Pub L No. 115-123)[13]	This act reforms the federal child welfare financing streams Title IV-E and Title IV-B of the Social Security Act to provide prevention services, including mental health services, substance use treatment, and in-home parenting training. Allows IV-E funds to support inpatient substance use disorder treatment settings that allow the placement of children with their parents when those settings can treat the needs of both the parent and child. Reauthorizes the Regional Partnership Grant program, which supports multidisciplinary approaches to addressing the effects of parental substance use on child welfare. Mandates that services be trauma informed and evidence based. Seeks to improve the well-being of children already in foster care by incentivizing states to reduce placement of children in congregate care while raising standards for residential treatment programs.
Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub L No. 110-351)[16–18]	States must make reasonable efforts to place siblings in the same foster home unless doing so would be contrary to the safety or well-being of any of the siblings. If siblings are not placed together, the state must make reasonable efforts to provide frequent visitation or other ongoing interaction between siblings unless this interaction would be contrary to a sibling's safety or well-being. Ensure that children have permanency goals to improve the well-being of children served by public child welfare agencies. Child welfare agencies are required to notify relatives of the child's removal from the custody of the parent. Promote permanent placement with relatives. Maintain connections with siblings and family. Increase the number of adoptions for waiting children. Improve outcomes and transition for older youth. Improve outcomes for American Indian and Alaska Native children. Improve competencies of individuals working with children involved in the child welfare system. Improve education stability and coordination of medical needs.
Child and Family Services Improvement and Innovation Act of 2011 (Pub L No. 112-34)[19]	Requires states to monitor children removed from the home for emotional trauma States must track and enact protocols for appropriate use of psychotropic medications States must report on steps taken to ensure developmental health for young children in state care
Adoption and Safe Families Act of 1997 (Pub L No. 105-89)[20]	Provides a fundamental change in child welfare philosophy from a primary focus of reunification with the biological parents as the principal goal without regard to parental history, to a process of considering child well-being related to the child's health and safety in permanency planning. Improves the safety and promotes permanency for fostered children through adoption or the establishment of other permanent homes. Gives preference to the placement of abused and neglected children with relatives. Provides provisions to ensure family support. Places an emphasis on timeliness to permanency.
Indian Child Welfare Act of 1978 (Pub L No. 95–608).[21,22]	Enacted "to protect the best interests of Indian children and to promote the stability and security of Indian tribes and families by the establishment of minimum federal standards for the removal of Indian children from their families and the placement of such children in foster or adoptive homes which will reflect the unique values of Indian culture, and by providing for assistance to Indian tribes in the operation of child and family service programs." Gives greater authority to tribal governments to collaborate in decision-making in child custody proceedings. When a child lives on a reservation or is a ward of the tribe, tribal leadership can assert exclusive decision-making power.

disorders, and placement disruptions compared with their counterparts in nonkinship care.[26] Thirty-two percent of children placed in early kinship care showed behavioral problems 36 months after placement, compared with 46% of children placed in nonkinship homes when controlling for baseline behavior before placement.[27] Children also experienced less stigma and trauma from the separation from parents and were more likely to remain connected to siblings and maintain family cultural traditions.[28–32] Researchers have consistently shown that relative caregivers are more likely to be single, poorer, and older; to have less formal education than nonkin foster parents; to care for large sibling groups; and to have chronic health conditions or disabilities because of their age.[33,34] Children who come to the attention of child protection and

are placed with a relative but are not taken into state custody (voluntary kinship care) are more likely to be cared for by a grandparent (87%) than children placed in kinship foster care after being taken into state custody (43%). Conversely, children in kinship foster care are more likely to be in the care of an aunt or uncle (37%) than those in voluntary kinship care (10%).[33] Children in kinship care are more likely to be removed from the birth parent's home because of parental substance use and neglect than children in nonkinship care.[34] For kinship families, unexpected placement of children with relatives may exacerbate financial and daily life stress. A report by the Annie E. Casey Foundation revealed 38% of children living in kinship care live below the federal poverty threshold, and 63% live below 200% of the poverty level.[23] A recent report by Generations United revealed that of the 2 572 146 grandparents responsible for their grandchildren, 57% were in the workforce, with 20% living below the poverty line.[35]

Despite these challenges, voluntary and kinship foster caregivers are less likely to be aware of financial benefits and other support services available to children in nonkinship foster care.[23,36,37] The Annie E. Casey Foundation reports that fewer than 12% of kin caregivers receive help from Temporary Assistance for Needy Families program, although the majority of families are eligible to receive benefits.[23,37] Fifty-eight percent of low-income kinship families do not receive Supplemental Nutritional Assistance Program benefits (food stamps) or Medicaid health coverage.[23,37] Only 17% of families receive child care assistance, with a mere 15% seeking housing cost support.[23] These statistics highlight how little our current child welfare system and communities support kinship families, especially those outside of the child welfare system, and why pediatricians, through referral to benefit resources and simple acknowledgment of the dedication of kinship parents, can be an important part of a support network to kinship families who care for children who would otherwise be placed in a nonkinship home.

The Families First Act has several provisions to support kinship families by extending Title IV-E eligibility requirements at the end of 12 months while ensuring that programs provided to children are not counted against a kinship caregiver's eligibility for other programs.[9–11,13] The Family First Act funds the development of an electronic interstate database to help facilitate placement of children with relatives who live in states other than the child's state of origin. Additionally, the Family First Act allows states to receive funding for up to 50% of the state's expenditures on kinship navigator programs that work to help locate potential kinship placements for children in the child welfare system.[9–11,13]

In addition to placement in kinship care, placement of siblings in the same foster home helps maintain ties to a child's family of origin. Approximately two-thirds of children in the child welfare system have a sibling in care.[38,39] The Fostering Connections to Success and Increasing Adoptions Act of 2008 was the first federal law to address the placement and welfare of siblings and promote ongoing relationships with siblings, requiring:

[S]tates to make reasonable efforts to place siblings in the same foster care, kinship guardianship, or adoptive placement, unless doing so would be contrary to the safety or well-being of any of the siblings. If siblings are not placed together, the state must make reasonable efforts to provide frequent visitation or other ongoing interaction between the siblings, unless this interaction would be contrary to a sibling's safety or well-being.[16–18]

Efforts to maintain sibling placement can be complicated because of inaccurate contact information after sibling separation.[40] Furthermore, specialized medical and psychiatric needs of a child may require an exceptional foster home placement, which further complicates attempts to keep siblings together.[41] Maintaining contact with siblings and other members of a kinship family in such cases helps ameliorate the strains such separations put on ties to a child's birth family.

An often-forgotten venue of kinship care and placement of siblings is the adult sibling caregiver, which is the third largest relative caregiver group behind grandparents and aunts and uncles.[42] In their study, Denby and Ayala[42] reported adult sibling caregivers have the same unmet service needs as other kinship caregivers, and the emotional toll may be even greater because of their unique sibling relationship to the child's birth parents. Although sibling caregivers who express a relatively high degree of parenting ability report strong support systems, others with low levels of family involvement and social support report a dissatisfaction with available services.[42] Additionally, when younger siblings have special health care needs, the adult sibling caregiver is more likely to commit to adopt their siblings.[42] Pediatricians can help adult sibling caregivers connect with peer-aged parents and caregivers to support parenting skills. By educating sibling caregivers on the developmental abilities of their younger siblings, pediatricians can ease unrealistic caregiver expectations while encouraging activities to promote child development.[42]

Kinship caregivers report significantly fewer support services than other foster caregivers, such as parent training, peer support, and respite care.[43] Grandparents who become adoptive parents may have

the additional burden of grieving lost expectations of their own children becoming parents while coping with the stresses of raising another generation of children and managing the ongoing challenges that led to their grandchild's placement in care.[35] In some cases, the stress of taking in a grandchild may cause problems within a marriage, exacerbate preexisting health issues, and increase financial strain within the family. Kinship parents may experience guilt or resentment over the birth parents' inability to be primary caregivers for their children.[35] At the same time, kinship parents may face challenges from birth parents who may express anger over the circumstances that led to their children being placed in foster care and feel the kinship parent conspired against them to obtain custody.[35,44] In addition, children may not understand or may resent the kinship parent, blaming them for their inability to live with their birth parents.[28] Boundaries must be set regarding the type of contact, timing, and granting of parental responsibility to the birth parents. All family members may need to be reminded that the guardian or adoptive parent is the responsible parent.

ADOPTION AND PERMANENCY

Approximately 2.4% of the child population in the United States is adopted, accounting for 2.1 million children.[45] In 2014, there were a total of 110 373 adoptions, with 41 023 (37%) adoptions with at least 1 adoptive parent related to the child by blood or marriage, and 69 350 (63%) family-unrelated adoptions.[46] The number of children who are adopted in the United States has steadily declined, primarily because of a decrease in international adoptions. In 2004, 22 989 children were adopted internationally. In 2013, 7092 international adoptions occurred, dropping to 4714 in 2017.[47] Although this clinical report is focused on children who are served through the child welfare system, awareness of other venues for adoption is important, because many of the same issues exist for both groups.

Additional demographic data collected by the Children's Bureau at the Department of Health and Human Services Administration for Children and Families provide a broader picture of adoptive families.[48] Data reveal that the predominant family structures are married couples (68.8%) and female-headed households (26.5%). Previous families of fostered youth account for almost half of adoptions, with relatives making up 31% of adoptive families. Eighty-one percent of children adopted from the foster care system are classified as having special needs. Ninety-one percent of families receive an adoption subsidy. White children account for most adoptees (49%), whereas African American and Hispanic children represent 19% and 22%, respectively.[48] Younger children are more likely to be adopted than teenagers. According to a report from the Children's Bureau through a partnership with the Ad Council, AdoptUSKids, youth in the foster care system between the ages of 15 and 18 years represent 43% of all children with active photograph listings on AdoptUSKids.org, but only 5% of all children adopted in 2015 were in that age range.[49]

Two different forms of adoption influence a child's subsequent relationship to his or her family of origin. Closed adoption allows no sharing of identifying parental information with the adoptive parent, leaving large amounts of information and details of an adopted child's family of origin and birth unknown to the adoptive parent. In contrast to closed adoptions, open adoption allows a continuum of communication between birth families, adoptive parents, and the adopted child.[50] Open adoption may be restricted to birth parents' participation in the selection of the adoptive parents or may extend to regular communication between, or face-to-face meetings with, the adoptive parents, adopted child, or both.[51,52] Open adoption is a dynamic and fluid process with the goal of child-centered integration of a child's family of origin with the adoptive family that ensures the child's awareness of his or her origins and culture. Open adoption may be particularly important to an older child or adolescent with long-standing bonds to members of his or her birth family. Postadoption contact between families is typically unregulated; in rare cases, a judge may order postadoption contact with birth family relatives, even over the adoptive parents' objection. Although these statutes are present in most states, their implementation is varied.[53]

As children age into adolescence and adulthood, they often wish to seek out more information about their biological families.[54] In attempting to gain information about their birth parents, adopted individuals who joined their families through intercountry adoption may choose to make a trip to their country of birth. Others seek information about their birth parents through commercially available DNA testing that matches an individual with those who share a similar DNA inheritance.[55] Advancements through social media have also made it much easier to locate relatives of their family of origin.[56] Other available routes include exploration of reunion registries, reestablishment of ties in a lapsed open adoption, or restoration of other ties that have connections to the child's family.

Although some adoptive parents may view their child's searching for his or her birth family as a sign of rejection, this transition is a normal sign of healthy emotional growth and

establishment of identity. The experience of a reunion with the biological family may be rewarding but may also cause the child to re-experience his or her loss. In preparing for contact and reunion, those who have been adopted or experienced foster care may need to anticipate a whole range of realities, including rejection by the birth parent(s) and family members.[57,58] Pediatricians need to be aware of the feelings children may have after meeting a sibling, either one who is older or who remained with the birth parent(s) or one who was born after the child was placed. Adoptive parents may fear birth parents will interfere in the adoptive family's life or affect the child's bond with the adoptive family. All members of this triad may need the help of mental health professionals to work through these situations. An adoption-competent social worker and/or counselor can discuss the extent of communication between the adoptive family and birth family and provide needed support by identifying benefits and drawbacks to the relationship. Pediatricians are encouraged to become aware of local community resources, support groups, conferences, services, and mental health professionals to which families confronting these difficult issues can be referred. Some available resources are included later in the article.

MEDICAL ISSUES

Children, adolescents, and young adults involved in the child welfare system often have multiple health care needs.[59–66] Because children who have been in foster care may move through multiple placements, the resulting fracture of medical care places children at risk for having medical, developmental, and psychiatric needs that remain either unaddressed and/or untreated. In addition to developmental delays and behavioral issues that can occur because of neglect and early environmental deprivation, physical and sexual abuse can lead to marked behavioral challenges at any age. The effects of toxic stress in early childhood on the neuroendocrine–immune system not only leads to psychological and psychiatric morbidity but also can result in higher risks for later medical morbidity. Additional information on the effects of early life adversity on brain development and both physical and mental health can be found in the 2012 American Academy of Pediatrics (AAP) policy statement and technical report on early childhood adversity and toxic stress in addition to the AAP Trauma Toolkit (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/resilience/Pages/Training-Toolkit.aspx).[67,68]

Among the multiple factors associated with removal of a child from a parent's home, parental substance use is one of the most common. Although 36% of children in the child welfare system are referred because of documented parental substance use, children referred for neglect (62% of child welfare referrals) often have parental substance use that has not been documented at the time of intake.[1] Although parental substance use is often reported on foster care intake, the co-occurrence of alcohol use by the parents is often overlooked. This is especially important in caring for children born with neonatal abstinence syndrome. The prevalence of fetal alcohol spectrum disorders (FASDs) among children in foster care has been estimated to be 16.9%.[63] A recent study of children in foster care referred for developmental evaluation provides further evidence of the prevalence of FASD in foster care and lack of diagnosis of this disorder. Eighty percent of children subsequently diagnosed with an FASD had not been previously diagnosed with this disorder.[64] Given this prevalence, all children entering foster care should be screened for prenatal alcohol exposure. The AAP has created an implementation guide for pediatric primary care providers to increase screening for prenatal alcohol exposure (https://www.aap.org/en-us/Documents/FASD_PAE_Implementation_Guide_FINAL.pdf). In addition, a comprehensive medical evaluation, including behavioral health assessment by using validated tools to identify needs, is most effective when completed soon after placement.[61,62,66] An early evaluation allows the pediatrician to identify and address existing medical diagnoses, uncover issues unaddressed before placement, discuss developmental and behavioral concerns with parents, and make appropriate referrals when appropriate.[61,62,66] Other issues for exploration, particularly in the adolescent and young adult population, include a history of their own substance use, mental health history, and the potential of the adolescent or young adult to be involved in sex trafficking.

Review of past medical records allows successful coordination of the child's medical, developmental, and mental health needs. Children in foster care may arrive at the office or hospital with little or no documented medical history. Despite reasonable efforts to obtain past records, information may be incomplete or uncomprehensive in scope. Barriers to obtaining consent from birth parents can make these efforts frustrating. Determining who has legal authority to give consent to care and allow access to past medical records is critical. Access to a child's medical history is particularly important for children with complex health care needs. At the time of admission to the child welfare system, the person with legal custody of the child signs consent for general and emergency medical care. Consent for further medical intervention beyond routine care must be obtained from the legal guardian. Foster parents

may not be authorized to sign consent for medical care. Many states have passed medical consent laws that allow kinship caregivers to make health decisions on the child's behalf with parental consent and without having to obtain legal custody.[69] In cases in which, despite diligent efforts, obtaining consent is not possible or in cases of parent refusal to sign consent, local child welfare authorities or the family court system can override custody rights in acting toward the best interests of the child.[70] Such situations may include the need for surgery, medical tests, psychotropic medication, and developmental evaluation and intervention. These legal issues often require pediatricians to act as advocates for the child while working with the foster care agency and family court system. After adoption, adoptive parents gain the right to be legal guardians and make decisions separate from the birth parent. The AAP Council on Foster Care, Adoption, and Kinship Care has provided further guidance related to consent in "Health Care Issues for Children and Adolescents in Foster Care and Kinship Care"[61] and at the AAP Fostering Health Web site: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/healthy-foster-care-america/Pages/Fostering-Health.aspx.

Particularly relevant parts of the health care record include past medical history; complications of pregnancy; late recognition of pregnancy; lack of prenatal care; prenatal exposures to maternal alcohol, substances, and/or tobacco; poor maternal nutrition; preterm birth; maternal and paternal psychiatric illness; and genetic diseases within the family. Important history also includes the number of previous placements, significant past relationships, developmental delays, abnormalities in growth, behavioral challenges, mental health history, substance abuse, and any traumatic events such as physical and sexual abuse, including sex trafficking.[61,62,65,66] Pediatricians can use the time a child is in foster care to integrate the medical, developmental, and psychiatric history within an electronic health record that can be easily forwarded to new placements while working with their state child welfare system to advocate for centralized or portable records that can travel with the child across foster care placements. Examples of categories within such records may include birth and developmental history, prenatal drug and/or alcohol exposure risk factors, immunization records, past psychiatric treatment, and ongoing diseases and medications. When reviewing medical records, informed interpretation of the Health Insurance Portability and Accountability Act allows proper sharing of information to improve continuity and coordination of medical care. The Health Insurance Portability and Accountability Act contains several provisions that encourage information sharing regarding children in foster care.[71]

In collaboration with members of child welfare services, pediatricians can develop treatment recommendations that support caregivers in planning to best meet their child's physical and mental health needs while anticipating future challenges. Pediatricians without expertise in this area may seek resources through the AAP Council on Foster Care, Adoption, and Kinship Care to assist in this effort.[72] For internationally adopted children, this evaluation includes, but is not limited to, infectious disease and developmental screening tests and assessment of immunization status, as recommended in the AAP *Red Book*[73] and the Centers for Disease Control and Prevention *Yellow Book*.[74] The following AAP resources are also available to guide pediatricians: *Addressing Mental Health Concerns in Primary Care: A Clinician's Toolkit*,[75] *Developmental and Behavioral Pediatrics*,[76] and *Adoption Medicine: Caring for Children and Families*.[77]

Finally, identification and documentation of a child's medical diagnoses may be necessary in establishing eligibility for financial subsidies to support the child's needs. Although the type and amount of assistance vary by state and typically are negotiated before the adoption is finalized, financial subsidy may specifically support medical and/or psychiatric care, counseling or therapy, special equipment, tutoring programs, or other support services that may help children who have special needs.[78–80] Community services, such as early child intervention programs, quality early childhood learning centers, parent support groups, financial assistance, respite care, trauma-informed care, and community organizations, including local child welfare agencies, can also help support families. Organizations such as the Child Welfare League of America[81] and Generations United[82] may be valuable resources for pediatricians and families.

COMMUNICATING WITH CHILDREN AND ADOLESCENTS ABOUT PLACEMENT AND PERMANENCY

Even before a child understands the words "adoption," "adopted," "foster care," "kinship care," "guardianship," and "biological family" or "birth family," these words should become a part of a family's natural conversation, whether the adoption is open or confidential, kinship, or foster-adoptive placement.[83,84] Positive language lays a foundation for a child's later understanding of the abstract concepts of foster care, adoption, and separation from birth parents. It is generally not advisable for families to wait until "just the right minute" to talk to children about their permanency status, because this

may leave children feeling betrayed and wondering what else their parents may have hidden from them. Early communication that shares these sensitive histories, starting with placement or early childhood, helps maintain trust between the parent and child. Encouraging an honest, nonjudgmental discussion of a child's birth family and the placement or permanency process will give a child permission to ask questions and express thoughts and feelings that not only serve to develop trust and a feeling of security but also help ameliorate the shame and the stigma associated with being in the child welfare system.[85–87]

Some information in a child's past may be difficult to discuss, such as previous sexual or physical abuse or having been conceived in the context of rape or incest, and should be discussed on the basis of the child's questions and developmental ability to understand these difficult thoughts, feelings, and memories. Furthermore, for older youth and adolescents, discussion of parental psychiatric history, substance use disorder, and life challenges that might have hindered a parent from being a greater part of the child's life can help open future questions and dialogue. Pediatricians, potentially with the collaboration of a mental health specialist, may help the family decide how and when to disclose this information. Open discussion with a child is essential in building bridges of trust and security within a family, but it is also important that the discussion be framed with developmentally appropriate language.[87] Effective communication nurtures a child's self-esteem as he or she grows in the understanding of what it means to join a family and integrate disparate parts of their lives. A child's understanding of the meaning of permanency changes with his or her cognitive development. The pediatrician can counsel parents about the need to understand the child's specific questions surrounding placement and permanency in the context of the child's current development and answer questions in a way that supports a child's sense of self and self-efficacy (Table 2).

Children placed in families at a young age may not understand that they have another family besides the family with whom they live. For many children and adolescents, separation anxiety and other internalizing and externalizing disorders may be pronounced, especially with children who remember the loss of birth or foster parents, siblings, or other relatives. Children may fear that their current family will abandon them in the same way once their "hidden flaws" are discovered. Some children may express yearnings to have been "in the belly" of their mother with whom they are presently living.[86] By kindergarten, many children realize that most of their peers are not in foster care, kinship care, or adopted, which may lead children to feel responsible for their birth parents' inability to raise them as well as for the repeated losses through moves in and out of foster care. This feeling of responsibility is especially true when a foster placement does not advance to adoption of the child.[89–93]

Pediatricians are encouraged to model positive adoption language for all families. Adoptive, foster care, and kinship care families are "real" families; siblings who joined a family through any of these channels are "real siblings." Birth parents do not "give up a child for adoption," which might imply to the child that he or she was of less worth and was given away. Rather, they "make an adoption plan for a child." Furthermore, in modeling positive language, pediatricians can use vocabulary that reflects respect and permanency about children and their families.[84] A "life book," that compiles both happy and difficult periods of a child's life experiences can be an effective tool for parents in helping a child process their thoughts and feelings.[94] Some families choose to develop rituals with their child to honor the child's birth parents on birthdays or holidays or as a special prayer to commemorate the birth family. Rituals like these allow children to acknowledge and remember their past but also to honor their present status.[84]

LOSS, GRIEF, AND TRAUMA ASSOCIATED WITH FOSTER CARE PLACEMENT

Although birth parents may anticipate the loss of their parental rights or loss of their child through adoption, the surrendering of their child often precipitates grief and a sense of loss manifested as denial, sorrow, depression, anger, and guilt. Birth parents may grieve the loss of their role as a parent and of playing a significant part in their child's life. The later birth of other children may be a reminder of the loss of the child that they did not raise.[95] In cases in which change of custody is kept secret, friends and family may not even be aware of this loss or not understand the extent of the birth parent's loss.

Foster parents can experience loss and grief with each child for whom they care. In many instances, foster parents interact with birth families to support reunification of the family. Although reunification may be the mutually desired goal, the resulting separation can be traumatic to both the foster parent and child.[96] Moreover, other children in the home may experience loss and undergo their own grieving process. Birth children of foster parents report feelings of guilt, sadness, and blame at the departure of a child who had been fostered in their childhood home.[97] Anniversary reactions often occur for children with each passing year. Anniversaries may trigger thoughts of the birth family, and children may wonder whether their birth parents still love them or even

TABLE 2 Developmental Tasks and Issues Specific to Adopted and Foster Children

Age and Developmental Stage	Erikson's Psychosocial Stages of Development[88]	Issues That May Be Intensified for Adopted and Foster Children	Strategies for Families and Pediatricians
Birth to 16 mo	Trust versus mistrust	Difficulty or failure to develop a trusting, reliable attachment to caregivers Children may present with feeding problems, anxiety, depression, aggression, sleep disorders, and lack of trust[56]	Educate caregivers of the need to provide a consistent, sensitive, and responsive environment Caregivers should be vigilant for behavioral dysregulation that can be a sign of previous trauma and toxic stress[36]
18 mo to 3 y	Autonomy versus shame and doubt	A child's emerging self-centered perception of the world can become fragmented from experiences of multiple caregivers, previous neglect, and physical or sexual abuse	Caregivers should be aware of the manifestations of early childhood adversity and toxic stress[56,57] Create a highly structured, calm environment that provides a feeling of safety and security Address a child's questions and fears with acknowledgment tempered with reassurance of the child's current safety Be vigilant for developmental delays and behavioral problems, especially in cases of known or suspected prenatal alcohol or drug exposure and in such cases facilitate referral for evaluation for fetal alcohol spectrum disorders Refer to early intervention for developmental delays and behavioral concerns
3–5 y	Initiative versus guilt Problem-solving; attempts to understand permanency and past and current living arrangements	Children who have experienced trauma or been placed with multiple caregivers may exhibit anger, withdrawal, aggression, or sadness because of feelings of insecurity about their environment or caregivers Children who come into families by foster care or adoption experience loss in multiple areas of their life; loss should be viewed as a form of trauma and may manifest in variety of ways depending on the child's developmental level, the type of placement (temporary versus permanent), familiarity of surroundings and support systems[82–85]	Keep a daily, consistent routine Understand a child's current concerns and behaviors in the context of their past experiences and meet these challenges with acknowledgment and reassurance Validate a child's feelings while setting limits on problematic behavior Refer to mental health services when appropriate Refer for speech and other developmental or behavioral problems Consider referral to developmental-behavioral pediatrician and/or referral for evaluation for fetal alcohol spectrum disorders in cases of developmental or behavioral challenges Provide opportunities to nurture intellectual curiosity by allowing preschoolers to explore their environment through imaginative play and social engagement Encourage preschoolers to plan and participate in new activities of their own choosing within the bounds of a safe environment
Middle childhood	Industry versus inferiority Peer groups have increased influence over a child's self-esteem	Fostered or adopted children may experience low self-esteem and feelings of inferiority or rejection as they become aware of their differences from their peers. Such issues may be especially difficult for children placed in homes of a different racial or cultural background In addition to loss of their family of origin, fostered children may experience the loss of friends, surroundings, culture, and disruption of past routines	Caregivers can help their child integrate past experiences into their current life Caregivers can help a child begin to understand how current feelings and thoughts may be related to past experiences while grounding the child to their present life circumstances Refer to mental health services when appropriate Refer for educational support services if indicated Consider referral to developmental-behavioral pediatrician and/or referral for evaluation

TABLE 2 Continued

Age and Developmental Stage	Erikson's Psychosocial Stages of Development[88]	Issues That May Be Intensified for Adopted and Foster Children	Strategies for Families and Pediatricians
			for fetal alcohol spectrum disorders in cases of learning and/or behavioral challenges Caregivers can be encouraged to educate their child about their cultural history while being sensitive to nonverbal clues that they communicate about race and cultural differences
Adolescence	Identity versus role confusion Autonomy Abstract thought; concepts like adoption and permanency may be internalized and adolescents might go through an intense period of self-reflection in an attempt to define their identities. As adolescents develop and begin the task of separation and individuation, permanency issues commonly become important, changing relationships between the adolescent and family	Early life trauma and toxic stress can worsen as a child moves from childhood to adolescence, especially when compared with peers who have had more stable childhoods Adopted adolescents or adolescents in foster care often struggle to integrate their past life into their current life and their future Adolescents may challenge authority within and outside the family, which may result in conflict; Youth may "test" caregivers by challenging their commitment to their relationship Risk-taking or unhealthy peer relationships can place adolescents at high risk for substance use, chronic truancy, and/or involvement in the juvenile justice system; such behaviors are sometimes precipitated by contact with or identification with birth parents who may have had similar difficulties	Caregivers should be aware of the manifestations of past traumatic events and losses and meet challenging behaviors with understanding but age-appropriate limit setting Encourage diary and creative writing or other art forms as a path for integrating past and present experiences into a life story Ensure appropriate support services are provided in school Refer for mental health or substance use treatment services when indicated Consider referral for evaluation for fetal alcohol spectrum disorders Pediatricians can screen for and directly address risks for substance use, depression, suicidality, and criminal behavior in one-on-one conversations with the adolescent In cases in which adolescent risk-taking behavior becomes a risk to an adolescent's future or placement stability, caregivers can consider pursuing a person-in-need-of-supervision petition in family court
Young adulthood[86]	Experiment and exploration: love, work, and worldviews	Housing instability Educational dropout Unemployment Lack of trust, expectation of failure in life trials, and social acceptance Engagement in criminal activities	Support transition with extension of foster care to age 21 y Supportive housing Job placement Funding for college opportunities Social networks and mentoring

think about them. The Child Welfare Information Gateway provides useful resources for families on separation and grief.

FAMILY DIFFERENCES

Although all children, especially in adolescence, face the normal developmental task of clarifying their identity, adopted children and children living in foster care with parents of a different race, ethnicity, or cultural background face the additional challenges of assimilating disparate parts of their lives. Children as young as 3 or 4 years are aware of differences between themselves and members of other racial groups.[98–102] When children live in communities where they are members of an ethnic minority, the differences in racial identity will be easily apparent to classmates, other parents, and strangers. These differences may provoke a child's sense of confusion about their racial, ethnic, or cultural origins.[102]

Children may encounter racist remarks for the first time, particularly in situations in which they are not physically or emotionally safeguarded by their parents. Role-playing with children with respect to stereotypes and racist statements may help them to feel in control when they encounter comments from strangers, friends, or extended family members.[103,104] Parents who have not experienced racism personally may need to pay extra attention to teaching their children effective ways to respond to racism. Families should openly acknowledge racial differences while providing the child with relationships with others of the same race or ethnic group, including adults and children.[104] The child should also be given the opportunity to learn more about the heritage of

his or her racial and ethnic group and country of origin.

An estimated 220 000 children are being raised by more than 111 000 same-sex couples, with approximately 12% of children identified as adopted or in the foster care system.[105,106] Gates et al[107] reported that same-sex couples are 4 times more likely to adopt and are 6 times more likely to foster children than their different-sex counterparts. Additionally, approximately 25% of same-sex couples raising children are involved in kinship care arrangements. In the past, same-sex couples raising adopted children were typically older, more educated, and had more economic resources compared with other adoptive parents.[107] More recently, however, this trend may be changing secondary to the evolving societal acceptance and legal climate within the United States.[108,109] Between 2014 and 2016, 16.2% of all same-sex couples were raising children.[109] The majority (68%) of the couples were raising biological children; however, same-sex couples were more likely to have a child who was adopted (21% vs 3.0%) and/or a child in foster care (2.9% vs 0.4%) compared with male-female couples.[109]

In 2002, the AAP published a policy statement and technical report supporting coparent or second-parent adoption and reaffirmed the policy statement in May 2009.[110,111] Regardless of the sexual identity of the parent, children thrive best when raised in a home that provides a caring, supportive, and secure home environment. Children who grow up with gay or lesbian parents show the same emotional, cognitive, social, and sexual development as children who grow up with heterosexual parents.[112] Authors of a recent study exploring the perspectives of youth who were adopted by gay and lesbian parents reported that although many children experienced more bullying and teasing than their counterparts, children of gay or lesbian parents were more accepting, had greater understanding, and were more compassionate toward people and individual differences than their counterparts raised by heterosexual parents.[113] This growing literature supports pediatricians in their advocacy for all capable individuals to have the opportunity to become foster and adoptive parents.

EDUCATIONAL CHALLENGES

Information from a 2018 multistate study reveals that 65% of foster youth had had more than 1 foster care placement, 34% had experienced 5 or more school placements; up to 47% had been placed in special education, and 65% completed high school by age 21.[114] Additionally, 17- to 18-year-old youth in the child welfare system are 2 times more likely to be suspended and 3 times more likely to be expelled from school.[114] Researchers in the 2005 Midwest study of 736 foster care alumni found that although 57.8% of former foster youth earned a high school diploma and 5% completed a general equivalency diploma (GED), 37% had attained neither a high school diploma nor GED.[115] Youth who earn a high school diploma are 1.7 times more likely to complete an associate's degree and 3.9 times more likely to complete a bachelor's degree and have higher incomes than those with a GED credential.[115] A 2018 multistate study found that although 70% to 84% of high school graduates wished to pursue further college education, only 32% to 45% actually enrolled in college, and only 3% to 11% attained a bachelor's degree.[114]

Researchers have shown that a higher incidence of exposure to one or more traumatic adverse childhood experiences affects educational achievement.[116–118] Maltreatment experienced before kindergarten was associated with negative academic and behavioral outcomes by second grade.[117,118] Kovan et al[119] report children involved with the child welfare system had poorer outcomes than their peers with no involvement with the child welfare systems on measures of receptive vocabulary, math reasoning, and teacher ratings of anger or aggression and anxiety or withdrawal. These findings support previous studies with similar conclusions of poor outcomes of children who have experienced neglect in early childhood.[117] Similarly, poor science outcomes have also been reported for children who experience neglect before kindergarten compared with their peers.[117] Thus, disproportionate representation of children from minority populations in the child welfare system helps maintain disparities in academic outcomes.[3–6] Quality early child care and early education programs, such as Head Start and prekindergarten programs, can partially mitigate the effects of maltreatment on school readiness and child development.[118–121] For children younger than 3 years, referral to a federally funded early intervention program may be warranted. For children older than 3 years, Individualized Education Program and 504 plans under the Individual with Disabilities Act can be mechanisms to obtain services and resources to help meet the special needs of children in foster care or those who have been adopted.[122] In addition, the Uninterrupted Scholars Act (Pub L No. 112-278), passed in 2013, allows information sharing between schools, child welfare agencies, and tribal organizations without parental consent.[123]

TRANSITION CARE TO ADULTHOOD: BARRIERS AND OPPORTUNITIES

Most young adults not in foster care continue to receive ongoing financial and social support from their parents beyond age 18.[124] In 2018, approximately 19 000 young adults aged out of foster care, potentially

losing the financial, educational, and social support services of state foster care overnight when they turned 18 to 21 years old, depending on the state in which they resided.[1,125] Adolescents in foster care enter the world of adulthood all too often ill prepared, their prospects compounded by mental health problems, substance use, and underemployment.[126,127] The Midwest outcome study revealed that fewer than half of young adults leaving foster care were currently employed at age 26, approximately half of the young adults who had worked during the past year reported annual earnings of $9000 or less, and more than one-quarter had no earnings at all.[127] Researchers in a study of aged-out youth found that 20% were chronically homeless, with housing instability associated with emotional and behavioral problems, physical and sexual victimization, criminal conviction, and high school dropout.[128]

Title IV-E of the Social Security Act was amended in 1986 to create the Independent Living Program, allowing states to receive funds to provide independent living services.[129] State child welfare agencies are required to develop a transition plan in collaboration with the youth aging out of foster care that includes housing, health insurance, education, local opportunities for mentors and continuing support services, workforce supports, and employment services.[16–18,129,130] The age limit for foster care varies by state, with some states extending care to 21 years of age. The Fostering Connections to Success and Increasing Adoptions Act of 2008 amended Title IV-E to extend the age of Title IV-E eligibility from 18 to 21 years.[16–18,129] In one study, youth living in a state that extended the age of foster care to 21 years were nearly twice as likely to complete at least 1 year of college education.[126] Awareness of state-specific age limits on foster care placement allows early transition planning for all adolescents in the medical home.[131] Youth who remain in care past age 18 attain higher educational credentials, which translate into better employment outcomes.[126,127,132,133] Furthermore, even when the level of educational achievement is controlled for, the number of years in care after the age of 18 positively affects employment and higher wages of the youth.[134] This study suggests a window of opportunity within transition planning for obtaining employment before discharge from foster care. It also supports the extension of foster care from age 18 to age 21.[134]

Youth transitioning out of foster care report that the most important support for working toward their educational and employment goals are job preparation skills, transportation, child care, educational services, and overall life skills.[135] Yet, former fostered youth who currently live independently overwhelmingly describe a lack of resources in the areas of employment, education, finances, housing, access to independent living classes, personal care, and networking.[135] Although parents outside the foster care system often contribute to the development of young adult independence by advancing important skill-building activities early in life, empowering youth to make decisions for their own lives, and reinforcing the youth's ability to learn and cope with the consequences of those decisions in a supportive environment, this support often fails to be included in the transition care of children in foster care.[136]

Mental health challenges further complicate transition planning from foster care. More than half of young adults leaving care (54.4%) have current mental health problems, compared with less than one-quarter of the general population (22.1%).[137] The prevalence of posttraumatic stress disorder within the previous 12 months is higher among young adults in foster care (25.2%) than among the general US population (4.0%) and nearly twice the rate of that experienced by American war veterans (Vietnam: 15%; Afghanistan: 6%; and Iraq: 12–13%).[137] The prevalence of major depression within the previous 12 months is significantly higher among foster alumni (20.1%) than among the general population (10.2%).[137] Although mental health challenges might be thought to be solely linked to foster care placement, researchers of studies among US adoptees suggest otherwise. Among 96% of the adopted children placed before 1 year of age and all children adopted before their second birthday, adoptees were 4 times more likely to attempt suicide than nonadoptees.[138] Potential contributing factors for the increased risk of suicide attempt include early trauma before adoption, prenatal substance and alcohol exposure, and genetic predisposition to psychiatric illness.[138]

In the face of these adversities lie barriers to medical and psychiatric care. In a study of foster care alumni, only 47% of young adults had health insurance as they prepared to leave foster care.[139] Young adults in foster care are more likely to have health conditions that limit their daily activities, report more emergency department visits and hospitalizations during the previous 5 years than their peers, and suffer medical problems that are left untreated because of lack of health insurance.[61,140] Pediatricians can help youth prepare to transition their health care needs by identifying medical issues that require regular follow-up and educating youth on how to use health insurance benefits and nonemergent medical care.[133] Information on billing for the delivery of health care transition services can be found in the 2017 Transition Coding and Reimbursement Tip

Sheet, as well as other resources, on the Got Transition Web site.[141]

Finally, children placed in foster care are at risk for "crossing over" to the juvenile justice system, and inversely, many juvenile justice–involved youth later become involved in the child welfare system. These youth are commonly referred to as crossover youth, whereas youth with concurrent involvement in both the child welfare and juvenile justice system are described as dually involved or dually adjudicated youth.[142,143] Children who have experienced maltreatment average a 47% greater risk for future delinquency relative to children who have not experienced abuse or neglect.[144] An estimated 56% of crossover youth have mental health problems. A growing body of research indicates that running away from foster care increases the probability of subsequent involvement in the juvenile and/or adult justice system, especially for male individuals, with 42% of youth with runaway histories in one study having at least 1 juvenile and/or adult conviction.[145] Approximately 16% of children placed into foster care experience at least 1 delinquency court involvement compared with 7% of all maltreatment victims who are not removed from their family.[144] Other characteristics related to delinquency include age at first child welfare placement, years in placement, number of placements, total length of time in residential care, and sex, race, and recurrence of maltreatment.[144,146] African American youth involved in the child welfare system are up to 13 times more likely than white fostered youth to become involved in the juvenile justice system.[147] Reasons for this disparity are complex; however, structural racism should be considered.[7,8,147] Structural racism refers to the policies and practices that reinforce racial group inequity by allowing privilege associated with race, in this case white-colored skin, while withholding those same privileges from communities of color. Structural racism is insidious and embedded within historical, cultural, and ideological norms of organizations and systems.[8] Norms around language, behavior, and practices, such as policing and court judgments, are typically based on white middle class expectations and contribute to the disproportionate involvement of youth of color in both the child welfare and juvenile justice systems.[147] Recognition of structural racism in current systems allows for education and interventions to be put in place to mitigate its effects.

One of several promising approaches to juvenile court involvement is multisystemic therapy.[148] Multisystemic therapy interventions target problems identified by the child, family, and worker within and between the multiple systems of the home, school, and neighborhood to problem-solve challenges and support success.[146,148] Pediatricians can affect the outcomes of these youth by participating in a multidisciplinary team that includes members from the juvenile justice system, child welfare organizations, and the family. This coordinated approach provides opportunities to change the trajectory of children with judicial involvement and affect the long-term outcome of their lives.[149]

THE LAST WORD: RESILIENCE

Resilience is the developmental process by which an individual can use internal and external resources to negotiate and adapt to current challenges while developing skills to aid future challenges. Resilience implies the presence of adaptive capacities to negotiate life challenges effectively.[150] In a study of 164 young adults emancipated from foster care, nearly half (47%) managed challenges in education, employment, civic engagement, relationships, self-esteem, and mental health, and 16.5% had low educational and low occupational competence, low civic engagement, problematic interpersonal relationships, low self-esteem, and high depressive symptoms. Yet among those youth having difficulties in their external life, 30% exhibited internal resilience, characterized by psychological well-being, despite having difficulties in external circumstances such as education, employment, homelessness, early parenthood, drug use, and criminal activity. In contrast, 6.5% of youth showed significant emotional difficulties despite the appearance of external competence.[151] Thus, young adults can demonstrate resilience in one area of their lives even as they struggle in others. The greatest association with improvement in resilience is having more than one strong network (biological family, peers, foster care), with multiple strong social networks ameliorating the psychological stress of life struggles.[152] In addition to biological family, foster parents, extended family, and peers, support can come from child welfare case workers, therapists, teachers, mentors, coaches, and pediatricians, many of whom often continue to be a resource after the formal placement has ended.[149] For this reason alone, pediatricians can never underestimate the effect of the day-to-day interactions they share with fostered youth. Conversations for even a simple medical concern can affect a child or foster parent in ways we can never foresee.

Further information on the care of children in foster care and children who have been adopted can be found on the AAP Council on Foster Care, Adoption, and Kinship Care Web site.

KEY POINTS AND RECOMMENDATIONS OF CLINICAL REPORT

- Children and adolescents involved in the child welfare system,

whether formally or informally, often have multiple health care needs that require an interdisciplinary team to maximize their well-being. See the AAP Fostering Health Web site for further information: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/healthy-foster-care-america/Pages/Fostering-Health.aspx.

- Children and adolescents in foster care and those who have been adopted are at far greater risk than the general population for neurodevelopmental disorders, such as fetal alcohol spectrum disorders. Pediatricians can provide surveillance and screening of socioemotional well-being using validated tools and being aware of developmental and mental health issues common among children and adolescents in foster care. See the AAP Fetal Alcohol Spectrum Disorders Toolkit for further information: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/fetal-alcohol-spectrum-disorders-toolkit/.
- Many children and adolescents experience social and emotional issues during periods of transition. It is important for pediatricians to counsel and provide information to parents in the recognition and management of current and future medical, developmental, and behavioral problems.
- Pediatricians can advocate for the development of a standardized process for consent and transfer of health information with their local Department of Social Services.
- Pediatricians can address the effects of adverse childhood experiences, early childhood adversity, and trauma on early brain development and life course trajectory for both physical and mental health, as recommended by AAP policy.[39] See the AAP Trauma Toolkit for further information: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/resilience/Pages/Training-Toolkit.aspx.
- Pediatricians can encourage parents to have developmentally appropriate discussions using developmentally appropriate language with their child or adolescent. Words such as "adoption," "adopted," "foster care," "kinship care," "guardianship," and "biological family" or "birth family" should become a part of a family's natural conversation, whether the adoption is open or confidential, kinship, or foster-adoptive placement.[84,85] Positive language lays a foundation for a child's later understanding of the abstract concepts of foster care, adoption, and separation from birth parents and facilitates the formation of an integrated identity.
- Pediatricians can help parents acknowledge racial and cultural differences and support children and adolescents in coming to an understanding of these differences. See HealthyChildren.org for further information for pediatricians Talking to children about racial bias https://www.healthychildren.org/English/healthy-living/emotional-wellness/Building-Resilience/Pages/Talking-to-Children-About-Racial-Bias.aspx Teaching children cultural and racial pride https://www.healthychildren.org/English/family-life/family-dynamics/Pages/Teaching-Children-Cultural-and-Racial-Pride.aspx
- Pediatricians can be aware of the complexity of losses experienced by children and adolescents in foster care or kinship care or adopted, in addition to losses experienced by foster, adoptive, and birth parents, while facilitating mental health referral as needed.
- Pediatricians can advocate for young adults who are transitioning out of care and/or involved in the juvenile justice system, because they are at risk for poor physical and mental health outcomes, low socioeconomic status, and lower educational attainment.

RESOURCES

Available resources include the following:

AAP, Council of Foster Care, Adoption, and Kinship Care (https://www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/Council-on-Foster-Care-Adoption-Kinship/Pages/Foster-Care-Adoption-Kinship.aspx);

AAP, Healthy Children (https://www.healthychildren.org/English/Pages/default.aspx);

National Council for Adoption (http://www.adoptioncouncil.org/);

Child Welfare Information Gateway (https://www.childwelfare.gov/):

- Legal Issues in Adoption (https://www.childwelfare.gov/topics/systemwide/courts/processes/legal-issues-in-adoption/);
- Working With American Indian Children and Families in Adoption (https://www.childwelfare.gov/topics/systemwide/cultural/adoption/american-indian-families/);
- Helping Children and Families with Separation and Grief (https://www.childwelfare.gov/topics/outofhome/casework/helping/); and
- Helping Youth Transition to Adulthood: Guidance for Foster Parents (https://www.childwelfare.gov/pubPDFs/youth_transition.pdf);

Grandparents Raising Grandchildren (http://www.raisingyourgrandchildren.com/Index.htm);

AdoptUsKids: Families for Native American Children: Consideration When Fostering and Adopting

(https://www.adoptuskids.org/adoption-and-foster-care/overview/who-can-adopt-foster/families-for-native-children);

Jones BJ, Tilden M, Gaines-Stoner K. *The Indian Child Welfare Act Handbook: A Legal Guide to the Custody and Adoption of Native American Children.* Chicago, IL: American Bar Association; 2008;

National Center for Mental Health and Juvenile Justice. Family Involvement in the Juvenile Justice System (https://www.ncmhjj.com/wp-content/uploads/2016/09/Family-Involvement-in-the-Juvenile-Justice-System-for-WEBSITE.pdf); and

Baker JL, Brown EJ, Schneiderman M, Sharma-Patel K, Berrill LM. Application of evidenced-based therapies to children in foster care: a survey of program developers. *APSAC Advisor.* 2013;27(3):27–34 (http://www.apsacny.org/wp-content/uploads/2014/11/APSAC_Advisor_Vol_26_1-pp27-34.pdf).

LEAD AUTHORS

Veronnie F. Jones, MD, MSPH, FAAP
Elaine E. Schulte, MD, MPH, FAAP
Douglas Waite, MD, FAAP

COUNCIL ON FOSTER CARE, ADOPTION, AND KINSHIP CARE EXECUTIVE COMMITTEE, 2018–2020

Sarah Springer, MD, FAAP, Chairperson
Moira Ann Szilagyi, MD, PhD, FAAP, Immediate Past Chair
Heather Forkey, MD, FAAP
Kristine Fortin, MD, FAAP
Mary V. Greiner, MD, MS, FAAP
David Harmon, MD, FAAP
Veronnie Faye Jones, MD, MSPH, FAAP
Anu N. Partap, MD MPH, FAAP
Linda Davidson Sagor, MD, MPH, FAAP
Mary Allen Staat, MD MPH, FAAP
Jonathan D. Thackery, MD, FAAP
Douglas Waite, MD, FAAP
Lisa W. Zetley, MD, FAAP

LIAISONS

George Alex Fouras, MD – *American Academy of Child and Adolescent Psychiatry*
Jeremy Harvey – *Foster Care Alumni of America*
Camille Robinson, MD – *American Academy of Pediatrics Section on Pediatric Trainees*

STAFF

Mary Crane, PhD, LSW
Tammy Piazza Hurley, BS

ABBREVIATIONS

AAP: American Academy of Pediatrics
GED: general equivalency diploma
FASD: fetal alcohol spectrum disorder

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. US Department of Health and Human Services, Administration on Children, Youth and Families, Children's Bureau. *The AFCARS Report #26. Preliminary FY 2018 Estimates as of August 22, 2019 - No. 26.* Washington, DC: US Department of Health and Human Services; 2019. Available at: https://www.acf.hhs.gov/sites/default/files/cb/afcarsreport26.pdf. Accessed January 28, 2020
2. Seltzer RR, Henderson CM, Boss RD. Medical foster care: what happens when children with medical complexity cannot be cared for by their families? *Pediatr Res.* 2016; 79(1–2):191–196
3. National Council of Juvenile and Family Court Judges. Disproportionality rates for children of color in foster care 2015 Technical Assistance Bulletin. 2017. Available at: https://www.ncjfcj.org/wp-content/uploads/2017/09/NCJFCJ-Disproportionality-TAB-2015_0.pdf. Accessed May 10, 2019
4. National Indian Child Welfare Association. National Indian Child Welfare Association (NICWA) disproportionality statistics. 2014. Available at: https://www.nicwa.org/wp-content/uploads/2017/09/Disproportionality-Table.pdf. Accessed May 10, 2019
5. Child Welfare and Information Gateway. Racial disproportionality and disparity in the child welfare continuum. 2016. Available at: https://www.childwelfare.gov/pubPDFs/racial_disproportionality.pdf. Accessed May 10, 2019
6. Hines AM, Lemon K, Wyatt P, Merdinger J. Factors related to the disproportionate involvement of children of color in the child welfare system: a review and emerging themes. *Child Youth Serv Rev.* 2004; 26(6):507–527
7. Trent M, Dooley DG, Dougé J; Section on Adolescent Health; Council on Community Pediatrics; Committee on Adolescence. The impact of racism on child and adolescent health. *Pediatrics.* 2019;144(2): e20191765
8. Pryce J. Child welfare is not exempt from structural racism and implicit bias. The Imprint. 2019. Available at: https://chronicleofsocialchange.org/opinion/child-welfare-is-not-exempt-from-structural-racism-and-implicit-

bias/33315. Accessed November 10, 2019

9. Torres K, Mathur R. Family first prevention services act. Fact sheet. Available at: https://campaignforchildren.org/resources/fact-sheet/fact-sheet-family-first-prevention-services-act/. Assessed May 10, 2019
10. National Conference of State Legislatures. Family first prevention services act. Updates. Available at: www.ncsl.org/research/human-services/family-first-prevention-services-act-ffpsa.aspx. Accessed May 10, 2019
11. Children's Defense Fund. The Family First Prevention Services Act: historic reforms to the child welfare system will improve outcomes for vulnerable children. 2018. Available at: https://www.childrensdefense.org/wp-content/uploads/2018/08/family-first-detailed-summary.pdf. Accessed May 10, 2019
12. Trends Child. Key facts about foster care. 2018. Available at: https://www.childtrends.org/indicators/foster-care. Accessed September 26, 2018
13. Administration for Children and Families. Information memorandum. Subject: New Legislation – Public Law 115-123, the Family First Prevention Services Act within Division E, Title VII of the Bipartisan Budget Act of 2018. 2018. Available at: https://www.acf.hhs.gov/sites/default/files/cb/im1802.pdf. Accessed May 10, 2019
14. Child Welfare Information Gateway. Legal and court issues in permanency. Available at: https://www.childwelfare.gov/topics/permanency/legal-court/. Accessed May 10, 2019
15. Child Welfare Information Gateway. Federal laws related to permanency. Available at: https://www.childwelfare.gov/topics/permanency/legal-court/fedlaws/. Accessed May 10, 2019
16. Fostering Connections to Success and Increasing Adoptions Act of 2008, Pub L No. 110–351, 122 Stat 3949 (2008). Available at: https://www.congress.gov/110/plaws/publ351/PLAW-110publ351.pdf. Accessed October 7, 2018
17. Court Appointed Special Advocates for Children. Fostering connections to success act. Available at: https://www.ncsc.org/services-and-experts/government-relations/child-welfare/fostering-connections-to-success-act. Accessed May 10, 2019
18. Children's Defense Fund. Fostering connections to success and increasing adoptions act summary. 2010. Available at: https://www.childrensdefense.org/wp-content/uploads/2018/08/FCSIAA-detailed-summary.pdf. Accessed May 10, 2019
19. The Child and Family Services Improvement and Innovation Act of 2011–2012, Pub L No. 112-34, 125 Stat 369 (2011). Available at: https://www.congress.gov/bill/112th-congress/house-bill/2883. Accessed May 10, 2019
20. Adoption and Safe Families Act of 1997, Pub L No. 105–89, 111 Stat 2115 (1997). Available at: https://www.gpo.gov/fdsys/pkg/PLAW-105publ89/pdf/PLAW-105publ89.pdf. Accessed May 10, 2019
21. Tribal Law and Policy Institute. The Indian child welfare act summary. Available at: http://nc.casaforchildren.org/files/public/community/programs/Tribal/indian-child-welfare-act-summary.pdf. Accessed May 10, 2019
22. Jones BJ. The Indian child welfare act. The need for a separate law. Available at: https://heinonline.org/HOL/LandingPage?handle=hein.journals/gpsolo12&div=46&id=&page=. Accessed May 28, 2019
23. Bissell M, Miller J. *Stepping Up for Kids: What Government and Communities Should Do to Support Kinship Families*. Baltimore, MD: The Annie E. Casey Foundation; 2012. Available at: https://www.aecf.org/resources/stepping-up-for-kids/. Accessed May 10, 2019
24. Jimenez J. The history of child protection in the African American community: implications for current child welfare policies. *Child Youth Serv Rev*. 2006;28(8):888–905
25. Xu Y, Bright CL. Children's mental health and its predictors in kinship and non-kinship foster care: a systematic review. *Child Youth Serv Rev*. 2018;89:243–262
26. Winokur M, Holtan A, Batchelder KE. Systemic review of kinship care effects on safety, permanency, and well-being outcomes. *Res Soc Work Pract*. 2018;28(1):19–32
27. Rubin DM, Downes KJ, O'Reilly ALR, Mekonnen R, Luan X, Localio R. Impact of kinship care on behavioral well-being for children in out-of-home care. *Arch Pediatr Adolesc Med*. 2008;162(6):550–556
28. Cywnar G. Kinship adoption: meeting the unique needs of a growing population. 2010. Available at: https://njarch.org/kinship-adoption-meeting-the-unique-needs-of-a-growing-population/. Accessed May 28, 2019
29. Cuddeback GS. Kinship family foster care: a methodological and substantive synthesis of research. *Child Youth Serv Rev*. 2004;26(7):623–639
30. Winokur M, Holtan A, Valentine D. Kinship care for the safety, permanency, and well-being of children removed from the home for maltreatment. *Cochrane Database Syst Rev*. 2009;(1):CD006546
31. Monahan DJ, Smith CJ, Greene VL. Kinship caregivers: health and burden. *J Fam Soc Work*. 2013;16(5):392–402
32. Peterson TL. Changes in health perceptions among older grandparents raising adolescent grandchildren. *Soc Work Public Health*. 2017;32(6):394–406
33. Ehrle J, Geen R. Kin and non-kin foster care–findings from a national survey. *Child Youth Serv Rev*. 2002;24(1–2):15–35
34. Rubin D, Springer SH, Zlotnik S, Kang-Yi CD; Council on Foster Care, Adoption, and Kinship Care. Needs of kinship care families and pediatric practice. *Pediatrics*. 2017;139(4):e20170099
35. Generations United. In loving arms: the protective role of grandparents and other relatives in raising children exposed to trauma. 2017. Available at: https://www.gu.org/app/uploads/2018/05/Grandfamilies-Report-SOGF-2017.pdf. Accessed November 11, 2019
36. Child Welfare and Information Gateway. Working with kinship caregivers. 2012. Available at: https://www.childwelfare.gov/pubPDFs/kinship.pdf. Accessed May 10, 2019
37. Annie E. Casey Foundation. What is kinship care? 2019. Available at: https://www.aecf.org/blog/what-is-kinship-care/. Accessed November 11, 2019

38. Webster D, Shlonsky A, Shaw T, Brookhart MA. The ties that bind II: reunification of siblings in out-of-home care using a statistical technique for examining non-independent observations. *Child Youth Serv Rev*. 2005;27(7):765–782

39. Wulczyn F, Zimmerman E. Sibling placements in longitudinal perspective. *Child Youth Serv Rev*. 2005;27(7): 741–763

40. Child Welfare Information Gateway. Sibling issues in foster care and adoption. 2014. Available at: https://www.childwelfare.gov/pubPDFs/siblingissues.pdf. Accessed May 10, 2019

41. Kernan E. Keeping siblings together: past, present, and future. 2006. Available at: https://youthlaw.org/publication/keeping-siblings-together-past-present-and-future/. Accessed May 10, 2019

42. Denby RW, Ayala J. Am I my brother's keeper: adult siblings raising younger siblings. *J Hum Behav Soc Environ*. 2013;23(2):192–210

43. Sakai C, Lin H, Flores G. Health outcomes and family services in kinship care: analysis of a national sample of children in the child welfare system. *Arch Pediatr Adolesc Med*. 2011;165(2):159–165

44. Lee E, Clarkson-Hendrix M, Lee Y. Parenting stress of grandparents and other kin as informal kinship caregivers: a mixed methods study. *Child Youth Serv Rev*. 2016;69:29–38

45. Lofquist D, Lugaila T, O'Connell M, Feli S. Households and families: 2010. 2012. Available at: https://www.census.gov/prod/cen2010/briefs/c2010br-14.pdf. Accessed May 10, 2019

46. Jones J, Placek P. *Adoption by the Numbers*. Alexandria, VA: National Council For Adoption; 2017. Available at: https://www.adoptioncouncil.org/publications/2017/02/adoption-by-the-numbers. Accessed May 10, 2019

47. Bureau of Consular Affairs, US Department of State. Intercountry adoption. 2016. Available at: https://travel.state.gov/content/travel/en/Intercountry-Adoption/adopt_ref/adoption-statistics.html. Accessed May 10, 2019

48. Children's Bureau. Adoption data 2014. Available at: https://www.acf.hhs.gov/cb/resource/adoption-data-2014. Accessed May 10, 2019

49. Children's Bureau, Department of Health and Human Services, Administration for Children and Families. New PSAs focus on the importance of adopting teenagers from foster care. 2017. Available at: https://www.acf.hhs.gov/media/press/2017/new-psas-focus-on-the-importance-of-adopting-teenagers-from-foster-care. Accessed May 10, 2019

50. Child Welfare Information Gateway. *Openness in Adoption: Building Relationships Between Adoptive and Birth Families*. Washington, DC: Department of Health and Human Services, Children's Bureau; 2013

51. Siegel DH. Open adoption of infants: adoptive parents' feelings seven years later. *Soc Work*. 2003;48(3): 409–419

52. Appell AR. The open adoption option. *Children's Rights Litigation*. 2010;13(1): 8–12

53. Child Welfare Information Gateway. Postadoption contact agreements between birth and adoptive families. Available at: https://www.childwelfare.gov/pubPDFs/cooperative.pdf. Accessed November 18, 2019

54. Muller U, Perry B. Adopted persons' search for and contact with their birth parents. I: who searches and why? *Adoption Q*. 2001;44(3):5–37

55. Kirkpatrick BE, Rashkin MD. Ancestry testing and the practice of genetic counseling. *J Genet Couns*. 2017;26(1): 6–20

56. Samuels J. Reframing adoptive family narratives through digital and social media technologies. *Interactions: Studies in Communication & Culture*. 2018;9(2):239–250

57. McWey LM, Acock A, Porter B. The impact of continued contact with biological parents upon the mental health of children in foster care. *Child Youth Serv Rev*. 2010;32(10): 1338–1345

58. Clapton G. Close relations? The long-term outcomes of adoption reunions. *Genealogy*. 2018;2(4):41

59. Schulte EE, Michaelson RL. *Caring for Your Adopted Child*. Elk Grove Village, IL: American Academy of Pediatrics; 2018

60. Child Welfare Information Gateway. *Access to Adoption Records*. Washington, DC: US Department of Health and Human Services, Administration for Children and Families, Children's Bureau; 2016

61. Szilagyi MA, Rosen DS, Rubin D, Zlotnik S; Council on Foster Care, Adoption, and Kinship Care; Committee on Adolescence; Council on Early Childhood. Health care issues for children and adolescents in foster care and kinship care. *Pediatrics*. 2015; 136(4). Available at: www.pediatrics.org/cgi/content/full/136/4/e1142

62. Jones VF, Schulte E; Committee On Early Childhood, Adoption, And Dependent Care. Comprehensive health evaluation of the newly adopted child. *Pediatrics*. 2012;129(1). Available at: www.pediatrics.org/cgi/content/full/129/1/e214

63. Lange S, Shield K, Rehm J, Popova S. Prevalence of fetal alcohol spectrum disorders in child care settings: a meta-analysis. *Pediatrics*. 2013;132(4). Available at: www.pediatrics.org/cgi/content/full/132/4/e980

64. Chasnoff IJ, Wells AM, King L. Misdiagnosis and missed diagnoses in foster and adopted children with prenatal alcohol exposure. *Pediatrics*. 2015;135(2):264–270

65. Beal SJ, Greiner MV. Children in nonparental care: health and social risks. *Pediatr Res*. 2016;79(1–2): 184–190

66. Pullmann MD, Jacobson J, Parker E, et al. Tracing the pathway from mental health screening to services for children and youth in foster care. *Child Youth Serv Rev*. 2018;89: 340–354

67. Shonkoff JP, Garner AS; Committee on Psychosocial Aspects of Child and Family Health; Committee on Early Childhood, Adoption, and Dependent Care; Section on Developmental and Behavioral Pediatrics. The lifelong effects of early childhood adversity and toxic stress. *Pediatrics*. 2012;129(1). Available at: www.pediatrics.org/cgi/content/full/129/1/e232

68. Garner AS, Shonkoff JP; Committee on Psychosocial Aspects of Child and Family Health; Committee on Early Childhood, Adoption, and Dependent Care; Section on Developmental and Behavioral Pediatrics. Early childhood adversity, toxic stress, and the role of the pediatrician: translating developmental science into lifelong health. *Pediatrics*. 2012;129(1). Available at: www.pediatrics.org/cgi/content/full/129/1/e224

69. National Conference of State Legislators. Education and medical consent laws. 2017. Available at: www.ncsl.org/research/human-services/educational-and-medical-consent-laws.aspx. Accessed May 10, 2019

70. Strassburger Z. Medical decision-making for youth in the foster care system. *John Marshall Law Rev.* 2016; 49(4):1103–1154

71. US Department of Health and Human Services, Administration on Children, Youth and Families, Children's Bureau. HIPAA for professionals. 2017. Available at: https://www.hhs.gov/hipaa/for-professionals/index.html. Accessed May 10, 2019

72. American Academy of Pediatrics. Council on Foster Care, Adoption, and Kinship Care Web site. Available at: https://www.aap.org/en-us/about-the-aap/Councils/Council-on-Foster-Care-Adoption-and-Kinship-Care/Pages/COFCAKC.aspx. Accessed January 28, 2020

73. American Academy of Pediatrics. Medical Evaluation of Internationally Adopted Children for Infectious Diseases. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases*, 31st ed. Elk Grove Village, IL: American Academy of Pediatrics; 2018:191–203

74. Centers for Disease Control and Prevention. *CDC Yellow Book 2020: Health Information for International Travel*. New York, NY: Oxford University Press; 2018

75. American Academy of Pediatrics, Task Force for Mental Health. *Addressing Mental Health Concerns in Primary Care: A Clinician's Toolkit*. Elk Grove Village, IL: American Academy of Pediatrics; 2010

76. American Academy of Pediatrics. *Section on Developmental and Behavioral Pediatrics*. Elk Grove, IL: American Academy of Pediatrics; 2010

77. American Academy of Pediatrics. *Adoption Medicine: Caring for Children and Families*. Elk Grove, IL: American Academy of Pediatrics; 2014

78. Child Welfare Information Gateway. Adoption assistance by state. Available at: https://www.childwelfare.gov/topics/adoption/adopt-assistance/?CWIGFunctionsaction=adoptionByState:main.getAnswersByQuestion&questionID=12. Accessed May 10, 2019

79. Child Welfare Information Gateway. Financial assistance for kinship caregivers: legal and financial information. Available at: https://www.childwelfare.gov/topics/outofhome/kinship/resourcesforcaregivers/legalinfo/. Accessed May 28, 2019

80. Child Welfare Information Gateway. Adoption assistance for children adopted from foster care. 2011. Available at: https://www.childwelfare.gov/pubpdfs/f_subsid.pdf. Accessed May 10, 2019

81. Child Welfare League of America. Social supports as (primary) maltreatment prevention. Available at: https://www.cwla.org/our-work/advocacy/family-community-support/social-supports-as-primary-maltreatment-prevention/. Accessed October 10, 2020

82. Generations United. Adoption and guardianship for children in kinship foster care. Available at: https://www.gu.org/resources/adoption-and-guardianship-for-children-in-kinship-foster-care/. Accessed October 10, 2020

83. American Academy of Pediatrics, Council on Foster Care, Adoption, and Kinship Care. Respectful ways to talk about adoption: a list of do's & dont's. 2015. Available at: https://www.healthychildren.org/English/family-life/family-dynamics/adoption-and-foster-care/Pages/Respectful-Ways-to-Talk-about-Adoption-A-List-of-Dos-Donts.aspx. Accessed May 10, 2019

84. AdoptiveFamlies. *Positive Adoption Conversations: The Complete Guide to Talking About Adoption*. New York, NY: Adoptive Families Magazine; 2015. Available at: https://www.adoptivefamilies.com/store/adoption-ebook/positive-adoption-conversations/. Accessed January 28, 2020

85. Keefer B, Schooler JE. *Telling the Truth to Your Adopted or Foster Child: Making Sense of the Past*. Westport, CT: Bergin & Garvey; 2000

86. Springer S; American Academy of Pediatrics, Council on Foster Care, Adoption, and Kinship Care. Anticipatory guidance for pediatricians on addressing difficult adoption, foster care, & kinship care topics. 2016. Available at: https://www.aap.org/en-us/Documents/cofcakc_anticipatory_guidance.pdf. Accessed January 28, 2020

87. Springer S; American Academy of Pediatrics, Council on Foster Care, Adoption, and Kinship Care. Talking with families about adoption, foster care & kinship care in the pediatrician's office. 2016. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/healthy-foster-care-america/Documents/TalkingWithFamilies.pdf. Accessed January 28, 2020

88. Erikson EH. *Identity and the Life Cycle*. New York, NY: WW Norton & Company; 1994

89. Baxter C. Understanding adoption: a developmental approach. *Paediatr Child Health*. 2001;6(5):281–291

90. Singer E. *Children and Adoption The School Age Years (6-11)*. Burtonsville, MD: Center for Adoption Support and Education; 2016. Available at: https://adoptionsupport.org/wp-content/uploads/2015/12/02-The-School-Age-Years.pdf. Accessed January 28, 2020

91. Berrier S. The effects of grief and loss on children in foster care. *Fostering Perspectives*. 2001;6(1). Available at: https://fosteringperspectives.org/fp_vol6no1/effects_griefloss_children.htm. Accessed January 28, 2020

92. Forkey H, Garner A, Nalven L, Schilling S, Sterling J. *Helping Foster and Adoptive Families Cope With Trauma*. Elk Grove Village, IL: American Academy of Pediatrics and Dave Thomas Foundation for Adoption; 2015. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/healthy-foster-care-america/Documents/Guide.pdf. Accessed January 28, 2020

93. Arnett JJ. Emerging adulthood. A theory of development from the late teens through the twenties. *Am Psychol*. 2000; 55(5):469–480

94. Child Welfare Information Gateway. Lifebooks. Available at: https://www.childwelfare.gov/topics/adoption/adopt-parenting/lifebooks/. Accessed November 20, 2019

95. Child Welfare Information Gateway. Impact of adoption on birth parents. 2013. Available at: https://www.childwelfare.gov/pubs/f_impact/index.cfm. Accessed May 10, 2019

96. Edelstein SB, Burge D, Waterman J. Helping foster parents cope with separation, loss, and grief. *Child Welfare*. 2001;80(1):5–25

97. Williams D. Grief, loss, and separation: experiences of birth children of foster careers. *Child Fam Soc Work*. 2017; 22(4):1448–1455

98. Clark KB, Clark MK. Segregation as a factor in the racial identification of Negro pre-school children: a preliminary report. *J Exp Educ*. 1939; 8(2):161–163

99. Clark KB, Clark MK. Skin color as a factor in racial identification of Negro preschool children. *J Soc Psychol*. 1940; 11(1):159–169

100. Quintana SM. Children's developmental understanding of ethnicity and race. *Appl Prev Psychol*. 1998;7:27–45

101. Singarajah A, Chanley J, Gutierrez Y, et al. Infant attention to same- and other-race faces. *Cognition*. 2017;159: 76–84

102. Brodzinsky DM. Adoptive Identity and Children's Understanding of Adoption: Implications for Pediatric Practice. In: Mason P, Johnson D, Albers Prock L, eds. *Adoption Medicine: Caring for Children and Families*. Elk Grove Village, IL: American Academy of Pediatrics; 2014

103. Ito-Gates J, Dariotos WM. Talking about race and racism. Available at: https://holtinternational.org/adoption/parent-training/wp-content/uploads/2018/08/Talking-About-Race-and-Racism-have-permission-to-reprint.pdf. Accessed November 20, 2019

104. Anderson A, Douge J. Talking to children about racial bias. Available at: https://www.healthychildren.org/English/healthy-living/emotional-wellness/Building-Resilience/Pages/Talking-to-Children-About-Racial-Bias.aspx. Accessed November 20, 2019

105. Gates GJ. LGBT parenting in the United States. 2013. Available at: http://williamsinstitute.law.ucla.edu/wp-content/uploads/LGBT-Parenting.pdf. Accessed May 10, 2019

106. Gates GJ. Marriage and family: LGBT individuals and same-sex couples. *Future Child*. 2015;25(2):67–87

107. Gates GJ, Lee Badgett MV, Macomber JE, Chambers K. *Adoption and Foster Care by Gay and Lesbian Parents in the United States*. Washington, DC: The Urban Institute and the Charles R. Williams Institute on Sexual Orientation and Policy; 2007. Available at: https://www.urban.org/sites/default/files/publication/46401/411437-Adoption-and-Foster-Care-by-Lesbian-and-Gay-Parents-in-the-United-States.PDF. Accessed January 28, 2020

108. Family Equity Council. LGBTQ family fact Sheet. 2017. Available at: https://www2.census.gov/cac/nac/meetings/2017-11/LGBTQ-families-factsheet.pdf. Accessed January 28, 2020

109. Goldberg SK, Conron KJ. How many same-sex couples in the U.S. are raising children? 2018. Available at: https://williamsinstitute.law.ucla.edu/wp-content/uploads/Parenting-Among-Same-Sex-Couples.pdf. Accessed November 11, 2019

110. Perrin EC; Committee on Psychosocial Aspects of Child and Family Health. Technical report: coparent or second-parent adoption by same-sex parents. *Pediatrics*. 2002;109(2): 341–344

111. Committee on Psychosocial Aspects of Child and Family Health. Coparent or second-parent adoption by same-sex parents. *Pediatrics*. 2002;109(2): 339–340

112. Perrin EC, Siegel BS; Committee on Psychosocial Aspects of Child and Family Health of the American Academy of Pediatrics. Promoting the well-being of children whose parents are gay or lesbian. *Pediatrics*. 2013;131(4). Available at: www.pediatrics.org/cgi/content/full/131/4/e1374

113. Cody PA, Farr RH, McRoy RG, Ayers-Lopez SJ, Lesdesma KJ. Youth perspectives on being adopted from foster care by lesbian and gay parents: implications for families and adoption professionals. *Adoption Q*. 2017;20(1): 98–118

114. National Working Group on Foster Care and Education. Fostering success in education: national factsheet on the educational outcomes of children in foster care. 2018. Available at: https://foster-ed.org/fostering-success-in-education-national-factsheet-on-the-educational-outcomes-of-children-in-foster-care/. Accessed January 28, 2020

115. Courtney ME, Dworsky A, Ruth G, Keller TE, Havlicek J, Bost N. Midwest evaluation of the adult functioning of former foster youths: outcomes at age 19. 2005. Available at: http://pdxscholar.library.pdx.edu/cgi/viewcontent.cgi?article=1015&context=socwork_fac. Accessed November 21, 2019

116. Metzler M, Merrick MT, Klevens J, Ports KA, Ford DC. Adverse childhood experiences and life opportunities: shifting the narrative. *Child Youth Serv Rev*. 2017;72:141–149

117. Fantuzzo JW, Perlman SM, Dobbins EK. Types and timing of child maltreatment and early school success: a population-based investigation. *Child Youth Serv Rev*. 2011;33:140–144

118. Klein S. *Benefits of Early Care and Education for Children in the Child Welfare System*. Washington, DC: Office of Planning, Research and Evaluation, Administration for Children and Families, US Department of Health and Human Services; 2016

119. Kovan N, Mishra S, Susman-Stillman A, Piescher KN, LaLiberte T. Differences in the early care and education needs of young children involved in child protection. *Child Youth Serv Rev*. 2014; 46:139–145

120. Lipscomb ST, Schmitt SA, Pratt M, Acock A, Pears KC. Living in non-parental care moderates effects of prekindergarten experiences on externalizing behavior problems in school. *Child Youth Serv Rev*. 2014;40:41–50

121. Merritt DH, Klein S. Do early care and education services improve language development for maltreated children? Evidence from a national child welfare

sample. *Child Abuse Negl*. 2015;39: 185–196

122. University of Washington. What is the difference between an IEP and a 504 plan? 2018. Available at: https://www.washington.edu/accesscomputing/what-difference-between-iep-and-504-plan. Accessed May 10, 2019
123. Styles KM, Yudin MK. Guidance on the amendments to the family educational rights and privacy act by the Uninterrupted Scholars Act. Available at: https://www2.ed.gov/policy/gen/guid/fpco/ferpa/uninterrupted-scholars-act-guidance.pdf. Accessed January 28, 2020
124. Barraso A, Parker K, Fry R. Majority of Americans say parents are doing too much for their young adult children. 2019. Available at: https://www.pewsocialtrends.org/2019/10/23/majority-of-americans-say-parents-are-doing-too-much-for-their-young-adult-children/. Accessed November 15, 2019
125. Fowler PJ, Marcal KE, Zhang J, Day O, Landsverk J. Homelessness and aging out of foster care: a national comparison of child welfare-involved adolescents. *Child Youth Serv Rev*. 2017; 77:27–33
126. Courtney ME, Dworsky A, Cusick GR, Havlicek J, Perez A, Keller T. Midwest evaluation of the adult functioning of former foster youth: outcomes at age 21. 2007. Available at: https://www.chapinhall.org/wp-content/uploads/Midwest-Eval-Outcomes-at-Age-21.pdf. Accessed May 10, 2019
127. Courtney M, Dworsky A, Brown A, Cary C, Love K, Vorhies V. *Midwest Evaluation of the Adult Functioning of Former Foster Youth: Outcomes at Age 26*. Chicago, IL: Chapin Hall at the University of Chicago; 2011. Available at https://www.researchgate.net/publication/264883847_Midwest_Evaluation_of_the_Adult_Functioning_of_Former_Foster_Youth_Outcomes_at_Age_26. Accessed May 10, 2019
128. Fowler PJ, Toro PA, Miles BW. Pathways to and from homelessness and associated psychosocial outcomes among adolescents leaving the foster care system. *Am J Public Health*. 2009; 99(8):1453–1458
129. US Department of Health and Human Services Administration for Children. Youth and families. Independent living initiatives. Available at: https://www.acf.hhs.gov/sites/default/files/cb/pi8701.pdf. Accessed November 21, 2019
130. Fernandes-Alcantara AL. Youth transitioning from foster care: background and federal programs. 2016. Available at: https://fas.org/sgp/crs/misc/RL34499.pdf. Accessed May 10, 2019
131. US Department of Health and Human Services, Administration on Children, Youth and Families. Children's Bureau. Extension of foster care beyond age 18. 2017. Available at: https://www.childwelfare.gov/pubPDFs/extensionfc.pdf. Accessed October 11, 2020
132. Dworsky A, Courtney M. Does extending foster care beyond age 18 promote postsecondary educational attainment? 2010. Available at: https://www.chapinhall.org/wp-content/uploads/Midwest_IB1_Educational_Attainment.pdf. Accessed January 28, 2020
133. Courtney ME, Hook JL. The potential educational benefits of extending foster care to young adults: findings from a natural experiment. *Child Youth Serv Rev*. 2017;72:124–132
134. Hook JL, Courtney ME. Employment outcomes of former foster youth as young adults: the importance of human, personal, and social capital. *Child Youth Serv Rev*. 2011;3310:1855–1865
135. Thompson HM, Wojciak AS, Cooley ME. The experience with independent living services for youth in care and those formerly in care. *Child Youth Serv Rev*. 2018;84:17–25
136. Child Welfare Information Gateway. Helping youth transition to adulthood: guidance for foster parents. 2013. Available at: https://www.childwelfare.gov/pubPDFs/youth_transition.pdf. Accessed May 10, 2019
137. Pecora PJ, Kessler RC, Williams J, et al. *Improving Family Foster Care: Findings from the Northwest Foster Care Alumni Study. The Foster Care Alumni Studies*. Seattle, WA: Casey Family Programs; 2005. Available at: https://caseyfamilypro-wpengine.netdna-ssl.com/media/AlumniStudies_NW_Report_ES.pdf. Accessed May 10, 2019
138. Keyes MA, Malone SM, Sharma A, Iacono WG, McGue M. Risk of suicide attempt in adopted and nonadopted offspring. *Pediatrics*. 2013;132(4):639–646
139. Jaudes P; Council on Foster Care, Adoption, and Kinship Care and Committee on Early Childhood. Health care of youth aging out of foster care. *Pediatrics*. 2012;130(6):1170–1173
140. Stolzfus E, Baumrucker EP, Fernandes-Alcantara AL, Fernandez B. Child welfare: Health care needs of children in foster care and related federal issues. Available at: https://www.everycrsreport.com/reports/R42378.html. Accessed January 28, 2020
141. McManus M, White P, Harwood C; National Alliance to Advance Adolescent Health. 2017 coding and reimbursement tip sheet for transition from pediatric to adult health care. Available at: www.gottransition.org/resourceGet.cfm?id=352. 2017. Accessed May 10, 2019
142. Herz D, Lee P, Lutz L, Stewart M, Tuell J, Wig J. *Addressing the Needs of Multi-System Youth: Strengthening the Connection Between Child Welfare and Juvenile Justice*. Washington, DC: Center for Juvenile Justice Reform-Georgetown University, Robert F. Kennedy Children's Action Corp; 2012
143. Herz DC, Ryan JP, Bilchik S. Challenges facing crossover youth: an examination of juvenile-justice decision-making and recidivism. *Fam Court Rev*. 2010;48(2): 305–321
144. Ryan JP, Testa MF. Child maltreatment and juvenile delinquency: investigating the role of placement and placement instability. *Child Youth Serv Rev*. 2005; 27(3):227–249
145. Sarri RC, Stoffregen E, Ryan JP. Running away from child welfare placements: justice system entry risk. *Child Youth Serv Rev*. 2016;67:191–197
146. Vidal S, Prince D, Connell CM, Caron CM, Kaufman JS, Tebes JK. Maltreatment, family environment, and social risk factors: Determinants of the child welfare to juvenile justice transition among maltreated children and adolescents. *Child Abuse Negl*. 2017;63: 7–18
147. Marshall JM, Haight WL. Understanding racial disproportionality affecting African American Youth who cross over from the child welfare to the juvenile justice system: communication, power,

race and social class. *Child Youth Serv Rev.* 2014;42:82–90

148. Borduin CM. Multisystemic treatment of criminality and violence in adolescents. *J Am Acad Child Adolesc Psychiatry.* 1999;38(3):242–249

149. Jones T, McMahon J. Tips for preventing delinquent behavior. *Fostering Perspectives.* 2014;18(2). Available at: http://fosteringperspectives.org/fpv18n2/tips.htm. Accessed January 28, 2020

150. Shpiegel S. Resilience among older adolescents in foster care: the impact of risk and protective factors. *Int J Ment Health Addict.* 2016;14:6–22

151. Yates TM, Grey IK. Adapting to aging out: profiles of risk and resilience among emancipated foster youth. *Dev Psychopathol.* 2012;24(2):475–492

152. Collins ME, Spencer R, Ward R. Supporting youth in the transition from foster care: formal and informal connections. *Child Welfare.* 2010;89(1):125–143

Physical Activity Assessment and Counseling in Pediatric Clinical Settings

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Physical Activity Assessment and Counseling in Pediatric Clinical Settings

Felipe Lobelo, MD, PhD,[a] Natalie D. Muth, MD, MPH, FAAP, FACSM,[b] Sara Hanson, PhD,[c] Blaise A. Nemeth, MD, FAAP,[d] COUNCIL ON SPORTS MEDICINE AND FITNESS, SECTION ON OBESITY

Physical activity plays an important role in children's cardiovascular health, musculoskeletal health, mental and behavioral health, and physical, social, and cognitive development. Despite the importance in children's lives, pediatricians are unfamiliar with assessment and guidance regarding physical activity in children. With the release of the 2018 Physical Activity Guidelines by the US Department of Health and Human Services, pediatricians play a critical role in encouraging physical activity in children through assessing physical activity and physical literacy; providing guidance toward meeting recommendations by children and their families; advocating for opportunities for physical activity for all children in schools, communities, and hospitals; setting an example and remaining physically active personally; advocating for the use of assessment tools and insurance coverage of physical activity and physical literacy screening; and incorporating physical activity assessment and prescription in medical school curricula.

INTRODUCTION AND RATIONALE FOR PHYSICAL ACTIVITY ASSESSMENT AND COUNSELING

The 2017 Youth Risk Behavior Survey (YRBS) revealed that only 26.1% of American adolescents reported levels of activity consistent with current guidelines, and 15.4% of students reported not being physically active for at least 1 hour on a single day in the previous week.[1] With the exception of increased sports participation among high school female students, overall youth physical activity levels have decreased.[2] The lowest rates of physical activity occur among adolescent girls, children and youth with special health care needs (CYSHCN), and youth of minority status; rates of inactivity increased with age.[1,3] Although only approximately one-fourth of children report meeting physical activity guidelines, objective measurement of activity by accelerometer reveals that less than half of children and 8% of adolescents were meeting the 2008 Physical Activity Guidelines from the US Department of Health and Human Services of 60 minutes daily of moderate-to-vigorous physical activity (MVPA) as

abstract

[a]Hubert Department of Global Health and [c]Nutrition and Health Sciences Program, Laney Graduate School and Exercise is Medicine Global Research and Collaboration Center, Rollins School of Public Health, Emory University, Atlanta, Georgia; [b]Children's Primary Care Medical Group, Carlsbad, California; and [d]American Family Children's Hospital and School of Medicine and Public Health, University of Wisconsin–Madison, Madison, Wisconsin

Drs Lobelo, Muth, Hanson, and Nemeth served as coauthors of the manuscript, providing substantial input into content and revision; and all authors approved the final manuscript as submitted.

DOI: https://doi.org/10.1542/peds.2019-3992

Address correspondence to Blaise A. Nemeth, MD, FAAP. E-mail: bnemeth@ortho.wisc.edu

To cite: Lobelo F, Muth ND, Hanson S, et al. AAP COUNCIL ON SPORTS MEDICINE AND FITNESS, AAP SECTION ON OBESITY. Physical Activity Assessment and Counseling in Pediatric Clinical Settings. *Pediatrics*. 2020;145(3): e20193992

recently as 2016.[1,4,5] With rates of obesity rising over the last decades, annual relative increases of 4.8% in the incidence of type 2 diabetes mellitus,[6] and declines in estimated life expectancy at time of birth since 1993, the role of physical activity on child, and later adult, health remains an important component of preventive care and disease treatment.[7,8]

In 2006, the American Academy of Pediatrics (AAP) published the policy statement "Active Healthy Living: Prevention of Childhood Obesity through Increased Physical Activity."[9] That statement addressed not only the role of physical activity in obesity but also identification of individuals at risk for decreased physical activity, age-appropriate activity recommendations, and the role of schools in promoting activity.[9] Since that time, the AAP and other organizations have published statements on the assessment, prevention, and treatment of pediatric obesity that include recommendations to promote improved nutrition and sleep, decreased sedentary time, and increased physical activity, although details regarding how to achieve physical activity recommendations are limited.[10–13] Unfortunately, 5 years after the 2008 Physical Activity Guidelines were released, only 23% of family physicians and 33% of pediatricians were able to correctly identify current physical activity guidelines for children 6 to 18 years of age.[14,15] Physical activity is a "priority topic" in *Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents, Fourth Edition*, for every health supervision visit starting at 18 months of age, with inclusion of recommending meeting the Physical Activity Guidelines beginning at 5 years of age.[16] The 2018 Physical Activity Guidelines outline the recommended physical activity levels for children and adolescents, provide guidelines for children younger than 6 years, and support the role of physical activity on not just physical health but also in development, mental health, and school performance (Table 1).[17] As such, this clinical report replaces the previous statement on active healthy living, augments existing statements, highlights the role of physical activity in all children's health, and provides guidance for physicians to better assist families in increasing physical activity.

PHYSICAL ACTIVITY AND HEALTH OUTCOMES IN CHILDREN AND YOUTH

The relationships between physical activity, cardiovascular health, and body composition have been well established. Morris et al[18] demonstrated decreased rates of adult coronary heart disease in active versus sedentary employees of the London Transport Executive in 1953. In the absence of longitudinal studies assessing the impact of childhood physical activity on adult mortality, studies have confirmed the benefit of physical activity on children's cardiorespiratory fitness, lipid profiles, insulin sensitivity, and serum glucose concentrations in individuals with obesity as well as associations with more optimal cardiovascular profiles in the most physically active children.[19–24] Importantly, for the developing child, aerobic activity and strength training result in increased muscle mass and decreased fat mass.[21,22,25] Physical activity also increases bone density and improves balance, protecting against falls and injury both in childhood and later in life.[26–30] Overall, strong evidence supports that MVPA improves cardiovascular and muscular fitness, bone health, weight status, and cardiometabolic risk factor status in children and adolescents, as outlined by the 2018 Physical Activity Guidelines Advisory Committee.[31]

Less widely appreciated, physical activity benefits behavioral, cognitive, and social aspects of child health. Increased physical activity has also been shown to be associated with decreased rates of smoking and fewer symptoms of depression, and increased rates of inactivity and sedentary activity can predict future alcohol and drug use in adolescents.[32–34] Both randomized controlled trials and systematic reviews support the effect of physical activity on academic performance, possibly even in a dose-response relationship.[35–41] Children who are provided opportunities to be physically active during school focus and behave better, including children with attention-deficit/hyperactivity disorder.[42–44] Benefits may be even greater in children with autism spectrum disorder who show decreased perseverative behavior and easier redirection after a bout of physical activity.[45,46] The 2018 Physical Activity Guidelines Advisory Committee concluded that in children ages 5 to 13 years, acute bouts of physical activity and regular MVPA

TABLE 1 2018 Physical Activity Guidelines Applicable to Children

Age	Activity Amount	Intensity
3–5 y	3+ h/d	Light, moderate, vigorous
6–17 y	≥60 min/d	Moderate or vigorous aerobic activity daily
		Vigorous at least 3 d/wk
		Muscle-strengthening activities at least 3 d/wk
		Bone-strengthening activities at least 3 d per wk
Children not meeting guidelines	Gradually increase activity in ways the child enjoys	Moderate-vigorous; increase time per d and No. days per wk; use multiple, smaller time increments in activity that are additive throughout the day

Adapted from US Department of Health and Human Services. *Physical Activity Guidelines for Americans*. 2nd ed. Washington, DC: US Department of Health and Human Services; 2018. Available at: https://health.gov/paguidelines/second-edition/pdf/Physical_Activity_Guidelines_2nd_edition.pdf. Accessed December 10, 2018.

improve cognition, including memory, processing speed, attention, and academic performance.[31]

Even more concerning than the rates of inactivity among children overall is the low rate of physical activity among CYSHCN.[3] CYSHCN represent a wide range of children with chronic physical, developmental, behavioral, or emotional conditions.[47] The benefits of physical activity for CYSHCN are substantial. Physical activity plays a vital role in strength, endurance, and bone health for all children and especially for children with neuromotor disorders such as spina bifida, muscular dystrophy and other myopathies, Prader-Willi syndrome, and cerebral palsy.[48–54] Beyond musculoskeletal benefits, activity may play a role in speech and fine motor development, possibly through opportunities for social interaction, postural control and positioning, and use of orofacial muscles required for breathing during physical activity.[55–60] Despite its pronounced benefits, rates of physical activity in CYSHCN are much lower than in health-normative peers.[3,61] Any successful effort to increase physical activity requires approaches tailored to an individual's unique needs.[62]

Physical activity may also create unexpected benefits in children with other chronic health conditions. Children with a history of cancer experience increased rates of cardiovascular events, and physical activity has been shown to improve cardiovascular risk factors in this population.[63–65] Physical activity also improves immune function, which may decrease pulmonary infection, and improves weight gain in children with cystic fibrosis.[66–69] Physical activity benefits cardiorespiratory function in, and may be engaged in safely by, children with congenital heart disease under properly advised and supervised programs.[70–72]

CURRENT PHYSICAL ACTIVITY GUIDELINES IN YOUTH

The 2018 Physical Activity Guidelines Advisory Committee reaffirmed the 2008 Physical Activity Guidelines, which recommend children and adolescents (6–17 years of age) engage in at least 60 minutes of physical activity every day, including vigorous-intensity as well as muscle- and bone-strengthening activities, at least 3 days per week (Table 1).[31] The AAP has advised that physical activity should also include a muscle-strengthening program that targets all major muscle groups, starts with no load and incrementally may add load once exercise technique is mastered, involves 2 to 3 sets of 8 to 15 repetitions, and is performed 2 to 3 days per week for at least 8 weeks.[73]

The 2018 Physical Activity Guidelines Advisory Committee concluded there is strong evidence that a greater volume of physical activity among children ages 3 to 5 years of age is associated with a decreased risk of excessive weight gain and improved bone health.[31] The committee concluded these children should aim to achieve at least the median level of physical activity of children this age, which is 3 hours or more of physical activity per day.[31] This is consistent with other guidelines that suggest that adults should provide opportunities for free play and unstructured physical activity for children 3 to 5 years of age,[15,74] including at least 180 minutes of physical activity throughout the day (approximately 15 minutes every hour while awake) that helps to develop movement skills in a variety of activities and in a variety of environments. The higher volume of activity recommendation for children 3 to 5 years of age is based on the nature of their activity being intermittent and typically of lower intensity than older children.[75] Infants should be physically active several times per day, mostly through interactive floor-based play.[75] The AAP clinical report "The Power of Play: A Pediatric Role in Enhancing Development in Young Children" offers guidance on appropriate approaches for young children.[76] *Caring for Our Children: National Health and Safety Performance Standards; Guidelines for Early Care and Education Programs* is another AAP publication providing guidance for child care settings.[77]

For all children and adolescents, it is important that activities are appropriate to a child's age, enjoyable, and varied.[75] Examples of child and youth physical activities as well as recommendations based on the principles of frequency, intensity, time, and type of activity are included in Tables 2 and 3.

THE IMPORTANCE OF PHYSICAL LITERACY IN SHAPING PHYSICAL ACTIVITY PARTICIPATION

Attention to physical literacy, defined by the Aspen Institute as "the ability, confidence, and desire to be physically active for life" may provide an opportunity to increase and sustain physical activity across childhood and adolescence.[85] Ability includes competence in fundamental movement skills including throwing, catching, jumping, striking, running, kicking, agility, balance, and coordination. Fundamental movement skills emerge starting with gross motor skill development in infancy and early childhood, progress throughout early and midchildhood, and are honed in preadolescence and adolescence (see Table 4).[85] Competency in fundamental movement skills is a strong predictor of both current and future physical activity levels, cardiovascular fitness, BMI, and risk of overweight and obesity.[86–88] Confidence, or self-efficacy in one's ability to play sports or enjoy physical activity, develops from early positive experiences with physical play and a variety of sports that are inclusive and welcoming of

TABLE 2 Examples of Types of Physical Activity

	MET	Physical Symptoms	Examples of Activities
Rest	1	—	—
Light	<3	Easily able to converse	Household chores
			Walking
		No sweating or shortness of breath	Playing catch
			Fishing
Moderate	3–6	Some difficulty talking	Yardwork
		Feeling warm	Jogging or fast walking
		Light sweating	Tag
		Slight shortness of breath	Movement portion of ball sports
Vigorous	>6	Unable to talk	Manual labor
		Short of breath	Run
		Face red	Skipping rope
		Sweating	Skiing, skating
Wheelchair use or use of assistive devices (crutches or ankle-foot orthoses)	Comparable METs expended for comparable examples noted above (eg, wheeling on a smooth surface = light; wheeling fast or up an incline or as part of ball sports = moderate; wheelchair racing or sit-skiing = vigorous) (use of crutches or ankle-foot orthoses involves higher METs but usually not enough to increase the level of PA, eg, from light to moderate)	—	—
Muscle strengthening	—	Pushing and/or pulling one's body or an object	Climbing
			Pushups, curl-ups, or resistance training
			Wheeling a wheelchair
Bone strengthening	—	Increased impact	Jumping rope
			Tumbling
			Running

Data are from references 78–82. MET, metabolic equivalent of task; PA, physical activity; —, not applicable.

all children, regardless of their abilities.[85] Desire encompasses the interest and enjoyment in physical activity and movement.[85]

Teenagers report the strongest facilitators of physical activity include a favorable attitude toward physical activity; motivation; perception of competence and body image; fun; influence of friends, family, and physical education teachers; and environmental physical activity opportunities.[91] Higher physical literacy is associated with higher physical activity levels and cardiorespiratory fitness in children and adolescents.[92,93] On the other hand, children who do not develop fundamental movement skills are unlikely to develop the confidence and desire to be active and are at increased risk for sedentary lifestyle and its associated risks, as demonstrated by children with developmental coordination disorder who experience increased rates of obesity.[94,95]

Children who do not engage in regular physical activity miss out on important benefits such as improved self-esteem, leadership and team building skills, decreased stress and anxiety, decreased depression, and fun, as well as improved physical and brain health.[74] Because physical activity is essential to normal pediatric development and health, the term "exercise deficit disorder" has been proposed to identify children who, for a variety of reasons, do not engage in sufficient physical activity to promote overall health.[96]

Many groups experience barriers to being physically active and developing fundamental movement skills, such as girls, children of minority status, children from low-income households (rural and urban), and CYSHCN.[85] If these skills do not develop, the likelihood of being physically inactive later in life increases, creating an integral role for the pediatrician in screening for physical literacy, physical activity opportunities, and exercise deficit disorder[97] and referring to a youth fitness specialist, physical education teacher, or physical and/or occupational therapist because structured programming improves fitness, strength, and functional movement skills.[98,99] National standards outline physical literacy as the primary purpose of physical education classes in schools.[100]

The role of early physical activity and literacy on later adult health may play a role in fracture risk beyond effects of impact activities on bone density and geometry.[101] Multidirectional ball sports earlier in life appear to protect against stress fractures in adolescent runners.[102] Physical function or, rather, dysfunction has been found to be a contributor to adult "fragility"

TABLE 3 Age-Appropriate Recommendations for Increased Physical Activity

	Infant (0–1 y)	Toddler (1–3 y)	Preschool (3–5 y)	Elementary (5–10 y)	Middle School (11–14 y)	Adolescence (15–18 y)
Frequency	Daily	Daily	Daily	Daily	Daily	Daily
Intensity	Any	Any	Any, including some moderate to vigorous	Moderate to vigorous	Moderate to vigorous	Moderate to vigorous
Time	Several times per day	At least 180 min/d	At least 180 min/d, of which at least 60 min are moderate-to-vigorous intensity	At least 60 min/d	At least 60 min/d	At least 60 min/d
Type	Interactive floor-based play and at least 30 min of tummy time spread throughout the day while awake	Activities that develop gross motor skills; examples include walking in the neighborhood, unorganized free play outdoors, walking through a park or zoo, or playing on a playground for toddlers	Activities that develop gross motor skills; unorganized free play in a safe environment; activities include walking, running, swimming, tumbling, throwing, and catching	Aerobic daily; vigorous activity, muscle, and bone- strengthening at least 3 d/wk; include free play with opportunities for fundamental movement skill development through walk, dance, jump rope. Introduce organized sports with flexible rules and short instruction time with a focus on enjoyment rather than competition	Aerobic daily; vigorous activity, muscle, and bone-strengthening at least 3 d/wk; incorporate activities that are enjoyable and encourage socialization; avoid sports specialization	Aerobic daily; vigorous activity, muscle, and bone-strengthening at least 3 d/wk; incorporate activities that are enjoyable and encourage socialization and competition, when appropriate

Data are from references 9, 15, 73, 75, 83, and 84.

fracture risk.[103] Because osteopenia only explains part of fracture risk, the role of sarcopenia, the loss of muscle, especially with aging, has been proposed as an important risk factor to the extent that, similar to exercise deficit disorder, the term "dysmobility syndrome" has been coined for adults, both resulting from dynapenia, the loss of muscle.[104,105]

INACTIVITY AND SEDENTARY TIME

The typical preschooler spends more than 6 hours per day in sedentary activity and just under 15 minutes per day in MVPA.[106] More than 20% of children watch 3 or more hours of television per day on school days,[1] and the average 8- to 18-year-old spends more than 7 hours per day in front of a screen.[107]

The health effects of a sedentary lifestyle are an area of intense research and emerging concern. For adults, physical inactivity is associated with increased all-cause mortality, cardiovascular disease incidence and mortality, cancer incidence and mortality, and diabetes incidence,[108] among other harmful health consequences. The 2018 Physical Activity Guidelines Advisory Committee concluded that there is limited available scientific evidence linking sedentary behavior to health outcomes; however, given the high prevalence of physical inactivity in youth, especially CYSHCN, replacing some sedentary time with MVPA could improve health, given the strong association.[31,109] More research is needed to better understand the effects of time spent sitting and in light-intensity physical activity among children and adolescents.[110]

Although the advent of exergaming, or active video games, pose an attractive option to promote physical activity in children drawn to electronic media and video games and averse to traditional physical activity, exergaming primarily

TABLE 4 Supporting Physical Literacy

Infancy: supporting rudimentary motor skill development
Grasping (3–4 mo)
Offer toys to support hand-eye coordination
Roll over (4–6 mo)
Tummy time to build core strength
Sitting (6 mo)
Tummy time to increase strength and coordination
Crawling (7–10 mo)
Place toys to help build strength and balance
Cruising (9 mo)
Offer a safe environment to explore which increases strength and balance
Walking (12 mo)
Create a safe environment to explore which improves balance and coordination
Toddler or preschool age: support development of fundamental skills
Encourage fun and socialization, incorporating activities preferred by the child, family walks, and chores (picking up, retrieving items, helping clean)
Running (by 2 y)
Play chase, visit parks, and offer a safe environment to practice
Throwing (2 y)
Play catch with easy-to-grasp foam or fabric balls
Catching (2+ y)
Create a "basket" with arms to catch
Kicking (2 y)
Play soccer with light, foam balls
Swimming (1–4 y)
Enroll in swimming lessons
Skating (4 y)
Elementary school age: improve fundamental skills and develop self-efficacy
Encourage fun and socialization, incorporating fitness preferences (such as dance, yoga, running, hiking, sports), active transportation (walking, cycling to school and activities), and chores (walking the dog)
Running
Build fitness and skills with tag, introduce sports like soccer by age 6
Throwing and catching
Falling and tumbling
Helps decrease injury by learning to tuck head, knees, and arms
Hopping and jumping
Hopscotch and jump rope
Cycling
Teach a child to ride a bike
Striking sports
Practice at home with a plastic ball and bat, hockey stick, etc; introduce sports programs
Dribbling sports
Fine motor skills develop through practice and repetition
Gymnastics
One of the best activities for agility, balance, coordination, strength, and flexibility
Skiing
Low center of gravity makes it easier; it helps with balance
Preadolescence and adolescence: honing physical literacy
Encourage fun and socialization, incorporating fitness preferences (such as dance, yoga, running, hiking, sports), active transportation (walking, cycling to school and activities), and chores (walking the dog)
Identify gaps in fundamental movement skills development, confidence, or desire to be active and devise a plan to remedy (eg, motivational interviewing, physical therapy, community program)
Introduce skill development and strategy through coaching and camps
Introduce more complex sports that incorporate multidirectional movement and attention (eg, sports with equipment and strategy and/or plays)
Introduce resistance training with supervision and instruction on proper technique
Avoid sports specialization until mid-to-late teenaged years

Data are from references 16, 76, 83–85, 89, and 90.

promotes only light physical activity, with few games demonstrating effectiveness in increasing activity to moderate or vigorous levels.[111] Although MVPA occurs with specific games in structured settings, applicability to home settings and the ability to achieve sustained, or cumulative, durations necessary to meet physical activity guidelines has not been demonstrated.[112,113]

The AAP advises that parents develop a family media use plan to help children limit screen time activities to ensure they do not replace adequate sleep, physical activity, and other behaviors essential to health.[114] Likewise, *Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents, Fourth Edition*, recommends physical activity and play as alternatives to screen time, as well as a way to promote family routine and social interaction, in addition to benefitting normal growth and development.[16]

EVIDENCE IN SUPPORT OF PHYSICAL ACTIVITY PROMOTION IN PEDIATRIC CARE SETTINGS

Among adults, substantial international evidence supports the use of multiprong physical activity counseling and referral strategies, particularly those linking health care and community-based resources, to improve physical activity levels.[115,116] Meta-analyses and systematic reviews have shown that physician counseling (odds ratio, 1.42; 95% confidence interval, 1.17–1.73) and exercise referral systems (relative risk, 1.20; 95% confidence interval, 1.06–1.35) promote improvements in adult patients' physical activity for up to 12 months,[117–120] with evidence supporting the notion that physical activity counseling can be successfully implemented in routine clinical practice[121,122] and that protocols are acceptable among health care providers.[123] Integration of physical activity counseling and referral strategies into adult primary

care settings has also been found to be cost-effective,[124–128] provide early return on investment because of lower health care use and costs,[129,130] and have been successfully scaled to national levels with adequate sustainability.[128]

Although the experience from adult medicine shows that multicomponent intervention approaches can be effectively implemented within established primary care practices making use of existing resources and personnel, evidence on the effectiveness of physical activity promotion in pediatric settings is more limited.[131] To date, most interventions have been centered on multiple health behaviors including sedentary time and healthy diet in the context of weight management. For example, the Patient-Centered Assessment and Counseling for Exercise Plus Nutrition (PACE+) intervention showed that computer-assisted, individually tailored counseling for physical activity in children 11 to 15 years of age can be effective in reducing sedentary time and improving compliance with physical activity guidelines at 12 months, particular among boys.[132]

The Physical Activity Guidelines for Americans Midcourse Report assessed evidence-based recommendations to increase youth physical activity across multiple sectors.[31] In this report, the authors found insufficient evidence to support specific strategies for physical activity promotion in the clinical setting.[31] The 2018 Physical Activity Guidelines Advisory Committee remarked that this could be improved with more robust and standardized strategies incorporating additional team members and tools such as motivational interviewing and a specific exercise prescription.[31] The committee also noted that individually focused interventions delivered in a variety of settings can successfully increase youth physical activity, especially when families and schools are incorporated into the interventions.[31]

The Healthcare Effectiveness Data and Information Set measure on Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents assesses the percentage of patients 2 to 17 years of age who had an outpatient visit with a primary care provider and who had evidence of BMI percentile documentation, counseling for nutrition, and counseling for physical activity during the measurement year.[133] Depending on insurance type, 60% or fewer pediatric visits contained documentation of counseling for physical activity or referral for physical activity on the basis of administrative data or medical record review that included a note indicating the date and at least one of the following activities: (1) discussion of current physical activity behaviors (eg, exercise routine, participation in sports activities, examination for sports participation); (2) checklist indicating physical activity was addressed; (3) counseling or referral for physical activity; (4) member received educational materials on physical activity; or (5) anticipatory guidance for physical activity. Examples of notations that do not count toward this requirement include "notation of 'cleared for gym class' alone without any documentation of a discussion" or "notation of 'health education' or 'anticipatory guidance' without any specific mention of physical activity."[133]

The US Preventive Services Task Force recommends that clinicians screen children 6 years and older for obesity and offer them or refer them to comprehensive, intensive behavioral intervention that includes physical activity and nutritional counseling to promote improvement in weight status. Rated as a "B" recommendation, this strategy must be included in health plans under the Affordable Care Act's Prevention and Health Promotion activities.[134] Similarly, the AAP clinical report on obesity prevention also underscores the importance of physical activity promotion by pediatricians and other health care providers.[10] Given the critical importance of play in childhood, of which physical play is one type, the AAP recommends that clinicians write a "prescription for play" at well-child visits in the first 2 years of life.[76] *Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents, Fourth Edition*, encourages play as a way to decrease screen time starting at 18 months of age, promoting behavioral management and social development starting at 2 years of age, and advancing to promotion of physical activity guidelines at 5 years of age for growth and development.[16] As such, physical activity is a component of the *Bright Futures* health supervision priorities of social and emotional well-being, school readiness and performance, and risk-behavior reduction.[16]

ROLE OF PARENTS IN PHYSICAL ACTIVITY FOR CHILDREN

Early in life, opportunities for the development of physical literacy occur at home. Parents are integral, not only in role-modeling movement, but also in playing with their children to allow for acquisition of necessary skills.[76] The role of parents is even more important in CYHSCN given the complexity of needs and barriers to participation that children with disabilities face.[135] Free-play is the primary exposure of necessity.[76] Playing catch, climbing structures and natural elements, such as boulders and trees, and tag address skills in travel, hand-eye coordination, and balance and strength through natural exploration and fun play. Organized sports are unnecessary at early ages but are beneficial for more specific skill development once a child is ready on the basis of physical,

cognitive, and behavioral readiness.[136] Children who engage in a variety of different activities and sports, especially those that help build fundamental movement skills such as gymnastics, swimming, and track will be more likely to develop physical literacy as well as enjoyment of physical activity and attain recommended levels of MVPA.[85] Sport specialization, as outlined in the AAP statement "Sports Specialization and Intensive Training in Young Athletes," is discouraged before puberty because there is no evidence that young children will benefit from early sport specialization in the majority of sports, and some data suggest that early specialization leads to higher rates of overuse injury and burnout from concentrated activity.[83,137,138] Exposure to nature has also been shown to have its own benefits on health; thus, opportunities for play and movement outdoors, even in the smallest of green spaces, are important and create an increased appreciation of movement and nature.[139,140]

ROLE OF SCHOOLS IN PROMOTING PHYSICAL ACTIVITY IN YOUTH

In many areas, school provides the primary opportunity for physical activity and acquisition of physical literacy. In fact, the 2018 Physical Activity Guidelines Advisory Committee found strong evidence that interventions that affect multiple components of schools are effective for increasing youth physical activity, particularly among those at highest risk of physical inactivity, such as adolescent girls and children with limited access to safe and affordable activity opportunities outside of school.[31] The American Heart Association calls for schools to become the central element in a community system that ensures that students participate in enough physical activity to develop healthy lifestyles.[141] Developing physical education curricula that promotes enjoyment of movement and skill development is important, especially including CYSHCN, as is providing opportunities for movement before, during, and after school.[142] National standards outline the role of physical education classes in physical literacy.[100] It is important to recognize that in physical education classes at school, a number of factors have been shown to result in children spending less than 50% of class time engaged in MVPA.[143,144] Opportunities for additional movement throughout the day through active classrooms benefit not only the child through increased physical activity but also the learning environment as a result of improved behavior.[36,42,145] Opportunities for recess and physical education during school that maximize movement and minimize sedentary and/or standing time and encourage social interaction are critical.[146,147] Schools also provide a safe place for physical activity before and after school that many children do not have at home, especially outside, increasing the time spent in MVPA.[148–150] SHAPE America, the Society of Health and Physical Educators, discourages the use and withholding of physical activity as punishment in schools.[100]

TOOLS FOR ASSESSING PHYSICAL ACTIVITY IN PEDIATRIC CLINICAL SETTINGS

In a nationally representative sample (N = 811) of US primary care physicians caring for children and adolescents (pediatrics and family medicine), most physicians reported assessing physical activity in youth using general questions about the amount of physical activity (98%).[14] However, a lower proportion (66%) asked specific questions about duration, intensity, and type of physical activity, and only a minority reported using a standardized questionnaire (7%) or other written physical activity assessments (6%).[14] In comparison, 98% of physicians reported regularly measuring weight objectively on a scale in the office setting.[14] That the majority of pediatric primary care physicians report somehow assessing physical activity levels in their clinical practice is encouraging, but the study by Huang et al[14] that revealed fewer than one-third of pediatricians could correctly identify guidelines calls into question the degree to which providers are correctly screening for insufficient physical activity or adequately counseling adolescents and their families on the recommended "dose" of physical activity for health.

Several methods have been used to assess physical activity in children and adolescents including questionnaires, activity logs, pedometers, and research-grade and consumer-oriented accelerometers. Practicality, validity, and reliability are important considerations when deciding appropriate methods to assess physical activity levels in clinical settings.[120] Although physical activity is important, assessment of physical literacy (Table 4) is first necessary to quantify current activity, create appropriate goals for improvement, and allow for dose-response relationships to changes in other health parameters (and subsequent studies to demonstrate benefit or lack thereof) (Table 5). In the absence of opportunities to directly assess movement, quantification of physical activity may serve as a surrogate measure for younger children in representing opportunities for development of physical literacy. Simply asking children about their enjoyment of movement may provide insight into their physical literacy.[105]

In the adult population, systematic assessment of physical activity levels in clinical settings has been established through the integration of a self-reported physical activity vital sign (PAVS) into electronic health records (EHRs).[151] The PAVS has

TABLE 5 Steps Toward Integrating Physical Activity Assessment and Counseling Into Clinical Practice

1. Ask about current physical activity frequency and duration and enjoyment of movement.
2. If it is an acute or subspecialty visit, connect benefit of physical activity to current health condition and advise on restrictions in physical activity (if applicable).
3. If it is a health supervision visit, assess physical literacy and any gap between current and recommended activity level. Assess the patient and family interest in discussing promotion of physical activity.
   a. If not interested, provide information on the benefit of physical activity to current health, if the patient has any chronic issues, and/or future health (including athletic performance).
   b. If interested, discuss the reason for interest and potential area of change and establish a specific, attainable incremental goal to progress toward physical activity guidelines. Connect patient and/or family to resources to support achievement of goal, such as a physical education teacher, exercise specialist, physical or occupational therapist, or coach.
4. Recommend scheduling an appointment to discuss achievement toward goal; identify obstacles to change and establish new goals.

been promoted through the Exercise is Medicine initiative of the American College of Sports Medicine.[115,152–154] The PAVS consists of 2 questions (Fig 1), adapted from the Behavioral Risk Factor Surveillance System and validated to screen for inactivity in clinical settings.[155–157] Integration of the PAVS into the EHR of large health care systems resulted in greater physical activity–related counseling, weight change in adult patients with obesity, and hemoglobin A1c changes in those with diabetes.[158,159] The Institute of Medicine (now National Academy of Medicine) has supported the inclusion of the PAVS and/or objective assessment of physical activity in EHRs.[160]

Assessment of physical activity levels in youth via self-report is a more complex undertaking because youth are less likely to make accurate self-report assessments than adults because of developmental differences, especially in the ability to perform detailed recall and understand concepts regarding physical activity duration and intensity.[161,162] In addition, youth have an activity pattern that is more variable and intermittent compared with adults.[163] Furthermore, sports practices involve MVPA for only a fraction of the time, and the amount of time varies greatly by sport.[164] A thorough review of physical activity assessment tools is included in the Supplemental Information.

STRATEGIES TO OVERCOME BARRIERS TO PHYSICAL ACTIVITY ASSESSMENT, COUNSELING, AND REFERRAL IN CLINICAL PRACTICE

Physicians face many barriers to implementing physical activity assessment, counseling, and referral in the clinical setting.[151] Clinical visit times are short, and the list of preventive guidance to incorporate into well-child checks is long.[151] Solutions will likely require interprofessional approaches and engagement with community organizations in development of tools to provide interventions and track physical activity, integration of measurements of activity into the EHR, and identification of associations with health outcomes.[151] Regardless, physical activity assessment, counseling, and promotion follows the same approach as used in other areas of lifestyle change for chronic disease, yet it is applicable to all patients (Table 5).[165]

Pediatricians will need efficient workflows to incorporate physical activity assessment, counseling, and referral into the clinical visit. This could be accomplished through a PAVS in the medical record, previsit questionnaires, or screening performed by support staff.[151] EHR companies and health care institutions are encouraged to include tools to measure, document, report, and investigate physical activity measures and association with other health outcomes, including assessing for physical literacy. For example, the Intermountain Healthcare system developed and integrated into their EHR system a pediatric PAVS for use at preventive care visits for children ages 6 to 18 years.[151] This tool combines the PACE+ validated item with the addition of questions to assess activity participation on specific settings and domains (physical education, recreation, sports, transportation, home, after school, sedentary or screen time) in an effort to facilitate compliance assessment and guide goal-setting and domain-specific counseling.[151] Since 2011, the Kaiser Permanente Health System integrated into its EHR system and clinical workflows the pediatric exercise vital sign, modeled after the YRBS questions, for youth 5 to 18 years (Fig 1).[166] Although not yet formally validated in children, implementing the PAVS as a part of the health visit and within the EHR represents a starting point in initiating the conversation around physical activity in primary care and assessing the potential to predict future disease risk[158] as well as determining the validity of the PAVS in pediatric practice.[167] Brief tools for assessing physical activity are included in Table 6 (see the Supplemental Information for a full discussion regarding the tools and methodology used to identify advantages and disadvantages of each).

Similar to adult-based approaches, once the current physical activity level of the child is understood, providers can offer more specific, developmentally tailored physical activity advice or set an appropriate incremental goal for increase in activity and can include further guidance and referral resources in the after-visit summary.[120] For children identified as needing further intervention, a brief follow-up visit could be scheduled, or the patient could be referred to a community

a. ACSM Exercise is Medicine PAVS (minutes per week of MVPA)

Question 1. On average, how many days per week do you engage in moderate-to-strenous exercise (like a brisk walk)?

_____days

Question 2. On average, how many minutes do you engage in exercise at this level?

_____minutes

PAVS (minutes per week) = _____ days × _____ minutes

b. YRBS physical activity question (days per week of ≥60 minutes of MVPA)

During the past 7 days, on how many days were you physically active for a total of ≥60 minutes/day (add up all the time you spent in any kind of physical activity that increased your heart rate and made you breathe hard some of the time)?

_____days

c. Intermountain Healthcare pediatric PAVS

On average, how many days per week does your child get ≥60 minutes of MVPA or play (heart beating faster than normal, breathing harder than normal)?

_____days/week

On most days of the week, does your child

- walk or bike to school? ____Yes ___No
- participate in physical education class at school? ____Yes ___No
- participate in organized physical activity (sports, dance, martial arts, etc) or spend 30 minutes or more playing outside? ____Yes ___No

On average, how many hours per day of recreational screen time (video games, television, Internet, phone, etc) does your child get?

_____hours/day

Is physical activity an area that you want to work on with your family to improve?

____Yes ___No

FIGURE 1

Brief office-based assessments of physical activity. Adapted from Joy EA, Lobelo F. Promoting the athlete in every child: physical activity assessment and promotion in healthcare. *Br J Sports Med*. 2017;51(3):143–145. Adapted from Exercise is Medicine. Healthcare providers' action guide. Available at: https://exerciseismedicine.org/assets/page_documents/Complete%20HCP%20Action%20Guide_2016_01_01.pdf. Accessed September 5, 2018. Adapted from Centers for Disease Control and Prevention. YRBS Questionnaire Content - 1991–2017. Available at: https://www.cdc.gov/healthyyouth/data/yrbs/pdf/2017/YRBS_questionnaire_content_1991-2017.pdf. Accessed September 5, 2018. ACSM, American College of Sports Medicine.

resource (such as a teacher or community center).[120] In addition, support staff could receive appropriate training to elaborate on a provider's physical activity prescription and connect patients with community and technology resources to fill the prescription.[120] Special emphasis on addressing barriers for CYSHCN may be needed to assist patients and families with underlying mobility issues.[168,169] Further guidance for CYSHCN may be found in the AAP clinical report "Promoting the Participation of Children With Disabilities in Sports, Recreation, and Physical Activities."[128]

Institutional support of pediatric physical therapists, occupational therapists, athletic trainers, exercise specialists, social workers, and other professionals is necessary to assist in addressing the needs of the children most at risk for inactivity, such as CYSHCN; children of minority, rural, and urban status who experience insufficient access or resources to physical activity; and adolescent girls.[116,170] Ideal partnerships result in access to programs that are safe, close to home, financially feasible, fun, and culturally appropriate and offer adaptive experiences and intellectually appropriate programming (eg, Special Olympics) so that children facing barriers receive the same opportunities as their peers (Table 6).[168]

Insurance companies can play a role by providing coverage for necessary services and reducing reasons for payment denials because improved physical literacy and physical activity, even for nonambulatory individuals, result in later health benefit and savings in health care expenditures.[171]

ROLE OF PHYSICIANS IN PROMOTING PEDIATRIC PHYSICAL ACTIVITY OUTSIDE OF DIRECT PATIENT CARE

Many patients, families, and community organizations look to pediatricians to provide physical activity recommendations for sports participation, modifications for children with special needs or an acute or chronic injury, and increasingly for management of many physical and behavioral conditions such as prediabetes and attention-deficit/hyperactivity disorder.[172] Yet many pediatricians may feel they do not have the experience or training needed to guide their patients toward meeting physical activity recommendations. In medical school, they likely received little to no training in exercise prescription.[173] Most did not fare any better in residency, with only 26% of pediatric residency programs reported having a curriculum in physical activity counseling, with the greatest barrier being the lack of faculty with training in physical activity counseling, limiting provider knowledge and self-efficacy.[174–176] Encouragingly, training pediatric residents in physical activity counseling has been shown to improve the physical activity of

TABLE 6 Resources for Pediatricians on Physical Activity Assessment and Counseling

Institute for Healthy Childhood Weight: http://ihcw.aap.org
Exercise is Medicine: www.exerciseismedicine.org
National Physical Activity Plan: http://www.physicalactivityplan.org
National Association of Physical Literacy: http://naplusa.org
SHAPE America: 2016 Shape of the Nation: https://www.shapeamerica.org/advocacy/son/default.aspx
Prescription for Activity: https://www.prescriptionforactivity.org/
Lifestyle Medicine Education Collaborative: http://lifestylemedicineeducation.org/
National Recreation and Park Association: "Prescribing Parks for Better Health Success Stories": https://www.nrpa.org/contentassets/f768428a39aa4035ae55b2aaff372617/final-prescribing-parks-for-better-health-success-stories.pdf
National Association for the Education of Young Children: https://www.naeyc.org/ (including *Developmentally Appropriate Practice in Early Childhood Programs Serving Children from Birth through Age 8, Third Edition*, as a resource for schools)

SHAPE, Society of Health and Physical Educators.

patients.[177] Implementing curricula and providing education is an effective first step (Table 7), which could be expanded to continuing medical education for practicing clinicians.

Clinicians have a responsibility to model physical activity for their patients and families through their own physical activity and community engagement. Several studies have shown that physicians' personal physical activity behaviors are an important correlate of their attitudes and clinical practice regarding physical activity.[178,179] Interestingly, the greatest predictor of asking about physical activity by pediatricians is being personally "fit and healthy" themselves.[180] In addition, physical activity is integral to personal well-being for the health care professional, improving quality of life and work-life balance and decreasing burnout.[181–184] The AAP has published a clinical report on the subject.[185]

RECOMMENDATIONS

Pediatricians are encouraged to promote physical literacy and activity in children and progress toward recommended physical activity guidelines in one or more of the following ways.

1. Assess and document gross motor skills and physical activity as appropriate at health care visits (Table 5, Fig 1).
   a. Assess gross motor skill development, physical literacy, and physical activity levels at all health supervision visits, with early referral to assess and treat identified delays or deficits (Table 4). A PAVS may be a useful screening tool to guide specific counseling (Fig 1).
   b. For CYSHCN, discuss physical activity prescription and any physical activity limitations with subspecialists who are sharing in a patient's care. Clearly document a patient's individual physical activity prescription so that other providers, therapists, caretakers, and parents can help a child implement the prescription.
   c. For children who are insufficiently active, identify barriers to activity and use behavioral strategies such as motivational interviewing to help patients and families identify doable strategies to increase activity.
2. Discuss the role and benefits of physical activity on physical and social growth and development and management of other health conditions as well as in mental health, school performance, behavioral management, and risk-behavior reduction specifically related to the patient.
3. Encourage parents to not only "do as I say" but also "do as I do" because children who grow up in families with active parents are much more likely to be active themselves.
4. Provide specific tools and resources to help families build skills. Assist families in overcoming barriers to physical activity by referring families to community advocates and community-based activity programs and other places to be active, such as sports clubs, recreation centers, parks, walking and biking trails, skate parks, and playgrounds.
5. Advocate with health care organizations, insurance providers, schools, and community organizations to increase opportunities for physical activity for all children.
   a. Encourage healthy child care centers and preschools to provide ample opportunities for children to move in ways

TABLE 7 Recommendations for Promoting Physical Activity Assessment and Counseling in Medical Education

1. Demonstrate assessment and counseling in practice for learners.
a. Primary care pediatricians and health care providers: general physical activity assessment and screening, counseling and goal-setting, and activity or exercise prescription and referral to community partners and resources.
b. Subspecialists: guidance on physical activity benefits and restrictions as related to relevant medical condition to patient, family, and other physicians involved in the patient's care.
2. Advocate for the inclusion of education regarding physical activity guidelines within medical school and residency training.
3. Advocate for the inclusion of education regarding physical activity counseling and exercise prescription as part of longitudinal curricula within medical school and residency training.

that they were designed to move, that is, in frequent, short bursts.

b. Support education policies that engineer physical education and literacy back into the school day and shared use policies that allow for safe, accessible, affordable access to recreational space.

c. Support the development of programs that provide resources for physical activity of children who are hospitalized (and their siblings) and for children needing additional resources to be physically active, such as CYSHCN and those who experience socioeconomic barriers.

6. Identify opportunities for physical activity assessment and prescription for children facing barriers to activity. Those most at risk for inactivity include children of minority, urban, and rural status, adolescent girls, and CYSHCN. In many cases, school-based physical activity interventions are the most promising approach to increase physical activity.[186]

7. Advocate for the inclusion of physical activity assessments within EHRs and use the assessments to provide patient-specific physical activity recommendations for pediatric patients.

a. Advocate for payment from public and private payers for administration of validated physical activity assessment instruments.

b. Investigate the type and effects of physical activity on health outcomes of pediatric patients.

8. Work with medical schools, residency programs, and health care institutions to develop curricula in exercise prescription and methods for physical activity assessment and prescription that include the recommended frequency, intensity, duration, and type of activity, taking into consideration the child's current health, fitness, and preferences (Table 7).

LEAD AUTHORS

Felipe Lobelo, MD, PhD
Natalie D. Muth, MD, MPH, FAAP, FACSM
Sara Hanson, PhD
Blaise A. Nemeth, MD, MS, FAAP

COUNCIL ON SPORTS MEDICINE AND FITNESS EXECUTIVE COMMITTEE, 2017–2018

Cynthia R. LaBella, MD, FAAP, Chairperson
M. Alison Brooks, MD, FAAP
Greg Canty, MD, FAAP
Alex B. Diamond, DO, MPH, FAAP
William Hennrikus, MD, FAAP
Kelsey Logan, MD, MPH, FAAP
Kody Moffatt, MD, FAAP
Blaise A. Nemeth, MD, MS, FAAP
K. Brooke Pengel, MD, FAAP
Andrew R. Peterson, MD, MSPH, FAAP
Paul R. Stricker, MD, FAAP

LIAISONS

Donald W. Bagnall – National Athletic Trainers' Association

STAFF

Anjie Emanuel, MPH

SECTION ON OBESITY EXECUTIVE COMMITTEE, 2017–2018

Christopher F. Bolling, MD, FAAP, Chairperson
Sarah Armstrong, MD, FAAP
Matthew Allen Haemer, MD, MPH, FAAP
Natalie D. Muth, MD, MPH, FAAP
John Rausch, MD, MPH, FAAP
Victoria Rogers, MD, FAAP
Stephanie Moore Walsh, MD, FAAP

LIAISON

Alyson B. Goodman, MD, MPH – *Centers for Disease Control and Prevention*

STAFF

Mala Thapar, MPH

ABBREVIATIONS

AAP: American Academy of Pediatrics
CYSHCN: children and youth with special health care needs
EHR: electronic health record
MVPA: moderate-to-vigorous physical activity
PACE+: Patient-centered Assessment and Counseling for Exercise plus Nutrition
PAVS: physical activity vital sign
YRBS: Youth Risk Behavior Survey

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: Dr Muth receives royalties from the American Academy of Pediatrics and F.A. Davis and previously had a consulting relationship with the American Council on Exercise; Drs Hanson, Lobelo, and Nemeth have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Dr Muth receives royalties from the American Academy of Pediatrics and F.A. Davis and previously had a consulting relationship with the American Council on Exercise; Drs Hanson, Lobelo, and Nemeth have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Kann L, McManus T, Harris WA, et al. Youth risk behavior surveillance - United States, 2015. *MMWR Surveill Summ*. 2018;67(8):1–479
2. Bassett DR, John D, Conger SA, Fitzhugh EC, Coe DP. Trends in physical activity and sedentary behaviors of United States youth. *J Phys Act Health*. 2015;12(8):1102–1111
3. Woodmansee C, Hahne A, Imms C, Shields N. Comparing participation in physical recreation activities between children with disability and children with typical development: a secondary analysis of matched data. *Res Dev Disabil*. 2016;49–50:268–276
4. Troiano RP, Berrigan D, Dodd KW, Mâsse LC, Tilert T, McDowell M. Physical activity in the United States measured by accelerometer. *Med Sci Sports Exerc*. 2008;40(1):181–188
5. Li K, Haynie D, Lipsky L, Iannotti RJ, Pratt C, Simons-Morton B. Changes in moderate-to-vigorous physical activity among older adolescents. *Pediatrics*. 2016;138(4):e20161372
6. Mayer-Davis EJ, Lawrence JM, Dabelea D, et al; SEARCH for Diabetes in Youth Study. Incidence trends of type 1 and type 2 diabetes among youths, 2002-2012. *N Engl J Med*. 2017;376(15):1419–1429
7. Arias E, Heron M, Xu J. United States Life Tables, 2012. In: *Natl Vital Stat Rep*, vol. 65. 2016:1–65
8. Xu J, Murphy SL, Kochanek KD, Arias E. Mortality in the United States, 2015. In: *NCHS Data Brief*. 2016:1–8
9. Council on Sports Medicine and Fitness; Council on School Health. Active healthy living: prevention of childhood obesity through increased physical activity. *Pediatrics*. 2006;117(5):1834–1842
10. Daniels SR, Hassink SG; Committee on Nutrition. The role of the pediatrician in primary prevention of obesity. *Pediatrics*. 2015;136(1). Available at: www.pediatrics.org/cgi/content/full/136/1/e275
11. Barlow SE; Expert Committee. Expert Committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics*. 2007;120(suppl 4):S164–S192
12. Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709–757
13. Spear BA, Barlow SE, Ervin C, et al. Recommendations for treatment of child and adolescent overweight and obesity. *Pediatrics*. 2007;120(suppl 4):S254–S288
14. Huang TT, Borowski LA, Liu B, et al. Pediatricians' and family physicians' weight-related care of children in the U.S. *Am J Prev Med*. 2011;41(1):24–32
15. US Department of Health and Human Services. Physical activity guidelines. 2008. Available at: www.health.gov/PAGuidelines. Accessed January 7, 2013
16. Hagan JF Jr, Shaw JS, Duncan PM, eds. *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*. 4th ed. Elk Grove, IL: American Academy of Pediatrics; 2017
17. US Department of Health and Human Services. *Physical Activity Guidelines for Americans*. 2nd ed. Washington, DC: US Department of Health and Human Services; 2018. Available at: https://health.gov/paguidelines/second-edition/pdf/Physical_Activity_Guidelines_2nd_edition.pdf. Accessed December 10, 2018
18. Morris JN, Heady JA, Raffle PA, Roberts CG, Parks JW. Coronary heart-disease and physical activity of work. *Lancet*. 1953;262(6796):1111–1120; concl
19. Herrmann SD, Angadi SS. Children's physical activity and sedentary time and cardiometabolic risk factors. *Clinical J Sport Med*. 2013;23(5):408–409
20. Belcher BR, Berrigan D, Papachristopoulou A, et al. Effects of interrupting children's sedentary behaviors with activity on metabolic function: a randomized trial. *J Clin Endocrinol Metab*. 2015;100(10):3735–3743
21. van der Baan-Slootweg O, Benninga MA, Beelen A, et al. Inpatient treatment of children and adolescents with severe obesity in the Netherlands: a randomized clinical trial. *JAMA Pediatr*. 2014;168(9):807–814
22. Davis CL, Pollock NK, Waller JL, et al. Exercise dose and diabetes risk in overweight and obese children: a randomized controlled trial. *JAMA*. 2012;308(11):1103–1112
23. Moore JB, Beets MW, Brazendale K, et al. Associations of vigorous-intensity physical activity with biomarkers in youth. *Med Sci Sports Exerc*. 2017;49(7):1366–1374
24. Tarp J, Child A, White T, et al; International Children's Accelerometry Database (ICAD) Collaborators. Physical activity intensity, bout-duration, and cardiometabolic risk markers in children and adolescents [published correction appears in *Int J Obes (Lond)*. 2019;43(11):2346]. *Int J Obes (Lond)*. 2018;42(9):1639–1650
25. Sigal RJ, Alberga AS, Goldfield GS, et al. Effects of aerobic training, resistance training, or both on percentage body fat and cardiometabolic risk markers in obese adolescents: the healthy eating aerobic and resistance training in youth randomized clinical trial. *JAMA Pediatr*. 2014;168(11):1006–1014
26. Hind K, Burrows M. Weight-bearing exercise and bone mineral accrual in children and adolescents: a review of controlled trials. *Bone*. 2007;40(1):14–27
27. Wu F, Callisaya M, Wills K, Laslett LL, Jones G, Winzenberg T. Both baseline and change in lower limb muscle strength in younger women are independent predictors of balance in middle age: a 12-year population-based prospective study. *J Bone Miner Res*. 2017;32(6):1201–1208
28. Collard DC, Verhagen EA, Chinapaw MJ, Knol DL, van Mechelen W. Effectiveness of a school-based physical activity injury prevention program: a cluster randomized controlled trial. *Arch Pediatr Adolesc Med*. 2010;164(2):145–150
29. MacKelvie KJ, Khan KM, Petit MA, Janssen PA, McKay HA. A school-based exercise intervention elicits substantial bone health benefits: a 2-year randomized controlled trial in girls.

Pediatrics. 2003;112(6 pt 1). Available at: www.pediatrics.org/cgi/content/full/112/6/e447

30. Detter F, Rosengren BE, Dencker M, Lorentzon M, Nilsson J, Karlsson MK. A 6-year exercise program improves skeletal traits without affecting fracture risk: a prospective controlled study in 2621 children. *J Bone Miner Res*. 2014; 29(6):1325–1336
31. Physical Activity Guidelines Scientific Advisory Committee. *Physical Activity Guidelines Advisory Committee Report*. Washington, DC: US Department of Health and Human Services; 2018
32. Ali MM, Amialchuk A, Heller LR. The influence of physical activity on cigarette smoking among adolescents: evidence from Add Health. *Nicotine Tob Res*. 2015;17(5):539–545
33. Korhonen T, Kujala UM, Rose RJ, Kaprio J. Physical activity in adolescence as a predictor of alcohol and illicit drug use in early adulthood: a longitudinal population-based twin study. *Twin Res Hum Genet*. 2009;12(3):261–268
34. Korczak DJ, Madigan S, Colasanto M. Children's physical activity and depression: a meta-analysis. *Pediatrics*. 2017;139(4):e20162266
35. Van Dusen DP, Kelder SH, Kohl HW III, Ranjit N, Perry CL. Associations of physical fitness and academic performance among schoolchildren. *J Sch Health*. 2011;81(12):733–740
36. Mullender-Wijnsma MJ, Hartman E, de Greeff JW, Doolaard S, Bosker RJ, Visscher C. Physically active math and language lessons improve academic achievement: a cluster randomized controlled trial. *Pediatrics*. 2016;137(3): e20152743
37. Ardoy DN, Fernández-Rodríguez JM, Jiménez-Pavón D, Castillo R, Ruiz JR, Ortega FB. A physical education trial improves adolescents' cognitive performance and academic achievement: the EDUFIT study. *Scand J Med Sci Sports*. 2014;24(1):e52–e61
38. Martin A, Saunders DH, Shenkin SD, Sproule J. Lifestyle intervention for improving school achievement in overweight or obese children and adolescents. *Cochrane Database Syst Rev*. 2014;(3):CD009728
39. Bass RW, Brown DD, Laurson KR, Coleman MM. Physical fitness and academic performance in middle school students. *Acta Paediatr*. 2013; 102(8):832–837
40. Rauner RR, Walters RW, Avery M, Wanser TJ. Evidence that aerobic fitness is more salient than weight status in predicting standardized math and reading outcomes in fourth- through eighth-grade students. *J Pediatr*. 2013; 163(2):344–348
41. Lamming L, Pears S, Mason D, et al; VBI Programme Team. What do we know about brief interventions for physical activity that could be delivered in primary care consultations? A systematic review of reviews. *Prev Med*. 2017;99:152–163
42. Mahar MT. Impact of short bouts of physical activity on attention-to-task in elementary school children. *Prev Med*. 2011;52(suppl 1):S60–S64
43. Carlson JA, Engelberg JK, Cain KL, et al. Implementing classroom physical activity breaks: associations with student physical activity and classroom behavior. *Prev Med*. 2015;81:67–72
44. Silva AP, Prado SO, Scardovelli TA, Boschi SR, Campos LC, Frère AF. Measurement of the effect of physical exercise on the concentration of individuals with ADHD. *PLoS One*. 2015; 10(3):e0122119
45. Neely L, Rispoli M, Gerow S, Ninci J. Effects of antecedent exercise on academic engagement and stereotypy during instruction. *Behav Modif*. 2015; 39(1):98–116
46. Oriel KN, George CL, Peckus R, Semon A. The effects of aerobic exercise on academic engagement in young children with autism spectrum disorder. *Pediatr Phys Ther*. 2011;23(2): 187–193
47. McPherson M, Arango P, Fox H, et al. A new definition of children with special health care needs. *Pediatrics*. 1998; 102(1 pt 1):137–140
48. Schoenmakers MA, de Groot JF, Gorter JW, Hillaert JL, Helders PJ, Takken T. Muscle strength, aerobic capacity and physical activity in independent ambulating children with lumbosacral spina bifida. *Disabil Rehabil*. 2009;31(4): 259–266
49. Jansen M, van Alfen N, Geurts AC, de Groot IJ. Assisted bicycle training delays functional deterioration in boys with Duchenne muscular dystrophy: the randomized controlled trial "no use is disuse". *Neurorehabil Neural Repair*. 2013;27(9):816–827
50. Voet NB, van der Kooi EL, Riphagen II, Lindeman E, van Engelen BG, Geurts AC. Strength training and aerobic exercise training for muscle disease. *Cochrane Database Syst Rev*. 2010;(1):CD003907
51. Reus L, Pillen S, Pelzer BJ, et al. Growth hormone therapy, muscle thickness, and motor development in Prader-Willi syndrome: an RCT. *Pediatrics*. 2014; 134(6). Available at: www.pediatrics.org/cgi/content/full/134/6/e1619
52. Chad KE, Bailey DA, McKay HA, Zello GA, Snyder RE. The effect of a weight-bearing physical activity program on bone mineral content and estimated volumetric density in children with spastic cerebral palsy. *J Pediatr*. 1999; 135(1):115–117
53. Henderson RC, Lark RK, Gurka MJ, et al. Bone density and metabolism in children and adolescents with moderate to severe cerebral palsy. *Pediatrics*. 2002;110(1 pt 1). Available at: www.pediatrics.org/cgi/content/full/110/1/e5
54. Szalay EA, Cheema A. Children with spina bifida are at risk for low bone density. *Clin Orthop Relat Res*. 2011; 469(5):1253–1257
55. Coleman A, Weir KA, Ware RS, Boyd RN. Relationship between communication skills and gross motor function in preschool-aged children with cerebral palsy. *Arch Phys Med Rehabil*. 2013; 94(11):2210–2217
56. Visscher C, Houwen S, Scherder EJ, Moolenaar B, Hartman E. Motor profile of children with developmental speech and language disorders. *Pediatrics*. 2007;120(1). Available at: www.pediatrics.org/cgi/content/full/120/1/e158
57. Oudgenoeg-Paz O, Volman MC, Leseman PP. Attainment of sitting and walking predicts development of productive vocabulary between ages 16 and 28 months. *Infant Behav Dev*. 2012;35(4): 733–736

58. Oudgenoeg-Paz O, Volman MC, Leseman PP. First steps into language? Examining the specific longitudinal relations between walking, exploration and linguistic skills. *Front Psychol*. 2016;7: 1458

59. Apkon SD, Grady R, Hart S, et al. Advances in the care of children with spina bifida. *Adv Pediatr*. 2014;61(1): 33–74

60. Casey AF, Emes C. The effects of swim training on respiratory aspects of speech production in adolescents with down syndrome. *Adapt Phys Activ Q*. 2011;28(4):326–341

61. Pan CY, Tsai CL, Chu CH, Sung MC, Ma WY, Huang CY. Objectively measured physical activity and health-related physical fitness in secondary school-aged male students with autism spectrum disorders. *Phys Ther*. 2016; 96(4):511–520

62. Murphy NA, Carbone PS; American Academy of Pediatrics Council on Children With Disabilities. Promoting the participation of children with disabilities in sports, recreation, and physical activities. *Pediatrics*. 2008; 121(5):1057–1061

63. Mulrooney DA, Yeazel MW, Kawashima T, et al. Cardiac outcomes in a cohort of adult survivors of childhood and adolescent cancer: retrospective analysis of the Childhood Cancer Survivor Study cohort. *BMJ*. 2009;339: b4606

64. Järvelä LS, Kemppainen J, Niinikoski H, et al. Effects of a home-based exercise program on metabolic risk factors and fitness in long-term survivors of childhood acute lymphoblastic leukemia. *Pediatr Blood Cancer*. 2012; 59(1):155–160

65. Järvelä LS, Niinikoski H, Heinonen OJ, Lähteenmäki PM, Arola M, Kemppainen J. Endothelial function in long-term survivors of childhood acute lymphoblastic leukemia: effects of a home-based exercise program. *Pediatr Blood Cancer*. 2013;60(9): 1546–1551

66. Boas SR, Danduran MJ, McBride AL, McColley SA, O'Gorman MR. Postexercise immune correlates in children with and without cystic fibrosis. *Med Sci Sports Exerc*. 2000; 32(12):1997–2004

67. van de Weert-van Leeuwen PB, Slieker MG, Hulzebos HJ, Kruitwagen CL, van der Ent CK, Arets HG. Chronic infection and inflammation affect exercise capacity in cystic fibrosis. *Eur Respir J*. 2012;39(4):893–898

68. van de Weert-van Leeuwen PB, Hulzebos HJ, Werkman MS, et al. Chronic inflammation and infection associate with a lower exercise training response in cystic fibrosis adolescents. *Respir Med*. 2014;108(3):445–452

69. Selvadurai HC, Blimkie CJ, Meyers N, Mellis CM, Cooper PJ, Van Asperen PP. Randomized controlled study of in-hospital exercise training programs in children with cystic fibrosis. *Pediatr Pulmonol*. 2002;33(3):194–200

70. Duppen N, Etnel JR, Spaans L, et al. Does exercise training improve cardiopulmonary fitness and daily physical activity in children and young adults with corrected tetralogy of Fallot or Fontan circulation? A randomized controlled trial. *Am Heart J*. 2015; 170(3):606–614

71. Takken T, Giardini A, Reybrouck T, et al. Recommendations for physical activity, recreation sport, and exercise training in paediatric patients with congenital heart disease: a report from the Exercise, Basic & Translational Research Section of the European Association of Cardiovascular Prevention and Rehabilitation, the European Congenital Heart and Lung Exercise Group, and the Association for European Paediatric Cardiology. *Eur J Prev Cardiol*. 2012;19(5):1034–1065

72. Lantin-Hermoso MR, Berger S, Bhatt AB, et al; Section on Cardiology; Cardiac Surgery. The care of children with congenital heart disease in their primary medical home. *Pediatrics*. 2017;140(5):e20172607

73. McCambridge TM, Stricker PR; American Academy of Pediatrics Council on Sports Medicine and Fitness. Strength training by children and adolescents. *Pediatrics*. 2008;121(4): 835–840

74. US Department of Health and Human Services. Physical Activity Guidelines for Americans Midcourse Report: strategies to increase physical activity among youth. 2012. Available at: www.health.gov/paguidelines/midcourse/pag-mid-course-report-final.pdf. Accessed September 27, 2016

75. Lipnowski S, Leblanc CM; Canadian Paediatric Society, Healthy Active Living and Sports Medicine Committee. Healthy active living: physical activity guidelines for children and adolescents. *Paediatr Child Health*. 2012;17(4):209–212

76. Yogman M, Garner A, Hutchinson J, Hirsh-Pasek K, Golinkoff RM; Committee on Psychosocial Aspects of Child and Family Health; Council on Communications and Media. The power of play: a pediatric role in enhancing development in young children. *Pediatrics*. 2018;142(3):e20182058

77. American Academy of Pediatrics; American Public Health Association; National Resource Center for Health and Safety in Child Care and Early Education. *Preventing Childhood Obesity in Early Care and Education: Selected Standards From Caring for Our Children: National Health and Safety Performance Standards*, 4th ed. Itasca, IL: American Academy of Pediatrics; 2019

78. Garber CE, Blissmer B, Deschenes MR, et al; American College of Sports Medicine. American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: guidance for prescribing exercise. *Med Sci Sports Exerc*. 2011;43(7):1334–1359

79. Jetté M, Sidney K, Blümchen G. Metabolic equivalents (METS) in exercise testing, exercise prescription, and evaluation of functional capacity. *Clin Cardiol*. 1990;13(8):555–565

80. Conger SA, Bassett DR. A compendium of energy costs of physical activities for individuals who use manual wheelchairs. *Adapt Phys Activ Q*. 2011; 28(4):310–325

81. Clanchy KM, Tweedy SM, Boyd RN, Trost SG. Validity of accelerometry in ambulatory children and adolescents with cerebral palsy. *Eur J Appl Physiol*. 2011;111(12):2951–2959

82. Butte NF, Watson KB, Ridley K, et al. A youth compendium of physical activities: activity codes and metabolic

intensities. *Med Sci Sports Exerc*. 2018; 50(2):246–256

83. Brenner JS; Council on Sports Medicine and Fitness. Sports specialization and intensive training in young athletes. *Pediatrics*. 2016;138(3):e20162148
84. Denny SA, Quan L, Gilchrist J, et al; Council on Injury, Violence, and Poison Prevention. Prevention of drowning. *Pediatrics*. 2019;143(5):e20190850
85. The Aspen Institute. Physical literacy in the United States: A model, strategic plan, and call to action. Available at: https://assets.aspeninstitute.org/content/uploads/files/content/docs/pubs/PhysicalLiteracy_AspenInstitute.pdf. Accessed January 18, 2020
86. Lubans DR, Morgan PJ, Cliff DP, Barnett LM, Okely AD. Fundamental movement skills in children and adolescents: review of associated health benefits. *Sports Med*. 2010;40(12):1019–1035
87. O' Brien W, Belton S, Issartel J. The relationship between adolescents' physical activity, fundamental movement skills and weight status. *J Sports Sci*. 2016;34(12):1159–1167
88. Jaakkola T, Yli-Piipari S, Huotari P, Watt A, Liukkonen J. Fundamental movement skills and physical fitness as predictors of physical activity: a 6-year follow-up study. *Scand J Med Sci Sports*. 2016; 26(1):74–81
89. Centers for Disease Control and Prevention. CDC's developmental milestones. Available at: https://www.cdc.gov/ncbddd/actearly/milestones/index.html. Accessed May 4, 2019
90. US Olympic and Paralympic Committee. American Development Model. Available at: https://www.teamusa.org/About-the-USOC/Programs/Coaching-Education/American-Development-Model. Accessed May 4, 2019
91. Martins J, Marques A, Sarmento H, Carreiro da Costa F. Adolescents' perspectives on the barriers and facilitators of physical activity: a systematic review of qualitative studies. *Health Educ Res*. 2015;30(5): 742–755
92. Belanger K, Barnes JD, Longmuir PE, et al. The relationship between physical literacy scores and adherence to Canadian physical activity and sedentary behaviour guidelines. *BMC Public Health*. 2018;18(suppl 2):1042
93. Lang JJ, Chaput JP, Longmuir PE, et al. Cardiorespiratory fitness is associated with physical literacy in a large sample of Canadian children aged 8 to 12 years. *BMC Public Health*. 2018; 18(suppl 2):1041
94. Hendrix CG, Prins MR, Dekkers H. Developmental coordination disorder and overweight and obesity in children: a systematic review. *Obes Rev*. 2014; 15(5):408–423
95. Cairney J, Hay JA, Faught BE, Hawes R. Developmental coordination disorder and overweight and obesity in children aged 9-14 y. *Int J Obes (Lond)*. 2005; 29(4):369–372
96. Myer GD, Faigenbaum AD, Stracciolini A, Hewett TE, Micheli LJ, Best TM. Exercise deficit disorder in youth: a paradigm shift toward disease prevention and comprehensive care. *Curr Sports Med Rep*. 2013;12(4):248–255
97. Kantomaa MT, Purtsi J, Taanila AM, et al. Suspected motor problems and low preference for active play in childhood are associated with physical inactivity and low fitness in adolescence. *PLoS One*. 2011;6(1):e14554
98. Farhat F, Masmoudi K, Hsairi I, et al. The effects of 8 weeks of motor skill training on cardiorespiratory fitness and endurance performance in children with developmental coordination disorder. *Appl Physiol Nutr Metab*. 2015;40(12):1269–1278
99. Faigenbaum AD, Rial Rebullido T, MacDonald JP. The unsolved problem of paediatric physical inactivity: it's time for a new perspective. *Acta Paediatr*. 2018;107(11):1857–1859
100. Society of Health and Physical Educators; American Heart Association. 2016 Shape of the Nation report: status of physical education in the USA. 2016. Available at: https://www.shapeamerica.org/advocacy/son/. Accessed May 4, 2019
101. Scerpella TA, Bernardoni B, Wang S, Rathouz PJ, Li Q, Dowthwaite JN. Site-specific, adult bone benefits attributed to loading during youth: a preliminary longitudinal analysis. *Bone*. 2016;85: 148–159
102. Tenforde AS, Sainani KL, Carter Sayres L, Milgrom C, Fredericson M. Participation in ball sports may represent a prehabilitation strategy to prevent future stress fractures and promote bone health in young athletes. *PM R*. 2015;7(2):222–225
103. Cawthon PM, Fullman RL, Marshall L, et al; Osteoporotic Fractures in Men (MrOS) Research Group. Physical performance and risk of hip fractures in older men. *J Bone Miner Res*. 2008; 23(7):1037–1044
104. Binkley N, Krueger D, Buehring B. What's in a name revisited: should osteoporosis and sarcopenia be considered components of "dysmobility syndrome?". *Osteoporos Int*. 2013; 24(12):2955–2959
105. Faigenbaum AD, Rebullido TR, MacDonald JP. Pediatric inactivity triad: a risky PIT. *Curr Sports Med Rep*. 2018; 17(2):45–47
106. Dolinsky DH, Brouwer RJ, Evenson KR, Siega-Riz AM, Østbye T. Correlates of sedentary time and physical activity among preschool-aged children. *Prev Chronic Dis*. 2011;8(6):A131
107. Kaiser Family Foundation. Generation M2: media in the lives of 8- to 18-year-olds. 2010. Available at: http://kff.org/other/event/generation-m2-media-in-the-lives-of/. Accessed September 29, 2016
108. Biswas A, Oh PI, Faulkner GE, et al. Sedentary time and its association with risk for disease incidence, mortality, and hospitalization in adults: a systematic review and meta-analysis [published correction appears in *Ann Intern Med*. 2015;163(5):400]. *Ann Intern Med*. 2015;162(2):123–132
109. Lobenius-Palmér K, Sjöqvist B, Hurtig-Wennlöf A, Lundqvist LO. Accelerometer-assessed physical activity and sedentary time in youth with disabilities. *Adapt Phys Activ Q*. 2018; 35(1):1–19
110. Cliff DP, Hesketh KD, Vella SA, et al. Objectively measured sedentary behaviour and health and development in children and adolescents: systematic review and meta-analysis. *Obes Rev*. 2016;17(4):330–344
111. Biddiss E, Irwin J. Active video games to promote physical activity in children

and youth: a systematic review. *Arch Pediatr Adolesc Med*. 2010;164(7):664–672

112. Barnett A, Cerin E, Baranowski T. Active video games for youth: a systematic review. *J Phys Act Health*. 2011;8(5):724–737

113. Lamboglia CM, da Silva VT, de Vasconcelos Filho JE, et al. Exergaming as a strategic tool in the fight against childhood obesity: a systematic review. *J Obes*. 2013;2013:438364

114. Council on Communications and Media. Media use in school-aged children and adolescents. *Pediatrics*. 2016;138(5):e20162592

115. Lobelo F, Stoutenberg M, Hutber A. The exercise is medicine global health initiative: a 2014 update. *Br J Sports Med*. 2014;48(22):1627–1633

116. Vuori IM, Lavie CJ, Blair SN. Physical activity promotion in the health care system. *Mayo Clinic Proc*. 2013;88(12):1446–1461

117. Orrow G, Kinmonth AL, Sanderson S, Sutton S. Effectiveness of physical activity promotion based in primary care: systematic review and meta-analysis of randomised controlled trials. *BMJ*. 2012;344:e1389

118. Williams NH, Hendry M, France B, Lewis R, Wilkinson C. Effectiveness of exercise-referral schemes to promote physical activity in adults: systematic review. *Br J Gen Pract*. 2007;57(545):979–986

119. Sanchez A, Bully P, Martinez C, Grandes G. Effectiveness of physical activity promotion interventions in primary care: a review of reviews. *Prev Med*. 2015;76(suppl):S56–S67

120. Lobelo F, Rohm Young D, Sallis R, et al; American Heart Association Physical Activity Committee of the Council on Lifestyle and Cardiometabolic Health; Council on Epidemiology and Prevention; Council on Clinical Cardiology; Council on Genomic and Precision Medicine; Council on Cardiovascular Surgery and Anesthesia; and Stroke Council. Routine assessment and promotion of physical activity in healthcare settings: a scientific statement from the American Heart Association. *Circulation*. 2018;137(18):e495–e522

121. Eakin EG, Brown WJ, Marshall AL, Mummery K, Larsen E. Physical activity promotion in primary care: bridging the gap between research and practice. *Am J Prev Med*. 2004;27(4):297–303

122. Grandes G, Sanchez A, Sanchez-Pinilla RO, et al; PEPAF Group. Effectiveness of physical activity advice and prescription by physicians in routine primary care: a cluster randomized trial. *Arch Intern Med*. 2009;169(7):694–701

123. Aittasalo M, Miilunpalo S, Kukkonen-Harjula K, Pasanen M. A randomized intervention of physical activity promotion and patient self-monitoring in primary health care. *Prev Med*. 2006;42(1):40–46

124. Garrett S, Elley CR, Rose SB, O'Dea D, Lawton BA, Dowell AC. Are physical activity interventions in primary care and the community cost-effective? A systematic review of the evidence. *Br J Gen Pract*. 2011;61(584):e125–e133

125. Murphy SM, Edwards RT, Williams N, et al. An evaluation of the effectiveness and cost effectiveness of the National Exercise Referral Scheme in Wales, UK: a randomised controlled trial of a public health policy initiative. *J Epidemiol Community Health*. 2012;66(8):745–753

126. Hogg WE, Zhao X, Angus D, et al. The cost of integrating a physical activity counselor in the primary health care team. *J Am Board Fam Med*. 2012;25(2):250–252

127. Anokye NK, Lord J, Fox-Rushby J. Is brief advice in primary care a cost-effective way to promote physical activity? *Br J Sports Med*. 2014;48(3):202–206

128. Edwards RT, Linck P, Hounsome N, et al. Cost-effectiveness of a national exercise referral programme for primary care patients in Wales: results of a randomised controlled trial. *BMC Public Health*. 2013;13:1021

129. Nguyen HQ, Ackermann RT, Maciejewski M, et al. Managed-Medicare health club benefit and reduced health care costs among older adults. *Prev Chronic Dis*. 2008;5(1):A14

130. Ackermann RT, Williams B, Nguyen HQ, Berke EM, Maciejewski ML, LoGerfo JP. Healthcare cost differences with participation in a community-based group physical activity benefit for Medicare managed care health plan members. *J Am Geriatr Soc*. 2008;56(8):1459–1465

131. Meriwether RA, Lobelo F, Pate RR. Themed review: clinical interventions to promote physical activity in youth. *Am J Lifestyle Med*. 2008;2(1):7–25

132. Patrick K, Calfas KJ, Norman GJ, et al. Randomized controlled trial of a primary care and home-based intervention for physical activity and nutrition behaviors: PACE+ for adolescents. *Arch Pediatr Adolesc Med*. 2006;160(2):128–136

133. National Committee for Quality Assurance. *Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents (WCC)*. Washington, DC: National Committee for Quality Assurance

134. Grossman DC, Bibbins-Domingo K, Curry SJ, et al; US Preventive Services Task Force. Screening for Obesity in Children and Adolescents: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2017;317(23):2417–2426

135. Yazdani S, Yee CT, Chung PJ. Factors predicting physical activity among children with special needs. *Prev Chronic Dis*. 2013;10:E119

136. Logan K, Cuff S; Council on Sports Medicine and Fitness. Organized sports for children, preadolescents, and adolescents. *Pediatrics*. 2019;143(6):e20190997

137. LaPrade RF, Agel J, Baker J, et al. AOSSM early sport specialization consensus statement. *Orthop J Sports Med*. 2016;4(4):2325967116644241

138. Jayanthi NA, LaBella CR, Fischer D, Pasulka J, Dugas LR. Sports-specialized intensive training and the risk of injury in young athletes: a clinical case-control study. *Am J Sports Med*. 2015;43(4):794–801

139. Tremblay MS, Gray C, Babcock S, et al. Position statement on active outdoor play. *Int J Environ Res Public Health*. 2015;12(6):6475–6505

140. Aggio D, Gardner B, Roberts J, et al. Correlates of children's independent outdoor play: cross-sectional analyses from the Millennium Cohort Study. *Prev Med Rep*. 2017;8:10–14

141. Pate RR, Davis MG, Robinson TN, Stone EJ, McKenzie TL, Young JC; American Heart Association Council on Nutrition, Physical Activity, and Metabolism (Physical Activity Committee); Council on Cardiovascular Disease in the Young; Council on Cardiovascular Nursing. Promoting physical activity in children and youth: a leadership role for schools: a scientific statement from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism (Physical Activity Committee) in collaboration with the Councils on Cardiovascular Disease in the Young and Cardiovascular Nursing. *Circulation*. 2006;114(11):1214–1224

142. Jin J, Yun J, Agiovlasitis S. Impact of enjoyment on physical activity and health among children with disabilities in schools. *Disabil Health J*. 2018;11(1): 14–19

143. Sutherland R, Campbell E, Lubans DR, et al. Physical education in secondary schools located in low-income communities: physical activity levels, lesson context and teacher interaction. *J Sci Med Sport*. 2016;19(2):135–141

144. Hollis JL, Williams AJ, Sutherland R, et al. A systematic review and meta-analysis of moderate-to-vigorous physical activity levels in elementary school physical education lessons. *Prev Med*. 2016;86:34–54

145. Beets MW, Banda JA, Erwin HE, Beighle A. A pictorial view of the physical activity socialization of young adolescents outside of school. *Res Q Exerc Sport*. 2011;82(4):769–778

146. Dobbins M, Husson H, DeCorby K, LaRocca RL. School-based physical activity programs for promoting physical activity and fitness in children and adolescents aged 6 to 18. *Cochrane Database Syst Rev*. 2013;(2):CD007651

147. Murray R, Ramstetter C; Council on School Health; American Academy of Pediatrics. The crucial role of recess in school. *Pediatrics*. 2013;131(1):183–188

148. Cradock AL, Barrett JL, Giles CM, et al. Promoting physical activity with the Out of School Nutrition and Physical Activity (OSNAP) Initiative: a cluster-randomized controlled trial. *JAMA Pediatr*. 2016; 170(2):155–162

149. Madsen K, Thompson H, Adkins A, Crawford Y. School-community partnerships: a cluster-randomized trial of an after-school soccer program. *JAMA Pediatr*. 2013;167(4):321–326

150. Harmon BE. Rethinking physical activity for children: implications for the working poor. *Transl Behav Med*. 2017; 7(1):69–71

151. Joy EA, Lobelo F. Promoting the athlete in every child: physical activity assessment and promotion in healthcare. *Br J Sports Med*. 2017; 51(3):143–145

152. Sallis RE, Baggish AL, Franklin BA, Whitehead JR. The call for a physical activity vital sign in clinical practice. *Am J Med*. 2016;129(9):903–905

153. Sallis R. Exercise is medicine: a call to action for physicians to assess and prescribe exercise. *Phys Sportsmed*. 2015;43(1):22–26

154. Sallis RE, Matuszak JM, Baggish AL, et al. Call to action on making physical activity assessment and prescription a medical standard of care. *Curr Sports Med Rep*. 2016;15(3):207–214

155. Coleman KJ, Ngor E, Reynolds K, et al. Initial validation of an exercise "vital sign" in electronic medical records. *Med Sci Sports Exerc*. 2012;44(11): 2071–2076

156. Ball TJ, Joy EA, Gren LH, Shaw JM. Concurrent validity of a self-reported physical activity "vital sign" questionnaire with adult primary care patients. *Prev Chronic Dis*. 2016;13:E16

157. Ball TJ, Joy EA, Goh TL, Hannon JC, Gren LH, Shaw JM. Validity of two brief primary care physical activity questionnaires with accelerometry in clinic staff. *Prim Health Care Res Dev*. 2015;16(1):100–108

158. Grant RW, Schmittdiel JA, Neugebauer RS, Uratsu CS, Sternfeld B. Exercise as a vital sign: a quasi-experimental analysis of a health system intervention to collect patient-reported exercise levels. *J Gen Intern Med*. 2014;29(2): 341–348

159. Mann DM, Palmisano J, Lin JJ. A pilot randomized trial of technology-assisted goal setting to improve physical activity among primary care patients with prediabetes. *Prev Med Rep*. 2016;4: 107–112

160. Institute of Medicine. *Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 1*. Washington, DC: National Academies Press; 2014

161. Rangul V, Holmen TL, Kurtze N, Cuypers K, Midthjell K. Reliability and validity of two frequently used self-administered physical activity questionnaires in adolescents. *BMC Med Res Methodol*. 2008;8:47

162. Ekelund U, Tomkinson G, Armstrong N. What proportion of youth are physically active? Measurement issues, levels and recent time trends. *Br J Sports Med*. 2011;45(11):859–865

163. Sallis JF. Self-report measures of children's physical activity. *J Sch Health*. 1991;61(5):215–219

164. Leek D, Carlson JA, Cain KL, et al. Physical activity during youth sports practices. *Arch Pediatr Adolesc Med*. 2011;165(4):294–299

165. AuYoung M, Linke SE, Pagoto S, et al. Integrating physical activity in primary care practice. *Am J Med*. 2016;129(10): 1022–1029

166. McGlynn EA, Lieu TA, Durham ML, et al. Developing a data infrastructure for a learning health system: the PORTAL network. *J Am Med Inform Assoc*. 2014; 21(4):596–601

167. Adirim T, Meade K, Mistry K; Council on Quality Improvement and Patient Safety; Committee on Practice and Ambulatory Management. A new era in quality measurement: the development and application of quality measures. *Pediatrics*. 2017;139(1):e20163442

168. Buffart LM, Westendorp T, van den Berg-Emons RJ, Stam HJ, Roebroeck ME. Perceived barriers to and facilitators of physical activity in young adults with childhood-onset physical disabilities. *J Rehabil Med*. 2009;41(11):881–885

169. Shields N, Synnot A. Perceived barriers and facilitators to participation in physical activity for children with disability: a qualitative study. *BMC Pediatr*. 2016;16:9

170. Bloemen MA, Verschuren O, van Mechelen C, et al. Personal and environmental factors to consider when aiming to improve participation in physical activity in children with

spina bifida: a qualitative study. *BMC Neurol*. 2015;15:11

171. Cradock AL, Barrett JL, Kenney EL, et al. Using cost-effectiveness analysis to prioritize policy and programmatic approaches to physical activity promotion and obesity prevention in childhood. *Prev Med*. 2017;95(suppl): S17–S27

172. Leijon ME, Stark-Ekman D, Nilsen P, et al. Is there a demand for physical activity interventions provided by the health care sector? Findings from a population survey. *BMC Public Health*. 2010;10:34

173. Connaughton AV, Weiler RM, Connaughton DP. Graduating medical students' exercise prescription competence as perceived by deans and directors of medical education in the United States: implications for Healthy People 2010. *Public Health Rep*. 2001; 116(3):226–234

174. Cardinal BJ, Park EA, Kim M, Cardinal MK. If exercise is medicine, where is exercise in medicine? Review of U.S. medical education curricula for physical activity-related content. *J Phys Act Health*. 2015;12(9):1336–1343

175. Stoutenberg M, Stasi S, Stamatakis E, et al. Physical activity training in US medical schools: preparing future physicians to engage in primary prevention. *Phys Sportsmed*. 2015; 43(4):388–394

176. Goff SL, Holboe ES, Concato J. Pediatricians and physical activity counseling: how does residency prepare them for this task? *Teach Learn Med*. 2010;22(2):107–111

177. Stahl CE, Necheles JW, Mayefsky JH, Wright LK, Rankin KM. 5-4-3-2-1 go! Coordinating pediatric resident education and community health promotion to address the obesity epidemic in children and youth. *Clin Pediatr (Phila)*. 2011;50(3):215–224

178. Lobelo F, Duperly J, Frank E. Physical activity habits of doctors and medical students influence their counselling practices. *Br J Sports Med*. 2009;43(2): 89–92

179. Lobelo F, de Quevedo IG. The evidence in support of physicians and health care providers as physical activity role models. *Am J Lifestyle Med*. 2016;10(1): 36–52

180. Binns HJ, Mueller MM, Ariza AJ. Healthy and fit for prevention: the influence of clinician health and fitness on promotion of healthy lifestyles during health supervision visits. *Clin Pediatr (Phila)*. 2007;46(9):780–786

181. Dyrbye LN, Satele D, Shanafelt TD. Healthy exercise habits are associated with lower risk of burnout and higher quality of life among U.S. medical students. *Acad Med*. 2017;92(7): 1006–1011

182. Olson SM, Odo NU, Duran AM, Pereira AG, Mandel JH. Burnout and physical activity in Minnesota internal medicine resident physicians. *J Grad Med Educ*. 2014;6(4):669–674

183. Weight CJ, Sellon JL, Lessard-Anderson CR, Shanafelt TD, Olsen KD, Laskowski ER. Physical activity, quality of life, and burnout among physician trainees: the effect of a team-based, incentivized exercise program. *Mayo Clin Proc*. 2013; 88(12):1435–1442

184. Jonsdottir IH, Rödjer L, Hadzibajramovic E, Börjesson M, Ahlborg G Jr.. A prospective study of leisure-time physical activity and mental health in Swedish health care workers and social insurance officers. *Prev Med*. 2010;51(5):373–377

185. McClafferty H, Brown OW; Section on Integrative Medicine; Committee on Practice and Ambulatory Medicine; Section on Integrative Medicine. Physician health and wellness. *Pediatrics*. 2014;134(4):830–835

186. Owen MB, Curry WB, Kerner C, Newson L, Fairclough SJ. The effectiveness of school-based physical activity interventions for adolescent girls: a systematic review and meta-analysis. *Prev Med*. 2017;105:237–249

187. Chinapaw MJ, Mokkink LB, van Poppel MN, van Mechelen W, Terwee CB. Physical activity questionnaires for youth: a systematic review of measurement properties. *Sports Med*. 2010;40(7):539–563

188. Adamo KB, Prince SA, Tricco AC, Connor-Gorber S, Tremblay M. A comparison of indirect versus direct measures for assessing physical activity in the pediatric population: a systematic review. *Int J Pediatr Obes*. 2009;4(1): 2–27

189. Helmerhorst HJ, Brage S, Warren J, Besson H, Ekelund U. A systematic review of reliability and objective criterion-related validity of physical activity questionnaires. *Int J Behav Nutr Phys Act*. 2012;9:103

190. Cancela JM, Ayán C, Castro A. An evaluation of questionnaires assessing physical activity levels in youth populations. *J Child Health Care*. 2013; 17(3):274–293

191. Biddle SJ, Gorely T, Pearson N, Bull FC. An assessment of self-reported physical activity instruments in young people for population surveillance: Project ALPHA. *Int J Behav Nutr Phys Act*. 2011;8:1

192. Strath SJ, Kaminsky LA, Ainsworth BE, et al; American Heart Association Physical Activity Committee of the Council on Lifestyle and Cardiometabolic Health and Cardiovascular, Exercise, Cardiac Rehabilitation and Prevention Committee of the Council on Clinical Cardiology, and Council. Guide to the assessment of physical activity: clinical and research applications: a scientific statement from the American Heart Association. *Circulation*. 2013;128(20): 2259–2279

193. Booth ML, Okely AD, Chey T, Bauman A. The reliability and validity of the physical activity questions in the WHO Health Behaviour in Schoolchildren (HBSC) survey: a population study. *Br J Sports Med*. 2001;35(4):263–267

194. Crocker PR, Bailey DA, Faulkner RA, Kowalski KC, McGrath R. Measuring general levels of physical activity: preliminary evidence for the Physical Activity Questionnaire for Older Children. *Med Sci Sports Exerc*. 1997; 29(10):1344–1349

195. Bacardi-Gascón M, Reveles-Rojas C, Woodward-Lopez G, Crawford P, Jiménez-Cruz A. Assessing the validity of a physical activity questionnaire developed for parents of preschool children in Mexico. *J Health Popul Nutr*. 2012;30(4):439–446

196. Brener ND, Kann L, McManus T, Kinchen SA, Sundberg EC, Ross JG. Reliability of the 1999 Youth Risk Behavior Survey questionnaire. *J Adolesc Health*. 2002; 31(4):336–342

197. Brener ND, Collins JL, Kann L, Warren CW, Williams BI. Reliability of the Youth

Risk Behavior Survey questionnaire. *Am J Epidemiol*. 1995;141(6):575–580

198. Troped PJ, Wiecha JL, Fragala MS, et al. Reliability and validity of YRBS physical activity items among middle school students. *Med Sci Sports Exerc*. 2007; 39(3):416–425

199. Prochaska JJ, Sallis JF, Long B. A physical activity screening measure for use with adolescents in primary care. *Arch Pediatr Adolesc Med*. 2001;155(5): 554–559

200. Martínez-Gómez D, Martínez-De-Haro V, Del-Campo J, et al. [Validity of four questionnaires to assess physical activity in Spanish adolescents] [in Spanish]. *Gac Sanit*. 2009;23(6):512–517

201. Ridgers ND, Timperio A, Crawford D, Salmon J. Validity of a brief self-report instrument for assessing compliance with physical activity guidelines amongst adolescents. *J Sci Med Sport*. 2012;15(2):136–141

202. Liu Y, Wang M, Tynjälä J, et al. Test-retest reliability of selected items of Health Behaviour in School-aged Children (HBSC) survey questionnaire in Beijing, China. *BMC Med Res Methodol*. 2010;10: 73

203. Hardie Murphy M, Rowe DA, Belton S, Woods CB. Validity of a two-item physical activity questionnaire for assessing attainment of physical activity guidelines in youth. *BMC Public Health*. 2015;15:1080

204. Patrick K, Sallis JF, Prochaska JJ, et al. A multicomponent program for nutrition and physical activity change in primary care: PACE+ for adolescents. *Arch Pediatr Adolesc Med*. 2001;155(8): 940–946

205. World Health Organization. *Global School-Based Student Health Survey (GSHS)*. Geneva, Switzerland: World Health Organization; 2013

206. Haug E, Rasmussen M, Samdal O, et al; HBSC Obesity Writing Group. Overweight in school-aged children and its relationship with demographic and lifestyle factors: results from the WHO-Collaborative Health Behaviour in School-aged Children (HBSC) study. *Int J Public Health*. 2009;54(suppl 2): 167–179

207. Pate RR, McIver KL, Dowda M, Schenkelberg MA, Beets MV, Distefano C. EASY-an instrument for surveillance of physical activity in youth. *Med Sci Sports Exerc*. 2018;50(6):1216–1223

208. Trost SG, O'Neil M. Clinical use of objective measures of physical activity. *Br J Sports Med*. 2014;48(3):178–181

209. Guthrie N, Bradlyn A, Thompson SK, et al. Development of an accelerometer-linked online intervention system to promote physical activity in adolescents. *PLoS One*. 2015;10(5): e0128639

210. Lobelo F, Kelli HM, Tejedor SC, et al. The wild wild West: a framework to integrate mHealth software applications and wearables to support physical activity assessment, counseling and interventions for cardiovascular disease risk reduction. *Prog Cardiovasc Dis*. 2016;58(6): 584–594

211. Paridon SM, Alpert BS, Boas SR, et al; American Heart Association Council on Cardiovascular Disease in the Young, Committee on Atherosclerosis, Hypertension, and Obesity in Youth. Clinical stress testing in the pediatric age group: a statement from the American Heart Association Council on Cardiovascular Disease in the Young, Committee on Atherosclerosis, Hypertension, and Obesity in Youth. *Circulation*. 2006;113(15):1905–1920

212. Welk GJ, Going SB, Morrow JR Jr., Meredith MD. Development of new criterion-referenced fitness standards in the FITNESSGRAM® program: rationale and conceptual overview. *Am J Prev Med*. 2011;41(4 suppl 2):S63–S67

213. Lobelo F, Pate RR, Dowda M, Liese AD, Ruiz JR. Validity of cardiorespiratory fitness criterion-referenced standards for adolescents. *Med Sci Sports Exerc*. 2009;41(6):1222–1229

214. Ortega FB, Ruiz JR, Castillo MJ, Sjöström M. Physical fitness in childhood and adolescence: a powerful marker of health. *Int J Obes (Lond)*. 2008;32(1):1–11

215. Bai Y, Saint-Maurice PF, Welk GJ, Allums-Featherston K, Candelaria N, Anderson K. Prevalence of youth fitness in the United States: baseline results from the NFL PLAY 60 FITNESSGRAM Partnership Project. *J Pediatr*. 2015;167(3):662–668

216. Janz KF, Broffitt B, Levy SM. Validation evidence for the Netherlands physical activity questionnaire for young children: the Iowa Bone Development Study. *Res Q Exerc Sport*. 2005;76(3): 363–369

217. Chen X, Sekine M, Hamanishi S, et al. Validation of a self-reported physical activity questionnaire for schoolchildren. *J Epidemiol*. 2003;13(5): 278–287

218. Godin G, Shephard RJ. A simple method to assess exercise behavior in the community. *Can J Appl Sport Sci*. 1985; 10(3):141–146

219. Sallis JF, Buono MJ, Roby JJ, Micale FG, Nelson JA. Seven-day recall and other physical activity self-reports in children and adolescents. *Med Sci Sports Exerc*. 1993;25(1):99–108

220. Fulkerson JA, Sherwood NE, Perry CL, Neumark-Sztainer D, Story M. Depressive symptoms and adolescent eating and health behaviors: a multifaceted view in a population-based sample. *Prev Med*. 2004;38(6): 865–875

221. Gao S, Harnack L, Schmitz K, et al. Reliability and validity of a brief tool to measure children's physical activity. *J Phys Act Health*. 2006;3(4):415–422

222. Scerpella TA, Tuladhar P, Kanaley JA. Validation of the Godin-Shephard Questionnaire in prepubertal girls. *Med Sci Sports Exerc*. 2002;34(5):845–850

223. Koo MM, Rohan TE. Comparison of four habitual physical activity questionnaires in girls aged 7-15 yr. *Med Sci Sports Exerc*. 1999;31(3): 421–427

224. Janz KF, Witt J, Mahoney LT. The stability of children's physical activity as measured by accelerometry and self-report. *Med Sci Sports Exerc*. 1995; 27(9):1326–1332

225. Treuth MS, Hou N, Young DR, Maynard LM. Validity and reliability of the Fels Physical Activity Questionnaire for children. *Med Sci Sports Exerc*. 2005; 37(3):488–495

226. Burdette HL, Whitaker RC, Daniels SR. Parental report of outdoor playtime as a measure of physical activity in preschool-aged children. *Arch Pediatr Adolesc Med*. 2004;158(4):353–357

227. Schmidt GJ, Walkuski JJ, Stensel DJ. The Singapore Youth Coronary Risk and Physical Activity study. *Med Sci Sports Exerc*. 1998;30(1): 105–113

228. Ihmels MA, Welk GJ, Eisenmann JC, Nusser SM. Development and preliminary validation of a Family Nutrition and Physical Activity (FNPA) Screening Tool. *Int J Behav Nutr Phys Act*. 2009;6:14

229. Christison AL, Daley BM, Asche CV, et al. Pairing motivational interviewing with a nutrition and physical activity assessment and counseling tool in pediatric clinical practice: a pilot study. *Child Obes*. 2014;10(5):432–441

230. Janz KF, Lutuchy EM, Wenthe P, Levy SM. Measuring activity in children and adolescents using self-report: PAQ-C and PAQ-A. *Med Sci Sports Exerc*. 2008; 40(4):767–772

231. Park JM, Han AK, Cho YH. Construct equivalence and latent means analysis of health behaviors between male and female middle school students. *Asian Nurs Res (Korean Soc Nurs Sci)*. 2011; 5(4):216–221

232. Fernald DH, Froshaug DB, Dickinson LM, et al. Common Measures, Better Outcomes (COMBO): a field test of brief health behavior measures in primary care. *Am J Prev Med*. 2008;35(5 suppl):S414–S422

Principles of Financing the Medical Home for Children

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Principles of Financing the Medical Home for Children

Jonathan Price, MD, FAAP,[a] Mary L. Brandt, MD, FACS, FAAP,[b] Mark L. Hudak, MD, FAAP,[c] COMMITTEE ON CHILD HEALTH FINANCING

A well-implemented and adequately funded medical home not only is the best approach to optimize the health of the individual patient but also can function as an effective instrument for improving population health. Key financing elements to providing quality, effective, comprehensive care in the pediatric medical home include the following: (1) first dollar coverage without deductibles, copays, or other cost-sharing for necessary preventive care services as recommended by *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*; (2) adoption of a uniform definition of medical necessity across payers that embraces services that promote optimal growth and development and prevent, diagnose, and treat the full range of pediatric physical, mental, behavioral, and developmental conditions, in accord with evidence-based science or evidence-informed expert opinion; (3) payment models that promote appropriate use of pediatric primary care and pediatric specialty services and discourage inappropriate, inefficient, or excessive use of medical services; and (4) payment models that strengthen the patient- and family-physician relationship and do not impose additional administrative burdens that will only erode the effectiveness of the medical home. These goals can be met by designing payment models that provide adequate funding of the cost of medical encounters, care coordination, population health services, and quality improvement activities; provide incentives for quality and effectiveness of care; and ease administrative burdens.

INTRODUCTION

The American Academy of Pediatrics (AAP) originally developed the concept of a medical home in 1967.[1] Since that time, the AAP has continuously refined its vision of the mission, structure, and function of a medical home consistent with evolving best practices. A well-implemented and adequately funded medical home not only is the best approach to optimize the health of the individual patient but can also play a key role in improving population health. As public and private

abstract

[a]*Department of Pediatrics, Nationwide Children's Hospital, The Ohio State University College of Medicine, Columbus, Ohio;* [b]*Department of Surgery, Texas Children's Hospital, Houston, Texas; and* [c]*Department of Pediatrics, College of Medicine, University of Florida–Jacksonville, Jacksonville, Florida*

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Dr Price wrote the initial draft and contributed to subsequent revisions; Dr Brandt wrote the initial draft; Dr Hudak reviewed all drafts and provided input on all revisions; members of the Committee on Child Health Financing provided guidance on content and key edits; and all authors reviewed and approved the final manuscript as submitted.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2019-3451

Address correspondence to Jonathan Price, MD, FAAP. E-mail: njnprice@gmail.com

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Price J, Brandt ML, Hudak ML, AAP COMMITTEE ON CHILD HEALTH FINANCING. Principles of Financing the Medical Home for Children. *Pediatrics*. 2020;145(1): e20193451

payers modify traditional ways of paying for medical care or create alternative payment models in an effort to provide greater value (an improved ratio of population health to health care expense), they should recognize the contribution to value that the medical home makes.[2,3] Pediatricians must be knowledgeable about certain basic principles in their work with payers to make the medical home fully effective in improving the health of children and to ensure the medical home's fiscal viability.

DEFINITIONS

The "pediatric medical home" delivers accessible, continuous, comprehensive, patient- and family-centered, coordinated, compassionate, and culturally effective health care. In this venue, well-trained pediatric physicians known to the child and family deliver or direct primary medical care.[4] By extension, a "pediatric medical neighborhood" includes pediatric medical subspecialists, surgical specialists, mental and behavioral health specialists, and others who work collaboratively with the pediatric medical home.

The "triple aim," as adopted by payers, is to improve the value of health care (defined as the ratio of proven benefit or quality of care to the cost of care), to improve the individual patient's experience of care, and to improve community health as a whole. The foundational document that describes the triple aim envisions that payers must undertake or delegate several crucial tasks that include partnering with individuals and families, redesigning primary care, managing population health, managing system financing, and integrating care within large systems.[5] This triple aim has expanded to a quadruple aim by recognizing that improved provider satisfaction is another key goal of the health system enterprise. Attention to how the care team experiences the quality of its work life is required to counter the erosion of provider manpower, efficiency, and empathy resulting from accelerating and often onerous administrative demands.[6]

RECOGNIZING AND DELIVERING VALUE

Approximately one-third of the US population consists of children and young adults younger than 25 years.[7] Despite recent advances, however, the vast majority of health care spending, benefit design efforts, and medical home pilot projects are focused on older adults. In a growing body of evidence, it has been demonstrated that a greater achievable health value lies in identifying, preventing, ameliorating, or treating problems that may begin early in life and have lifelong consequences.[8–12] Prevention and early interventions undertaken between birth and school entry have significant effects on adult health[13–15] and remain important when initiated in later childhood, adolescence, and early adulthood. In this respect, greater investments in medical homes that enable or enhance their unique capabilities may be expected to generate compound long-term returns.

Health insurance, therefore, should cover the full range of essential services for children. These services include the traditionally recognized areas of newborn care; acute, urgent, and emergent outpatient care; inpatient and chronic care services; and prescription drugs. Essential services also include screening and early detection of developmental and behavioral problems and the full range of preventive and wellness services, including anticipatory guidance, habilitative and rehabilitative therapies and devices, oral health and vision care services, behavioral and mental health services, reproductive and pregnancy-related care, substance use disorder treatment, and transition to adult care services as well as home health, palliative, and hospice care services.[16] To achieve the full downstream effects of early-in-life prevention and intervention, payers should also cover other services, many of which can be integrated with the medical home. These include home visitations during pregnancy, infancy, and early childhood, the importance of which to child cognition and health have become well recognized.[17–20] Other evidence-based programs that have been shown to improve important short- and long-term child outcomes include Reach Out and Read, Healthy Steps, the Video Interaction Project, Incredible Years, medical-legal partnerships, and the Triple P Positive Parenting Program.[21–26]

PROVIDING EFFECTIVE COMPREHENSIVE CARE IN THE MEDICAL HOME

Accomplishing the goal of providing effective, comprehensive care in the medical home requires the following.

1. Insurers provide first dollar coverage for the preventive care services recommended in *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*[13] and for vaccines recommended by the AAP and the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. All should be exempt from cost-sharing.
2. Health insurers adopt a uniform definition of medical necessity to include those services that promote optimal growth and development as well as prevent, diagnose, and treat the full range of pediatric physical, mental, behavioral, and developmental

conditions, in accord with evidence-based science or evidence-informed expert opinion.[16,27] Expert pediatric providers must be included in adjudication of disputes over medically necessary services for children.

3. Cost-sharing policies relating to deductibles, copays, and coinsurance focus only on discouraging inappropriate, inefficient, or excessive use of medical services. They should not deter appropriate use of primary care or specialist services. Out-of-pocket limits should be set as a function of family income rather than in absolute terms. Out-of-pocket limits should be minimized for these services. A generous number of primary care visits or, alternately, outpatient visits in general should be available without a deductible and with minimal cost-sharing limitations. A similar approach should apply to medically necessary services and procedures that are typically provided by medical subspecialists, surgical specialists, and mental and behavioral health specialists. High-deductible health plans are not appropriate for the pediatric population because they are not congruent with these principles.[28] A developing body of evidence suggests that high-deductible health plans indiscriminately discourage families from seeking high-value and/or medically necessary medical services. Hence, high-deductible health plans not only decrease inappropriate or excessive use but also restrict access to appropriate care.[29,30]
4. The provider and patient become able to determine from the payer the patient's cost responsibility at the time of service to achieve timely and efficient collections necessary to sustain the medical home.

IMPROVING THE PATIENT AND PROVIDER EXPERIENCE OF CARE

For children to receive accessible, continuous, comprehensive, and coordinated care from the medical home, payment for services must be timely and adequate. For the medical home to plan effective delivery of care, the payment methodology for encounters, coordination of care, quality improvement, and data generation must be understandable, transparent, and verifiable and must incentivize improving the patient experience of care. This can effectively be accomplished by implementation of the following principles, which will also improve provider satisfaction, the fourth item of the quadruple aim.

A. Adequate and Fair Payment for Medical Encounters

1. Base payments for encounters should reflect the complexity of service.[31]
2. Payers should value the additional global services that a practice incurs to effect transition of care, especially from pediatric to adult providers[32] as well as from hospital to home care and from home or hospital to residential or other treatment venues, by paying fairly for existing transition *Current Procedural Terminology* (CPT) codes.
3. Payments for vaccines, medications, and medical supplies should be based on the total costs of acquisition, patient counseling, storage, inventory tracking and reporting, quality control, administration, and documentation. Payments should be updated promptly for changes in purchase cost.
4. Appropriate non–face-to-face encounters via telephone and video and those on digital platforms, such as the Internet, e-mail, electronic health record portals, and other secure encrypted communication, that provide meaningful care should be paid for adequately to facilitate optimal function of the medical home and to improve patient and family satisfaction. These interactions may occur between the patient and family and the medical home or between the medical home and specialty care providers. These visits have their greatest value when they are performed within the medical neighborhood because they facilitate more timely access to care, promote continuity and thereby enhance quality, and prevent use of more-expensive medical venues. Payers should recognize this greater value by incentivizing patients and families to coordinate care through the medical home.

B. Adequate and Fair Payment for Coordination of Care

1. Payment for coordination of care allows services outside of face-to-face encounters that optimize care. This is especially important for children with special health care needs. Examples of these services include providing reminders and other outreach to patients and coordination and communication with medical subspecialists, surgical specialists, therapists, educators, and community resources.
2. Payment should be proportional to the specific services provided in this regard by the medical home and should consider the complexity of the patient panel. It is essential to understand that complexity relates not only to patient-specific medical and psychological factors but also, and especially in pediatrics, factors specific to parents and caregivers as well as overarching household and social factors, such as food and housing insecurity, neighborhood and household

violence, poverty, immigration status, and need for legal services.[33]

3. Coordination payments could be made as enhanced fee-for-service payment or as supplemental per-member per-month payment. Supplemental per-member per-month methodology can also enable providers to establish and maintain health information technology and collect data for quality improvement and population health initiatives. Payers should pay fairly for existing CPT codes that apply to care management of children with chronic and/or complex medical and behavioral conditions.

C. Implementing Well-Designed Incentives and Eliminating Disincentives

1. To achieve the full benefits of the medical home, its financiers should not simultaneously incentivize efforts that undermine it.
2. Vaccines, including the influenza vaccine, provided by the Vaccines for Children program and the Centers for Disease Control and Prevention are properly viewed as an important type of "in-kind" financing. As such, they should be supplied in a way that is as timely and adequate as monetary financing. In particular, release of annual influenza vaccine to accessible medical homes should be prioritized. Delayed delivery relative to other venues, such as pharmacies and retail-based clinics, results in lost opportunities for families to engage the medical home and potentially benefit from other interventions or health education at the same time.
3. Payers should not design cost-sharing to encourage the family to use venues, including retail-based clinics and telehealth ventures, that do not meaningfully communicate with the medical home or that deviate from professional standards of care (eg, fail to adhere to antibiotic stewardship principles or fail to conduct patient evaluations adequate for the complaint). Likewise, payers should not support provision of care to children younger than 2 years by acute care venues that lack pediatric expertise.[34]

D. Easing the Administrative Burden

1. Payers using fee-for-service payments should consistently adhere to CPT definitions of services. Providers waste administrative resources encoding the same service differently for different payers. Resultant errors in billing can reduce revenue. In addition, variant coding enfeebles a practice's ability to conduct internal analyses of its services.
2. Pediatricians choose from among specific quality improvement programs designed by the American Board of Pediatrics or one of its chartered entities for maintenance of certification (MOC). They also separately participate in specific programs designed by health care payers to qualify for incentive payments. Synergy between these programs would ease administrative burden within the medical home and better promote community health. Payers and MOC program administrators, via sponsorship or other means of collaboration, can develop and share large amounts of data, which can increase the impact of these programs on health outcomes. The efficiency of the medical home would benefit from reducing the multiplicity of efforts necessary to satisfy separate MOC and payer incentive rules.

IMPROVING THE HEALTH OF THE POPULATION

Pediatricians and payers can improve community health outside the traditional office encounter in a variety of ways. A venue committed to being a medical home for children and young adults should seek broadly innovative ways of improving health outcomes for children in its practice and can also consider extending its efforts to the greater pediatric community.[35,36] Payers should value and encourage research and initiatives that are likely to elevate health outcome trajectories over the long-term.[37] Continuous real-time sharing of data about patient populations between payers and practices can be a powerful way to help both groups respond to health needs in a timely way. All public and private payers should invest in providers, families, and communities to achieve better short-term health outcomes and to stimulate changes that will result in sustained improvement in the long-term life course.

Payers Have a Unique Opportunity and Ability to Enhance the Effectiveness of the Medical Home and Incentivize Families

A payer that covers both a parent and a child has important timely data about the family unit that may allow the medical home to optimize a child's comprehensive care. Payers and providers should consider sharing such data. Social determinants of health (including parental and socioeconomic factors) largely shape many adverse conditions and experiences affecting vulnerable children. Some childhood adverse conditions begin during fetal development; some are associated with preterm birth. Other conditions involve situations, actions, and deficiencies that cause children to become medically, behaviorally, or emotionally complex. Many social determinants of health culminate with children reaching maturity in socioeconomic conditions and habitual

behavior patterns associated with lifelong chronic and expensive adult conditions.[38] Relevant parental factors include the parents' or caregivers' employment status; past and present physical, mental, or behavioral health; use of tobacco and other substances; previous experience with and attitudes toward medical care; and competencies as parents or caregivers. Knowledge of these parental factors may allow the medical home to tailor medical care and parental education to prevent or mitigate those adverse childhood experiences that are predictable yet potentially modifiable. These same factors also influence whether a parent creates and maintains a relationship with a pediatric medical home for their child. Some payers already incentivize pregnant mothers to remain engaged with their prenatal care, such as by providing portable safe sleepers and play yards or coupons for infant products for those who attend nearly all of their prenatal visits; those with the data and resources should also incentivize parents to engage appropriate services on their own behalf and engage with a comprehensive, coordinated medical home for their children. Resources should also be deployed when necessary to provide or subsidize essential transportation for necessary encounters.

Payers Have a Unique Opportunity and Ability to Shape the Community

For children and youth, and especially for those with special health care needs, high-quality care must support family members, who provide the bulk of day-to-day care and advocacy for the child. Some metrics of quality outcomes pertinent to pediatrics reflect enhancements to the family's ability to support the child. Parents, for example, indicate that a meaningful outcome of a health intervention is reducing the number of school days and workdays that an illness, injury, or condition cause to be missed within the family.[39]

A key factor that impedes delivery of quality care is a lack of appropriate, affordable, community-based family services and supports.[40] In addition, a lack of appropriate pediatric-oriented medical, surgical, mental health, substance use, and other therapeutic services within a geographic area or a payer's network of providers can impose a significant barrier. Payers, public and private, should invest in the necessary infrastructure to support the pediatric medical home and medical neighborhood.

Where they exist, payers should support community-based efforts that identify children and adults in high-risk families, provide care coordination, and measure results in housing, education, employment, and engagement with the health system.[41,42]

Payments for Quality Improvement Activities Should Be Adequate and Fair

Ideally, "pay-for-performance" or similarly named programs can be used to promote high levels of quality, value, and outcomes. These programs reward providers either monetarily or by reducing administrative burdens. Examples of the aims of such programs include reducing inappropriate antibiotic use, promoting cost-effective medications, and rewarding follow-up in the medical home after hospitalizations and emergency department visits. Many of the elements that constitute proper design of such programs are delineated in a forthcoming AAP policy statement, "Beyond Fee-for-Service: New and Evolving Payment Models and Pediatrics" (S. Berman, MD, M.L. Hudak, MD, unpublished observations). Some programs are demonstrating positive results.[43] On the other hand, pay-for-performance programs are still evolving. Many adult programs have features that are not pertinent to improving care provided to children or that cannot easily be translated into pediatric equivalents.

1. Pediatricians should be involved in the creation and revision of performance goals, the metrics used to quantify them, and the process of validating them. Uniquely pediatric performance goals include use of evidence-based or evidence-informed screenings, interventions, and coordination that promote the optimal growth and development of children and youth.
2. The criteria for achieving rewards should be transparent. Incentives are ineffective if a provider does not know how a payment was earned or not earned.
3. A detailed "explanation of payment" document should explain how an incentive payment (or lack thereof) was determined and delineate which encounters or actions led either toward or away from a goal.
4. Providers should be able to use such transparency in an active and timely process to appeal payer errors.
5. Payment models that aim to calibrate fee-for-service payments, distribute incentive payments, or impose financial penalties on the basis of process or medical outcome metrics must incorporate a rational, robust, and validated risk adjustment methodology that accounts for the strong influence of social determinants of health on many metrics. Payment models should not discourage providers from caring for patients who are most in need of expert care. Moreover, payers should choose process or quality metrics in consultation with pediatric providers to ensure that the metrics are relevant to improving the care or outcomes of care in children, meaningful to the pediatrician, and feasible to accomplish within the medical home.

6. A robust electronic health record facilitates effective quality improvement activities within the practice population through its ability to create registries and track process and quality outcomes. Payment models should consider ways to encourage investment in this important yet costly infrastructural need.

CONCLUSIONS

For a medical home for children to be both effective and fiscally viable, payers must adequately finance the full range of services required to optimize the physical, developmental, emotional, and behavioral well-being of children, which critically influence health throughout the life course. Some support is required to engage families initially with the medical home. Once engaged, appropriate support is needed for encounters, care coordination, continuous quality improvement, implementation of an effective electronic health record system, and innovative efforts to improve community health. This support should not impose additional administrative burdens that will erode the effectiveness of the medical home. Payers should consider how best to achieve better health care value without encouraging fragmented care outside the medical home.

LEAD AUTHORS

Jonathan Price, MD, FAAP
Mark L. Hudak, MD, FAAP
Mary L. Brandt, MD, FACS, FAAP

COMMITTEE ON CHILD HEALTH FINANCING, 2018–2018

Jonathan Price, MD, FAAP, Chairperson
Mark L. Hudak, MD, FAAP, Past Chairperson
Suzanne K. Berman, MD, FAAP
Mary L. Brandt, MD, FACS, FAAP
Kenneth M. Carlson, MD, FAAP
Angelo P. Giardino, MD, FAAP
Lawrence Hammer, MD, FAAP
Kimberly Heggen, MD, FAAP
Stephen A. Pearlman, MD, MS, FAAP
Beena Gaind Sood, MD, MS, FAAP

LIAISIONS

Peter G. Szilagyi, MD, MPH, FAAP – *Medicaid and CHIP Payment and Access Commission*

STAFF

Lou Terranova, MHA

ABBREVIATIONS

AAP: American Academy of Pediatrics
CPT: *Current Procedural Terminology*
MOC: maintenance of certification

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Sia C, Tonniges TF, Osterhus E, Taba S. History of the medical home concept. *Pediatrics*. 2004;113(5 suppl):1473–1478
2. McConnell KJ, Renfro S, Chan BK, et al. Early performance in Medicaid accountable care organizations: a comparison of Oregon and Colorado. *JAMA Intern Med*. 2017;177(4):538–545
3. Kelleher KJ, Cooper J, Deans K, et al. Cost saving and quality of care in a pediatric accountable care organization. *Pediatrics*. 2015;135(3). Available at: www.pediatrics.org/cgi/content/full/135/3/e582
4. Medical Home Initiatives for Children With Special Needs Project Advisory Committee. American Academy of Pediatrics. The medical home. *Pediatrics*. 2002;110(1 pt 1):184–186
5. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. *Health Aff (Millwood)*. 2008;27(3):759–769
6. Bodenheimer T, Sinsky C. From triple to quadruple aim: care of the patient requires care of the provider. *Ann Fam Med*. 2014;12(6):573–576
7. US Census Bureau. Age and sex composition: 2010. Available at: www.census.gov/prod/cen2010/briefs/c2010br-03.pdf. Accessed June 11, 2019
8. Conti G, Heckman JJ. The developmental approach to child and adult health. *Pediatrics*. 2013;131(suppl 2):S133–S141
9. Barker DJ. The origins of the developmental origins theory. *J Intern Med*. 2007;261(5):412–417
10. Walker SP, Chang SM, Vera-Hernández M, Grantham-McGregor S. Early childhood stimulation benefits adult competence and reduces violent behavior. *Pediatrics*. 2011;127(5):849–857
11. Raphael JL, Giardino AP. Accounting for kids in accountable care: a policy perspective. *Clin Pediatr (Phila)*. 2013;52(8):695–698
12. Conroy E, Degenhardt L, Mattick RP, Nelson EC. Child maltreatment as a risk factor for opioid dependence: comparison of family characteristics and type and severity of child maltreatment with a matched control group. *Child Abuse Negl*. 2009;33(6):343–352
13. Hagan J, Shaw J, Duncan P, eds. *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*, 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017
14. Campbell F, Conti G, Heckman JJ, et al. Early childhood investments

substantially boost adult health. *Science*. 2014;343(6178):1478–1485

15. Perrin EC, Sheldrick RC, McMenamy JM, Henson BS, Carter AS. Improving parenting skills for families of young children in pediatric settings: a randomized clinical trial. *JAMA Pediatr*. 2014;168(1):16–24
16. Committee On Child Health Financing. Scope of health care benefits for children from birth through age 26. *Pediatrics*. 2012;129(1):185–189
17. Filene JH, Kaminski JW, Valle LA, Cachat P. Components associated with home visiting program outcomes: a meta-analysis. *Pediatrics*. 2013;132(suppl 2): S100–S109
18. Avellar SA, Supplee LH. Effectiveness of home visiting in improving child health and reducing child maltreatment. *Pediatrics*. 2013;132(suppl 2):S90–S99
19. American Academy of Pediatrics. *Blueprint for Children: How the Next President Can Build a Foundation for a Healthy Future*. Elk Grove Village, IL: American Academy of Pediatrics; 2016. Available at: https://www.aap.org/en-us/Documents/BluePrintForChildren.pdf. Accessed June 11, 2019
20. Council on Community Pediatrics. Poverty and child health in the United States. *Pediatrics*. 2016;137(4): e20160339
21. High PC, LaGasse L, Becker S, Ahlgren I, Gardner A. Literacy promotion in primary care pediatrics: can we make a difference? *Pediatrics*. 2000;105(4, pt 2):927–934
22. Zero to Three. HealthySteps outcomes summary. Available at: https://www.healthysteps.org/article/healthysteps-outcomes-summary-20. Accessed August 26, 2019
23. Cates CB, Weisleder A, Dreyer BP, et al. Leveraging healthcare to promote responsive parenting: impacts of the Video Interaction Project on parenting stress. *J Child Fam Stud*. 2016;25(3): 827–835
24. Menting AT, Orobio de Castro B, Matthys W. Effectiveness of the Incredible Years parent training to modify disruptive and prosocial child behavior: a meta-analytic review. *Clin Psychol Rev*. 2013; 33(8):901–913
25. Beeson T, McAllister BD, Regenstein M. *Making the Case for Medical-Legal Partnerships: A Review of the Evidence*. Washington, DC: The National Center for Medical-Legal Partnership, Department of Health Policy, School of Public Health Services, George Washington University; 2013. Available at: https://medical-legalpartnership.org/wp-content/uploads/2014/03/Medical-Legal-Partnership-Literature-Review-February-2013.pdf. Accessed August 26, 2019
26. Prinz RJ, Sanders MR, Shapiro CJ, Whitaker DJ, Lutzker JR. Population-based prevention of child maltreatment: the U.S. Triple p system population trial. *Prev Sci*. 2009;10(1): 1–12
27. American Academy of Pediatrics; Committee on Child Health Financing. Essential contractual language for medical necessity in children. *Pediatrics*. 2013;132(2):398–401
28. American Academy of Pediatrics, Committee on Child Health Finance. Policy statement: high-deductible health plans. *Pediatrics*. 2014;133(5). Available at: www.pediatrics.org/cgi/content/full/133/5/e1461
29. Brot-Goldberg ZC, Chandra A, Handel BR. What does a deductible do? The impact of cost-sharing on health care prices, quantities, and spending dynamics. 2015. Available at: www.nber.org/papers/w21632. Accessed March 9, 2016
30. Agarwal R, Mazurenko O, Menachemi N. High-deductible health plans reduce health care cost and utilization, including use of needed preventive services. *Health Aff (Millwood)*. 2017; 36(10):1762–1768
31. Hudak ML, Helm ME, White PH; American Academy of Pediatrics, Committee on Child Health Financing. Principles of child health care financing. *Pediatrics*. 2017;140(3):e20172098
32. Cooley WC, Sagerman PJ; American Academy of Pediatrics; American Academy of Family Physicians; American College of Physicians; Transitions Clinical Report Authoring Group. Supporting the health care transition from adolescence to adulthood in the medical home. *Pediatrics*. 2011;128(1):182–200
33. Bailit Health. Value-based payment models for Medicaid child health services. 2016. Available at: https://uhfnyc.org/publications/publication/value-based-payment-models-for-medicaid-child-health-services/. Accessed June 11, 2019
34. Conners GP, Kressly SJ, Perrin JM, Richerson JE, Sankrithi UM; Committee on Practice and Ambulatory Medicine; Committee on Pediatric Emergency Medicine; Section on Telehealth Care; Section on Emergency Medicine; Subcommittee on Urgent Care; Task Force on Pediatric Practice Change. Nonemergency acute care: when it's not the medical home. *Pediatrics*. 2017; 139(5):e20170629
35. Sege R, Preer G, Morton SJ, et al. Medical-legal strategies to improve infant health care: a randomized trial. *Pediatrics*. 2015;136(1):97–106
36. Garg A, Toy S, Tripodis Y, Silverstein M, Freeman E. Addressing social determinants of health at well child care visits: a cluster RCT. *Pediatrics*. 2015; 135(2). Available at: www.pediatrics.org/cgi/content/full/135/2/e296
37. Redding M, Hoornbeek J, Zeigler BP, et al. Risk reduction research initiative: a national community-academic framework to improve health and social outcomes. *Popul Health Manag*. 2019;22(4):289–291
38. Bitsko RH, Holbrook JR, Robinson LR, et al; EdS. Health care, family, and community factors associated with mental, behavioral, and developmental disorders in early childhood—United States, 2011–2012. *MMWR Morb Mortal Wkly Rep*. 2016;65(9):221–226
39. Anderson B, Beckett J, Wells N, Comeau M. The eye of the beholder: a discussion of value and quality from the perspective of families of children and youth with special health care needs. *Pediatrics*. 2017;139(suppl 2):S99–S108
40. Bachman SS, Comeau C, Long TF. Statement of the Problem: health reform, value-based purchasing, alternative payment strategies, and children and youth with special health care needs. *Pediatrics*. 2017;139(suppl 2):S89–S98
41. Community Care Coordination Learning Network; Pathways Community HUB Institute. *Connecting Those at Risk to Care: The Quick Start Guide to*

Developing Community Care Coordination Pathways. A Companion to the Pathways Community Hub Manual. Rockville, MD: Agency for Healthcare Research and Quality; 2016

42. Redding S, Conrey E, Porter K, Paulson J, Hughes K, Redding M. Pathways community care coordination in low birth weight prevention. *Matern Child Health J.* 2015;19(3):643–650

43. Gleeson S, Kelleher K, Gardner W. Evaluating a pay-for-performance program for Medicaid children in an accountable care organization. *JAMA Pediatr.* 2016;170(3):259–266

Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening

Paul H. Lipkin, MD, FAAP,[a] Michelle M. Macias, MD, FAAP,[b] COUNCIL ON CHILDREN WITH DISABILITIES, SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS

abstract

Early identification and intervention for developmental disorders are critical to the well-being of children and are the responsibility of pediatric professionals as an integral function of the medical home. This report models a universal system of developmental surveillance and screening for the early identification of conditions that affect children's early and long-term development and achievement, followed by ongoing care. These conditions include autism, deafness/hard-of-hearing, intellectual and motor disabilities, behavioral conditions, and those seen in other medical conditions. Developmental surveillance is supported at every health supervision visit, as is as the administration of standardized screening tests at the 9-, 18-, and 30-month visits. Developmental concerns elicited on surveillance at any visit should be followed by standardized developmental screening testing or direct referral to intervention and specialty medical care. Special attention to surveillance is recommended at the 4- to 5-year well-child visit, prior to entry into elementary education, with screening completed if there are any concerns. Developmental surveillance includes bidirectional communication with early childhood professionals in child care, preschools, Head Start, and other programs, including home visitation and parenting, particularly around developmental screening. The identification of problems should lead to developmental and medical evaluations, diagnosis, counseling, and treatment, in addition to early developmental intervention. Children with diagnosed developmental disorders are identified as having special health care needs, with initiation of chronic condition management in the pediatric medical home.

[a]Department of Neurology and Development Medicine, Kennedy Krieger Institute, and Department of Pediatrics, Johns Hopkins School of Medicine, Baltimore, Maryland; and [b]Division of Developmental-Behavioral Pediatrics, Department of Pediatrics, Medical University of South Carolina, Charleston, South Carolina

Drs Lipkin and Macias equally participated in the concept and design, drafting, and revising of the manuscript and approved the manuscript as submitted.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

To cite: Lipkin PH, Macias MM, AAP COUNCIL ON CHILDREN WITH DISABILITIES, SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS. Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening. *Pediatrics*. 2020;145(1):e20193449

Pediatricians and other child health care professionals have made significant progress over the past decade in meeting the goal of early identification and treatment of children with developmental and behavioral disorders. There has been an increase in the practice of formalized developmental screening in primary health care settings. Specific efforts from within the American Academy of Pediatrics (AAP)[1–6] and external to the AAP[7,8] have been focused on improving screening methods. Multiple efforts also have been made to improve implementation.[9–14] These initiatives have included broad guidelines focused on identifying general delays in development[1] as well as others to identify specific disorders or conditions.[2,3,6,15] The 2006 AAP policy statement on developmental surveillance and screening provided the pediatric health care professional with a new paradigm and an accompanying algorithm[1] that focused on the use of general, standardized developmental screening tests with strong psychometric properties, including reliability, validity, sensitivity, and specificity. Discrete ages for use of these tests are recommended in *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition* and the accompanying periodicity schedule at the 9-, 18-, and 30-month well-child visits.[16,17,*] The recommendation for screening at discrete ages contrasted with earlier statements in which screening at every visit was recommended. The algorithm was designed to fit within the medical home model of care and with use in the screening of all children during key preventive care visits. The policy statement offered guidance on consultation and referral to other specialty physicians as well as to other child development professionals, early intervention services, and preschool. It also recommended incorporating the principles of care for children with special health care needs in the primary care medical home. The policy statement also considered developmental screening payment issues and worked toward improving pediatric health care professionals' knowledge on billing and coding for the recommended procedures, resulting in improved payment across payers[18] (AAP, 2012, unpublished analysis of 2005 Medstat and 2011 TruvenHealth MarketScan outpatient database).

This developmental surveillance and screening model was incorporated into other initiatives and prompted the writing and revision of several similarly designed guidelines for related conditions, including autism spectrum disorder (ASD),[2] neuromotor disorders,[3] early hearing detection,[6] attention-deficit/hyperactivity disorder (ADHD),[19] and behavioral conditions.[5] These guidelines increased pediatric attention to these conditions and improved screening overall; however, universal screening still has not been achieved. AAP surveys of pediatricians report screening rates of 23% in 2002, 45% in 2009, and 63% in 2016.[20,21] Pediatricians have reported difficulties in incorporating multiple new guidelines for related conditions into their practices[22] and continue to report time limitations and inadequate payment as barriers to implementation.[21]

Although there are similarities among recommended screening strategies for delays and disabilities in cognitive disorders, motor disorders, language disorders, autism, and social-emotional and behavioral disorders, there are also substantive differences in their timing, measurement, and implications for intervention. Thus, this revision of the 2006 policy statement describes only the first category. Future reports will provide detailed recommendations regarding screening for ASD and social-emotional and behavioral disorders. The algorithm is intended to serve as a model for the refinement of a universal system of screening of all children in the primary care setting, as illustrated in Fig 1.

This universal system would include the wide range of neurodevelopmental and behavioral conditions that affect the early and long-term development and achievement of children. These conditions include ASD; language disorders; and deafness or hard-of-hearing, also referred to as deafness, hearing loss (*International Classification of Diseases, 10th Revision* codes H91.90 through H91.93), or hearing impairment (the Individuals With Disabilities Education Act [IDEA])[23]; vision disorders; neuromotor conditions (such as cerebral palsy); neuromuscular disorders (such as Duchenne muscular dystrophy); intellectual and learning disabilities; and behavioral conditions (such as ADHD). At the same time, certain conditions have high rates of co-occurring developmental or behavioral disorders (eg, children born preterm or with other perinatal complications and children with complex congenital heart disease, sickle cell disease, intrauterine alcohol exposure, lead toxicity, congenital infections, and other chronic health conditions). Especially vulnerable to developmental and/or behavioral problems are those negatively affected by the social determinants of health and other adverse childhood or family experiences such as children in poverty[24]; children exposed to racism[25]; and children experiencing toxic stress, including exposure to abuse, neglect, parental mental illness, parental drug or alcohol use,

* Developmental screening has traditionally been recommended at the 24-month well-child visit, and since 2006, has been recommended at the 30-month visit. Screening for ASD is still recommended at the 18- and 24-month visits.

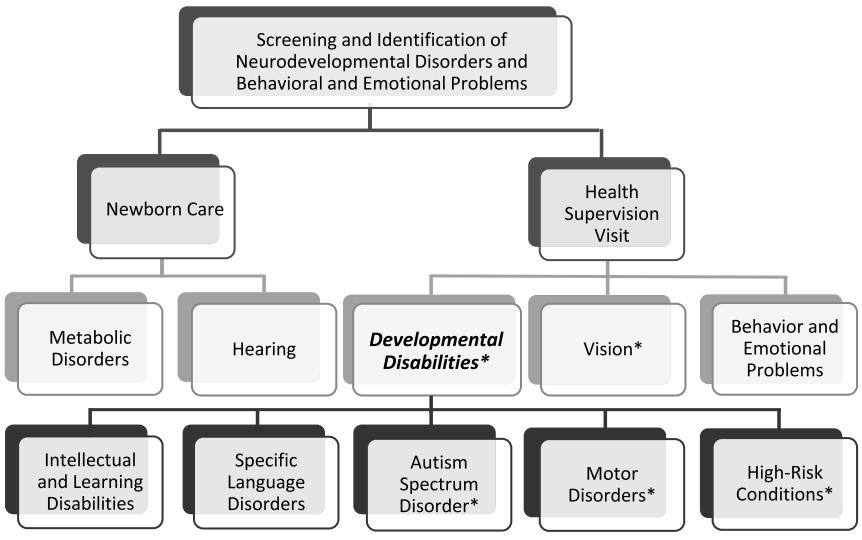


FIGURE 1
Early childhood screening for the identification of neurodevelopmental disorders and behavioral and emotional problems. (Content with an asterisk corresponds to current AAP guidance, using broad categories. This figure may not be inclusive of all specific developmental and behavioral disorders.)

caregiver depression, and foster care. Screening principles being used in developmental surveillance and screening of children without known developmental risks can be applied universally, including use in the identification of developmental and behavioral conditions in children with chronic health conditions. Additionally, given the importance of coordinated patient- and family-centered care in pediatrics, families should be engaged as collaborative partners in developmental screening and surveillance practices. The act of screening itself provides engagement conversations and builds relationships with families. The algorithm and discussion that follow can be used to guide pediatric health care professionals through the surveillance and screening process for the early identification of developmental disorders, including autism; it is important to note that this algorithm is focused on children who do not have already identified risks or developmental problems.

Although this clinical report is focused on children ages 0 to 5 years, these recommendations may be considered a minimum and are not intended to be prescriptive. National and international groups focused on young children concur that early childhood spans ages 0 to 8 years and endorse screening beyond age 3 years. The US Administration for Families, Office of Planning, Research and Evaluation[26] states that to be effective, screening should begin early and be repeated through early childhood. Therefore, it is argued that developmental screening may need to be more frequent to optimize the opportunities for detection of risk and connection to intervention.

NOTE ON TERMINOLOGY

As in the previous policy statement, clear distinctions are drawn within the context of this document among (1) surveillance, the process of recognizing children who may be at risk for developmental delays; (2) screening, the use of standardized tools to identify and refine that recognized risk; and (3) evaluation, a complex process to identify specific developmental disorders that affect a child. "Developmental disorder" and "developmental disability" refer to a childhood mental or physical impairment or combination of mental and physical impairments that result in substantial functional limitations in major life activities.[27]

THE ALGORITHM

The algorithm (Fig 2) presents steps for screening a patient without identified risks for developmental problems at a health supervision visit.

Step 1: Patient Without Identified Risks or Developmental Problems Arrives for Health Supervision Visit

A parent's or professional's developmental concerns should be addressed by the pediatric health care professional as part of developmental surveillance at each pediatric health supervision visit throughout the first 5 years of life, as outlined in the AAP *Bright Futures, Fourth Edition* and related national health promotion and prevention initiative.[16,17] In multiple studies, researchers have shown that developmental disorders are detected at low rates when physicians rely on judgment alone.[28] Including developmental screening tests at targeted ages enhances the precision of the developmental surveillance process.[29]

The recommended ages for developmental screening at the health supervision visit are a starting point for children who are without known identified risks and are not suspected of having a developmental concern. Because development is dynamic in nature and surveillance has limits, periodic screening with a validated instrument should occur so that a developmental concern not detected by surveillance or an earlier screening can be detected by subsequent screening. Using a validated developmental screening test at the 9-, 18-, and 30-month visits is outlined in *Bright Futures, Fourth Edition*.[16,17] Developmental surveillance should continue through childhood, including surveillance at the 4- or 5-year visit as a child prepares to enter elementary school.

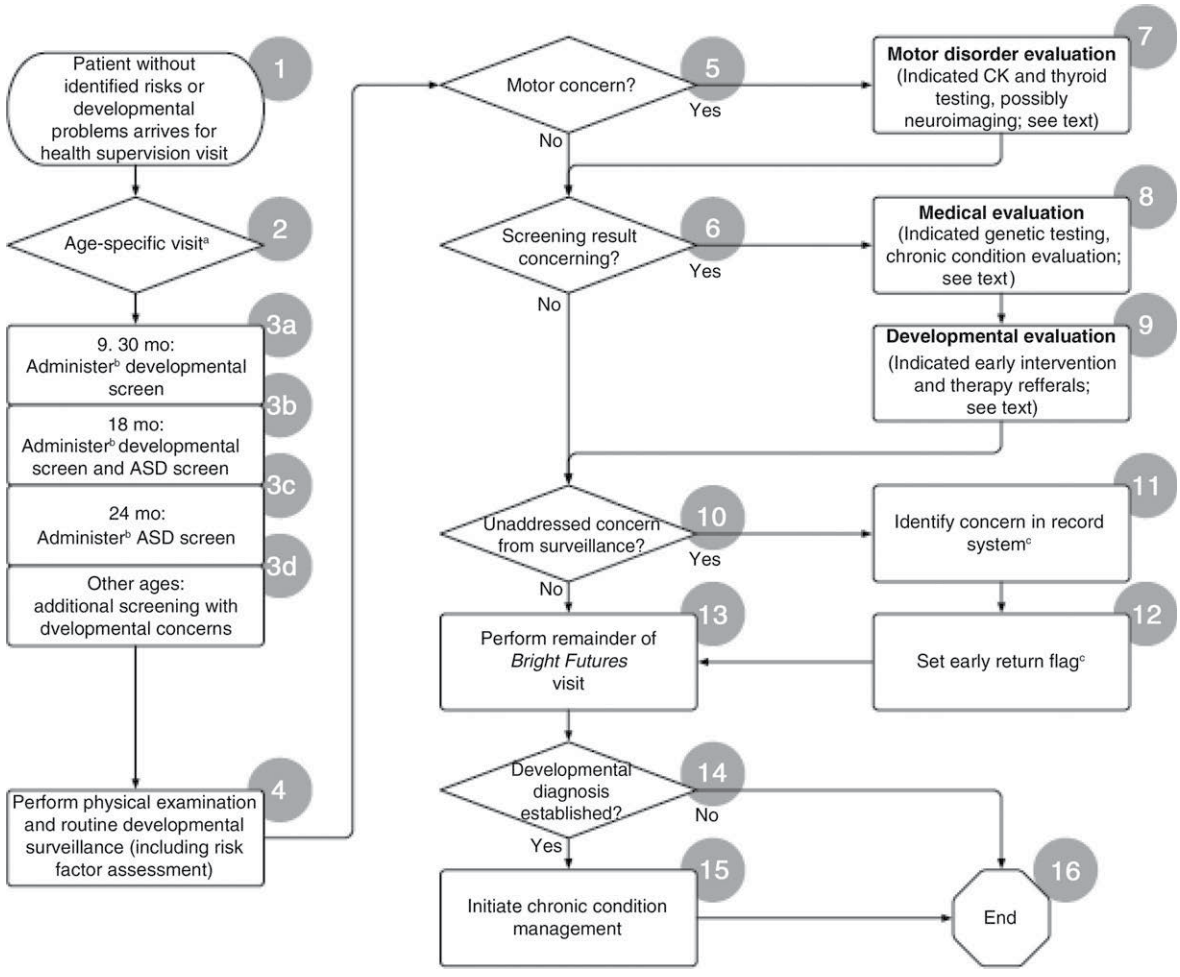


FIGURE 2

Algorithm for screening a patient without identified risks for developmental problems at a health supervision visit. Numbers and headings refer to steps in the algorithm. [a]To identify problems not previously recognized during earlier screenings, clinicians should pay particular attention to developmental surveillance at the age 4- or 5-year visit, before entering kindergarten. Developmental surveillance should continue throughout childhood. [b]Screening instruments may be administered through a previsit process initiated by the practice or by the family. [c]Providers should create methods in their record system (paper or electronic) to ensure that these facts are visible to clinicians in future visits and in the appointment scheduling process. CK, creatine kinase.

Any time that parents, professionals, or others involved in the care of the child raise concerns during surveillance, it is appropriate to perform additional developmental screens using validated tests. These screenings should be recognized separately, with appropriate coding, billing, and payment and with the additional cost acknowledged in capitated expectation (see Supplemental Information).

Given that developmental and behavioral risks increase with age, a child identified with risks or concerns may merit at least annual formal screening if concerns continue to be identified through surveillance.

Step 2: Is This a 9-, 18-, 24-, or 30-Month Visit?

All children should receive periodic developmental screening using a standardized test. In the absence of established risk factors or parental or provider concerns, a general developmental screen continues to be recommended at the 9-, 18-, and 30-month visits. Screening for behavioral and emotional problems is recommended at the same time points, at a minimum.[5] In addition, screening for ASD is recommended at the 18- and 24-month visits.[30]

In addition, to identify problems not previously recognized in earlier screenings and to identify issues with regard to developmental skills necessary for school readiness,[31] surveillance, with close attention to these developmental skills necessary for school readiness, should be performed at the 4- or 5-year visit, with screening performed when concerns are noted. Additional information about the pediatrician's role in promoting school readiness, as well as developmental surveillance

for school readiness, can be found in the AAP policy statement, "The Pediatrician's Role in Optimizing School Readiness."[31] Given the lack of strong evidence validating screening at the 4- to 5-year visit, universal screening is not presently recommended as part of the periodicity schedule.

Step 3: Administer Screening Test

The administration of a brief, standardized screening test helps identify children at risk for a developmental disorder. Well-validated screening tests can be completed by parents and scored by office staff. The pediatric health care professional interprets the screening results.

Developmental screening does not result in a diagnosis but rather identifies areas in which a child's development differs from same-aged norms. Repeated and regular screening is more likely than a single screen to identify problems, especially in skills that develop later, such as language. Waiting until a young child misses a major milestone may result in late rather than early recognition, increasing parental dissatisfaction and anxiety, and can deprive the child and family of the benefits of early identification and intervention.

A table of developmental screening tests is included in this document (Supplemental Table 1), and a discussion of how to choose an appropriate screening test is included in the section below entitled "Implementing the Algorithm."

9- and 30-Month Visits: Administer Developmental Screen

- A screening at the 9-month visit provides an opportunity to attend to the child's motor, visual, and hearing abilities. Early communication skills also are emerging, and symptoms of ASD, such as lack of eye contact, orienting to name being called, or pointing, may be recognizable in the first year of life.[32,33] Infants 9 months of age who have a medical condition that increases risk for developmental disorders, such as a genetic condition or significant perinatal complications, should be referred to early intervention programs, if not previously referred. The 9-month visit also provides an educational opportunity to inform parents about developmental screening and to encourage parents to attend to communication and early language skills. Social and nonverbal communication, including vocalizations and gestures, are important aspects of emerging communication that can be assessed at this visit. Although ASD is not diagnosed at this age, social and emotional delays may qualify a child for early intervention programs (eg, Part C, IDEA [0–36 months])[23,33] and provide valuable support to a family.
- The 30-month visit provides an additional opportunity to identify motor, language, and cognitive problems, including more subtle delays, and represents another opportunity to identify the child with delays qualifying for early intervention services. An early intervention program also assists the child and family in transition to a school-based program as needed.
- As noted previously, this updated clinical report recommends developmental surveillance through childhood, with particular attention to surveillance and administration of a formal screening test at the 4- or 5-year visit when developmental risks, concerns, or problems occur. As age increases, corresponding increases in delays are seen.[34,35] Without routine screening, at least 50% of children with developmental or behavioral disorders are not detected before kindergarten.[36] Therefore, administration of a standardized developmental screen at 4 years of age for children with developmental concerns or risks may improve detection and referral of a child with previously unrecognized learning and attention disorders to the school system or other resources before his or her entry into kindergarten. Additional behavioral surveillance may also help identify ADHD symptoms at preschool age, when behavioral therapy and behavioral parent training may be especially helpful. In addition, symptoms of ASD may become more apparent after children become more verbal and are in the social milieu of preschool. Children 5 years of age who are not yet in kindergarten should receive continued close surveillance followed by screening, if concerns arise.

18-Month Visit: Administer Developmental Screen and ASD Screen

- A developmental screen is recommended at the 18-month visit because delays in fine motor, communication, and language development are often evident by 18 months of age, as are previously undetected gross motor delays. Medical interventions for motor disorders have been shown to be effective in children age 18 months, and effective early intervention for delayed language development also is available.[37]
- In addition to a general developmental screening test, an ASD-specific screen should be administered to all children at the 18-month visit, as originally recommended in 2006.[1] Early symptoms of ASD are often present at this age, and effective early intervention strategies are available.[38,39] Current evidence supports screening for ASD at both the 18- and 24-month visits because ASD symptomatology may be identified after 12 months of age, with accurate screening by 18

months.[40] However, a recent systematic review of primary care screening for ASD by the US Preventive Services Task Force (USPSTF) concluded that insufficient evidence existed on potential benefits and harms of such screening and that, therefore, it was unable to make a recommendation for or against such screening.[41] The USPSTF also called for further research on the screening tests, best ages for screening, and best treatment of those identified.[41] Screening by pediatric health care professionals continues to be recommended for the early identification of and intervention for ASD, while research continues.[42] Children with ASD demonstrate sleep, eating, and behavioral challenges in early childhood, and the pediatric health care professional can help the family manage these issues directly and through appropriate referrals and connect families to valuable peer support organizations.

- Close surveillance and earlier screening remains warranted if a child is at high risk for ASD, for example, if symptoms are present, the child has a sibling with ASD, the child has a genetic condition with known ASD risk, or the child has a history of prematurity or prenatal exposures (such as toxins or infection).[43] Research shows that behaviors concerning for ASD emerge earlier than 18 months of age.[33] Therefore, incorporation of surveillance for "red flags" into health supervision visits before formal screening at the 18- and 24-month visits is recommended.[30] (Note: the USPSTF did not address high-risk individuals.)

24-Month Visit: Administer ASD Screen

- An ASD-specific screen should again be administered to all children at the 24-month visit to further ensure the early identification of children with ASD.

Other Ages: Additional Screening With Developmental Concerns

If parents, pediatric health care professionals, or others involved in the care of the child raise concerns at other times about the child's development, it is appropriate to perform additional developmental screens using validated tests. This screening may require a separate visit and should be conducted as soon as possible.

Additionally, if a child has missed a 9-, 18-, or 30-month visit, a developmental screen should be administered at the next opportunity.

Step 4: Perform Physical Examination and Routine Developmental Surveillance (Including Risk Factor Assessment)

When the results of the periodic screening test are normal, the pediatric health care professional can inform the parents that, at this time, the child is at low risk for a developmental disorder and continue with other aspects of the health supervision visit.[17] Normal screening results provide an opportunity to focus on developmental and behavioral health promotion.[44]

Developmental surveillance continues to be defined with this report as a flexible, longitudinal, continuous, and cumulative process in which knowledgeable health care professionals identify children who may have developmental problems.[1,45] Surveillance also can be useful for determining appropriate referrals, providing patient education and family-centered care to support healthy development, and monitoring the effects of developmental health promotion through early intervention and therapy. Because a great breadth and depth of information, including health and developmental risk factors and previous screening results, is accumulated across a child's life through developmental surveillance, relevant developmental information should be flagged and available for review before or at each visit.

Developmental surveillance has 6 components: (1) eliciting and attending to the parents' concerns about their child's development; (2) obtaining, documenting, and maintaining a developmental history; (3) making accurate and informed observations of the child; (4) identifying risks and strengths and protective factors; (5) maintaining an accurate record of the process and findings; and (6) sharing and obtaining opinions and findings with other professionals, such as child care providers, home visitors, preschool teachers, and developmental therapists, especially when concerns arise.[45] In this updated report, additional emphasis is added to surveillance on the obtaining and sharing of information with professionals from outside of the medical home.

Eliciting and Attending to the Parents' Concerns

By asking about parents' concerns, the pediatric health care professional can elicit important information about the child's development, learning, or behavior.[46–48] A parent also may bring the results of screening or evaluation by an outside professional to the pediatrician's attention, particularly if concerns are noted.[49] In such instances, the pediatric health care professional should seek information on the test performed and its results for review and discussion with the family. Direct discussion with the outside professional about these concerns also may be beneficial. Discussions with the family or outside professionals should be documented in the medical record. The absence of parental or professional concern does not preclude the possibility of serious developmental delays, however.[50]

Obtaining, Documenting, and Maintaining a Developmental History

A developmental history is a vital component of any history taken during a health supervision visit. By asking questions about changes parents have seen in their child's development since the last visit or observing age-specific developmental skill attainment, such as whether the child is walking or pointing, the pediatric health care professional may identify delays or other abnormalities in a child's development that warrant further investigation.[51] Developmental milestones and "red flag" resources are available, including the Centers for Disease Control and Prevention's (CDC) "Learn the Signs. Act Early" program Web site (http://www.cdc.gov/ncbddd/actearly/)[13] and the AAP Screening Technical Assistance and Resource Center Web site (www.aap.org/screening), to engage families and other professionals as collaborative partners in surveillance.

Making Accurate and Informed Observations of the Child

As trained and experienced professionals, pediatricians and other pediatric health care professionals have the expertise and comparative knowledge to identify developmental concerns. A careful physical and developmental examination within the context of the health supervision visit is integral to developmental surveillance.[52] Limited evidence suggests observation of the parent-child interaction also may aid in identifying children with delayed development.[53]

Identifying Risks and Strengths and Protective Factors

A risk assessment is an important part of developmental surveillance. Environmental,[54] genetic, biological,[52,55] social, and demographic factors[56] can increase a child's risk for delays in development. Multiple risk factors can amplify each other.[57,58] Children with established risk factors may be referred directly for developmental evaluation and early intervention services or may require developmental surveillance at more-frequent intervals than children without risk factors.

Some medical conditions can increase a child's risk for developmental delays. These conditions include perinatal complications (eg, preterm delivery, low birth weight, intrauterine alcohol exposure, and hypoxic-ischemic encephalopathy), congenital and other neurologic conditions (eg, myelomeningocele, congenital brain anomalies, and epilepsy), complex congenital heart disease, genetic conditions, and other chronic conditions (eg, sickle cell disease).

Evidence is mounting about the negative effects of early adverse childhood events, which may cause or lead to "toxic stress," on brain architecture and child development and behavior.[59] Poverty and associated risk factors, such as food insecurity and caregiver depression, adds risk for developmental delays. Children who have these adverse experiences would meet the federal Maternal and Child Health definition of being at risk for having special health care needs.[60]

Using the strength-based approach, as exemplified in the AAP *Bright Futures, Fourth Edition*,[17] pediatric health care professionals should identify strengths and protective factors as well as risk factors in children's lives. Strong connections within a loving, supportive family, along with opportunities to interact with other children and grow in independence in an environment with appropriate structure, are important assets in a child's life. These factors, associated with resiliency in children, are important components of healthy development.[61,62] Similarly, strong systems of community supports, including local schools and public, private, and faith-based organizations, can play an important role in supporting the development and well-being of all children, including those with known developmental risks.

Maintaining an Accurate Record of the Process and Findings

Medical records should document the outcome of all surveillance and screening activities during preventive care visits. Additionally, specific actions taken or planned, such as scheduling an early follow-up visit, scheduling a visit to discuss developmental concerns more fully, or referrals to medical specialists or early childhood programs and specialists, also should be noted as part of developmental surveillance and screening. A record might contain a table in which the date of administration and the results of developmental surveillance and formal screens are recorded in relationship to the child's age. If electronic health records are used, developmental findings and plans can be recorded, with automatic prompts created for further action.

Sharing and Obtaining Opinions and Findings With Other Professionals

Although developmental surveillance is performed in the pediatric medical home, the opinions and findings obtained by the pediatric health care professional about the child's development have importance beyond this setting. In particular, a wide range of other professionals may be engaged with the young and developing child and would benefit from conclusions reached by the pediatric health care professional's regular ongoing developmental surveillance. These include child care providers, home visitors, preschool teachers, and developmental therapists. At the same time, some also are likely making observations of their own of the child's development and may be performing their own

developmental screening, as promoted by the "Birth to 5: Watch Me Thrive!" program.[49] Early intervention therapists also may be actively engaged with the child for both evaluation and treatment of developmental concerns. Consistent with the team-based approach, coordination of care with 2-way communication between the patient- and family-centered medical home and entities outside the medical home needs to be systematic and consistent.[63] Any entity outside the medical home that provides screening should have a systematic approach to communication of screen results, both positive and negative, to the medical home. Communication between a member of the medical home staff and these professionals on the child's development is, therefore, a critical part of surveillance to ensure optimal care and coordination of efforts and activities to optimize the child's development.[64–66] When screening or evaluation is performed by another professional, these results must be shared and discussed with the parent and the pediatric health care professional, including the test performed and the results obtained. The "Birth to 5: Watch Me Thrive!" program offers a free screening passport to aid in sharing screening results. Direct communication between the pediatric health care professional and the other professional may be helpful.[64] It should be noted that such communication, particularly electronic communication, is subject to Health Insurance Portability and Accountability Act of 1996 security requirements and must be protected.

This additional information may increase the complexity of the patient encounter. If the screen was recently completed, interpretation, documentation, and related action are recommended, with possible changes in the complexity of the encounter resulting in a higher-level visit. An updated screen may need to be completed if months have elapsed since the outside screening because of rapid changes in the child's development. Pediatric health care professionals should not submit bills for screening processes performed outside the medical home, but the charge for their services could reflect any applicable increase in complexity of medical decision-making.

Step 5: Does the Screening Suggest a Motor Concern?

If the screening results suggest a motor concern, a motor disorder evaluation should be conducted (see Step 7: Perform Motor Disorder Evaluation).

Step 6: Is the Screening Result Concerning?

If screening results are negative or not concerning, the pediatric health care professional can proceed to Step 10: Unaddressed Concern From Surveillance? If there is an unaddressed concern, identify the concern in the record system and set an early return flag before proceeding to Step 13. If there is no concern, proceed to Step 13: Perform Remainder of Health Supervision Visit. If screening results are concerning, a focused history and physical examination should be completed to identify any previously undetected medical conditions (see Step 8: Perform Complete Medical Evaluation below). The physical examination should target physical stigmata suggestive of an underlying genetic abnormality. The neurologic examination may suggest an underlying neurologic condition. The general physical examination may identify undetected medical conditions (eg, cardiac, renal, hematologic disease).

For a child who is determined by the pediatric health care professional to be at increased risk for a developmental disorder on the basis of medical, environmental, or social factors, referral to early intervention (under IDEA Part C[23,67]) or preschool special education (under IDEA Part B)[23,68] is recommended.

Reassurance has a role in the clinical encounter but varies depending on the progress and outcome of developmental surveillance and screening. Reassurance should be rooted in and reference the findings of developmental surveillance and screening. If, for example, developmental surveillance or screening does not identify a concern, specific, simple, age-specific developmental goals can be identified, and parents can be encouraged to schedule follow-up appointments if the child is not attaining those goals. Discussion of normal screening results should also include promotion of developmental and behavioral skills. In reassuring the parents, the pediatric health care professional should emphasize the importance of continual surveillance and screening. Enrollment in Early Head Start or Head Start, child care, or early childhood education should be considered, if appropriate.

Step 7: Perform Motor Disorder Evaluation

The child with motor concerns identified on surveillance and/or screening should undergo a comprehensive neurologic examination. When tone is increased, brain imaging should be considered. The child with normal or decreased tone should have laboratory testing of creatine kinase and thyroid-stimulating hormone.[3] More detailed guidance can be found in the AAP clinical report "Motor Delays: Early Identification and Evaluation."[3]

Step 8: Perform Complete Medical Evaluation

A medical diagnostic evaluation should be undertaken to identify an underlying etiology when the child's development is concerning or a delay is confirmed. This evaluation should consider biological, environmental,

and established risk factors for delayed development.[69–72] Audiologic evaluation should be performed for the child with a developmental concern. Vision screening,[15] review of newborn metabolic screening and hearing screening, growth review, and an update of environmental, medical, family, and social history for additional risk factors are also integral.

Further medical evaluation will vary with the risk factors, and findings may suggest further genetic, neurologic, metabolic, or other medical testing. The child with suspected global developmental delay or intellectual disability should have laboratory testing done, including chromosomal microarray and fragile X testing.[30] Metabolic testing should be considered if indicated by history and physical examination.[73] Further testing may be indicated when a diagnosis is not established with initial laboratory evaluation, including whole exome sequencing and gene panels. Brain imaging should be considered in the presence of abnormal neurologic examination, microcephaly, macrocephaly, or other clinical indicators. The initial genetic workup of the child with suspected ASD is evolving; current recommendations also include chromosomal microarray and fragile X testing.[30] Consultation with a medical geneticist to help guide the genetic workup should be considered. The pediatric health care professional should make additional specialty referrals as needed or when additional testing is warranted.

Identification of an etiology may give parents a greater depth of understanding of their child's disability. It also can affect various aspects of treatment planning, including specific prognostic information, genetic counseling around recurrence risk and heritability, specific medical treatments for improved health and function of the child, and therapeutic intervention programming.[74] This evaluation can be initiated by a general pediatrician or through a pediatric medical subspecialist, such as a neurodevelopmental pediatrician, pediatric neurologist, developmental-behavioral pediatrician, pediatric geneticist, or pediatric physiatrist. The pediatric health care professional within the medical home should develop an explicit comanagement plan with subspecialist(s) and care coordination with the family.

Step 9: Perform or Refer for Developmental Evaluation and Refer to Early Intervention or Early Childhood Education

If screening results performed either in the primary care medical home or in the child's child care or preschool are concerning, the child should have a comprehensive developmental evaluation performed. This evaluation may occur at a different visit or in a series of visits in the primary care medical home or in a different setting by developmental or other medical professionals. The visits should be scheduled as quickly as possible, and professionals should coordinate activities and share findings. Tracking of referrals should be incorporated to ensure follow-up.

Developmental Evaluation

When developmental surveillance or screening identifies a child as being at high risk for a developmental disorder, diagnostic developmental evaluation should be pursued. This evaluation will help to identify the specific developmental disorder or disorders affecting the child, thus providing further prognostic information and allowing prompt initiation of specific and appropriate early childhood therapeutic interventions.

Children with neurodevelopmental disorders often have co-occurring areas of developmental or behavioral problems.[75–77] For example, a child with ASD may have an intellectual or learning disorder, ADHD, anxiety disorder, or a motor coordination disorder. Similarly, the child with cerebral palsy often has problems in these same areas as well as in speech and language development. Identifying these disorders can lead to further evaluation and additional treatments. Pediatric medical subspecialists, such as neurodevelopmental pediatricians, developmental-behavioral pediatricians, pediatric neurologists, and pediatric physiatrists, as well as advanced practice nurses, can perform the developmental diagnostic evaluation, as can other early childhood professionals, in conjunction with the child's pediatric health care professional. These early childhood professionals include early childhood educators, child psychologists, speech-language pathologists, audiologists, social workers, physical therapists, or occupational therapists, ideally working with families as part of an interdisciplinary team and in coordination and communication with the medical home.

Early Developmental Intervention and Early Childhood Education Services

Early intervention programs can be particularly valuable when a child is first identified to be at high risk for delayed development because these programs can provide evaluation services and offer other services to the child and family even before an evaluation is complete.[68,78] Suggestions for effective collaboration and communication between the patient- and family-centered medical home and early childhood education programs are outlined in the AAP policy statement "Patient- and Family-Centered Care Coordination: A Framework for Integrating Care for Children and Youth Across Multiple Systems" (see Supplemental Table 1, Care Coordination Tools and Organizations Supporting Care Coordination).[63]

Early intervention and early childhood education programs include federally funded programs, such as IDEA Part B and C services, Early Head Start, and Head Start, but also encompass quality preschools and parent education programs. These programs provide services that can include developmental therapies, service coordination, social work services, assistance with transportation and related costs, family training, counseling, and home visits.[23] The diagnosis of a specific developmental disorder is not necessary for an early intervention referral to be made. Pediatric health care professionals should realize that a community-based early intervention evaluation may not address children with specific medical risks, and further developmental and medical evaluation will often be necessary for children with established delays. The CDC provides a list of early intervention contact information for US states and territories.[67] Tracking of referrals and good communication with the families should be incorporated to ensure follow-up. This has been found to be problematic in some systems in which a minority of families ultimately connect with early intervention programs, are evaluated, and receive services.[79]

Step 10: Unaddressed Concern From Surveillance?

If concerns were raised during developmental surveillance (see Step 4: Perform Physical Examination and Routine Developmental Surveillance), but a disorder or condition was not identified, the pediatric health care professional should document the concern in the practice's record system (see Step 11: Identify Concern in Record System) and continue to monitor the child's developmental progress. An early return visit is recommended to provide additional developmental surveillance (see Step 12: Set Early Return Flag). Likewise, if concerns were raised during developmental surveillance (Step 4) but developmental screening was unable to be completed, the concern should be noted in the record system (Step 11) and flagged for an early return visit (Step 12), and the return visit should be held as soon as possible. If concerns are significant, then direct referral to early intervention is appropriate.

Step 13: Perform Remainder of Health Supervision Visit

When the results of the periodic screening test are normal (Steps 4 and 6), the pediatric health care professional can inform the parents that at this time, the child is at low risk for a developmental disorder, and continue with other aspects of the preventive visit.[17] Discussion of normal screening results provides an opportunity to focus on developmental and behavioral promotion using a strengths-based approach.

If developmental surveillance did not identify a concern and the child was not at high risk for or identified with a developmental or behavioral disorder or a chronic health condition, the pediatric health care professional should schedule the next health supervision visit after completing the examination and visit.

Steps 14 and 15: Developmental Diagnosis Established? and Initiate Chronic Condition Management

When a developmental disorder has been diagnosed in a child, that child meets the criteria for a child with special health care needs.[60] The child should be identified by the medical home for appropriate chronic condition management and regular monitoring and entered into the practice's registry of children and youth with special health care needs.[60]

The child may be assigned a care coordinator from the practice or from the community who will work with the family to ensure that all needed services can be accessed. Proactive care planning is needed, and routine follow-up with the medical home between health supervision visits may be warranted to assess progress and minimize unmet family needs.

The child health professional should actively participate in all care coordination activities for children who have complex health conditions in addition to developmental problems. Decisions regarding appropriate therapies and their scope and intensity should be determined in consultation with the child's family, therapists, and educators (including early intervention or school-based programs) and should be based on knowledge of the scientific evidence for their use.

Children with established developmental disorders often benefit from referral to community-based family support services, such as respite care, parent-to-parent programs, Parent Training Information Centers (http://www.parentcenterhub.org/find-your-center), and advocacy organizations. Some children may qualify for additional benefits, such as Supplemental Security Income, public insurance, waiver programs, and state programs for children and youth with special health care needs (Title V Maternal and Child Health Block Grant Programs).[80] Parent organizations, such as Family Voices,[81] Family-to-Family Health Information Centers,[82] and condition-specific associations, can provide parents with information and support and can provide an opportunity for advocacy.

IMPLEMENTING THE ALGORITHM

Choosing Developmental Screening Tests

No single screening test is appropriate for all children of all ages. Currently available screening tests vary from broad general

developmental screening tests to those screening for specific conditions, such as ASD, and others that focus on specific areas of development, such as communication skills. Broad screening tests are designed to address all developmental domains, including fine and gross motor development, language and communication, cognitive development, adaptive development, and social-emotional development. Their psychometric properties vary in characteristics, such as their standardization, the comparison group used for determining sensitivity and specificity, and population risk status. Screening tests also need to be culturally and linguistically sensitive.

Many screening tests are available, and the choice of which test to use depends on the population being screened, the types of problems being screened for in that population, administration and scoring time, any administration training time, the cost of the test, ease of fit into practice workflow, and the possibilities for adequate payment.

Screening tests should be both reliable and valid, with good sensitivity and specificity. Positive predictive value (PPV) and negative predictive value (NPV) must also be considered. A test that incorrectly identifies a child as delayed will result in overreferrals. A test that incorrectly identifies a child as typically developing will result in underreferrals. For developmental screening tests, scoring systems must be developed that minimize under- and overreferrals. Trade-offs between sensitivity and specificity occur when devising these scoring systems.[83] All indices (sensitivity, specificity, PPV, and NPV) are dependent on the gold standard used in the clinical evaluation and would vary as a function of the clinical measure(s) used and the cutoff selected (eg, –1 to 1.5 SD). Overidentification of children by using standardized screening tests may indicate that this group of children includes some with below-average development and/or significant psychosocial risk factors.[84] These children may benefit from other community programs to support the family and child as well as closer monitoring of their development by their families, pediatric health care professionals, and teachers or caregivers. Combining developmental surveillance and periodic screening increases the opportunity for identification of undetected delays in early development (Text Box 1).

A list of developmental screening tests and their psychometric testing properties is included in this document (Supplemental Table 1). These screening tests, which are focused on parent-completed tools, have acceptable psychometric properties. The list is not exhaustive, and other standardized, published tests are available. Additional tests are under development. Pediatric health care professionals are encouraged to familiarize themselves with a variety of screening tests and choose those that best fit their populations, practice needs, and skill level. Given the continual evolution of such screening tests, establishing a system for annual review of current and newly available screening tests and the dissemination of the results would be useful to provide guidance to pediatric health care and other professionals on the validity of currently available screening tests for use in the primary care medical home.

Incorporating Surveillance and Screening in the Medical Home

Incorporating developmental surveillance and screening into the pediatric office setting has been successfully achieved through the use of a "whole-office," team-based approach. Implementation projects[9,11,85–92] have demonstrated success with the pediatric health care professional or clinical team leading the office team in integrating the practice into the clinic flow. The process may begin in the child's home or at office visit registration and continue through the child's visit with the pediatric health care professional in the medical office or clinic room. With the assistance of office staff, parents can complete parent-report paper or electronic developmental

TEXT BOX 1 DEVELOPMENTAL SCREENING TEST PROPERTIES

Developmental Screening Test Properties

Reliability: ability of a test to produce consistent results

Validity: ability of a developmental screening test to discriminate between a child at a determined level of risk for delay (ie, high, moderate) from the rest of the population (ie, low risk)

Sensitivity: accuracy of the test in identifying delayed development. Those incorrectly identified as typically developing by the test are false-negatives

Specificity: accuracy of the test in identifying children who are not delayed. Those incorrectly identified as delayed by the test are false-positives

PPV: the proportion of children with a positive test result who are truly delayed; the lower the prevalence or base rate of the disorder, the lower the PPV

NPV: the proportion of children with negative test results who do not have developmental delays; this is also influenced by the prevalence of the disorder

Prevalence rate: No. children in population with a disorder, measured at a given time

Base rate: rate of a given disorder

General screening test: a test that evaluates multiple areas of development

Domain-specific screening test: a test that evaluates one area or domain of development (eg, motor or language)

Disorder-specific screening test: a test aimed at identifying a specific developmental disorder (eg, ASD)

surveillance and screening forms either before the office visit or within the medical office itself. A quality improvement approach may be the most effective means to build surveillance and screening elements into the process of care.[93] In addition to the use of office staff for distribution of surveillance or screening tests to families, team members can help with surveillance through observation of behaviors, interactions, and language. When a concern has been identified, office-based procedures can be used to schedule preventive care or follow-up visits, flag children with established risk factors, and help families with referrals to early intervention, developmental specialists, and pediatric medical subspecialists as needed. With the introduction of developmental screening to child care and early childhood programs, office staff also can serve as links between the family, the programs, and the child's medical home. Nonphysician staff also may score developmental screening tests, with interpretation and discussion with the family by the pediatric health care professional.

Since the publication of the 2006 policy statement, many local, state, and national initiatives have been used to increase developmental surveillance and screening practices in pediatric clinical programs. The results include major increases in screening rates, often with a majority of children screened.[9,21,85–92] However, in one study, rates of screening in family medicine practices for ASD have been reported to be lower.[94] Feasibility and effectiveness of parent-report screening tools also have been verified.[9,21,86,88] However, despite the success of screening, a few studies have shown that rates of referral to early intervention were good but not universal, and referrals to specialists were low.[9,77,86,89,95–97] Establishing an effective and efficient partnership with early childhood professionals is an important ingredient of successful care coordination for children within the medical home.[63] The federal government is supporting these partnerships through its "Birth to 5: Watch Me Thrive!" program,[49] which is particularly centered on universal developmental and behavioral screening for children across settings. The partnership includes early care and education providers, early intervention service and early childhood special education providers, child welfare professionals, home visitors, behavioral health providers, housing and homeless shelter providers, as well as the community and the family. It is built on shared interest in the developmental outcomes of children and recognition of the different skill sets of child health professionals and educators.

Whenever possible, communities should attempt to coordinate resources; this is especially true in preventing delays in care or unnecessary duplication of service. National initiatives that are being implemented to address the low rate of early detection of developmental disorders, much within the context of system-building, also address the problem of successive fall-off between early detection, referral, and initiation of services. The Collaborative Improvement and Innovation Network initiatives[98] include quality improvement projects, home visiting programs, and screening at child care facilities, both public (eg, Head Start, Early Head Start) and private. These Collaborative Improvement and Innovation Network initiatives have evolved from an initial focus on screening to a comprehensive process of engaging families as partners, interpreting screening results in the context of the family, ensuring referral for comprehensive assessment and intervention, and ensuring linkage to services. Use of a computer-based decision support system built into an electronic health record system shows promise as a strategy for increasing screening as well as referral and tracking.[99] Electronic referral systems have also been suggested.[79]

SUMMARY

The early identification of young children with developmental disabilities can be achieved through the combined processes of developmental surveillance and developmental screening in the patient- and family-centered medical home. Developmental surveillance should be a component of every health supervision visit through discussion with a child's parent, with incorporation of information from other child care professionals when appropriate. Screening should be implemented through the use of standardized developmental screening tests with all children at the 9-, 18-, and 30-month visits and when such surveillance identifies concerns about a child's development. Implementation of screening can be performed under the direction of the pediatric health care professional through other clinic or office staff. Children with known high-risk conditions should have close developmental monitoring and intervention, as needed. A child with motor delay also should undergo careful physical examination and have specific laboratory testing performed for treatable neurologic disorders. ASD screening should be performed similarly to general developmental screening using an ASD-specific screening test at the 18- and 24-month visits until the time that accurate measures are validated for other ages.

When a child has a concerning screening result on developmental screening, further developmental and medical evaluations to identify the specific developmental disorders and related medical problems are

warranted. In addition, children who have concerning screening results for developmental problems should be referred to early intervention and early childhood services and scheduled for earlier return visits to increase developmental surveillance.

Children in whom a developmental disorder is diagnosed may be considered as children with special health care needs, and chronic condition management for these children should be initiated, as warranted.

CLINICAL GUIDANCE FOR DEVELOPMENTAL SURVEILLANCE AND SCREENING

For the Medical Home

1. Perform developmental surveillance for the child at every health supervision visit from early childhood through adolescence, and ensure that such surveillance evaluates the child comprehensively.
2. Establish working relationships and dialogue with local child care professionals, early childhood therapists and educators, home visitors, and other early childhood professionals for ongoing developmental surveillance and discussion of a child's screening results in the medical home or elsewhere.
3. Consider direct referral of the child to early intervention or preschool special education for performance of comprehensive developmental and medical evaluations when the child is determined to be at increased risk for a developmental disorder on the basis of medical, environmental, or social factors or when surveillance raises significant concerns for delay.
4. Administer a standardized developmental screening test for all children at the 9-, 18-, and 30-month visits and for those whose surveillance yields concerns about delayed or disordered development. Screening those with concerns observed on surveillance should especially be noted in children seen at the 4- or 5-year visits, at which surveillance may identify concerns not previously noted and that may be of importance on initiation of kindergarten or elementary school.
5. Administer a standardized ASD screening test for children at the 18- and 24-month visits and at any time for those whose surveillance yields concerns about delayed or disordered social development.
6. Undertake a medical diagnostic evaluation of a child when development is concerning to identify an underlying etiology and to provide related counseling and treatment.
7. Schedule early return visits for continued close surveillance of children whose surveillance raises concerns that are not confirmed by a developmental screening test. Such developmental concerns may include those of the parent, the pediatric health care professional, and other medical, educational, or early intervention professionals as well as known high-risk medical or social risk factors.
8. Refer the child for whom screening results are concerning to early intervention and early childhood programs and initiate medical workup, if indicated.
9. Refer the child for whom screening results are concerning for further developmental evaluation to identify a specific developmental disorder.
10. Initiate a program of chronic condition management for any child identified with a developmental disorder.
11. Establish linkages and collaborations with state and local community and government programs, services, and resources for assisting the child in need of special services or assistance.[63]
12. Document all surveillance, screening, evaluation, and referral activities in the child's health record.
13. Family support services (eg, local and national Family Voices organizations [www.familyvoices.org], Parent to Parent USA, state-based Family-to-Family Health Information Centers, and other specific programs) should be offered to families of children identified with special health care needs, and assistance should be provided to access these services.
14. Quality improvement models may be helpful to providers in integrating surveillance and screening into office procedures and for monitoring their effectiveness and outcomes.

For Policy and Advocacy

1. Identify and address barriers to screening in the medical home (such as payment, professional and staff education, and office workflow) to achieve universal screening of all children during early childhood.
2. Provide appropriate payment for developmental screening, testing, evaluation, and treatment. Payment for these separately identifiable and reportable services should not be bundled into the preventive care visit or any other office visit. Payment for follow-up visits to monitor progress and outcomes should also be provided.
3. Provide payment for chronic condition management in the medical home for children identified with a developmental disorder to address the child's ongoing medical, social, and developmental needs and to

identify associated and address newly associated conditions and needs.

4. Continue current unified national efforts to increase early screening and detection rates across health care, education, and social service sectors with refinement and coordination among entities (including the professional associations such as the AAP, American Academy of Family Physicians, American Academy of Physician Assistants, National Association of Pediatric Nurse Practitioners, and the Association of University Centers on Disabilities and federal agencies such as Administration for Children and Families Office of Head Start and Office of Child Care, CDC, and the Maternal and Child Health Bureau and Health Resources and Services Administration). Support for these efforts should continue with a focus on integrated systems for early detection and care coordination to work in a timely, effective way.[100]
5. Guidance on specific ages for behavioral screening should be developed and integrated with developmental and ASD screening, given the close interrelationship of development and behavior and common coexistence of problems in both domains.

For Research and Development

1. Encourage ongoing investigation around screening and referral rates directed to the goal of universal screening of all children, with related referral into systems of medical and developmental care for those identified with specific developmental disorders. Obstacles and barriers to referral and ongoing management should be identified.
2. Support ongoing investigation directed to the goal of earliest identification of all children with developmental disorders and referral into specialty systems of developmental evaluation and care, medical evaluation and care, and education.
3. Expand the evidence base for the effectiveness of developmental surveillance activities, including the long-standing use and validity of developmental milestones for this purpose.
4. Expand the evidence base comparing the effectiveness of developmental surveillance, developmental screening, and their combination in the identification of children with developmental disorders.
5. Identify barriers that limit pediatric health care professionals from conducting medical workup for etiology and known associated medical conditions in children with developmental concerns.
6. Develop information systems and data-gathering tests to automate and operationalize the surveillance and screening processes recommended within this report and its algorithm. These could include integration and documentation into the child's electronic health record of developmental surveillance and screening of all children as well as chronic condition management of those children identified with developmental disorders.
7. Support continued research on the practice of developmental and ASD surveillance and screening, including

   examining the efficacy of surveillance for early identification of developmental concerns in use at nonscreening visits;

   examining the utility and validity of methods of surveillance and current tools;

   establishing the validity of both general developmental and ASD-specific screening;

   expanding the evidence base for the use and effectiveness of optimal ages for recommended developmental screening, including school-readiness screening and associated behavioral screening; and

   investigating the short- and long-term benefits of developmental surveillance and screening, given the current limitations of the evidence base.

   Note that these recommendations are consistent with the recent recommendation from the USPSTF[42] in its review of ASD screening. Although such research continues, developmental surveillance and screening by pediatric health care professionals in the patient- and family-centered medical home continues to be recommended for the early identification and intervention of children with developmental disorders, including ASD, reports of benefit from early and intensive intervention for ASD, and the national legislative mandate for provision of early intervention and special education services to children with developmental disorders.
8. Unification of all current related screenings is recommended, including early hearing screening, motor screening, behavioral and mental health screening, and neurodevelopmental screening in other health conditions (eg, prematurity and congenital heart disease). This would be valuable, considering the multiple screenings recommended for the wide range of health conditions during childhood. Such a vision and schedule would accommodate age and condition overlaps (such as newborn, anemia, hearing, developmental screening), the complexities for their implementation in the pediatric office by pediatric health care professionals and staff, and the need for families and community providers to understand the utility

of such screening. This integration would simplify the process of screening and would benefit affected children, their families, and the pediatric health care professional.

LEAD AUTHORS

Paul H. Lipkin, MD, FAAP
Michelle M. Macias, MD, FAAP

CONTRIBUTORS

Susan L. Hyman, MD, FAAP
Susan E. Levy, MD, MPH, FAAP
S. Andrew Spooner, MD, MS, FAAP

EDITOR

Anne B. Rodgers

COUNCIL ON CHILDREN WITH DISABILITIES EXECUTIVE COMMITTEE, 2019–2020

Dennis Z. Kuo, MD, MHS, FAAP, Chairperson
Susan Apkon, MD, FAAP
Lynn F. Davidson, MD, FAAP
Kathryn A. Ellerbeck, MD, MPH, FAAP
Jessica E.A. Foster, MD, MPH, FAAP
Susan L. Hyman, MD, FAAP
Garey H. Noritz, MD, FAAP
Mary O'Connor Leppert, MD, FAAP
Barbara S. Saunders, DO, FAAP
Christopher Stille, MD, MPH, FAAP
Larry Yin, MD, MSPH, FAAP

PAST COUNCIL ON CHILDREN WITH DISABILITIES EXECUTIVE COMMITTEE MEMBERS

Timothy Brei, MD, FAAP
Beth Ellen Davis, MD, MPH, FAAP
Susan E. Levy, MD, MPH, FAAP
Paul H. Lipkin, MD, FAAP
Scott M. Myers, MD, FAAP
Kenneth Norwood, Jr, MD, FAAP, Immediate Past Chairperson

LIAISONS

Cara Coleman, MPH, JD – *Family Voices*
Marie Mann, MD, MPH, FAAP – *Maternal and Child Health Bureau*
Edwin Simpser, MD, FAAP – *Section on Home Care*
Peter J. Smith, MD, MA, FAAP – *Section on Developmental and Behavioral Pediatrics*
Marshalyn Yeargin-Allsopp, MD, FAAP – *Centers for Disease Control and Prevention*

STAFF

Alexandra Kuznetsov, RD akuznetsov@aap.org

SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS EXECUTIVE COMMITTEE, 2018–2019

Carol C. Weitzman, MD, FAAP, Chairperson
David Omer Childers, Jr, MD, FAAP
Jack M. Levine, MD, FAAP
Myriam Peralta-Carcelen, MD, MPH, FAAP
Jennifer K. Poon, MD, FAAP
Peter J. Smith, MD, MA, FAAP
Nathan Jon Blum, MD, FAAP, Immediate Past Chairperson
John Ichiro Takayama, MD, MPH, FAAP, Website Editor
Rebecca Baum, MD, FAAP, Section Member, COPACFH
Robert G. Voigt, MD, FAAP, Newsletter Editor
Carolyn Bridgemohan, MD, FAAP, Program Chairperson

PAST SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS EXECUTIVE COMMITTEE MEMBERS

Nerissa S. Bauer, MD, MPH, FAAP
Edward Goldson, MD, FAAP
Michelle M. Macias, MD, FAAP
Laura Joan McGuinn, MD, FAAP

LIAISONS

Marilyn Augustyn, MD, FAAP – *Society for Developmental and Behavioral Pediatrics*
Beth Ellen Davis, MD, MPH, FAAP – *Council on Children With Disabilities*
Alice Meng, MD – *Section on Pediatric Trainees*
Pamela C. High, MD, MS, FAAP – *Former liaison, Society for Developmental and Behavioral Pediatrics*

STAFF

Carolyn McCarty, PhD cmccarty@aap.org
Linda Paul, MPH lpaul@aap.org

ABBREVIATIONS

AAP: American Academy of Pediatrics
ADHD: attention-deficit/hyperactivity disorder
ASD: autism spectrum disorder
CDC: Centers for Disease Control and Prevention
IDEA: Individuals With Disabilities Education Act
NPV: negative predictive value
PPV: positive predictive value
USPSTF: US Preventive Services Task Force

DOI: https://doi.org/10.1542/peds.2019-3449

Address correspondence to Paul H. Lipkin, MD. Email: lipkin@kennedykrieger.org and Michelle M. Macias, MD. Email: maciasm@musc.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Council on Children With Disabilities; Section on Developmental Behavioral Pediatrics; Bright Futures Steering Committee; Medical Home Initiatives for Children With Special Needs Project Advisory Committee. Identifying infants and young children with developmental disorders in the medical home: an algorithm for developmental surveillance and screening. *Pediatrics*. 2006;118(1): 405–420
2. Johnson CP, Myers SM; American Academy of Pediatrics, Council on Children With Disabilities. Clinical report: identification and evaluation of children with autism spectrum disorders. *Pediatrics*. 2007;120(5): 1183–1215
3. Noritz GH, Murphy NA; Neuromotor Screening Expert Panel. Motor delays: early identification and evaluation [published correction appears in *Pediatrics*. 2017;140(3):e20172081]. *Pediatrics*. 2013;131(6). Available at: www.pediatrics.org/cgi/content/full/131/6/e2016
4. American Academy of Pediatrics Task Force on Mental Health.. Appendix S4: the case for routine mental health screening. *Pediatrics*. 2010;125(suppl 3):S133–S139
5. Weitzman C, Wegner L; Section on Developmental and Behavioral Pediatrics; Committee on Psychosocial Aspects of Child and Family Health; Council on Early Childhood; Society for Developmental and Behavioral Pediatrics; American Academy of Pediatrics. Promoting optimal development: screening for behavioral and emotional problems [published correction appears in *Pediatrics*. 2015; 135(5):946]. *Pediatrics*. 2015;135(2): 384–395
6. American Academy of Pediatrics, Joint Committee on Infant Hearing. Year 2007 position statement: principles and guidelines for early hearing detection and intervention programs. *Pediatrics*. 2007;120(4):898–921
7. Marino BS, Lipkin PH, Newburger JW, et al; American Heart Association Congenital Heart Defects Committee, Council on Cardiovascular Disease in the Young, Council on Cardiovascular Nursing, and Stroke Council. Neurodevelopmental outcomes in children with congenital heart disease: evaluation and management: a scientific statement from the American Heart Association. *Circulation*. 2012;126(9):1143–1172
8. Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. *Genet Med*. 2013; 15(5):399–407
9. King TM, Tandon SD, Macias MM, et al. Implementing developmental screening and referrals: lessons learned from a national project. *Pediatrics*. 2010;125(2):350–360
10. Sices L, Stancin T, Kirchner L, Bauchner H. PEDS and ASQ developmental screening tests may not identify the same children. *Pediatrics*. 2009;124(4). Available at: www.pediatrics.org/cgi/content/full/124/4/e640
11. Earls MF, Andrews JE, Hay SS. A longitudinal study of developmental and behavioral screening and referral in North Carolina's Assuring Better Child Health and Development participating practices. *Clin Pediatr (Phila)*. 2009;48(8):824–833
12. Six by '15. Early childhood. Available at: http://sixbyfifteen.org/six-goals-by-2015/early-childhood/. Accessed July 2, 2018
13. Centers for Disease Control and Prevention. Learn the signs. Act early. Available at: www.cdc.gov/ncbddd/actearly/. Accessed July 2, 2018
14. Help Me Grow National Center. Help Me Grow National Center. Available at: www.helpmegrownational.org/. Accessed July 2, 2018
15. Donahue SP, Baker CN; Committee on Practice and Ambulatory Medicine, American Academy of Pediatrics; Section on Ophthalmology, American Academy of Pediatrics; American Association of Certified Orthoptists; American Association for Pediatric Ophthalmology and Strabismus; American Academy of Ophthalmology. Procedures for the evaluation of the visual system by pediatricians. *Pediatrics*. 2016;137(1):e20153597
16. Committee on Practice and Ambulatory Medicine; Bright Futures Periodicity Schedule Workgroup. 2019 recommendations for preventive pediatric health care. *Pediatrics*. 2019; 143(3):e20183971
17. Hagan JF, Shaw JS, Duncan PM. *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*, 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017
18. Wegner LM, Macias MM. Services for children and adolescents with autism spectrum disorders: payment issues. *Pediatr Ann*. 2009;38(1):57–61
19. Wolraich M, Hagan JF, Allan C, et al; Subcommittee on Children and Adolescents With Attention-Deficit/Hyperactivity Disorder. Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. *Pediatrics*. 2019;144(4): e20192528
20. Radecki L, Sand-Loud N, O'Connor KG, Sharp S, Olson LM. Trends in the use of standardized tools for developmental screening in early childhood: 2002-2009. *Pediatrics*. 2011;128(1):14–19
21. Lipkin PH, Macias MM, Baer B, et al Trends in pediatricians' developmental screening: 2002–2016. *Pediatrics*. 2020, In press
22. Belamarich PF, Gandica R, Stein RE, Racine AD. Drowning in a sea of advice: pediatricians and American Academy of Pediatrics policy statements. *Pediatrics*. 2006;118(4). Available at: www.pediatrics.org/cgi/content/full/118/4/e964
23. US Department of Education. Individuals with Disabilities Education Act: statute and regulations. Available at: https://sites.ed.gov/idea/statuteregulations/. Accessed October 12, 2018
24. Council on Community Pediatrics. Poverty and child health in the United States. *Pediatrics*. 2016;137(4): e20160339
25. Trent M, Dooley DG, Dougé J; Section on Adolescent Health; Council on

Community Pediatrics; Committee on Adolescence. The impact of racism on child and adolescent health. *Pediatrics*. 2019;144(2):e20191765

26. Moodie S, Daneri P, Goldhagen S, Halle T, Green K, LaMonte L. *Early Childhood Developmental Screening: A Compendium of Measures for Children Ages Birth to Five. OPRE Report 2014-11*. Washington, DC: Office of Planning, Research and Evaluation, Administration for Children and Families, US Department of Health and Human Services; 2014. Available at: https://www.acf.hhs.gov/sites/default/files/opre/compendium_2013_508_compliant_final_2_5_2014.pdf. Accessed March 2, 2019
27. Accardo PJ, Whitman BY, Behr SK, Farrell A, Magenis E, Morrow-Gorton J. *Dictionary of Developmental Disabilities Terminology*, 2nd ed. Baltimore, MD: Paul H. Brookes Publishing Co Inc; 2003
28. Sheldrick RC, Merchant S, Perrin EC. Identification of developmental-behavioral problems in primary care: a systematic review. *Pediatrics*. 2011; 128(2):356–363
29. Glascoe GP, Marks KP. A Process Approach to Developmental-Behavioral Screening and Surveillance with Children Birth to Six-Years. In: Glascoe FP, Poon JK, Marks K, Macias MM, eds. *Early Detection Handbook: Practical Guidance on Identifying and Addressing Developmental, Behavioral, Academic, and Mental Health Problems in Children*. Nashville, TN: Ellesworth and Vandemeer Press; 2013:65–105
30. Hyman SL, Levy SE, Myers SM; American Academy of Pediatrics, Council on Children With Disabilities and Section on Developmental and Behavioral Pediatrics. Clinical report: identification, evaluation, and management of children with autism spectrum disorder. *Pediatrics*. 2020; 145(1):e20193447
31. Council on Early Childhood; Council on School Health. The pediatrician's role in optimizing school readiness. *Pediatrics*. 2016;138(3):e20162293
32. Zwaigenbaum L, Bauman ML, Fein D, et al. Early screening of autism spectrum disorder: recommendations for practice and research. *Pediatrics*. 2015;136(suppl 1):S41–S59
33. Zwaigenbaum L, Bauman ML, Stone WL, et al. Early identification of autism spectrum disorder: recommendations for practice and research. *Pediatrics*. 2015;136(suppl 1):S10–S40
34. Newacheck PW, Strickland B, Shonkoff JP, et al. An epidemiologic profile of children with special health care needs. *Pediatrics*. 1998;102(1, pt 1):117–123
35. Glascoe FP. Evidence-based early detection of developmental-behavioral problems in primary care: what to expect and how to do it. *J Pediatr Health Care*. 2015;29(1):46–53
36. Rice CE, Naarden Braun KV, Kogan MD, et al; Centers for Disease Control and Prevention (CDC). Screening for developmental delays among young children–National Survey of Children's Health, United States, 2007. *MMWR Suppl*. 2014;63(2):27–35
37. Lipkin PH, Schertz M. Early Intervention and Its Efficacy. In: Accardo PJ, ed. *Capute & Accardo's Neurodevelopmental Disabilities in Infancy and Childhood: Neurodevelopmental Diagnosis and Treatment*, 3rd ed, vol. Vol 1. Baltimore, MD: Paul H. Brookes Publishing; 2008: 519–552
38. Reichow B, Barton EE, Boyd BA, Hume K. Early intensive behavioral intervention (EIBI) for young children with autism spectrum disorders (ASD). *Cochrane Database Syst Rev*. 2012;10(10): CD009260
39. Warren Z, McPheeters ML, Sathe N, Foss-Feig JH, Glasser A, Veenstra-Vanderweele J. A systematic review of early intensive intervention for autism spectrum disorders. *Pediatrics*. 2011; 127(5). Available at: www.pediatrics.org/cgi/content/full/127/5/e1303
40. Guevara JP, Gerdes M, Localio R, et al. Effectiveness of developmental screening in an urban setting. *Pediatrics*. 2013;131(1):30–37
41. Siu AL, Bibbins-Domingo K, Grossman DC, et al; US Preventive Services Task Force (USPSTF). Screening for autism spectrum disorder in young children: US Preventive Services Task Force recommendation statement. *JAMA*. 2016;315(7):691–696
42. Jenco M. Academy calls for continued autism screening, despite USPSTF recommendation. *AAP News*. August 4, 2015. Available at: www.aappublications.org/content/early/2015/08/04/aapnews.20150804-1. Accessed July 2, 2018
43. Ozonoff S, Young GS, Carter A, et al. Recurrence risk for autism spectrum disorders: a Baby Siblings Research Consortium study. *Pediatrics*. 2011; 128(3). Available at: www.pediatrics.org/cgi/content/full/128/3/e488
44. Glascoe FP, Trimm F. Brief approaches to developmental-behavioral promotion in primary care: updates on methods and technology. *Pediatrics*. 2014;133(5): 884–897
45. Dworkin PH. British and American recommendations for developmental monitoring: the role of surveillance. *Pediatrics*. 1989;84(6):1000–1010
46. Thomas SA, Cotton W, Pan X, Ratliff-Schaub K. Comparison of systematic developmental surveillance with standardized developmental screening in primary care. *Clin Pediatr (Phila)*. 2012;51(2):154–159
47. Brothers KB, Glascoe FP, Robertshaw NS. PEDS: developmental milestones–an accurate brief tool for surveillance and screening. *Clin Pediatr (Phila)*. 2008; 47(3):271–279
48. Tervo RC. Parent's reports predict their child's developmental problems. *Clin Pediatr (Phila)*. 2005;44(7):601–611
49. Administration for Children and Families. Birth to 5: Watch Me Thrive! Available at: www.acf.hhs.gov/programs/ecd/child-health-development/watch-me-thrive. Accessed July 2, 2018
50. King TM, Rosenberg LA, Fuddy L, McFarlane E, Sia C, Duggan AK. Prevalence and early identification of language delays among at-risk three year olds. *J Dev Behav Pediatr*. 2005; 26(4):293–303
51. Capute AJ, Accardo PJ. A Neurodevelopmental Perspective on the Continuum of Developmental Disabilities. In: Capute AJ, Accardo PJ, eds. *Developmental Disabilities in Infancy and Childhood*, 2nd ed, vol. Vol 1. Baltimore, MD: Paul H. Brookes Publishing; 1996:1–22

52. Bear LM. Early identification of infants at risk for developmental disabilities. *Pediatr Clin North Am*. 2004;51(3):685–701

53. Dinkevich E, Ozuah PO. Well-child care: effectiveness of current recommendations. *Clin Pediatr (Phila)*. 2002;41(4):211–217

54. Council on Environmental Health. Prevention of childhood lead toxicity. *Pediatrics*. 2016;138(1):e20161493

55. Boyle RJ. Effects of certain prenatal drugs on the fetus and newborn. *Pediatr Rev*. 2002;23(1):17–24

56. Glascoe FP, Leew S. Parenting behaviors, perceptions, and psychosocial risk: impacts on young children's development. *Pediatrics*. 2010;125(2):313–319

57. Parker S, Greer S, Zuckerman B. Double jeopardy: the impact of poverty on early child development. *Pediatr Clin North Am*. 1988;35(6):1227–1240

58. Escalona SK. Babies at double hazard: early development of infants at biologic and social risk. *Pediatrics*. 1982;70(5):670–676

59. Garner AS, Shonkoff JP; Committee on Psychosocial Aspects of Child and Family Health; Committee on Early Childhood, Adoption, and Dependent Care; Section on Developmental and Behavioral Pediatrics. Early childhood adversity, toxic stress, and the role of the pediatrician: translating developmental science into lifelong health. *Pediatrics*. 2012;129(1). Available at: www.pediatrics.org/cgi/content/full/129/1/e224

60. McPherson M, Arango P, Fox H, et al. A new definition of children with special health care needs. *Pediatrics*. 1998; 102(1, pt 1):137–140

61. National Research Council and Institute of Medicine, Committee on Integrating the Science of Early Childhood Development. In: Shonkoff JP, Phillips DA, eds. *From Neurons to Neighborhoods: The Science of Early Childhood Development*. Washington, DC: National Academies Press; 2000

62. Center for the Study of Social Policy's Strengthening Families; American Academy of Pediatrics. Primary health partners, promoting children's health and resiliency: a strengthening families approach. Available at: https://cssp.org/resource/messaging-at-the-intersections-primary-care/. Accessed April 18, 2019

63. Council on Children with Disabilities and Medical Home Implementation Project Advisory Committee. Patient- and family-centered care coordination: a framework for integrating care for children and youth across multiple systems. *Pediatrics*. 2014;133(5). Available at: www.pediatrics.org/cgi/content/full/133/5/e1451

64. Duffee JH, Mendelsohn AL, Kuo AA, Legano LA, Earls MF; Council on Community Pediatrics; Council on Early Childhood; Committee on Child Abuse And Neglect. Early childhood home visiting. *Pediatrics*. 2017;140(3): e20172150

65. Medical Home Initiatives for Children With Special Needs Project Advisory Committee. American Academy of Pediatrics. The medical home. *Pediatrics*. 2002;110(1, pt 1):184–186

66. Katkin JP, Kressly SJ, Edwards AR, et al; Task Force on Pediatric Practice Change. Guiding principles for team-based pediatric care. *Pediatrics*. 2017; 140(2):e20171489

67. Early Childhood Technical Assistance Center. Early Childhood Technical Assistance Center. Available at: http://ectacenter.org/. Accessed October 12, 2018

68. Lipkin PH, Okamoto J; Council on Children with Disabilities; Council on School Health. The Individuals With Disabilities Education Act (IDEA) for children with special educational needs. *Pediatrics*. 2015;136(6). Available at: www.pediatrics.org/cgi/content/full/136/6/e1650

69. Tjossem TD. *Intervention Strategies for High Risk Infants and Young Children*. Baltimore, MD: University Park Press; 1976

70. Ashwal S, Russman BS, Blasco PA, et al; Quality Standards Subcommittee of the American Academy of Neurology; Practice Committee of the Child Neurology Society. Practice parameter: diagnostic assessment of the child with cerebral palsy: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2004;62(6):851–863

71. Filipek PA, Accardo PJ, Ashwal S, et al. Practice parameter: screening and diagnosis of autism: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Child Neurology Society. *Neurology*. 2000;55(4):468–479

72. Michelson DJ, Shevell MI, Sherr EH, Moeschler JB, Gropman AL, Ashwal S. Evidence report: genetic and metabolic testing on children with global developmental delay: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2011; 77(17):1629–1635

73. Moeschler JB, Shevell M; Committee on Genetics. Comprehensive evaluation of the child with intellectual disability or global developmental delays. *Pediatrics*. 2014;134(3). Available at: www.pediatrics.org/cgi/content/full/134/3/e903

74. Bailey DB Jr., Skinner D, Sparkman KL. Discovering fragile X syndrome: family experiences and perceptions. *Pediatrics*. 2003;111(2):407–416

75. Lipkin PH. Epidemiology of the Developmental Disabilities. In: Capute AJ, Accardo PJ, eds. *Developmental Disabilities in Infancy and Childhood*, 2nd ed, vol. Vol 1. Baltimore, MD: Paul H. Brookes Publishing; 1996:137–156

76. Rubin IL, Crocker AC. *Medical Care for Children and Adults With Developmental Disabilities*, 2nd ed. Baltimore, MD: Paul H. Brookes Publishing; 2005

77. Nickel RE, Desch LW. *The Physician's Guide to Caring for Children With Disabilities and Chronic Conditions*. Baltimore, MD: Paul H. Brookes Publishing; 2000

78. Adams RC, Tapia C; Council on Children With Disabilities. Early intervention, IDEA Part C services, and the medical home: collaboration for best practice and best outcomes. *Pediatrics*. 2013; 132(4). Available at: www.pediatrics.org/cgi/content/full/132/4/e1073

79. Jimenez ME, Fiks AG, Shah LR, et al. Factors associated with early intervention referral and evaluation: a mixed methods analysis. *Acad Pediatr*. 2014;14(3):315–323

80. Health Resources and Services Administration, Maternal and Child Health Bureau. Title V Maternal and Child Health Block Grant Program. Available at: https://mchb.hrsa.gov/maternal-child-health-initiatives/title-v-maternal-and-child-health-services-block-grant-program. Accessed October 10, 2018

81. Family Voices. Family Voices. Available at: http://familyvoices.org/. Accessed October 10, 2018

82. Family Voices. Family-to-Family Health Information Centers. Available at: http://familyvoices.org/ncfpp/f2fs/. Accessed October 10, 2018

83. Sheldrick RC, Garfinkel D. Is a positive developmental-behavioral screening score sufficient to justify referral? A review of evidence and theory. *Acad Pediatr*. 2017;17(5):464–470

84. Glascoe FP. Are overreferrals on developmental screening tests really a problem? *Arch Pediatr Adolesc Med*. 2001;155(1):54–59

85. Earls MF, Hay SS. Setting the stage for success: implementation of developmental and behavioral screening and surveillance in primary care practice–the North Carolina Assuring Better Child Health and Development (ABCD) Project. *Pediatrics*. 2006;118(1). Available at: www.pediatrics.org/cgi/content/full/118/1/e183

86. Hix-Small H, Marks K, Squires J, Nickel R. Impact of implementing developmental screening at 12 and 24 months in a pediatric practice. *Pediatrics*. 2007;120(2):381–389

87. Schonwald A, Huntington N, Chan E, Risko W, Bridgemohan C. Routine developmental screening implemented in urban primary care settings: more evidence of feasibility and effectiveness. *Pediatrics*. 2009;123(2):660–668

88. Schonwald A, Horan K, Huntington N. Developmental screening: is there enough time? *Clin Pediatr (Phila)*. 2009;48(6):648–655

89. Klein S, McCarthy D. North Carolina's ABCD program: using community care networks to improve the delivery of childhood developmental screening and referral to early intervention services. *Issue Brief (Commonw Fund)*. 2009;66:1–28

90. Hacker KA, Penfold R, Arsenault L, Zhang F, Murphy M, Wissow L. Screening for behavioral health issues in children enrolled in Massachusetts Medicaid. *Pediatrics*. 2014;133(1):46–54

91. Malik F, Booker JM, Brown S, McClain C, McGrath J. Improving developmental screening among pediatricians in New Mexico: findings from the developmental screening initiative. *Clin Pediatr (Phila)*. 2014;53(6):531–538

92. Allen SG, Berry AD, Brewster JA, Chalasani RK, Mack PK. Enhancing developmentally oriented primary care: an Illinois initiative to increase developmental screening in medical homes. *Pediatrics*. 2010;126(suppl 3):S160–S164

93. Cooley WC, McAllister JW. Building medical homes: improvement strategies in primary care for children with special health care needs. *Pediatrics*. 2004;113(suppl 5):1499–1506

94. Fenikilé TS, Ellerbeck K, Filippi MK, Daley CM. Barriers to autism screening in family medicine practice: a qualitative study. *Prim Health Care Res Dev*. 2015;16(4):356–366

95. Macias MM, Levy SE, Lipkin PH, et al. Referral trends of young children screened for developmental delay and autism: results from national surveys of pediatricians, 2002-2016. In: Proceedings from the Pediatric Academic Societies Annual Meeting; May 6–9, 2017; San Francisco, CA

96. Hughes S, Herrera-Mata L, Dunn J. Impact of healthy steps on developmental referral rates. *Fam Med*. 2014;46(10):788–791

97. Talmi A, Bunik M, Asherin R, et al. Improving developmental screening documentation and referral completion. *Pediatrics*. 2014;134(4). Available at: www.pediatrics.org/cgi/content/full/134/4/e1181

98. Health Resources and Services Administration. Collaborative Improvement & Innovation Networks (CoIINs). Available at: https://mchb.hrsa.gov/maternal-child-health-initiatives/collaborative-improvement-innovation-networks-coiins. Accessed October 12, 2018

99. Carroll AE, Bauer NS, Dugan TM, Anand V, Saha C, Downs SM. Use of a computerized decision aid for developmental surveillance and screening: a randomized clinical trial. *JAMA Pediatr*. 2014;168(9):815–821

100. Marks KP, Griffen AK, Herrera P, Macias MM, Rice CE, Robinson C. Systemwide solutions to improve early intervention for developmental-behavioral concerns. *Pediatrics*. 2015;136(6). Available at: www.pediatrics.org/cgi/content/full/136/6/e1492

Providing Care for Infants Born at Home

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Providing Care for Infants Born at Home

Kristi Watterberg, MD, FAAP, COMMITTEE ON FETUS AND NEWBORN

The American Academy of Pediatrics (AAP) believes that current data show that hospitals and accredited birth centers are the safest settings for birth in the United States. The AAP does not recommend planned home birth, which has been reported to be associated with a twofold to threefold increase in infant mortality in the United States. The AAP recognizes that women may choose to plan a home birth. This statement is intended to help pediatricians provide constructive, informed counsel to women considering home birth while retaining their role as child advocates and to summarize appropriate care for newborn infants born at home that is consistent with care provided for infants born in a medical care facility. Regardless of the circumstances of his or her birth, including location, every newborn infant deserves health care consistent with that highlighted in this statement, which is more completely described in other publications from the AAP, including *Guidelines for Perinatal Care* and the *Textbook of Neonatal Resuscitation*. All health care clinicians and institutions should promote communications and understanding on the basis of professional interaction and mutual respect.

INTRODUCTION

Women and their families may desire a home birth for a variety of reasons, including cultural or religious beliefs and traditions, hopes for a more family-friendly setting, increased control of the process, and decreased obstetric intervention.[1] The incidence of home birth has increased over the past decade, with the largest increase occurring in white, non-Hispanic women; more than 2% of births to these women now occur at home, with wide variation in incidence among states.[2] However, a woman's choice to plan a home birth is not well supported in the United States. Problems with home birth include wide variation in state laws and regulations, lack of appropriately trained and willing providers, and lack of supporting systems to ensure the availability of specialty consultation and timely transport to a hospital. Geography also may adversely affect the safety of planned home birth because travel times longer than 15 to 20 minutes to a medical facility have been associated with increased risk for adverse

abstract

Department of Pediatrics, The University of New Mexico, Albuquerque, New Mexico

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Dr Watterberg was responsible for revising and updating the draft and responding to all suggestions from internal and external reviewers as well as the Board of Directors; and she approved the final manuscript as submitted.

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-0626

Address correspondence to Kristi Watterberg, MD, FAAP. E-mail: kwatterberg@salud.unm.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The author has indicated she has no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

To cite: Watterberg K, AAP COMMITTEE ON FETUS AND NEWBORN. Providing Care for Infants Born at Home. *Pediatrics*. 2020;145(5):e20200626

neonatal outcomes, including mortality.[3,4]

Planned home birth in the United States has previously been reported to be associated with a twofold to threefold increase in perinatal (fetal or newborn) death or an absolute risk increase of approximately 1 to 2 deaths per 1000 live births.[5–7] These findings were recently confirmed in a population-based study by using birth certificates with information on intended place of birth as well as actual place of birth, permitting analysis of birth outcomes after intrapartum transfer to the hospital.[8] This study also confirmed previous findings that infants born at home in the United States have an increased incidence of low Apgar scores and of neonatal seizures.[5,6] There may be an irreducible minimum increase in adverse outcomes with planned home births, even in a well-integrated health care system such as that in England. For example, the English National Institute for Health and Care Excellence recommends that practitioners "advise low-risk nulliparous women that planning to give birth in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit. Explain that if they plan birth at home there is a small increase in the risk of an adverse outcome for the baby."[9] This advice is based on the Birthplace in England study, which revealed an increase in composite adverse outcomes of intrapartum stillbirths and early neonatal deaths, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, and fractured humerus or clavicle.[10]

In a recent position statement, the Committee on Obstetric Practice of the American College of Obstetricians and Gynecologists stated, "Although the College believes that hospitals and accredited birth centers are the safest settings for birth, each woman has the right to make a medically informed decision about delivery."[11] In addition, "Women inquiring about planned home birth should be informed of its risks and benefits based on recent evidence."[11] In the statement, the authors reviewed appropriate candidates for home birth and health care system components "critical to reducing perinatal mortality rates and achieving favorable home birth outcomes" (Table 1).

If requested, pediatric health care providers in the United States should be prepared to provide constructive, informed counsel to women considering home birth while retaining their role as child advocates in assessing whether the situation is appropriate to support a planned home birth (Table 1). In addition to apprising the expectant mother of the increase in neonatal mortality and other neonatal complications with planned home birth (Table 1), the health care provider counseling a pregnant woman about planned home birth should make her aware that some women who plan to deliver at home will need transfer to a hospital before birth because of unanticipated complications. This percentage varies widely among reports, from approximately 10% to 40%, with a higher transfer rate for primiparous women.[10,13] The mother should be encouraged to see transfer to a hospital not as a failure of the home birth but rather as a success of the system to provide a healthy outcome for both mother and infant.

Care of the newborn infant born at home is a particularly important topic because infants born at home are cared for outside the safeguards of the systems-based protocols required of hospitals and birthing centers, placing a larger burden on health care providers attending home births to remember and perform all components of assessment and care of the newborn infant. To assist providers, this policy statement addresses the following specific areas: resuscitation and evaluation of the newborn infant immediately after birth and essential elements of care and follow-up for the healthy term newborn infant.

TABLE 1 Planned Home Birth Considerations

Potential candidate for home birth
• Absence of preexisting maternal disease
• Absence of significant disease arising during the pregnancy
• A gestation of 37 + 0/7 to 41 + 6/7 weeks
• A singleton fetus estimated to be appropriate for gestational age
• A cephalic presentation
• Labor that is spontaneous or induced as an outpatient
Reported risks to the newborn associated with planned home birth in the United States
• Increased fetal and/or neonatal mortality[5–8]
• Increased incidence of neonatal seizures[5,6,8]
• Higher incidence of an Apgar score <4 at 5 min[5,6,8]
Systems needed to support planned home birth
• The availability of a physician or a midwife certified by the American Midwifery Certification Board (or its predecessor organizations) or whose education and licensure meet the International Confederation of Midwives Global Standards for Midwifery Education practicing within an integrated and regulated health system
• Attendance by at least 2 care providers, one of whom is an appropriately trained individual (see text) whose primary responsibility is the care of the newborn infant
• Availability of appropriate equipment for neonatal resuscitation[12]
• Ready access to medical consultation
• Access to safe and timely transport to a nearby hospital with a preexisting arrangement

As stated in *Guidelines for Perinatal Care*, fetal malpresentation, multiple gestation, and previous cesarean delivery are considered absolute contraindications to planned home birth.

ASSESSMENT, RESUSCITATION, AND CARE OF THE NEWBORN INFANT IMMEDIATELY AFTER BIRTH

As recommended by the American Academy of Pediatrics (AAP) and the American Heart Association, there should be 2 care providers present at every birth, at least 1 of whom has the primary responsibility to care for the newborn infant.[12] Situations in which both the mother and the newborn infant simultaneously require urgent attention are infrequent but will, nonetheless, occur. Thus, of the 2 care providers who should attend each birth, at least 1 should have the appropriate training, skills, and equipment to perform a full resuscitation of the infant in accordance with the principles of the Neonatal Resuscitation Program.[12,14] To facilitate obtaining emergency assistance when needed, the operational integrity of the telephone or other communication system should be tested before the delivery (as should every other piece of medical equipment), and the weather should be monitored. In addition, access to safe and timely transport to a medical facility should be available, and a previous arrangement with that facility should be in place. Examples of guidelines and forms for maternal and infant transport, developed by the Home Birth Summit organization, can be found at http://www.homebirthsummit.org.

Care of the newborn infant immediately after delivery should adhere to practices described in *Guidelines for Perinatal Care*[15,16] and should include provision of warmth, initiation of appropriate resuscitation measures, and assignment of Apgar scores. Although skin-to-skin contact with the mother is the most effective way to provide warmth, portable warming pads should be available in case a newborn infant requires resuscitation and cannot be placed on the mother's chest. The infant should be monitored closely in the transitional period. Temperature, heart rate, skin color, peripheral circulation, respiration, level of consciousness, tone, and activity should be monitored and recorded at least once every 30 minutes until the infant's condition has remained stable for 2 hours. Infants who receive extensive resuscitation (eg, positive-pressure ventilation for more than 30 to 60 seconds[12]) should be transferred to a medical facility for close monitoring and evaluation. Additionally, any infant who has respiratory distress, continued cyanosis, or other signs of illness should be immediately transferred to a medical facility.

CARE OF THE NEWBORN INFANT

Subsequent newborn care should adhere to that described in *Guidelines for Perinatal Care* as well as the AAP statement regarding care of the well newborn infant.[15–17] Although a comprehensive review of these guidelines would be far too lengthy to include in this statement, a few practice points are worthy of specific mention.

- Transitional care (first 4–8 hours): The infant should be kept warm and should undergo a detailed physical examination that includes an assessment of gestational age and intrauterine growth status as well as a comprehensive risk assessment for neonatal conditions that require additional monitoring or intervention. Temperature, heart and respiratory rates, skin color, peripheral circulation, respiration, level of consciousness, tone, and activity should be monitored and recorded at least once every 30 minutes until the infant's condition is considered normal and has remained stable for 2 hours. A newborn infant who is determined to be $<$37 weeks' gestational age by physical assessment[18] should be transferred to a medical facility for continuing observation for conditions associated with prematurity, including respiratory distress, poor feeding, hypoglycemia, and hyperbilirubinemia.
- Monitoring for early-onset sepsis: As recommended by the Centers for Disease Control and Prevention and the AAP, all pregnant women should be screened for group B *Streptococcus* colonization at 35 to 37 weeks' gestation.[19] Women who are colonized should be given an intrapartum antibiotic (penicillin, ampicillin, or cefazolin) at least 4 hours before delivery. If the mother has received this intrapartum treatment and both she and her newborn infant remain asymptomatic, they can remain at home if the infant can be observed frequently by an experienced and knowledgeable health care provider.[20] If the mother shows signs of intraamniotic infection (chorioamnionitis) but the infant appears completely well, the infant also can remain at home as long as he or she is observed frequently by an experienced and knowledgeable health care provider. A quantitative estimate of the risk of newborn infection (as can be obtained from use of the sepsis risk calculator at https://neonatalsepsiscalculator.kaiserpermanente.org) may help guide the decision to transfer the infant to a medical facility.[21] If the infant does not appear completely well, the infant should be transferred rapidly to a medical facility for further evaluation and monitoring in accordance with AAP guidelines.[20]
- Glucose screening: Infants who have intrauterine growth restriction or whose mothers have diabetes should be delivered in a hospital or birthing center because of the increased risk of hypoglycemia and other neonatal

complications. If, after birth, an infant is discovered to be small or large for gestational age or an infant has required resuscitation, he or she should be screened for hypoglycemia, as outlined in the AAP statement.[22] If hypoglycemia (glucose level <45 mg/dL) is identified and persists after feeding, the infant should be transferred promptly to a medical facility for continuing evaluation and treatment.

- Eye prophylaxis: every newborn infant should receive prophylaxis against gonococcal ophthalmia neonatorum, as directed by local laws and regulations.
- Vitamin K: Every newborn infant should receive a single parenteral dose of vitamin K_1 oxide (phytonadione [0.5–1 mg]) to prevent vitamin K–dependent hemorrhagic disease of the newborn. Oral administration of vitamin K has not been shown to be as efficacious as parenteral administration for the prevention of late hemorrhagic disease.
- Hepatitis B vaccination: For all medically stable infants weighing >2000 g at birth who are born to hepatitis B surface antigen (HBsAg)–negative mothers, the first dose of vaccine should be administered within 24 hours of birth. Only single-antigen hepatitis B vaccine should be used for the birth dose, following proper storage and handling requirements for immunizations. Infants born to mothers who are HBsAg-positive or whose HBsAg status is unknown should also receive hepatitis B immune globulin, as guided by current recommendations.[23]
- Assessment of feeding: A trained caregiver should evaluate at least 1 session of breastfeeding, including observation of position, latch, and milk transfer. The mother should be encouraged to record the time and duration of each feeding, as well as urine and stool output, during the early days of breastfeeding. Nomograms providing hour-specific expected weight loss in the first postnatal week can be found at https://www.newbornweight.org/.
- Screening for hyperbilirubinemia: Infants whose mothers are Rh-negative should have cord blood sent for a Coombs direct antibody test; if the mother's blood type is O and she is Rh-positive, the cord blood may be tested for the infant's blood type and sent for a direct antibody test, but it is not required, provided that there is appropriate surveillance, risk assessment, and follow-up.[24] All newborn infants should be assessed for risk of hyperbilirubinemia and undergo bilirubin screening between 24 and 48 hours after birth. The bilirubin value should be plotted on the hour-specific nomogram to determine the risk of severe hyperbilirubinemia and the need for repeat determinations.[24]
- Universal newborn screening: Every newborn infant should undergo universal newborn screening in accordance with individual state mandates. A list of conditions for which screening is performed in each state is maintained online by the National Newborn Screening and Genetic Resource Center (available at http://genes-r-us.uthscsa.edu/resources/consumer/statemap.htm).
- Hearing screening: the newborn infant's initial caregiver should document arrangements for screening the infant's hearing.
- Pulse oximetry screening: Screening for congenital heart disease should be performed by using oxygen saturation testing, ideally between 24 and 48 hours' postnatal age. Earlier screening can be performed, although the incidence of false-positive screen results may be increased. Helpful information for oximetry screening for planned home births can be found at https://wisconsinshine.org/home-births/.[25,26]
- Provision of follow-up care: Documentation of prenatal care, delivery, and immediate postnatal course, in addition to prompt, comprehensive communication with the follow-up care provider, is essential. Completion of forms such as those found on the AAP Bright Futures Web site (https://brightfutures.aap.org) can help provide such communication. A knowledgeable and experienced health care professional should examine all infants within 24 hours of birth and subsequently within 48 hours of that first evaluation. The initial follow-up visit should include infant weight and physical examination, especially for jaundice and hydration. If the mother is breastfeeding, the visit should include evaluation of any maternal history of breast problems (eg, pain or engorgement), infant elimination patterns, and a formal observed evaluation of breastfeeding, including position, latch, and milk transfer. Results of maternal and neonatal laboratory tests should be reviewed; clinically indicated tests, such as serum bilirubin, should be performed; and screening tests should be completed in accordance with state regulations. The documentation provided by the health care professional attending the birth should include whether tests and vaccinations usually performed as part of hospital protocols have been completed or scheduled.

CONCLUSIONS

The AAP does not recommend planned home birth. However, the AAP recognizes that women may choose to plan a home birth. The AAP concurs with the American College of Obstetricians and Gynecologists statement that "for quality and safety reasons, the College specifically supports the provision of care by

midwives who are certified by the American Midwifery Certification Board (or its predecessor organizations) or whose education and licensure meet the International Confederation of Midwives Global Standards for Midwifery Education. The College does not support provision of care by midwives who do not meet these standards."[11]

In the case of a home birth, as advocates for children, the AAP recommends that provisions for the potential resuscitation of a depressed newborn infant and immediate neonatal care be optimized in the home setting. Thus, each delivery should be attended by 2 care providers, at least 1 of whom has the primary responsibility for the newborn and has the appropriate training, skills, and equipment to perform a full resuscitation of the infant in accordance with the principles of the Neonatal Resuscitation Program.[12,14]

Regardless of the circumstances of his or her birth, including location, every newborn infant deserves health care that adheres to the guidelines highlighted in this statement and more completely described in other AAP publications.[15–17] Continuing efforts by all health care clinicians and institutions should promote communications and understanding on the basis of professional interaction and mutual respect.

LEAD AUTHOR

Kristi Watterberg, MD, FAAP

COMMITTEE ON FETUS AND NEWBORN, 2018–2019

James J. Cummings, MD, FAAP, Chairperson
Ira S. Adams-Chapman, MD, FAAP
Susan Wright Aucott, MD, FAAP
Jay P. Goldsmith, MD, FAAP
Ivan L. Hand, MD, FAAP
Sandra E. Juul, MD, PhD, FAAP
Brenda Bradley Poindexter, MD, MS, FAAP
Karen Marie Puopolo, MD, PhD, FAAP
Dan L. Stewart, MD, FAAP
RADM Wanda D. Barfield, MD, MPH, FAAP

LIAISONS

Yasser El-Sayed, MD – *American College of Obstetricians and Gynecologists*
Erin L. Keels, DNP, APRN, NNP-BC – *National Association of Neonatal Nurses*
Meredith Mowitz, MD, MS, FAAP – *Section on Neonatal Perinatal Medicine Trainees and Early Career Neonatologists*
Michael Ryan Narvey, MD, FAAP – *Canadian Paediatric Society*
Tonse N.K. Raju, MD, DCH, FAAP – *National Institutes of Health*
Kasper S. Wang, MD, FACS, FAAP – *Section on Surgery*

STAFF

Jim Couto, MA

ABBREVIATIONS

AAP: American Academy of Pediatrics
HBsAg: hepatitis B surface antigen

POTENTIAL CONFLICT OF INTEREST: The author has indicated she has no potential conflicts of interest to disclose.

REFERENCES

1. Zielinski R, Ackerson K, Kane Low L. Planned home birth: benefits, risks, and opportunities. *Int J Womens Health*. 2015;7:361–377
2. MacDorman MF, Declercq E. Trends and characteristics of United States out-of-hospital births 2004-2014: new information on risk status and access to care. *Birth*. 2016;43(2):116–124
3. Ravelli AC, Jager KJ, de Groot MH, et al. Travel time from home to hospital and adverse perinatal outcomes in women at term in the Netherlands. *BJOG*. 2011; 118(4):457–465
4. Paranjothy S, Watkins WJ, Rolfe K, et al. Perinatal outcomes and travel time from home to hospital: Welsh data from 1995 to 2009. *Acta Paediatr*. 2014; 103(12):e522–e527
5. Malloy MH. Infant outcomes of certified nurse midwife attended home births: United States 2000 to 2004. *J Perinatol*. 2010;30(9):622–627
6. Cheng YW, Snowden JM, King TL, Caughey AB. Selected perinatal outcomes associated with planned home births in the United States. *Am J Obstet Gynecol*. 2013;209(4):325.e1-325.e8
7. Chang JJ, Macones GA. Birth outcomes of planned home births in Missouri: a population-based study. *Am J Perinatol*. 2011;28(7):529–536
8. Snowden JM, Tilden EL, Snyder J, Quigley B, Caughey AB, Cheng YW. Planned out-of-hospital birth and birth outcomes. *N Engl J Med*. 2015;373(27): 2642–2653
9. National Institute for Health and Care Excellence. *Intrapartum Care for Healthy Women and Babies*. London, United Kingdom: National Institute for Health and Care Excellence; 2014. Available at: https://www.nice.org.uk/guidance/cg190. Accessed December 2, 2018
10. Brocklehurst P, Hardy P, Hollowell J, et al; Birthplace in England Collaborative Group. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. *BMJ*. 2011;343:d7400
11. American College of Obstetricians and Gynecologists' Committee on Obstetric Practice. Committee opinion No. 669: planned home birth. *Obstet Gynecol*. 2016;128(2):e26–e31
12. Wyckoff MH, Aziz K, Escobedo MB, et al. Part 13: neonatal resuscitation: 2015 American Heart Association guidelines update for cardiopulmonary resuscitation and emergency cardiovascular care (reprint).

Pediatrics. 2015;136(suppl 2): S196–S218

13. Lindgren HE, Rådestad IJ, Hildingsson IM. Transfer in planned home births in Sweden–effects on the experience of birth: a nationwide population-based study. *Sex Reprod Healthc*. 2011;2(3): 101–105
14. American Academy of Pediatrics; American Heart Association. Preparing for Resuscitation. In: Wiener GM, Zaichkin J, eds. *Textbook of Neonatal Resuscitation*, 7th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2016:17–32
15. American Academy of Pediatrics Committee on Fetus and Newborn; American College of Obstetricians and Gynecologists Committee on Obstetric Practice. Care of the Newborn. In: Kilpatrick SJ, Papile LA, Macones GA, Watterberg KL, eds. *Guidelines for Perinatal Care*, 8th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017:347–408
16. American Academy of Pediatrics Committee on Fetus and Newborn; American College of Obstetricians and Gynecologists Committee on Obstetric Practice. Neonatal Complications and Management of High-Risk Infants. In: Kilpatrick S, Papile LA, Macones G, Watterberg K, eds. *Guidelines for Perinatal Care*, 8th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2017:409–478
17. Benitz WE; Committee on Fetus and Newborn, American Academy of Pediatrics. Hospital stay for healthy term newborn infants. *Pediatrics*. 2015; 135(5):948–953
18. Ballard JL, Khoury JC, Wedig K, Wang L, Eilers-Walsman BL, Lipp R. New Ballard Score, expanded to include extremely premature infants. *J Pediatr*. 1991; 119(3):417–423
19. Baker CJ, Byington CL, Polin RA; Committee on Infectious Diseases; Committee on Fetus and Newborn. Policy statement—recommendations for the prevention of perinatal group B streptococcal (GBS) disease. *Pediatrics*. 2011;128(3):611–616
20. Benitz WE, Wynn JL, Polin RA. Reappraisal of guidelines for management of neonates with suspected early-onset sepsis. *J Pediatr*. 2015;166(4):1070–1074
21. Kuzniewicz MW, Puopolo KM, Fischer A, et al. A quantitative, risk-based approach to the management of neonatal early-onset sepsis. *JAMA Pediatr*. 2017;171(4):365–371
22. Adamkin DH; Committee on Fetus and Newborn. Postnatal glucose homeostasis in late-preterm and term infants. *Pediatrics*. 2011;127(3):575–579. Reaffirmed June 2015
23. Committee on Infectious Diseases; Committee on Fetus and Newborn. Elimination of perinatal hepatitis B: providing the first vaccine dose within 24 hours of birth. *Pediatrics*. 2017; 140(3):e20171870
24. American Academy of Pediatrics Subcommittee on Hyperbilirubinemia. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation [published correction appears in *Pediatrics*. 2004;114(4): 1138]. *Pediatrics*. 2004;114(1):297–316
25. Oster ME, Aucott SW, Glidewell J, et al. Lessons learned from newborn screening for critical congenital heart defects. *Pediatrics*. 2016;137(5): e20154573
26. Miller KK, Vig KS, Goetz EM, Spicer G, Yang AJ, Hokanson JS. Pulse oximetry screening for critical congenital heart disease in planned out of hospital births and the incidence of critical congenital heart disease in the Plain community. *J Perinatol*. 2016;36(12): 1088–1091

Recommendations for Prevention and Control of Influenza in Children, 2020–2021

- *Policy Statement*
  - *PPI: AAP Partnership for Policy Implementation*

See Appendix 1 for more information.

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Recommendations for Prevention and Control of Influenza in Children, 2020–2021

Committee on Infectious Diseases

This statement updates the recommendations of the American Academy of Pediatrics for the routine use of influenza vaccine and antiviral medications in the prevention and treatment of influenza in children during the 2020–2021 season.

The American Academy of Pediatrics (AAP) recommends routine influenza immunization of all children without medical contraindications, starting at 6 months of age. Influenza vaccination is an important intervention to protect vulnerable populations and reduce the burden of respiratory illnesses during the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) pandemic. Any licensed, recommended, age-appropriate vaccine available can be administered, without preference for one product or formulation over another. Antiviral treatment of influenza with any licensed, recommended, age-appropriate influenza antiviral medication is recommended for children with suspected or confirmed influenza who are hospitalized, have severe or progressive disease, or have underlying conditions that increase their risk of complications of influenza. Antiviral treatment may be considered for any previously healthy, symptomatic outpatient not at high risk for influenza complications in whom an influenza diagnosis is confirmed or suspected, if treatment can be initiated within 48 hours of illness onset, and for children whose siblings or household contacts either are younger than 6 months or have a high-risk condition that predisposes them to complications of influenza.

UPDATES FOR THE 2020–2021 INFLUENZA SEASON

1. The composition of the influenza vaccines for 2020–2021 has been updated. The recommended influenza A(H1N1)pdm09 and A(H3N2) components and the influenza B/Victoria component of the vaccine are new for this season. The B/Yamagata component is unchanged from the previous season. All quadrivalent influenza vaccines include these 4 components. The trivalent vaccines do not include influenza B/Yamagata.

abstract

DOI: https://doi.org/10.1542/peds.2020-024588

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: Dr Munoz has a royalties relationship with Up to Date and is a member of the data safety monitoring boards of Pfizer and Moderna.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: Dr Munoz had a previous research relationship with BioCryst and research relationships with the European Society of Pediatric Infectious Diseases (ESPID) and International Neonatal and Maternal Immunization Symposium (INMIS).

To cite: Infectious Diseases Con. Recommendations for Prevention and Control of Influenza in Children, 2020–2021. *Pediatrics.* 2020;146(4):e2020024588

2. All pediatric vaccines are quadrivalent. There are no trivalent vaccines available for children.
3. The vaccine formulations available for children 6 through 35 months of age have been updated. Afluria Quadrivalent will be the only vaccine for children 6 through 35 months of age with a dosing volume of 0.25 mL. Fluzone Quadrivalent, which is licensed in a 0.25-mL and a 0.5-mL dosing volume, will likely be available only in a 0.5-mL dosing volume for this age group this season. The dosing volume for the 2 other vaccines available for this age group, Fluarix and FluLaval, is 0.5 mL. The AAP has no preference for one product over another.
4. Children 6 months through 8 years of age who are receiving influenza vaccine for the first time, who have received only 1 dose ever before July 1, 2020, or whose vaccination status is unknown should be offered vaccination as soon as influenza vaccines become available and should receive 2 doses of vaccine, ideally by the end of October. Children needing only 1 dose of influenza vaccine, regardless of age, should also receive vaccination ideally by the end of October.
5. The contraindications for live attenuated influenza vaccine (LAIV) have been updated to harmonize with recommendations of the Advisory Committee on Immunization Practices (ACIP). Although there are no reports of additional safety risks for LAIV in children with immunodeficiencies, anatomic or functional asplenia, cochlear implants, or active cerebrospinal fluid leaks, because the vaccine is a live attenuated product, it is not recommended in these populations.
6. The importance of influenza vaccination during the SARS-CoV-2 pandemic is discussed.

INTRODUCTION

Children consistently have the highest attack rates of influenza in the community during seasonal influenza epidemics. They play a pivotal role in the transmission of influenza virus infection to household and other close contacts and can experience substantial morbidity, including severe or fatal complications from influenza infection.[1] Children younger than 5 years, especially those younger than 2 years, and children with certain underlying medical conditions are at increased risk of hospitalization and complications attributable to influenza.[1] School-aged children bear a large influenza disease burden and are more likely to seek influenza-related medical care compared with healthy adults.[1,2] Reducing influenza virus transmission among children decreases the burden of childhood influenza and transmission of influenza virus to household contacts and community members of all ages.[1,2] Influenza vaccination is particularly important during the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) pandemic to reduce the burden of respiratory illnesses and hospitalizations and preserve the capacity of the health care infrastructure. The American Academy of Pediatrics (AAP) recommends routine influenza vaccination and antiviral agents for the prevention and treatment of influenza in children, respectively.

SUMMARY OF RECENT INFLUENZA SEASONS IN THE UNITED STATES

2017–2018 and 2018–2019 Influenza Seasons

The 2017–2018 influenza season had an important impact in pediatric patients. It was the first classified as a high-severity season for all age groups, with high levels of outpatient clinic and emergency department visits for influenza-like illness, high rates of influenza-related hospitalization, and high mortality.[3–5] Influenza A (H3N2) predominated early, followed by a second wave of influenza B/Yamagata from March 2018 onward. Although hospitalization rates for children that season did not exceed those reported during the 2009 pandemic, they did surpass rates reported in previous high-severity A(H3N2)-predominant seasons. Excluding the 2009 pandemic, the 188 pediatric deaths reported during the 2017–2018 season (approximately half of which occurred in otherwise healthy children) were the highest reported since influenza-associated pediatric mortality became a nationally notifiable condition in 2004.[3–5] Among pediatric deaths of children 6 months and older who were eligible for vaccination and for whom vaccination status was known, approximately 80% had not received influenza vaccine during the 2017–2018 season.[3] Influenza vaccine effectiveness (VE) for the 2017–2018 season in children is shown in Table 1.[4]

The 2018–2019 season was of moderate severity, with similar hospitalization rates in children as during the 2017–2018 season (71/100 000 among children 0 through 4 years old and 20.4/100 000 among children 5 through 17 years old), which were higher than those observed in previous seasons from 2013–2014 to 2016–2017.[7] Among 1132 children hospitalized with influenza and for whom data were available, 55% had at least 1 underlying medical condition; the most commonly reported underlying conditions were asthma or reactive airway disease (26%), neurologic disorders (15.6%), and obesity (11.6%).[8] A total of 144 influenza-associated pediatric deaths were reported. The 2017–2018 influenza season was the longest-lasting season reported in the United States in the past decade, with elevated levels of

TABLE 1 Adjusted Vaccine Effectiveness (VE) in Children in the United States, by Season, as Reported by the Centers for Disease Control and Prevention (CDC), US Influenza Vaccine Effectiveness Network

Influenza Type/Age Group	2017–2018	2018–2019	2019–2020[a]
	H3N2 and B/Yamagata VE% (95% CI)	H1N1 and H3N2 VE% (95% CI)	B/Victoria and H1N1 VE% (95% CI)
Influenza A and B			
Overall all ages	38 (31 to 43)	29 (21 to 35)	45 (36 to 53)
6 mo–17 y	Not reported	Not reported	55 (42 to 65)
6 mo–8 y	68 (55 to 77)	48 (37 to 58)	NA
9–17 y	32 (16 to 44)	7 (–20 to 28)	NA
Influenza A(H1N1)pdm09			
Overall all ages	62 (50 to 71)	44 (37 to 51)	37 (19 to 52)
6 mo–17 y	Not reported	Not reported	51 (22 to 69)
6 mo–8 y	87 (71 to 95)	59 (47 to 69)	Not reported
9–17 y	70 (46 to 67)	24 (–18 to 51)	Not reported
Influenza A(H3N2)			
Overall all ages	22 (12 to 31)	9 (–4 to 20)	NA
6 mo–17 y	Not reported	Not reported	NA
6 mo–8 y	54 (33 to 69)	24 (1 to 42)	NA
9–17 y	18 (-6 to 36)	3 (–30 to 28)	NA
Influenza B Victoria			
Overall all ages	76 (45 to 89)	Not reported	50 (39 to 50)
6 mo–17 y	Not reported	Not reported	56 (42 to 67)
6 mo–8 y	Not reported	Not reported	Not reported
9–17 y	Note reported	Not reported	Not reported
Influenza B yamagata			
Overall all ages	48 (39 to 55)	Not reported	NA
6 mo–17 y	Not reported	Not reported	NA
6 mo–8 y	77 (49 to 90)	Not reported	NA
9–17 y	28 (1 to 48)	Not reported	NA

Vaccine effectiveness is estimated as 100% × (1 − odds ratio [ratio of odds of being vaccinated among outpatients with CDC's real-time RT-PCR influenza-positive test results to the odds of being vaccinated among outpatients with influenza-negative test results]); odds ratios were estimated using logistic regression. Adjusted for study site, age group, sex, race/ethnicity, self-rated general health, number of days from illness onset to enrollment, and month of illness using logistic regression.

[a] Interim results as of February 21, 2020.[6]

influenza-like illness activity for a total duration of 21 consecutive weeks (compared with an average duration of 16 weeks).[7] Variations in circulating strains affected vaccine efficacy. Influenza A(H1N1)pdm09 viruses predominated from October to mid-February, and influenza A(H3N2) viruses were identified more frequently from February to May. Influenza B (B/Victoria lineage predominant) represented approximately 5% of circulating strains. Most characterized influenza A(H3N2) viruses were antigenically distinct from the A(H3N2) component of the 2018–2019 vaccine. The vaccine's A(H3N2) virus belonged to subclade 3C.2a1. Cocirculation of multiple genetically diverse subclades of A(H3N2) was documented. Circulating viruses identified belonged to subclade 3C.2a1 or clade 3C.3a, with 3C.3a viruses accounting for >70% of the A(H3N2) in the United States. This likely contributed to an overall lower vaccine effectiveness (VE) against influenza A(H3N2) this season, despite achieving the highest vaccination coverage reported in the last decade in children (62.6% overall) (Table 1 and Fig 1).[7,9]

2019–2020 Influenza Season

The 2019–2020 influenza season was unusual and complicated by the emergence of the SARS-CoV-2 pandemic in early 2020. Influenza activity began early in October 2019, continuing through mid-March 2020, with an abrupt decline after the implementation of social distancing measures for mitigation of the pandemic. Although influenza B/Victoria viruses predominated early in the season, influenza A(H1N1)pdm09 viruses were the most predominant circulating strain this season. Influenza A(H3N2) and B/Yamagata lineage represented approximately 4.1% and 0.8% of circulating strains, respectively. The majority of characterized influenza A(H1N1)pdm09 (82.5%) and influenza B/Victoria (59.7%) viruses were antigenically similar to the viruses included in the 2019–2020 influenza vaccine. Less than half (46.5%) of influenza A(H3N2) viruses were antigenically similar to the A(H3N2) component of the 2019–2020 vaccine. During this season, the predominant A(H3N2) circulating clade was 3C.2a, subclade 3C.2a1, with cocirculation of a small proportion of 3C.3a, in contrast to the 2018–2019 season, when 3C.3a strains predominated. Preliminary estimates of the effectiveness of the 2019–2020 seasonal influenza vaccines against medically attended influenza illness from the US Flu VE Network are shown in Table 1.[6] These are preliminary data and are not vaccine specific. Susceptibility to available antiviral agents remains greater than 99% for all circulating strains, but 0.5% of A(H1N1)pdm09 isolates tested by the Centers for Disease Control and Prevention (CDC) exhibited highly reduced inhibition to oseltamivir and peramivir. Reduced susceptibility to baloxavir has not been reported in the United States to date.

The 2019–2020 season was of moderate severity, although 3 peaks of influenza-like illness activity and the highest hospitalization rates in children, 68.2 per 100 000 population overall, were reported this season. The first peak of activity occurred in early January, likely associated with influenza B circulation; the second peak occurred in February, when

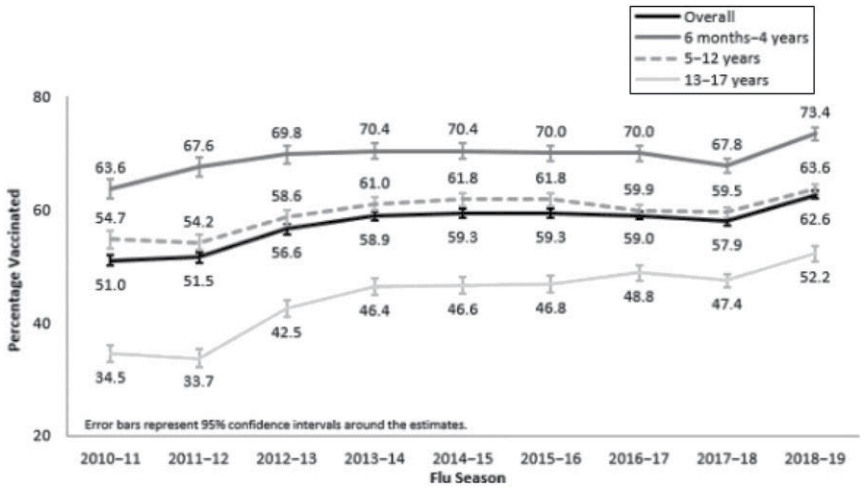


FIGURE 1
Influenza vaccination coverage in children 6 months to 17 years of age in the United States, 2010 to 2019. Source: Centers for Disease Control and Prevention (https://www.cdc.gov/flu/fluvaxview/coverage-1819estimates.htm).

influenza A(H1N1)pdm09 became predominant; and the third peak in March is thought to be associated with cocirculation of influenza and SARS-CoV-2. The CDC has now established a separate surveillance report for novel coronavirus disease 2019 (COVID-19)-like illness.[10] The cumulative influenza hospitalization rates per 100 000 population were 95.1 among children 0 through 4 years old, and 24.8 among children 5 through 17 years old. Hospitalization rates in children 0 to 4 years old were higher than those seen for this age group during the 2009 influenza pandemic, higher than the rate in adults 50 to 64 years old this season (91.8/100 000), and the highest on record for this age group. Among 168 children hospitalized with influenza and for whom data were available, 57.1% had no recorded underlying condition, and 42.9% had at least 1 underlying medical condition; the most commonly reported underlying conditions were asthma or reactive airway disease (19.7%), neurologic disorders (17.0%), and obesity (11.9%).

As of June 6, 2020, the following data were reported by the CDC:

- There were 182 laboratory-confirmed influenza-associated pediatric deaths. Most (63.0%) of those children died after being admitted to the hospital. The median age of the pediatric deaths was 6.1 years (range, 2 months to 17 years).
  - Seventy of the pediatric deaths were associated with influenza A viruses, and 112 were associated with influenza B viruses.
- Among the 168 children with known medical history, 42.9% of deaths occurred in children who had at least 1 underlying medical condition recognized by the Advisory Committee on Immunization Practices (ACIP) to increase the risk of influenza-attributable disease severity. Therefore, most (57.1%) had no known underlying medical conditions.
- The majority of the deaths occurred in children between 2 through 12 years of age: 37.4% were 5- through 11-year-olds, 20.9% were 2- through 4-year-olds, 20.3% were 12- through 17-year-olds, 15.9% were 6- through 23-month-olds, and 5.5% were younger than 6 months.
- Among 63 children who died and were tested, 46.0% had a bacterial coinfection.
- Among 141 children who were 6 months or older at the time of illness onset, and therefore, would have been eligible for influenza vaccination and for whom vaccination status was known, most (74%) were unvaccinated. Only 37 (26%) had received at least 1 dose of influenza vaccine (30 had complete vaccination, and 7 had received 1 of 2 ACIP-recommended doses).

INFLUENZA MORBIDITY AND MORTALITY IN CHILDREN

Influenza viruses are a common cause of acute lower respiratory tract infection (ALRTI) in children. Pediatric hospitalizations and deaths caused by influenza can be substantial. A recent study estimated that globally, influenza virus accounts for 7% of all ALRTIs, 5% of ALRTI hospitalizations, and 4% of ALRTI deaths in children younger than 5 years.[11] In the United States, the rates of influenza-associated hospitalization for children younger than 5 years consistently exceed the rates for children 5 through 17 years of age, and during the 2019–2020 season, they exceeded the hospitalization rates of adults 50 to 64 years of age.[8] Children 5 through 17 years of age also experienced higher than usual hospitalization rates during the 2019–2020 season. The impact of the anticipated SARS-CoV-2 cocirculation with influenza in the 2020–2021 season is unknown at this time. Elevated rates of influenza-like illness hospitalization and mortality were observed toward the end of the 2019–2020 season, suggesting the possibility of comorbidity. It is, therefore, particularly important that children are protected against influenza

through timely vaccination in the 2020–2021 influenza season.

HIGH-RISK GROUPS IN PEDIATRICS

Children and adolescents with certain underlying medical conditions have a high risk of complications from influenza (Table 2). While universal influenza vaccination is recommended for everyone starting at 6 months of age, emphasis should be placed in ensuring that people in high-risk groups and their household contacts and caregivers receive annual influenza vaccine.

EFFECTIVENESS OF INFLUENZA VACCINATION ON HOSPITALIZATION AND MORTALITY

Several studies demonstrate that influenza vaccination can effectively decrease hospitalization in children where universal pediatric immunization has been implemented. In a study during the 2015–2016 season conducted by the United States New Vaccine Surveillance Network (NVSN), among 1653 children enrolled from 7 pediatric hospitals, the adjusted VE in children with complete influenza immunization against any influenza-associated hospitalization was 56% (95% confidence interval [CI], 34% to 71%), against A(H1N1)pdm09 was 68% (95% CI, 36% to 84%), and against B viruses was 44% (95% CI, –1% to 69%).[17] A study in children 6 months to 8 years of age conducted in Israel over 3 influenza seasons from 2015 to 2017 demonstrated that over all seasons, fully vaccinated children had a VE against hospitalization of 53.9% (95% CI, 38.6% to 68.3%), while partial vaccination was not effective (25.6%; 95% CI, –3% to 47%).[18] In this study, a VE against hospitalization as high as 60% to 80% was observed when circulating and vaccine influenza A and B strains matched. After establishing free vaccination for preschool children and children at risk because of comorbid medical conditions in Australia in 2018, VE of influenza vaccine in preventing influenza hospitalization was estimated to be 78.8% (95% CI, 66.9% to 86.4%).[19] In the United Kingdom, during the 2018–2019 season, the overall adjusted VE against influenza-confirmed hospitalization was reported to be 53% (95% CI, 33.3% to 66.8%), with protection varying by strain. Protection was 63.5% (95% CI, 34.4% to 79.7%) against influenza A(H1N1)pdm09, but there was no protection against influenza A(H3N2).[20] Finally, a systematic review and meta-analysis of 28 studies conducted by Kalligeros et al[21] concluded that influenza vaccine offered significant protection against any type of influenza-related hospitalization in children 6 months through 17 years of age, with VE of 57.5% (95% CI, 54.8% to 65.5%). Strain-specific VE was higher for influenza A(H1N1)pdm09 (75.1%; 95% CI, 54.8% to 93.3%) and influenza B (50.9%; 95% CI, 41.7% to 59.9%), compared with influenza A(H3N2) (40.8%; 95% CI, 25.6% to 55.9%). As expected, children who were fully vaccinated were better protected (VE 61.8%; 95% CI, 54.4% to 69.1%) compared with those who were partially vaccinated (VE 33.91%; 95% CI, 21.1% to 46.7%). Notably, VE was higher in children younger than 5 years of age (61.7%; 95% CI, 49.3% to 74.1%) than in children 6 to 17 years old (54.4%; 95% CI, 35.1% to 73.6%). In the United States, the CDC estimates that during the 2018–2019 season, influenza vaccination prevented 20% of projected hospitalizations associated with infection with A(H1N1)pdm09 virus among children 5 through 17 years, and 43% among children 6 months through 4 years.[22]

Historically, up to 80% of influenza-associated pediatric deaths have occurred in unvaccinated children 6 months and older. Influenza vaccination is associated with

TABLE 2 People at High Risk of Influenza Complications

Children <5 y, and especially those <2 y,[a] regardless of the presence of underlying medical conditions
Adults ≥50 y, and especially those ≥65 y
Children and adults with chronic pulmonary (including asthma and cystic fibrosis); hemodynamically significant cardiovascular disease (except hypertension alone); or renal, hepatic, hematologic (including sickle cell disease and other hemoglobinopathies), or metabolic disorders (including diabetes mellitus)
Children and adults with immunosuppression attributable to any cause, including that caused by medications or by HIV infection
Children and adults with neurologic and neurodevelopment conditions (including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy, stroke, intellectual disability, moderate to severe developmental delay, muscular dystrophy, or spinal cord injury)
Children and adults with conditions that compromise respiratory function or handling of secretions (including tracheostomy and mechanical ventilation)[12]
Women who are pregnant or postpartum during the influenza season
Children and adolescents <19 y who are receiving long-term aspirin therapy or salicylate-containing medications (including those with Kawasaki disease and rheumatologic conditions) because of increased risk of Reye syndrome
American Indian/Alaska Native people[b]
Children and adults with extreme obesity (ie, BMI [BMI] ≥40 for adults, and based on age for children)
Residents of chronic care facilities and nursing homes

Source: Adapted from Centers for Disease Control and Prevention. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices—United States, 2020–21 influenza season. *MMWR Recomm Rep.* 2020; in press.

[a] The 2019–2020 CDC recommendations state: Although all children younger than 5 years old are considered at higher risk for complications from influenza, the highest risk is for those younger than 2 years old, with the highest hospitalization and death rates among infants younger than 6 months old.

[b] American Indian/Alaska Native (AI/AN) children have higher rate of influenza complications.[13–16] Most at-risk AI/AN children will also qualify in other high-risk categories to receive appropriate antiviral treatment. In the setting of a shortage, AI/AN children should be prioritized to receive influenza vaccine or anti-viral medications according to local public health guidelines.

reduced risk of laboratory-confirmed influenza-related pediatric death.[23] In one case-cohort analysis comparing vaccination uptake among laboratory-confirmed influenza-associated pediatric deaths with estimated vaccination coverage among pediatric cohorts in the United States from 2010 to 2014, Flannery et al[23] found that only 26% of children had received vaccine before illness onset, compared with an average vaccination coverage of 48%. Overall VE against influenza-associated death in children was 65% (95% CI, 54% to 74%). More than half of children in this study who died of influenza had ≥1 underlying medical condition associated with increased risk of severe influenza-related complications; only 1 in 3 of these at-risk children had been vaccinated; yet, VE against death in children with underlying conditions was 51% (95% CI, 31% to 67%). Similarly, influenza vaccination reduces by three quarters the risk of severe, life-threatening laboratory-confirmed influenza in children requiring admission to the ICU.[24] The influenza virus type might also affect the severity of disease. In a study of hospitalizations for influenza A versus B, the odds of mortality were significantly greater with influenza B than with influenza A and not entirely explained by underlying health conditions.[25]

SEASONAL INFLUENZA VACCINES

The seasonal influenza vaccines licensed for children and adults for the 2020–2021 season are shown in Table 3. More than one product may be appropriate for a given patient, and vaccination should not be delayed to obtain a specific product.

All 2020–2021 seasonal influenza vaccines contain the same influenza strains as recommended by the World Health Organization (WHO) and the US Food and Drug Administration (FDA)'s Vaccines and Related Biological Products Advisory Committee (VRBPAC) for the Northern Hemisphere.[26] Both influenza A(H1N1) and A(H3N2) and the B/Victoria components are different in this season's vaccine. The B/Yamagata component is unchanged. The influenza A strains are different for egg-based versus cell- or recombinant-based vaccines this year on the basis of their optimal characteristics for each platform, but all are matched to the strains expected to circulate in the 2020–2021 season.

1. Quadrivalent vaccines contain:
   a. Influenza A(H1N1) component:
      i. Egg-based vaccines: A/Guangdong-Maonan/SWL1536/2019 (H1N1) pdm09-like virus (new this season)
      ii. Cell- or recombinant-based vaccines: A/Hawaii/70/2019 (H1N1) pdm09-like virus (new this season)
   b. Influenza A(H3N2) component:
      i. Egg-based vaccines: A/Hong Kong/2671/2019 (H3N2)-like virus (new this season)
      ii. Cell- or recombinant-based vaccines: A/Hong Kong/45/2019 (H3N2)-like virus (new this season)
   c. B/Victoria component:
      i. All vaccines: B/Washington/02/2019-like virus (B/Victoria/2/87 lineage) (new this season)
   d. B/Yamagata component:
      i. All vaccines: B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage) (unchanged).
2. Trivalent vaccines do not include the B/Yamagata component.

Inactivated Influenza Vaccine

For the 2020–2021 season, all licensed inactivated influenza vaccines (IIVs) for children in the United States are quadrivalent unadjuvanted vaccines, with specific age indications for available formulations (Table 3). Four are egg-based (seed strains grown in eggs), and one is cell culture-based (seed strains grown in Madin-Darby canine kidney cells). All inactivated egg-based vaccines (Afluria Quadrivalent, Fluarix Quadrivalent, Flulaval Quadrivalent, and Fluzone Quadrivalent) are licensed for children 6 months and older and available in single-dose, thimerosal-free, prefilled syringes. The only pediatric cell culture-based vaccine (Flucelvax Quadrivalent) is licensed for children 4 years and older.[1]

A quadrivalent recombinant baculovirus-expressed hemagglutinin influenza vaccine (RIV4, Flublok Quadrivalent) is licensed only for people 18 years and older. A new quadrivalent high-dose inactivated influenza vaccine (HD-IIV4, Fluzone High Dose Quadrivalent) containing 4 times the amount of antigen for each virus strain than the standard dose vaccines, is licensed only for people 65 years and older. A trivalent high-dose formulation is no longer available. Both trivalent and quadrivalent MF-59 adjuvanted inactivated vaccines (aIIV3 Fluad and aIIV4 Fluad Quadrivalent) are now licensed for people 65 years and older. The quadrivalent formulation is new this year (licensed in February 2020).[1] Adjuvants may be included in a vaccine to elicit a more robust immune response, which could lead to a reduction in the number of doses required for children. In one pediatric study, the relative vaccine efficacy of a MF-59 adjuvanted influenza vaccine was significantly greater than nonadjuvanted vaccine in the 6- through 23-month age group.[27] Adjuvanted seasonal influenza vaccines are not licensed for children in the United States.

Children 36 months (3 years) and older can receive any age-appropriate licensed IIV, administered at a 0.5-mL dose containing 15 μg of hemagglutinin (HA) from each strain. Children 6

TABLE 3 Recommended Seasonal Influenza Vaccines for Different Age Groups: United States, 2020–2021 Influenza Season

Vaccine	Trade Name (Manufacturer)	Age Group	Presentation Hemagglutinin Antigen Content (IIVs and RIV4) or Virus Count (LAIV4) per dose for Each Antigen	Thimerosal Mercury Content (μg Hg/0.5-mL dose)	CPT Code
Quadrivalent standard dose – egg-based vaccines					
IIV4	Afluria Quadrivalent (Seqirus)	6–35 mo	0.25-mL prefilled syringe[a] (7.5 μg/0.25 mL)	0	
		≥36 mo	0.5-mL prefilled syringe (15 μg/0.5 mL)	0	90686
		≥6 mo	5.0-mL multidose vial[b] (15 μg/0.5 mL)	24.5	90688
IIV4	Fluarix Quadrivalent (GlaxoSmithKline)	≥6 mo	0.5-mL prefilled syringe (15 μg/0.5 mL)	0	90686
IIV4	FluLaval Quadrivalent (GlaxoSmithKline)	≥6 mo	0.5-mL prefilled syringe (15 μg/0.5 mL)	0	90686 90688
IIV4	Fluzone Quadrivalent (Sanofi Pasteur)	≥6 mo	0.5-mL prefilled syringe (15 μg/0.5 mL)[c]	0	90686
		≥6 mo	0.5-mL single-dose vial (15 μg/0.5 mL)	0	90687
		≥6 mo	5.0-mL multidose vial[b] (15 μg/0.5 mL)	25	90688
Quadrivalent standard dose – cell-based vaccines					
ccIIV4	Flucelvax Quadrivalent (Seqirus)	≥4 y	0.5-mL prefilled syringe (15 μg/0.5 mL)	0	90674
		≥4 y	5.0 mL multidose vial (15 μg/0.5 mL)	25	90756
Standard dose – egg-based with adjuvant vaccines					
aIIV3 MF-59 adjuvanted	Fluad Trivalent Seqirus	≥65 y	0.5-mL prefilled syringe (15 μg/0.5 mL)	0	90653
aIIV4 MF-59 adjuvanted	Fluad Quadrivalent Seqirus	≥65 y	0.5-mL prefilled syringe (15 μg/0.5 mL)	0	90653
Quadrivalent high dose – egg-based vaccine					
IIV4	Fluzone High-dose (Sanofi Pasteur)	≥65 y	0.7-mL prefilled syringe (60 μg/0.7 mL)	0	90662
Recombinant vaccine					
RIV4	Flublok Quadrivalent (Sanofi Pasteur)	≥18 y	0.5-mL prefilled syringe (45 μg/0.5 mL)	0	90682
Live attenuated vaccine					
LAIV4	FluMist Quadrivalent (MedImmune)	2–49 y	0.2-mL prefilled intranasal sprayer (Virus dose: 10 6.5–7.5 FFU/0.2 mL)	0	90672

Data sources: Centers for Disease Control and Prevention. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2020–2021 influenza season. *MMWR Recomm Rep.* 2020; in press. Implementation guidance on supply, pricing, payment, CPT coding, and liability issues can be found at www.aapredbook.org/implementation. (Table has been reformatted and updated).

[a] For Afluria Quadrivalent, children 6 through 35 months of age should receive 0.25 mL per dose; people ≥36 months (≥3 years) of age should receive 0.5 mL per dose.

[b] For vaccines that include a multidose vial presentation a maximum of 10 doses can be drawn from a multidose vial.

[c] The 7.5-μg/0.25-mL dosing volume is no longer available this season.

through 35 months of age may receive any age-appropriate licensed IIV without preference for one over another. Several vaccines have been licensed for children 6 through 35 months of age since 2017 (Table 3). All are quadrivalent, but the dose volume and, therefore, the antigen content vary among different IIV products. In addition to a 0.25-mL (7.5 μg of HA per vaccine virus) Fluzone Quadrivalent vaccine, a 0.5-mL formulation of Fluzone Quadrivalent containing 15 μg of HA per vaccine virus per dose was licensed in January 2019 after these 2 formulations were shown to have comparable safety and immunogenicity in a single randomized, multicenter study.[28–30] Only the 0.5-mL Fluzone product is expected to be available this season. In addition, 2 other vaccines, Fluarix Quadrivalent[31] and FluLaval Quadrivalent,[32] are licensed for a 0.5-mL dose in children 6 through 35 months of age. These 2 vaccines do not have a 0.25-mL dose formulation. Afluria Quadrivalent is the only pediatric vaccine that has a 0.25-mL (7.5 μg of HA per vaccine virus) presentation for children 6 through 35 months of age. Afluria Quadrivalent 0.5 mL (15 μg of HA per vaccine virus) is licensed for children 3 years and older only.[33] Given that different formulations of IIV for children 6 through 35 months of age are available, care should be taken to administer the appropriate volume and dose for each product. In each instance, the recommended volume may be administered from an appropriate prefilled syringe, a single-dose vial, or multidose vial, as supplied by the manufacturer. For vaccines that include a multidose vial presentation, a maximum of 10 doses can be drawn from a multidose vial. Importantly, dose volume is different from the number of doses needed to complete vaccination. Children 6 months through 8 years of age who require 2 doses of vaccine for the

2020–2021 season should receive 2 separate doses at the recommended dose volume specified for each product.

Inactivated influenza vaccines are well tolerated in children and can be used in healthy children as well as those with underlying chronic medical conditions. The most common injection site adverse reactions following administration of IIV in children are injection site pain, redness, and swelling. The most common systemic adverse events are drowsiness, irritability, loss of appetite, fatigue, muscle aches, headache, arthralgia, and gastrointestinal tract symptoms.

IIV can be administered concomitantly with other inactivated or live vaccines. During the 2 influenza seasons spanning 2010–2012, there were increased reports of febrile seizures in the United States in young children who received trivalent IIV (IIV3) and the 13-valent pneumococcal conjugate vaccine (PCV13) concomitantly. Subsequent retrospective analyses of past seasons demonstrated a slight increase in the risk of febrile seizures in children 6 through 23 months of age when PCV13 vaccines were administered concomitantly with IIV.[34] The concomitant administration of IIV3, PCV13, and diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) was associated with the greatest relative risk estimate, corresponding to a maximum additional 30 febrile seizure cases per 100 000 children vaccinated, compared with the administration of the vaccines on separate days. In contrast, data from the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) program of the FDA, revealed that there was no significant increase in febrile seizures associated with concomitant administration of these 3 vaccines in children 6 through 59 months of age during the 2010–2011 influenza season.[35] Similarly, in a subsequent sentinel CBER/PRISM surveillance report evaluating influenza vaccines and febrile seizures, there was no evidence of an elevated risk of febrile seizures in children 6 through 23 months of age following IIV administration during the 2013–2014 and 2014–2015 seasons, noting that the risk of seizures after PCV13 or concomitant PCV13 and IIV was low compared with a child's lifetime risk of febrile seizures from other causes.[36] Using a self-controlled interval study design, Baker et al[37] further evaluated the relative risk of febrile seizures following IIV or PCV13 in children 6 through 23 months, using the PRISM health care claims during those same 2 influenza seasons. When the febrile seizure rate was compared in a risk interval (0–1 days post vaccination) versus a control interval (14–20 days after vaccination), adjusting by age, calendar time, and concomitant administration of the other vaccine, an elevated risk of febrile seizures was identified after vaccination with PCV13 (incidence rate ratio [IRR], 1.80; 95% CI, 1.29 to 2.52), but not after IIV (IRR, 1.12; 95% CI, 0.80 to 1.56). Furthermore, in a study of children 12 to 16 months of age vaccinated during the 2017–2018 season, no difference was observed in the occurrence of fever when IIV administration was delayed for 2 weeks after PCV13 and DTaP vaccination (9.3%) compared with PCV13, DTaP and IIV given on the same day (8.1%) (adjusted risk ratio [aRR], 0.87; 95% CI, 0.36 to 2.19).[38] On the basis of these findings, simultaneous administration of IIV with PCV13 and/or other vaccines continues to be recommended for the 2020–2021 influenza season when these vaccines are indicated. Overall, the benefits of timely vaccination with same-day administration of IIV and PCV13 or DTaP outweigh the risk of febrile seizures. Vaccine-proximate febrile seizures rarely have any long-term sequelae, similar to nonvaccine–proximate febrile seizures.

Thimerosal-containing vaccines are not associated with an increased risk of autism spectrum disorder in children. Thimerosal from vaccines has not been linked to any neurologic condition. The American Academy of Pediatrics (AAP) supports the current WHO recommendations for use of thimerosal as a preservative in multiuse vials in the global vaccine supply.[39] Despite the lack of evidence of harm, some states have legislation restricting the use of vaccines that contain even trace amounts of thimerosal. The benefits of protecting children against the known risks of influenza are clear. Therefore, to the extent permitted by state law, children should receive any available formulation of IIV rather than delaying vaccination while waiting for reduced thimerosal-content or thimerosal-free vaccines. IIV formulations that are free of even trace amounts of thimerosal are widely available (Table 3).

Live Attenuated (Intranasal) Influenza Vaccine

The intranasal live attenuated influenza vaccine (LAIV) was initially licensed in the United States in 2003 for people 5 through 49 years of age as a trivalent formulation (LAIV3), and the approved age group was extended to 2 years of age in 2007. The quadrivalent formulation (LAIV4) licensed in 2012 was first available during the 2013–2014 influenza season, replacing LAIV3. The most commonly reported reactions of LAIV in children are runny nose or nasal congestion, headache, decreased activity or lethargy, and sore throat.

The CDC conducted a systematic review of published studies evaluating the effectiveness of LAIV3 and LAIV4 in children from the 2010–2011 to the 2016–2017 influenza seasons, including data from United States and European studies.[40] The data suggested that the

effectiveness of LAIV3 or LAIV4 for influenza A(H1N1)pdm09 strain was lower than that of IIV in children 2 through 17 years of age. LAIV was similarly effective against influenza B and A/H3N2 strains in some age groups compared with IIV. LAIV was not recommended by the CDC or AAP for use in children during the 2016–2017 and 2017–2018 seasons, given concerns about its effectiveness against A(H1N1)pdm09. For the 2017–2018 season, a new A(H1N1) pdm09-like virus strain (A/Slovenia/2903/2015) was included in LAIV4, replacing the prior A/Bolivia/559/2013 strain. A study conducted by the LAIV4 manufacturer evaluated viral shedding and immunogenicity associated with the LAIV4 formulation containing the new A(H1N1) pdm09-like virus among US children 24 to 48 months of age.[41] Shedding and immunogenicity data suggested that the new influenza A(H1N1)pdm09-like virus included in its latest formulation had improved replicative fitness over previous LAIV4 influenza A(H1N1)pdm09-like vaccine strains, resulting in an improved immune response, comparable with that of the LAIV3 available prior to the 2009 pandemic. Shedding and replicative fitness are not known to correlate with efficacy, and no published effectiveness estimates for this revised formulation of the vaccine against influenza A(/H1N1)pdm09 viruses were available prior to the start of the 2018–2019 influenza season, because influenza A(/H3N2) and influenza B viruses predominated during the 2017–2018 Northern Hemisphere season. Therefore, for the 2018–2019 influenza season, the AAP recommended IIV4 or IIV3 as the primary choice for influenza vaccination in children, with LAIV4 use reserved for children who would not otherwise receive an influenza vaccine and for whom LAIV utilization was appropriate for age (2 years and older) and health status (ie, healthy, without any underlying chronic medical condition).

In February 2019, the AAP Committee of Infectious Diseases (COID) reviewed available data on influenza epidemiology and vaccine effectiveness for the 2018–2019 season and agreed that harmonizing recommendations between the AAP and CDC for the use of LAIV in the 2019–2020 season was appropriate. After the February 2020 ACIP meeting, the AAP COID reviewed available epidemiologic and effectiveness data for the previous and current seasons to inform recommendations for the 2020–2021 season. Despite the early circulation of A(H1N1)pdm09 during the 2018–2019 season and its predominance during the 2019–2020 season, low utilization of LAIV4 in the United States population has limited the evaluation of product-specific vaccine effectiveness, and no additional US data on LAIV4 VE are available. Although the proportion of LAIV used for vaccination is unknown, interim overall VE (not specific to a type of vaccine) for the 2019–2020 influenza season shows reassuring protection in children against circulating influenza A and B strains (Table 1).[6] Furthermore, influenza vaccine coverage rates in children are stable.[9] In European surveillance networks where uninterrupted utilization of LAIV has continued from the 2016–2017 through the 2019–2020 seasons, the only country with LAIV VE estimates, the United Kingdom, reported final VE against medically attended influenza for the 2018–2019 season in children 2 through 17 years of age of 49.9% (95% CI, –14.3% to 78.0%) for A(H1N1)pdm09 and of 27.1% (95% CI, –130.5% to 77%) for A(H3N2).[42] The final adjusted VE in the United States (where mostly IIV was used) for 2018–2019 against A(H1N1)pdm09 was 59% (95% CI, 47% to 69%) for children 6 months through 8 years of age but only 24% (95% CI, –18% to 51%) for children 9 through 17 years and for A(H3N2) 24% (95% CI, 1% to 42%) in children 6 months through 8 years of age, and 3% (95% CI, –30% to 28%) in children 9 through 17 years of age.[43] Direct comparisons cannot be made given differences in reporting of VE for various age groups. Other countries that use LAIV (Canada, Finland) have not reported LAIV4-specific VE in past several seasons. Small case numbers and low LAIV use may also limit accurate VE calculations in these countries. In general, as long as use of LAIV is low relative to IIV, it will be difficult to estimate LAIV VE accurately. Furthermore, important variability in VE against all strains is reported for both IIV and LAIV.

Influenza VE varies from season to season and is affected by many factors, including age and health status of the recipient, influenza type and subtype, existing immunity from previous infection or vaccination, and degree of antigenic match between vaccine and circulating virus strains. It is possible that VE also differs among individual vaccine products; however, product-specific comparative effectiveness data are lacking for most vaccines. Additional experience over multiple influenza seasons will help to determine optimal utilization of the available vaccine formulations in children. The AAP will continue to monitor annual influenza surveillance and VE reports to update influenza vaccine recommendations if necessary.

CONTRAINDICATIONS AND PRECAUTIONS

Anaphylactic reactions to any vaccine are considered a contraindication to vaccination. The AAP recommends that children who have had an allergic reaction after a previous dose of any influenza vaccine should be evaluated by an allergist to determine whether future receipt of the vaccine is appropriate. Similarly, consultation

with an infectious disease specialist may be sought to assess potential contraindications and precautions and to determine which influenza vaccine is most appropriate to ensure immunization in special circumstances.

Minor illnesses, with or without fever, are not contraindications to the use of influenza vaccines, including among children with mild upper respiratory infection symptoms or allergic rhinitis. In children with a moderate to severe febrile illness (eg, high fever, active infection, requiring hospitalization, etc), on the basis of the judgment of the clinician, vaccination should be deferred until resolution of the illness. Children with confirmed COVID-19 can receive influenza vaccine when the acute illness has resolved. Children with an amount of nasal congestion that would notably impede vaccine delivery into the nasopharyngeal mucosa should have LAIV vaccination deferred until resolution.

A precaution for vaccination is a condition in a recipient that might increase the risk or seriousness of a possible vaccine-related adverse reaction. A precaution also may exist for conditions that might compromise the ability of the host to develop immunity after vaccination. Vaccination may be recommended in the presence of a precaution if the benefit of protection from the vaccine outweighs the potential risks.

History of Guillain-Barré syndrome (GBS) following influenza vaccine is considered a precaution for the administration of influenza vaccines. GBS is rare, especially in children, and there is a lack of evidence on risk of GBS following influenza vaccine in children. Nonetheless, regardless of age, a history of GBS less than 6 weeks after a previous dose of influenza vaccine is a precaution for administration of influenza vaccine. GBS may occur after influenza infection. The benefits of influenza vaccination might outweigh the risks for certain people who have a history of GBS (particularly if not associated with prior influenza vaccination) and who also are at high risk for severe complications from influenza.

Specific precautions for LAIV include a diagnosis of asthma in children 5 years and older and the presence of certain chronic underlying medical conditions, including metabolic disease, diabetes mellitus, other chronic disorders of the pulmonary or cardiovascular systems, renal dysfunction, or hemoglobinopathies. Although the safety of LAIV has not been definitely established in these situations, IIV can be considered. In a study comparing a large cohort of children 2 through 17 years old with asthma who received LAIV instead of IIV under established practice guidelines from 2007 to 2016, the occurrence of asthma exacerbation within 21 to 42 days of vaccination was not higher compared with children who received IIV.[44] In a prospective open-label phase IV study conducted in the United Kingdom, 478 children aged 2 to 18 years with physician-diagnosed asthma or recurrent wheezing received LAIV, with no significant change in asthma symptoms or exacerbation in the 4 weeks after vaccination.[45] However, 14.7% of patients eventually reported a severe asthma exacerbation after vaccination, requiring treatment. In post-licensure surveillance of LAIV (including LAIV3 and LAIV4), the Vaccine Adverse Event Reporting System (VAERS), jointly sponsored by the FDA and CDC, has not identified any new or unexpected safety concerns, including in people with a contraindication or precaution (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/).

People who should not receive LAIV are listed below.

People in Whom LAIV is Contraindicated

- Children younger than 2 years.
- Children 2 through 4 years of age with a diagnosis of asthma or history of recurrent wheezing or a medically attended wheezing episode in the previous 12 months because of the potential for increased wheezing after immunization. In this age range, many children have a history of wheezing with respiratory tract illnesses and are eventually diagnosed with asthma.
- Children with new cochlear implants or active cerebrospinal fluid leaks.
- Children who have a known or suspected primary or acquired immunodeficiency or who are receiving immunosuppressive or immunomodulatory therapies.
- Children with anatomic or functional asplenia, including from sickle cell disease.
- Close contacts and caregivers of those who are severely immunocompromised and require a protected environment.
- Children and adolescents receiving aspirin or salicylate-containing medications.
- Children who have received other live-virus vaccines within the previous 4 weeks (except for rotavirus vaccine); however, LAIV can be administered on the same day with other live-virus vaccines if necessary.
- Children taking an influenza antiviral medication and until 48 hours (oseltamivir, zanamivir) and up to 2 weeks (peramivir and baloxavir) after stopping the influenza antiviral therapy. If a child recently received LAIV but has an influenza illness for which antiviral agents are appropriate, the antiviral agents should be given. If antiviral agents are necessary for treatment within 5

to 7 days of LAIV immunization, reimmunization is indicated because of the potential effects of antiviral medications on LAIV replication and immunogenicity.

- Pregnant women.

LAIV and Immunocompromised Hosts

The inactivated influenza vaccine is the vaccine of choice for anyone in close contact with a subset of severely immunocompromised people (ie, those in a protected environment). IIV is preferred over LAIV for contacts of severely immunocompromised people because of a theoretical risk of infection attributable to LAIV strain in an immunocompromised contact of an LAIV-immunized person. Available data indicate a very low risk of transmission of the virus from both children and adults vaccinated with LAIV. Health care personnel (HCP) immunized with LAIV may continue to work in most units of a hospital, including the NICU and general oncology ward, using standard infection control techniques. As a precautionary measure, people recently vaccinated with LAIV should restrict contact with severely immunocompromised patients for 7 days after immunization, although there have been no reports of LAIV transmission from a vaccinated person to an immunocompromised person. In the theoretical scenario in which symptomatic LAIV infection develops in an immunocompromised host, LAIV strains are susceptible to antiviral medications.

INFLUENZA VACCINES AND EGG ALLERGY

There is strong evidence that egg-allergic individuals can safely receive influenza vaccine without any additional precautions beyond those recommended for any vaccine.[46,47] The presence of egg allergy in an individual is not a contraindication to receive IIV or LAIV. Vaccine recipients with egg allergy are at no greater risk for a systemic allergic reaction than those without egg allergy. Therefore, precautions such as choice of a particular vaccine, special observation periods, or restriction of administration to particular medical settings are not warranted and constitute an unnecessary barrier to immunization. It is not necessary to inquire about egg allergy before the administration of any influenza vaccine, including on screening forms. Routine prevaccination questions regarding anaphylaxis after receipt of any vaccine are appropriate. Standard vaccination practice for all vaccines in children should include the ability to respond to rare acute hypersensitivity reactions. Children who have had a previous allergic reaction to the influenza vaccine should be evaluated by an allergist to determine whether future receipt of the vaccine is appropriate.

INFLUENZA VACCINES DURING PREGNANCY AND BREASTFEEDING

Influenza vaccine is recommended by the ACIP, the American College of Obstetrics and Gynecology (ACOG), and the American Academy of Family Physicians (AAFP) for all women, during any trimester of gestation, for the protection of mothers against influenza and its complications.[1,48] Substantial evidence has accumulated regarding the efficacy of maternal influenza immunization in preventing laboratory-confirmed influenza disease and its complications in both mothers and their infants in the first 2 to 6 months of life.[48–53] Pregnant women who are immunized against influenza at any time during their pregnancy provide protection to their infants during their first 6 months of life, when they are too young to receive influenza vaccine themselves, through transplacental passage of antibodies.[50–58] Infants born to women who receive influenza vaccination during pregnancy can have a risk reduction of up to 72% (95% CI, 39% to 87%) for laboratory-confirmed influenza hospitalization in the first few months of life.[56]

It is safe to administer inactivated influenza vaccine to pregnant women during any trimester of gestation and postpartum. Any licensed, recommended, and age-appropriate influenza vaccine may be used, although experience with the use of RIV4 in pregnant women is limited. LAIV is contraindicated during pregnancy. Data on the safety of influenza vaccination at any time during pregnancy continues to support the safety of influenza immunization during pregnancy.[48,50–55,59] In a 5-year retrospective cohort study from 2003 to 2008 with more than 10 000 women, influenza vaccination in the first trimester was not associated with an increase in the rates of major congenital malformations.[60] Similarly, a systematic review and meta-analysis of studies of congenital anomalies after vaccination during pregnancy, including data from 15 studies (14 cohort studies and 1 case-control study) did not show any association between congenital defects and influenza vaccination in any trimester, including the first trimester of gestation.[61] Assessments of any association with influenza vaccination and preterm birth and small-for-gestational-age infants have yielded inconsistent results, with most studies reporting a protective effect or no association against these outcomes.[62,63] A cohort study from the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) of vaccine exposure during the 2010–2011 through 2013–2014 influenza seasons found no significant association of spontaneous abortion with influenza vaccine exposure in the first trimester or within the first 20 weeks of gestation.[64] One observational Vaccine Safety Datalink (VSD) study conducted during the 2010–2011 and 2011–2012 influenza seasons indicated an association between receipt of IIV containing

H1N1pdm09 and risk of spontaneous abortion, when an H1N1pdm-09-containing vaccine had also been received the previous season.[65] A follow-up study conducted by the same investigators with a larger population and stricter outcome measures did not show this association and further supported the safety of influenza vaccine during pregnancy.[66]

Women in the postpartum period who did not receive influenza vaccination during pregnancy should be encouraged to discuss with their obstetrician, family physician, nurse midwife, or other trusted provider receiving influenza vaccine before discharge from the hospital. Vaccination during breastfeeding is safe for mothers and their infants.

Breastfeeding is strongly recommended to protect infants against influenza viruses by activating innate antiviral mechanisms, specifically type 1 interferons. Human milk from mothers vaccinated during the third trimester also contains higher levels of influenza-specific immunoglobulin A (IgA).[67] Greater exclusivity of breastfeeding in the first 6 months of life decreases the episodes of respiratory illness with fever in infants of vaccinated mothers. For infants born to mothers with confirmed influenza illness at delivery, breastfeeding is encouraged, and guidance on breastfeeding practices can be found at https://www.cdc.gov/breastfeeding/breastfeeding-special-circumstances/maternal-or-infant-illnesses/influenza.html and https://www.cdc.gov/flu/professionals/infectioncontrol/peri-post-settings.htm. Breastfeeding should be encouraged even if the mother or infant has influenza illness. The mother should pump and feed expressed milk if she or her infant are too sick to breastfeed. If the breastfeeding mother requires antiviral agents, treatment with oral oseltamivir is preferred. The CDC does not recommend use of baloxavir for treatment of pregnant women or breastfeeding mothers. There are no available efficacy or safety data in pregnant women, and there are no available data on the presence of baloxavir in human milk, the effects on the breastfed infant, or the effects on milk production.

VACCINE STORAGE AND ADMINISTRATION

The AAP Storage and Handling Tip Sheet provides resources for practices to develop comprehensive vaccine management protocols to keep the temperature for vaccine storage constant during a power failure or other disaster (https://www.aap.org/en-us/Documents/immunization_disasterplanning.pdf). The AAP recommends the development of a written disaster plan for all practice settings. Additional information is available (www.aap.org/disasters). During the COVID-19 pandemic, the AAP recommends that influenza vaccine administration follow CDC guidance for administration of immunizations (https://www.cdc.gov/vaccines/pandemic-guidance/index.html). Vaccination in the medical home is ideal to ensure that pediatric patients receive other vaccinations and routine care in a timely manner and receive catch-up immunizations if delays have occurred because of the pandemic. In general, infection-prevention measures should be in place for all patient encounters, including screening for symptoms, physical distancing, respiratory and hand hygiene, and surface decontamination. In addition to standard precautions and hand hygiene, during the COVID-19 pandemic, it is recommended that vaccine administrators wear a surgical face mask (not N95 or respiratory) at all times and eye protection if the level of community spread is moderate or elevated. Administration of LAIV intranasally is not an aerosol-generating procedure; however, vaccine administrators are advised to wear gloves when injecting LAIV given the potential to coming in contact with respiratory secretions. Gloves used for intranasal or intramuscular vaccine administration should be changed with every patient. Gowns are not required.

Inactivated Influenza Vaccines

IIVs for intramuscular (IM) injection are shipped and stored at 2°C to 8°C (36°F–46°F); vaccines that are inadvertently frozen should not be used. These vaccines are administered intramuscularly into the anterolateral thigh of infants and young children and into the deltoid muscle of older children and adults. Given that various IIVs are available, careful attention should be used to ensure that each product is used according its approved age indication, dosing, and volume of administration (Table 3). A 0.5-mL unit dose of any IIV should not be split into 2 separate 0.25-mL doses. If a lower dose than recommended is inadvertently administered to a child 36 months or older (eg, 0.25 mL), an additional 0.25-mL dose should be administered to provide a full dose of 0.5 mL as soon as possible. The total number of full doses appropriate for age should be administered. If a child is inadvertently vaccinated with a formulation only approved for adults, the dose should be counted as valid.

Live Attenuated Influenza Vaccine

The cold-adapted, temperature-sensitive LAIV4 formulation is shipped and stored at 2°C to 8°C (35°F–46°F) and administered intranasally in a prefilled, single-use sprayer containing 0.2 mL of vaccine. A removable dose-divider clip is attached to the sprayer to facilitate administration of 0.1 mL separately into each nostril. If the child sneezes immediately after administration, the dose should not be repeated.

VACCINE DOSING RECOMMENDATIONS

The number of seasonal influenza vaccine doses recommended for children during the 2020–2021 influenza season depends on the child's age at the time of the first administered dose and vaccine history. The recommendations are unchanged from previous years, as shown in Fig 2.

- Influenza vaccines are not licensed for administration to infants younger than 6 months and should not be used in this age group.
- Children 9 years and older need only 1 dose, regardless of previous vaccination history.
- Children 6 months through 8 years of age:
  - Need 2 doses if they have received fewer than 2 doses of any trivalent or quadrivalent influenza vaccine (IIV or LAIV) before July 1, 2020, or if their vaccination status is unknown. The interval between the 2 doses should be at least 4 weeks. Two doses should be administered to children who receive their first dose before their ninth birthday, even if their ninth birthday occurs during the same season.
  - Require only 1 dose if they have previously received 2 or more total doses of any trivalent or quadrivalent influenza vaccine (IIV or LAIV) before July 1, 2020. The 2 previous doses do not need to have been received during the same influenza season or consecutive influenza seasons.

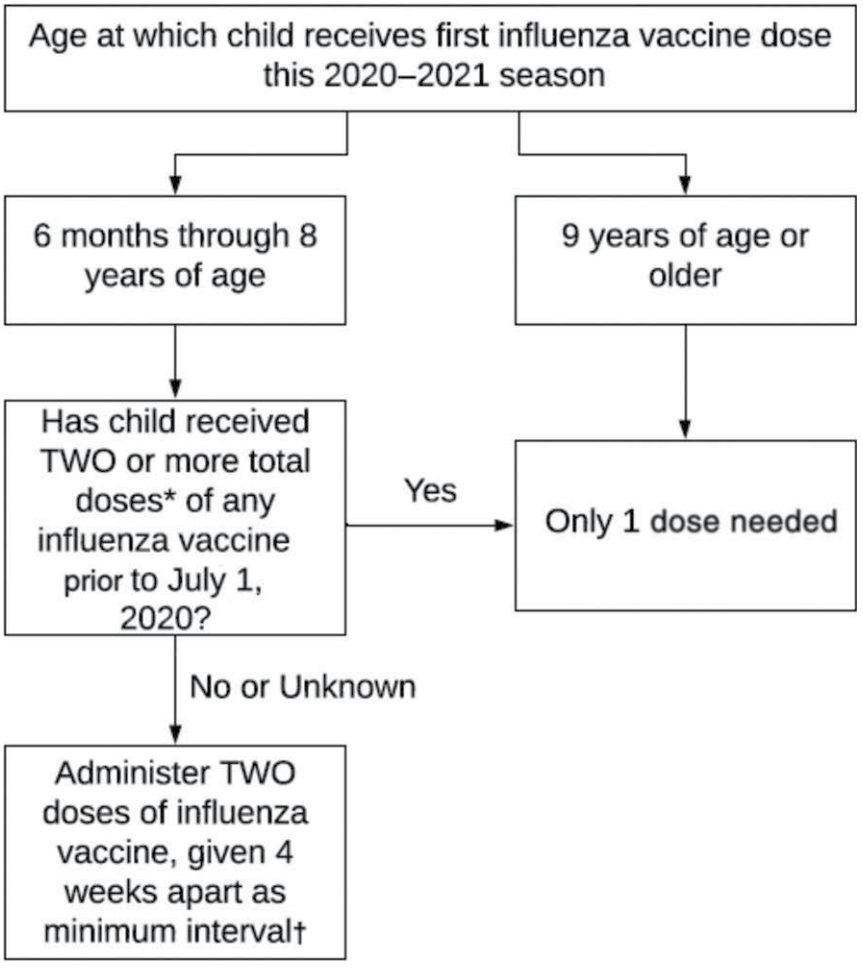


FIGURE 2
Number of 2020–2021 seasonal influenza vaccine doses for children based on age and prior vaccination history. * The 2 doses need not have been received during the same season or consecutive seasons. † Administer 2 doses based on age at receipt of the first dose of influenza vaccine during the season. Children who receive the first dose before their ninth birthday should receive 2 doses, even if they turn 9 years old during the same season.

TIMING OF VACCINATION AND DURATION OF PROTECTION

Although peak influenza activity in the United States tends to occur from January through March, influenza can circulate from early fall (October) to late spring (May), with one or more disease peaks. Predicting the onset and duration or the severity of the influenza season with accuracy is impossible. It is also challenging to balance public health strategies needed to achieve high vaccination coverage with achieving optimal individual immunity for protection against influenza at the peak of seasonal activity, knowing that the duration of immunity after vaccination can wane over time. Initiation of influenza vaccination before influenza is circulating in the community and continuing to vaccinate throughout the influenza season are important components of an effective influenza vaccination strategy, particularly this season, when circulation of SARS-CoV-2 is expected to continue.

Complete influenza vaccination by the end of October is recommended by the CDC and AAP. Children who need 2 doses of vaccine should receive their first dose as soon as possible when vaccine becomes available, to allow sufficient time for receipt of the second dose ≥4 weeks after the first, before the onset of the influenza season. Children who require only 1 dose of influenza vaccine should also ideally be vaccinated by end of October; however, recent data (mostly in adults) suggests that very early vaccination (July or August) might be associated with suboptimal immunity

before the end of the influenza season.

Although the evidence is limited in children, recent reports raise the possibility that early vaccination might contribute to reduced protection later in the influenza season.[68–79] In these studies, vaccine effectiveness decreased within a single influenza season, and this decrease was correlated with increasing time after vaccination. However, this decay in VE was not consistent across different age groups and varied by season and virus subtypes. In some studies, waning VE was more evident among older adults and younger children[71,73] and with influenza A(H3N2) viruses more than influenza A(H1N1) or B viruses.[72,75,77] A multiseason analysis from the US Influenza Vaccine Effectiveness Network found that VE declined by approximately 7% per month for influenza A (H3N2) and influenza B and by 6% to 11% per month for influenza A (H1N1)pdm09 in individuals 9 years and older.[70] VE remained greater than 0 for at least 5 to 6 months after vaccination. A more recent study including children older than 2 years also found evidence of declining vaccine effectiveness with an odds ratio increasing approximately 16% with each additional 28 days from vaccine administration.[80] In another study evaluating VE from the 2011–2012 through the 2013–2014 influenza seasons demonstrated 54% to 67% protection from 0 to 180 days after vaccination.[74] Finally, a multiseason study in Europe from 2011–2012 through 2014–2015 showed a steady decline in VE down to 0% protection by 111 days after vaccination.[75]

Further evaluation is needed before any policy change in timing of influenza administration is made. An early onset of the influenza season is a concern when considering delaying vaccination. Until there are definitive data that determine whether waning immunity influences VE in children, administration of influenza vaccine should not be delayed to a later date, because this increases the likelihood of missing influenza vaccination altogether.[81] Providers may continue to offer vaccine until June 30th of each year when the seasonal influenza vaccine expires, because the duration of influenza circulation is unpredictable. Furthermore, a person may experience more than one influenza infection during a given season because of the various cocirculating strains. Although influenza activity in the United States is typically low during the summer, influenza cases and outbreaks can occur, particularly among international travelers, who may be exposed to influenza year-round, depending on destination.

VACCINE IMPLEMENTATION

The AAP Partnership for Policy Implementation has developed a series of definitions using accepted health information technology standards to assist in the implementation of vaccine recommendations in computer systems and quality measurement efforts. This document is available at www2.aap.org/informatics/PPI.html. In addition, the AAP has developed implementation guidance on supply, payment, coding, and liability issues; these documents can be found at www.aapredbook.org/implementation.

HCP, influenza campaign organizers, and public health agencies are encouraged to collaborate to develop improved strategies for planning, distribution, communication, and administration of vaccines. For example, pediatricians can play a key role in educating and assisting early childhood education centers and schools in educating parents on the importance of influenza immunization. Resources for effective communication and messaging strategies are available on the AAP Web site – promoting vaccinations and providing resources for pediatricians to communicate with patients, families, and the communities they serve (https://www.aap.org/en-us/about-the-aap/aap-press-room/campaigns/immunizations/Pages/default.aspx and https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Influenza-Implementation-Guidance/Pages/Patient-Family-and-Community.aspx).

Pediatricians and other pediatric health care providers should plan to make influenza vaccine easily accessible for all children. Examples include sending alerts to families that vaccine is available (eg, e-mails, texts, letters, patient portals, practice-specific websites, or social media platforms); creating walk-in influenza vaccination clinics; extending hours beyond routine times during peak vaccination periods; administering influenza vaccine during both well child examinations and sick visits as well as in hospitalized patients, especially those at high risk of influenza complications, before hospital discharge (unless medically contraindicated); implementing standing orders for influenza vaccination; considering how to immunize parents, adult caregivers, and siblings (see risk management guidance associated with adult immunizations at http://pediatrics.aappublications.org/content/129/1/e247) at the same time as children; and working with other institutions (eg, schools, child care programs, local public health departments, and religious organizations) or alternative care sites, such as pharmacies and hospital emergency departments, to expand venues for administering vaccine. If a child receives influenza vaccine outside of his or her medical home, such as at a pharmacy, retail-based clinic, or another practice setting, appropriate documentation of vaccination should be provided to the patient to be shared with his or her

medical home and entered into the state or regional immunization information system (ie, registry).

Concerted efforts among the aforementioned groups, plus vaccine manufacturers, distributors, and payers, are necessary to prioritize distribution appropriately to the primary care office setting and patient-centered medical home before other venues, especially when vaccine supplies are delayed or limited. Payers should eliminate remaining "patient responsibility" cost barriers to influenza vaccine where they still exist. Similar efforts should be made to eliminate the vaccine supply discrepancy between privately insured patients and those eligible for vaccination through the Vaccines for Children (VFC) program. American Indian/Alaska Native children, who are eligible for vaccines through the VFC program, are at higher risk for influenza complications and should be prioritized in a vaccine shortage (Table 2).

Population health can benefit from pediatricians' discussions about vaccine safety and effectiveness. Pediatricians and their office staff can influence vaccine acceptance by explaining the importance of annual influenza vaccination for children and emphasizing when a second dose of vaccine is indicated. The AAP and CDC have created communication resources to convey these important messages and to help the public understand influenza recommendations. Resources will be available on *Red Book Online* (https://redbook.solutions.aap.org/selfserve/ssPage.aspx?SelfServeContentId=influenza-resources).

The AAP supports mandatory influenza vaccination programs for all HCP in all settings, including outpatient settings. Optimal prevention of influenza in the health care setting depends on the vaccination of at least 90% of HCP, which is consistent with the national *Healthy People 2020* target for annual influenza vaccination among HCP. Vaccine coverage among HCP was 81.1% during the 2018–2019 season, up from 78.4% the previous year.[82] Influenza vaccination programs for HCP benefit the health of employees, their patients, and members of the community, especially because HCP frequently come into contact with patients at high risk of influenza illness in their clinical settings. Mandatory influenza immunization for all HCP is considered to be ethical, just, and necessary to improve patient safety. For the prevention and control of influenza, HCP must prioritize the health and safety of their patients, honor the requirement of causing no harm, and act as role models for both their patients and colleagues by receiving influenza vaccination annually.

INFLUENZA VACCINE COVERAGE

Although national influenza vaccination coverage among children has not declined in the past several seasons, overall vaccination coverage remains suboptimal (Fig 1). Achieving high coverage rates of influenza vaccine in infants and children is a priority to protect them against influenza disease and its complications. Timely influenza vaccination is particularly important during the 2020–2021 influenza season, given the concurrent SARS-CoV-2 pandemic.

The AAP and CDC recommend vaccine administration at any visit to the medical home before and during influenza season when it is not contraindicated, at specially arranged vaccine-only sessions, and through cooperation with community sites, schools, and Head Start and child care facilities to provide influenza vaccine. The CDC has developed guidance for the planning of vaccination clinics during the COVID-19 pandemic (https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html?deliveryName=USCDC_7_3-DM33813). It is important that annual delivery of influenza vaccine to primary care medical homes should be timely to avoid missed opportunities. If alternate venues, including pharmacies and other retail-based clinics, are used for vaccination, a system of patient record transfer is crucial to maintain the accuracy of immunization records. Immunization information systems should be used whenever available and prioritized to document influenza vaccination. Two-dimensional barcodes have been used to facilitate more efficient and accurate documentation of vaccine administration with limited experience to date. Additional information concerning current vaccines shipped with 2-dimensional barcodes can be found at www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/.

Children's likelihood of being immunized according to recommendations appears to be associated with the immunization practices of their parents. One study found that children were 2.77 times (95% CI, 2.74 to 2.79) more likely to be immunized against seasonal influenza if their parents were immunized.[49] When parents who were previously not immunized had received immunization for seasonal influenza, their children were 5.44 times (95% CI, 5.35 to 5.53) more likely to receive influenza vaccine.

Pediatric offices may choose to serve as a venue for providing influenza vaccination for parents and other care providers of children, if the practice is acceptable to both pediatricians and the adults who are to be vaccinated. Medical liability and payment issues along with medical record documentation requirements need to be considered before a pediatrician begins immunizing adults (see risk management guidance associated

with adult immunizations at http://pediatrics.aappublications.org/content/129/1/e247). Pediatric practices should be aware of payment implications including nonpayment or having the parent inappropriately attributed by a payer as a patient of the pediatrician's office. The AAP supports efforts to overcome these payment barriers with insurance payers to maximize influenza immunization rates. To avoid errors in claims processing and payment and in the exchange of immunization data, pediatricians are reminded that parents should have their own basic medical record, where their influenza vaccination should be documented. Adults should be encouraged to have a medical home and communicate their vaccination status to their primary care provider. Offering adult vaccinations in the pediatric practice setting should not undermine the adult medical home model. Vaccination of close contacts of children at high risk of influenza-related complications (Table 2) is intended to reduce children's risk of exposure to influenza (ie, "cocooning"). The practice of cocooning also may help protect infants younger than 6 months who are too young to be immunized with influenza vaccine.

SURVEILLANCE

Information about influenza surveillance is available through the CDC Voice Information System (influenza update at 1-800-232-4636) or at www.cdc.gov/flu/index.htm. Although current influenza season data on circulating strains do not necessarily predict which and in what proportion strains will circulate in the subsequent season, it is instructive to be aware of 2019–2020 influenza surveillance data and use them as a guide to empirical therapy until current seasonal data are available from the CDC. Information is posted weekly on the CDC Web site (www.cdc.gov/flu/weekly/fluactivitysurv.htm). The AAP offers "What's the Latest with the Flu" messages to highlight those details most relevant for AAP members and child care providers on a monthly basis during influenza season (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Pages/What's-the-Latest-with-the-Flu.aspx).

INFLUENZA VACCINATION RECOMMENDATIONS

1. The AAP recommends annual influenza vaccination for *everyone* 6 months and older, including children and adolescents, during the 2020–2021 influenza season.
2. For the 2020–2021 influenza season, the AAP recommends that any licensed influenza vaccine appropriate for age and health status can be used for influenza vaccination in children. Inactivated influenza vaccine (IIV) and live attenuated vaccine (LAIV) are options for children for whom these vaccines are appropriate. This recommendation is based on review of current available data on LAIV and IIV vaccine efficacy (VE). The AAP will continue to review VE data as they become available and update these recommendations if necessary.
3. The AAP does not have a preference for any influenza vaccine product over another for children who have no contraindication to influenza vaccination and for whom more than one licensed product appropriate for age and health status is available. Pediatricians should administer whichever formulation is available in their communities to achieve the highest possible coverage this influenza season.
4. Children 6 through 35 months of age may receive any licensed, age-appropriate IIV available this season, at the dose indicated for the vaccine. No product is preferred over another for this age group. Children 36 months (3 years) and older should receive a 0.5-mL dose of any available, licensed, age-appropriate inactivated vaccine.
5. The number of seasonal influenza vaccine doses recommended to be administered to children in the 2020–2021 influenza season remains unchanged and depends on the child's age at the time of the first administered dose and vaccine history (Fig 2).
6. Children 6 months through 8 years of age who are receiving influenza vaccine for the first time or who have received only 1 dose, before July 1, 2020, or whose vaccination status is unknown should receive 2 doses of influenza vaccine, ideally by the end of October, and vaccines should be offered as soon as they become available. Children needing only 1 dose of influenza vaccine, regardless of age, should also receive vaccination, ideally by the end of October.
7. Efforts should be made to ensure vaccination for children in high-risk groups (Table 2) and their contacts, unless contraindicated.
8. Product-specific contraindications must be considered when selecting the type of vaccine to administer. Children who have had an allergic reaction after a previous dose of any influenza vaccine should be evaluated by an allergist to determine whether future receipt of the vaccine is appropriate.
9. Children with egg allergy can receive influenza vaccine without any additional precautions beyond those recommended for all vaccines.
10. Pregnant women may receive inactivated influenza vaccine at

any time during pregnancy, to protect themselves and their infants, who benefit from the transplacental transfer of antibodies. Women in the postpartum period who did not receive vaccination during pregnancy should be encouraged to receive influenza vaccine before discharge from the hospital. Influenza vaccination during breastfeeding is safe for mothers and their infants.

11. The AAP supports mandatory vaccination of health care personnel as a crucial element in preventing influenza and reducing health care-associated influenza infections, because health care personnel often care for individuals at high risk for influenza-related complications.

INFLUENZA ANTIVIRALS

Antiviral agents available for both influenza treatment and chemoprophylaxis in children of all ages can be found in Table 4 (including doses for preterm infants that have not been evaluated by the FDA) and on the CDC Web site (www.cdc.gov/flu/professionals/antivirals/index.htm). These include the neuraminidase inhibitors (NAIs) (oseltamivir, zanamivir, peramivir) and a selective inhibitor of influenza cap-dependent endonuclease (baloxavir), all of which have activity against influenza A and B viruses.[83]

Oral oseltamivir remains the antiviral drug of choice for the management of illness caused by influenza virus infections. Although more difficult to administer, inhaled zanamivir (Relenza) is an equally acceptable alternative for patients who do not have chronic respiratory disease. Options are limited for children who cannot absorb orally or enterally administered oseltamivir or tolerate inhaled zanamivir. Intravenous (IV) peramivir (Rapivab), a third NAI, was approved in September 2017 as treatment of acute uncomplicated influenza in nonhospitalized children 2 years and older who have been symptomatic for no more than 2 days. The efficacy of peramivir in patients with serious influenza requiring hospitalization has not been established.[83] IV zanamivir is not approved in the United States and has not been available for compassionate use since the 2017–2018 season.[68,69] The FDA-licensed baloxavir marboxil in 2018 for the early treatment of uncomplicated influenza in outpatients 12 years and older who have been ill for no more than 2 days.[84] This antiviral agent for influenza has a different mechanism of action (cap-endonuclease inhibitor) than NAIs and requires only a single oral dose for treatment of uncomplicated influenza. A clinical trial of baloxavir treatment of influenza in hospitalized patients 12 years and older is ongoing (https://clinicaltrials.gov/ct2/show/NCT03684044?cond=baloxavir&rank=6).

INFLUENZA TREATMENT

Randomized controlled trials (RCTs) conducted to date to evaluate the efficacy of influenza antiviral medications among outpatients with uncomplicated influenza have found that timely treatment can reduce the duration of influenza symptoms and fever in pediatric populations.[85–89] Observational studies in pediatric and adult populations suggest that antiviral agents could reduce the risk of certain influenza complications, including hospitalization and death.[90–93] The number of published RCTs in children is limited, and interpretation of the results of these studies needs to take into consideration the size of the study (the number of events might not be sufficient to assess specific outcomes in small studies), the variations in the case definition of influenza illness (clinically diagnosed versus laboratory confirmed), the time of treatment administration in relation to the onset of illness, and the child's age and health status as important variables. A Cochrane review of 6 RCTs involving treatment of 2356 children with clinically diagnosed influenza, of whom 1255 had laboratory-confirmed influenza, showed that in children with laboratory-confirmed influenza, oral oseltamivir and inhaled zanamivir reduced median duration of illness by 36 hours (26%; $P < .001$) and 1.3 days (24%, $P < .001$), respectively.[89] Among the studies reviewed, 1 trial of oseltamivir in children with asthma who had laboratory-confirmed influenza showed only a nonsignificant reduction in illness duration (10.4 hours; 8%; $P = .542$). Oseltamivir significantly reduced acute otitis media in children 1 through 5 years of age with laboratory-confirmed influenza (risk difference [RD], −0.14; 95% CI, −0.24 to −0.04).[89] Another Cochrane review of RCTs in adults and children, which included 20 oseltamivir (9623 participants) and 26 zanamivir trials (14 628 participants),[86] found no effect of oseltamivir in reducing the duration of illness in asthmatic children, but in otherwise healthy children, there was a reduction by a mean difference of 29 hours (95% CI, 12 to 47 hours; $P = .001$). No significant effect was observed with zanamivir. Regarding complications, this review did not find a significant effect of NAIs on reducing hospitalizations, pneumonia, bronchitis, otitis media, or sinusitis in children.[86] More recently, a meta-analysis of 5 new RCTs that included 1598 children with laboratory-confirmed influenza showed that treatment with oseltamivir significantly reduced the duration of illness in this population by 17.6 hours (95% CI, −34.7 to −0.62 hours).[87] When children with asthma were excluded, this difference was larger (−29.9 hours; 95% CI, −53.9 to −5.8 hours). The risk of otitis media was 34% lower in this group as well.

TABLE 4 Recommended Dosage and Schedule of Influenza Antiviral Medications for Treatment and Chemoprophylaxis in Children for the 2020–2021 Influenza Season: United States

Medication	Treatment (5 Days)	Chemoprophylaxis (10 Days)[a]
Oseltamivir[b]		
Adults	75 mg, twice daily	75 mg, once daily
Children ≥12 mo (based on body wt)		
≤15 kg (≤33 lb)	30 mg, twice daily	30 mg, once daily
>15 kg–23 kg (33 lb–51 lb)	45 mg, twice daily	45 mg, once daily
>23 kg–40 kg (>51 lb–88 lb)	60 mg, twice daily	60 mg, once daily
>40 kg (>88 lb)	75 mg, twice daily	75 mg, once daily
Infants 9–11 mo[c]	3.5 mg/kg per dose, twice daily	3.5 mg/kg per dose, once daily
Term infants 0–8 mo[c]	3 mg/kg per dose, twice daily	3 mg/kg per dose, once daily for infants 3–8 mo Not recommended for infants <3 mo old because of limited safety and efficacy data in this age group
Preterm infants[d]		
<38 wks' postmenstrual age	1.0 mg/kg per dose, twice daily	
38 through 40 wks' postmenstrual age	1.5 mg/kg per dose, twice daily	
>40 wks' postmenstrual age	3.0 mg/kg per dose, twice daily	
Zanamivir[e]		
Adults	10 mg (two 5-mg inhalations), twice daily	10 mg (two 5-mg inhalations), once daily
Children ≥7 y for treatment ≥5 y for chemoprophylaxis	10 mg (two 5-mg inhalations), twice daily	10 mg (two 5-mg inhalations), once daily
Peramivir		
Adults	One 600-mg intravenous infusion, given over 15–30 min	Not recommended
Children (2–12 y)	One 12 mg/kg dose, up to 600 mg maximum, via intravenous infusion for 15–30 min	Not recommended
Children (13–17 y)	One 600 mg dose, via intravenous infusion for 15–30 min	Not recommended
Baloxavir		
People ≥12 y who weigh more than 40 kg	40–80 kg: one 40-mg dose, orally ≥80 kg: one 80-mg dose, orally	Not recommended

Sources: 2018 IDSA Guidelines78 and https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm.

[a] CDC recommends for 7 days, and 10 days only if part of institutional outbreak (https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm).

[b] Oseltamivir is administered orally without regard to meals, although administration with meals may improve gastrointestinal tolerability. Oseltamivir is available as Tamiflu in 30-, 45-, and 75-mg capsules and as a powder for oral suspension that is reconstituted to provide a final concentration of 6 mg/mL. For the 6-mg/mL suspension, a 30-mg dose is given with 5 mL of oral suspension, a 45-mg dose is given with 7.5 mL oral suspension, a 60-mg dose is given with 10 mL oral suspension, and a 75-mg dose is given with 12.5 mL oral suspension. If the commercially manufactured oral suspension is not available, a suspension can be compounded by retail pharmacies (final concentration also 6 mg/mL), based on instructions contained in the package label. In patients with renal insufficiency, the dose should be adjusted on the basis of creatinine clearance. For treatment of patients with creatinine clearance 10–30 mL/min: 75 mg, once daily, for 5 days. For chemoprophylaxis of patients with creatinine clearance 10–30 mL/min: 30 mg, once daily, for 10 days after exposure or 75 mg, once every other day, for 10 days after exposure (5 doses). See https://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm and IDSA Guidelines.[83]

[c] Approved by the FDA for children as young as 2 weeks of age. Given preliminary pharmacokinetic data and limited safety data, oseltamivir can be used to treat influenza in both term and preterm infants from birth because benefits of therapy are likely to outweigh possible risks of treatment. Of note, the CDC recommends a 3 mg/kg/dose, twice daily, for all infants <12 months old; the IDSA guidelines[83] include both AAP and CDC recommendations.

[d] Oseltamivir dosing for preterm infants. The weight-based dosing recommendation for preterm infants is lower than for term infants. Preterm infants may have lower clearance of oseltamivir because of immature renal function, and doses recommended for full-term infants may lead to very high drug concentrations in this age group. Limited data from the National Institute of Allergy and Infectious Diseases Collaborative Antiviral Study Group provides the basis for dosing preterm infants using their postmenstrual age (gestational age + chronologic age). For extremely preterm infants (<28 wk), please consult a pediatric infectious disease physician.

[e] Zanamivir is administered by inhalation using a proprietary "Diskhaler" device distributed together with the medication. Zanamivir is a dry powder, not an aerosol, and should not be administered using nebulizers, ventilators, or other devices typically used for administering medications in aerosolized solutions. Zanamivir is not recommended for people with chronic respiratory diseases, such as asthma or chronic obstructive pulmonary disease, which increase the risk of bronchospasm.

Overall, efficacy outcomes are best demonstrated in patients with laboratory confirmed influenza. All these studies confirmed vomiting as an occasional adverse effect of oseltamivir, occurring in approximately 5% of treated patients. The balance between benefits and harms should be considered when making decisions about the use of NAIs for either treatment or chemoprophylaxis of influenza.

Although prospective comparative studies to determine the efficacy of influenza antiviral medications in hospitalized patients or pediatric patients with comorbidities have not been conducted, and prospectively collected data to determine the role of antiviral agents in treating severe influenza are limited, on the basis of information obtained from retrospective observational studies

and meta-analyses conducted to date in both adults and children, most experts support the use of antiviral medications as soon as possible to treat pediatric patients with severe influenza, including hospitalized patients.[88,90–94] An observational epidemiologic study conducted in adult patients hospitalized with severe laboratory-confirmed influenza in Spain over 6 influenza seasons (2010–2016) evaluated the effectiveness of NAIs, concluding that when started early after the onset of symptoms (≤48 hours or ≤5 days), NAI treatment was associated with a reduction in influenza-associated deaths (adjusted odds ratio [aOR], 0.37; 95% CI, 0.22 to 0.63; and aOR, 0.50; 95% CI, 0.32 to 0.79, respectively).[90] However, treatment initiation more than 5 days after the onset of influenza symptoms was not associated with reduction in mortality in hospitalized adults.

Importantly, and despite limited evidence from prospectively conducted trials, treatment with oseltamivir for children with serious, complicated, or progressive disease presumptively or definitively caused by influenza, irrespective of influenza vaccination status (the circulating strains may not be well matched with vaccine strains) or whether illness began greater than 48 hours before admission, is recommended by the AAP, CDC, Infectious Diseases Society of America (IDSA),[83] and Pediatric Infectious Diseases Society (PIDS). Earlier treatment provides better clinical responses. However, treatment after 48 hours of symptoms in adults and children with moderate to severe disease or with progressive disease has been shown to provide some benefit and should be offered.[95–97] In a retrospective study of 653 PICU admissions from 2009 to 2012, the estimated risk of death was reduced in NAI treated cases (OR 0.36, 95% CI: 0.16 to 0.83).[95] No additional benefit exists for double-dose NAI therapy on reduction of mortality or virologic clearance, compared with standard-dose therapy, on the basis of a recent systematic review and meta-analysis of 10 published studies[98] (4 RCT and 6 observational studies) involving 20 947 adult and pediatric patients.

Children younger than 2 years are at an increased risk of hospitalization and complications attributable to influenza. The FDA has approved oseltamivir for treatment of children as young as 2 weeks. Given preliminary pharmacokinetic data and limited safety data, the CDC and AAP support the use of oseltamivir to treat influenza in both term and preterm infants from birth, because benefits of therapy of neonatal influenza are likely to outweigh possible risks of treatment.

Oseltamivir is available in capsule and oral suspension formulations. The available capsule doses are 30, 45, and 75 mg, and the commercially manufactured liquid formulation has a concentration of 6 mg/mL in a 60-mL bottle. If the commercially manufactured oral suspension is not available, the capsule may be opened and the contents mixed with simple syrup or Ora-Sweet SF (sugar free) by retail pharmacies to a final concentration of 6 mg/mL.

In adverse event data collected systematically in prospective trials, vomiting was the only adverse effect reported more often with oseltamivir compared with placebo when studied in children 1 through 12 years of age (ie, 15% of treated children versus 9% receiving placebo). In addition, following reports from Japan of oseltamivir-attributable neuropsychiatric adverse effects, a review of controlled clinical trial data and ongoing surveillance has failed to establish a link between this drug and neurologic or psychiatric events.[99,100]

ANTIVIRAL TREATMENT AND INFLUENZA TESTING CONSIDERATIONS

Clinical judgment (on the basis of underlying conditions, disease severity, time since symptom onset, and local influenza activity) is an important factor in treatment decisions for pediatric patients who present with influenza-like illness. Antiviral treatment should be started as soon as possible after illness onset and should not be delayed while waiting for a definitive influenza test result, because early therapy provides the best outcomes. Influenza diagnostic tests vary by method, availability, processing time, sensitivity, and cost (Table 5), all of which should be considered in making the best clinical decision. Positive and negative predictive values of influenza test results are influenced by the level of influenza activity in the population being tested, the characteristics of a test compared with a gold standard, pretest probability, whether the influenza virus is actively replicating in the person, proper collection and transport of specimens, and proper test procedures. Testing should be performed when timely results will be available to influence clinical management or infection control measures. Given the similarities in clinical presentation, testing for influenza and for SARS-CoV-2 infection should be offered to patients with a febrile respiratory illness or influenza-like illness.

Although decisions on treatment and infection control can be made on the basis of positive rapid influenza diagnostic test (RIDT) results, negative results should not always be used in a similar fashion because of the suboptimal sensitivity and potential for false-negative results. An updated list of RIDTs is available at: https://www.cdc.gov/flu/professionals/diagnosis/table-ridt.html. Positive results of RIDTs are helpful, because they may reduce additional testing to identify

TABLE 5 Comparison of Types of Influenza Diagnostic Tests

Testing Category	Method	Influenza Viruses Detected	Distinguishes Influenza A Virus Subtypes	Time to Results	Performance
Rapid molecular assay	Nucleic acid amplification	Influenza A or B viral RNA	No	15–30 min	High sensitivity; high specificity
Rapid influenza diagnostic test	Antigen detection	Influenza A or B virus antigens	No	10–15 min	Low to moderate sensitivity (higher with analyzer devise); high specificity
Direct and indirect immunofluorescence assays	Antigen detection	Influenza A or B virus antigens	No	1–4 h	Moderate sensitivity; high specificity
Molecular assays (including RT-PCR)	Nucleic acid amplification	Influenza A or B viral RNA	Yes, if subtype primers are used	1–8 h	High sensitivity; high specificity
Multiplex molecular assays	Nucleic acid amplification	Influenza A or B viral RNA, other viral or bacterial targets (RNA or DNA)	Yes, if subtype primers are used	1–2 h	High sensitivity; high specificity
Rapid cell culture (shell vial and cell mixtures)	Virus isolation	Influenza A or B virus	Yes	1–3 d	High sensitivity; high specificity
Viral culture (tissue cell culture)	Virus isolation	Influenza A or B virus	Yes	3–10 d	High sensitivity; high specificity

Negative results may not rule out influenza. Respiratory tract specimens should be collected as close to illness onset as possible for testing. Clinicians should consult the manufacturer's package insert for the specific test for the approved respiratory specimen(s). Specificities are generally high (>95%) for all tests compared with reverse transcriptase-polymerase chain reaction (RT-PCR). FDA-cleared rapid influenza diagnostic tests are CLIA-waived; most FDA-cleared rapid influenza molecular assays are CLIA-waived, depending on the specimen. Source: Uyeki.[83]

alternative causes of the child's influenza-like illness, provide the opportunity for early antiviral treatment, promote appropriate antimicrobial stewardship, and allow the timely implementation of appropriate strategies to prevent transmission. Available FDA-approved rapid molecular assays based on nucleic acid detection are highly sensitive and specific diagnostic tests that can provide rapid results. An updated list of these tests is available here: https://www.cdc.gov/flu/professionals/diagnosis/table-nucleic-acid-detection.html. Molecular assays are preferred in hospitalized patients, because they are more sensitive compared with antigen detection. Early detection, prompt antiviral treatment, and infection control interventions can lead to improved individual patient outcomes and allow for effective cohorting and disease containment. This containment strategy is particularly relevant during the SARS-CoV-2 pandemic.

People with suspected influenza who are at higher risk of influenza complications should be offered treatment with antiviral medications (Table 2). Efforts should be made to minimize treatment of patients who are not infected with influenza. Otherwise healthy children who have suspected influenza with an uncomplicated presentation should be considered for antiviral medication, particularly if they are in contact with other children who either are younger than 6 months (as they are not able to receive influenza vaccine) or have high-risk conditions (including age <5 years) that predispose them to complications of influenza, when influenza viruses are known to be circulating in the community. If there is a local shortage of antiviral medications, local public health authorities should be consulted to provide additional guidance about testing and treatment. In previous years, local shortages of oseltamivir suspension have occurred because of uneven drug distribution, although national shortages have not occurred since 2009, particularly given the availability of the capsule formulation that can be made into a suspension for young children if needed (Table 4).

INFLUENZA CHEMOPROPHYLAXIS

Randomized placebo-controlled studies showed that oral oseltamivir and inhaled zanamivir were efficacious when administered as chemoprophylaxis to household contacts after a family member had laboratory-confirmed influenza.[83] There are no data on IV peramivir or oral baloxavir for chemoprophylaxis. Decisions on whether to administer antiviral chemoprophylaxis should take into account the exposed person's risk of influenza complications, vaccination status, the type and duration of contact, recommendations from local or public health authorities, and clinical judgment. Optimally, postexposure chemoprophylaxis should only be used when antiviral agents can be started within 48 hours of exposure; the lower once-daily dosing for chemoprophylaxis with oral oseltamivir or inhaled zanamivir should not be used for treatment of children symptomatic with influenza. Early, full treatment doses (rather than chemoprophylaxis doses) should be used in high-risk symptomatic patients without waiting for laboratory confirmation.

Chemoprophylaxis should not be considered a substitute for vaccination. Influenza vaccine should always be offered before and throughout the influenza season when not contraindicated. Antiviral medications are important adjuncts to influenza vaccination for control and prevention of influenza disease. Toxicities may be associated with antiviral agents, and indiscriminate use might limit availability. Pediatricians should inform recipients of antiviral chemoprophylaxis that risk of influenza is lowered but still remains while taking the medication, and susceptibility to influenza returns when medication is discontinued. Oseltamivir use is not a contraindication to vaccination with IIV, although LAIV effectiveness will be decreased for the child receiving oseltamivir.[83] No data are available on the impact of inhaled zanamivir, IV peramivir or oral baloxavir on effectiveness of LAIV, but it is likely that all antiviral agents will have some impact on effectiveness of LAIV. Among some high-risk people, both vaccination with IIV and antiviral chemoprophylaxis may be considered. Updates will be available at www.aapredbook.org/flu and www.cdc.gov/flu/professionals/antivirals/index.htm.

ANTIVIRAL RESISTANCE

Antiviral resistance to any drug can emerge, necessitating continuous population-based assessment that is conducted by the CDC. During the 2019–2020 season, >99% of influenza A(/H1N1)pdm09 and B/Victoria viruses tested were susceptible to oseltamivir, peramivir, and zanamivir, and all were susceptible to baloxavir. All tested influenza A(H3N2) and B/Yamagata viruses were susceptible to these antiviral agents. Decreased susceptibility to baloxavir has been reported in Japan, where utilization has been more common,[101–105] and surveillance for resistance among circulating influenza viruses is ongoing in Japan and the United States.[106–108] In contrast, high levels of resistance to amantadine and rimantadine persist among the influenza A viruses currently circulating. Adamantane medications are not recommended for use against influenza unless resistance patterns change.[83]

Viral surveillance and resistance data from the CDC and WHO indicate that the majority of currently circulating influenza viruses likely to cause influenza in North America during the 2020–2021 influenza season continue to be susceptible to oseltamivir, zanamivir, peramivir, and baloxavir (https://www.cdc.gov/flu/weekly/). If a newly emergent oseltamivir- or peramivir-resistant virus is a concern, recommendations for alternative treatment will be available from the CDC and AAP. Resistance characteristics can change for an individual patient over the duration of a treatment course, especially in those who are severely immunocompromised. Up-to-date information on current recommendations and therapeutic options can be found on the AAP Web site (www.aap.org or www.aapredbook.org/flu), through state-specific AAP chapter websites, or on the CDC Web site (www.cdc.gov/flu/).

INFLUENZA ANTIVIRALS RECOMMENDATIONS

Treatment recommendations for antiviral medications for the 2020–2021 influenza season are applicable to infants and children with suspected influenza when influenza viruses are known to be circulating in the community, or when infants or children are tested and confirmed to have influenza. Continuous monitoring of the epidemiology, change in severity, and resistance patterns of influenza virus strains by CDC may lead to new guidance. Oseltamivir (oral), zanamivir (inhaled), peramivir (IV), and baloxavir (oral) are FDA-approved for treatment of uncomplicated influenza virus infection in pediatric outpatients; published data exist to support the use of oseltamivir (oral) for hospitalized and children at high risk. For more serious influenza virus infections, particularly in immune compromised children, seeking the advice of an infectious diseases specialist is suggested.

ANTIVIRAL TREATMENT RECOMMENDATIONS

Regardless of influenza vaccination status, antiviral treatment should be offered as early as possible to:

- Any hospitalized child with suspected or confirmed influenza disease, regardless of duration of symptoms.
- Any child, inpatient or outpatient, with severe, complicated, or progressive illness attributable to influenza, regardless of duration of symptoms.
- Influenza virus infection of any severity in children at high risk of complications of influenza, as listed in Table 2, regardless of duration of symptoms.

Antiviral treatment may be considered for the following individuals:

- Any previously healthy, symptomatic outpatient not at high risk for influenza complications in whom an influenza diagnosis is confirmed or suspected on the basis of clinical judgment, if treatment can be initiated within 48 hours of illness onset.
- Children with suspected or confirmed influenza disease whose siblings or household contacts either are younger than 6 months or have a high-risk condition that predisposes them

to complications of influenza as listed in Table 2.

Shared informed decision making between providers and parents/legally authorized caregivers is encouraged to initiate therapy and monitor children for safety and efficacy while receiving antiviral agents. Efforts should be made to minimize treatment of patients who are not infected with influenza viruses.

ANTIVIRAL CHEMOPROPHYLAXIS RECOMMENDATIONS

Although vaccination is the preferred approach to prevention of infection, chemoprophylaxis during an influenza season is recommended in the following situations:

- For children at high risk of complications from influenza for whom influenza vaccine is contraindicated.
- For children at high risk during the 2 weeks after IIV influenza vaccination, before optimal immunity is achieved. Prophylaxis after LAIV may decrease vaccine efficacy.
- For family members or HCP who are unvaccinated and are likely to have ongoing, close exposure to:
  - unvaccinated children at high risk; or
  - unvaccinated infants and toddlers who are younger than 24 months.
- For control of influenza outbreaks for unvaccinated staff and children in a closed institutional setting with children at high risk (eg, extended-care facilities).
- As a supplement to IIV vaccination among children at high risk, including children who are immunocompromised and may not respond with sufficient protective immune responses following influenza vaccination.
- As postexposure antiviral chemoprophylaxis for family members and close contacts of an infected person if those people are at high risk of complications from influenza.
- For children at high risk of complications and their family members and close contacts, as well as for HCP, when circulating strains of influenza virus in the community are not well matched by seasonal influenza vaccine virus strains, on the basis of current data from the CDC and state or local health departments.

These recommendations apply to routine circumstances, but it should be noted that guidance may change on the basis of updated recommendations from the CDC in concert with antiviral availability, local resources, clinical judgment, recommendations from local or public health authorities, risk of influenza complications, type and duration of exposure contact, and change in epidemiology (resistance, antigenic shift) or severity of influenza. Children who have higher rates of influenza complications, including American Indian/Alaska Native children, should be prioritized to receive influenza antiviral agents in the setting of a shortage according to local public health guidelines (Table 2). Chemoprophylaxis is not routinely recommended for infants younger than 3 months given limited safety and efficacy data in this age group.

FUTURE DIRECTIONS

Safety and effectiveness data for influenza vaccines used during the 2020–2021 influenza season will be analyzed as they become available and reported by CDC as they are each season. Continued evaluation of the safety, immunogenicity, and effectiveness of influenza vaccines, especially for at risk populations, is important. The duration of protection, the potential role of previous influenza vaccination on overall vaccine effectiveness, and vaccine effectiveness by vaccine formulation, virus strain, timing of vaccination, and subject age and health status, in preventing outpatient medical visits, hospitalizations, and deaths continue to be evaluated. For the 2020–2021 influenza season, it will be particularly important to understand the effect of SARS-CoV-2 and influenza virus cocirculation on the epidemiology and morbidity of influenza in the pediatric population. Understanding how to better educate parents about influenza symptoms and how to recognize when to seek medical attention would be informative. Additionally, with limited data on the use of antiviral agents in hospitalized children and in children with underlying medical conditions, prospective clinical trials to inform optimal timing and efficacy of antiviral treatment in these populations are warranted. This is particularly relevant as new antiviral agents or new indications for existing antiviral agents become available. At this time, the FDA has accepted supplemental new drug applications for baloxavir marboxil. One application concerns the treatment of acute, uncomplicated influenza in pediatric patients from 1 year of age through 12 years of age. Another application addresses the use of baloxavir marboxil for postexposure prophylaxis (https://www.biospace.com/article/releases/fda-accepts-genentech-s-new-drug-application-for-xofluza-for-the-treatment-of-influenza-in-children-/).

There is also a need for more systematic health services research on influenza vaccine uptake and refusal as well as identification of methods to enhance uptake. Further investigation is needed about vaccine acceptance and hesitancy and methods to overcome parental concerns and improve coverage. This may include evaluating the strategy of

offering to immunize parents and adult child care providers in the pediatric office setting and understanding the level of family contact satisfaction with this approach; how practices handle the logistic, liability, legal, and financial barriers that limit or complicate this service; and most importantly, how this practice may affect disease rates in children and adults. Furthermore, ongoing efforts should include broader implementation and evaluation of mandatory HCP vaccination programs in both inpatient and outpatient settings.

Efforts should be made to create adequate outreach (eg, mobile integrated health care) and infrastructure to facilitate the optimal distribution of vaccine so that more people are immunized. Given the experience with COVID-19, pediatricians should become more involved in pandemic preparedness and disaster planning efforts. A bidirectional partner dialogue between pediatricians and public health decision makers assists efforts to address children's issues during the initial state, regional, and local plan development stages. Additional information can be found at www.aap.org/disasters/resourcekit and https://pediatrics.aappublications.org/content/pediatrics/early/2017/05/11/peds.2016-3690.full.pdf.

Access to care issues, lack of immunization records, and questions regarding who can provide consent may be addressed by linking children (eg, those in foster care/juvenile justice system or refugee, immigrant, or homeless children) with a medical home, using all health care encounters as vaccination opportunities, and more consistently using immunization registry data.

Development efforts continue for universal influenza vaccines that induce broader protection and eliminate the need for annual vaccination. Understanding the establishment of immunity against influenza in early life and the development of a safe, immunogenic vaccine for infants younger than 6 months are essential. Studies on the effectiveness and safety of influenza vaccines containing adjuvants that enhance immune responses to influenza vaccines or that use novel routes of administration are needed. Efforts to improve the vaccine development process to allow for a shorter interval between identification of vaccine strains and vaccine production continue. New antiviral drugs are in various development phases, given the need to improve options for the treatment and chemoprophylaxis of influenza.

Pediatricians can remain informed of advances and other updates during the influenza season by following the CDC Influenza page (www.cdc/gov/flu) and the AAP *Red Book Online* Influenza Resource Page (www.aapredbook.org/flu).

SUMMARY OF RECOMMENDATIONS

1. The AAP recommends annual influenza vaccination for everyone 6 months and older, including children and adolescents, during the 2020–2021 influenza season.
2. For the 2020–2021 influenza season, the AAP recommends that any licensed influenza vaccine appropriate for age and health status can be used for influenza vaccination in children. Inactivated influenza vaccine (IIV) and live attenuated vaccine (LAIV) are options for children for whom these vaccines are appropriate. This recommendation is based on review of current available data on LAIV and IIV vaccine efficacy (VE). The AAP will continue to review VE data as they become available and update these recommendations if necessary.
3. The AAP does not have a preference for any influenza vaccine product over another for children who have no contraindication to influenza vaccination and for whom more than one licensed product appropriate for age and health status is available. Pediatricians should administer whichever formulation is available in their communities to achieve the highest possible coverage this influenza season.
4. Children 6 through 35 months of age may receive any licensed, age-appropriate IIV available this season, at the dose indicated for the vaccine. No product is preferred over another for this age group. Children 36 months (3 years) and older should receive a 0.5-mL dose of any available, licensed, age-appropriate inactivated vaccine.
5. The number of seasonal influenza vaccine doses recommended to be administered to children in the 2020–2021 influenza season remains unchanged and depends on the child's age at the time of the first administered dose and vaccine history (Fig 2).
6. Children 6 months through 8 years of age who are receiving influenza vaccine for the first time or who have received only 1 dose, before July 1, 2020, or whose vaccination status is unknown, should receive 2 doses of influenza vaccine, ideally by the end of October, and vaccines should be offered as soon as they become available. Children needing only 1 dose of influenza vaccine, regardless of age, should also receive vaccination, ideally by the end of October.
7. Efforts should be made to ensure vaccination for children in high-risk groups (Table 2) and their contacts, unless contraindicated.

8. Product-specific contraindications must be considered when selecting the type of vaccine to administer. Children who have had an allergic reaction after a previous dose of any influenza vaccine should be evaluated by an allergist to determine whether future receipt of the vaccine is appropriate.
9. Children with egg allergy can receive influenza vaccine without any additional precautions beyond those recommended for all vaccines.
10. Pregnant women may receive inactivated influenza vaccine at any time during pregnancy, to protect themselves and their infants, who benefit from the transplacental transfer of antibodies. Women in the postpartum period who did not receive vaccination during pregnancy should be encouraged to receive influenza vaccine before discharge from the hospital. Influenza vaccination during breastfeeding is safe for mothers and their infants.
11. The AAP supports mandatory vaccination of health care personnel as a crucial element in preventing influenza and reducing health care-associated influenza infections, because health care personnel often care for individuals at high risk for influenza-related complications.
12. Antiviral medications are important in the control of influenza but are not a substitute for influenza vaccination. Pediatricians should promptly identify their patients suspected of having influenza infection for timely initiation of antiviral treatment, when indicated and based on shared decision making between the pediatrician and child's caregiver, to reduce morbidity and mortality. Although best results are observed when the child is treated within 48 hours of symptom onset, antiviral therapy should still be considered beyond 48 hours of symptom onset in children with severe disease or those at high risk of complications.
13. Antiviral treatment should be offered as early as possible to the following individuals, regardless of influenza vaccination status:
    - Any hospitalized child with suspected or confirmed influenza disease, regardless of duration of symptoms.
    - Any child, inpatient or outpatient, with severe, complicated, or progressive illness attributable to influenza, regardless of duration of symptoms.
    - Influenza infection of any severity in children at high risk of complications of influenza infection (Table 2), regardless of duration of symptoms.
14. Treatment may be considered for the following individuals:
    - Any previously healthy, symptomatic outpatient not at high risk for influenza complications in whom influenza is confirmed or suspected on the basis of clinical judgment, if treatment can be initiated within 48 hours of illness onset.
    - Children with suspected or confirmed influenza disease whose siblings or household contacts either are younger than 6 months or have a high-risk condition that predisposes them to complications of influenza (Table 2).
15. Antiviral chemoprophylaxis is recommended after known or suspected exposure influenza in the following situations:
    - For children at high risk of complications from influenza for whom influenza vaccine is contraindicated.
    - For children at high risk during the 2 weeks after influenza vaccination, before optimal immunity is achieved.
    - For family members or HCP who are unvaccinated and are likely to have ongoing, close exposure to:
    - unvaccinated children at high risk; or
    - unvaccinated infants and toddlers who are younger than 24 months.
    - For control of influenza outbreaks for unvaccinated staff and children in a closed institutional setting with children at high risk (eg, extended-care facilities).
    - As a supplement to vaccination among children at high risk, including children who are immunocompromised and may not respond with sufficient protective immune responses following influenza vaccination.
    - As postexposure antiviral chemoprophylaxis for family members and close contacts of an infected person if those people are at high risk of complications from influenza.
    - For children at high risk of complications and their family members and close contacts, as well as HCP, when circulating strains of influenza virus in the community are not well matched by seasonal influenza vaccine virus strains, on the basis of current data from the CDC and state or local health departments.

ADDITIONAL RESOURCES

Lessin HR; Edwards KM; American Academy of Pediatrics, Committee on Practice and Ambulatory

Medicine, Committee on Infectious Diseases. Immunizing parents and other close family contacts in the pediatric office setting. *Pediatrics.* 2012;129(1):e247.

American Academy of Pediatrics, Committee on Infectious Diseases. Policy statement: Influenza immunization for all health care personnel: keep it mandatory. *Pediatrics.* 2015;136(4):809-818.

American Academy of Pediatrics, Committee on Pediatric Emergency Medicine. Preparation for emergencies in the offices of pediatricians and pediatric primary care providers. *Pediatrics.* 2007;120(1):200-212. Reaffirmed June 2011.

American Academy of Pediatrics, Committee on Practice and Ambulatory Medicine, AAP Committee on Infectious Diseases, AAP Committee on State Government Affairs, AAP Council on School Health, AAP Section on Administration and Practice Management. Medical Versus Nonmedical Immunization Exemptions for Child Care and School Attendance. *Pediatrics.* 2016;138(3):e20162145.

Edwards KM, Hackell JM; American Academy of Pediatrics, Committee on Infectious Diseases, Committee on Practice and Ambulatory Medicine. Countering vaccine hesitancy. *Pediatrics.* 2016;138(3):e20162146.

American Academy of Pediatrics, Committee on Pediatric Emergency Medicine; American Academy of Pediatrics Committee on Medical Liability; Task Force on Terrorism. The pediatrician and disaster preparedness. *Pediatrics.* 2006; 117(2):560-565. Reaffirmed September 2013.

American Academy of Pediatrics. Influenza. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2018 Report of the Committee on Infectious Diseases.* 31st ed. Elk Grove Village, IL: American Academy of Pediatrics; 2018: 476–489. Available at: http://aapredbook.aappublications.org/flu.

ABBREVIATIONS

AAP: American Academy of Pediatrics
WHO: World Health Organization
ACIP: Advisory Committee on Immunization Practices
ANE: acute necrotizing encephalopathy
ccIIV4: quadrivalent cell culture-based inactivated influenza vaccine
CDC: Centers for Disease Control and Prevention
FDA: US Food and Drug Administration
GBS: Guillain-Barré syndrome
HA: hemagglutinin
HCP: health care personnel
IAE: influenza-associated encephalopathy
IIV: inactivated influenza vaccine
IIV3: trivalent inactivated influenza vaccine
IIV4: quadrivalent inactivated influenza vaccine
IM: intramuscular
LAIV4: quadrivalent live attenuated influenza vaccine
NAIs: neuraminidase inhibitors
PCR: polymerase chain reaction
PCV13: 13-valent pneumococcal conjugate vaccine
RIV4: quadrivalent recombinant influenza vaccine
SARS-CoV-2: severe acute respiratory syndrome-coronavirus 2
VE: vaccine effectiveness

REFERENCES

1. Grohskopf LA, Alyanak E, Broder KR, et al. Prevention and control of seasonal influenza with vaccines:

recommendations of the Advisory Committee on Immunization Practices, United States, 2020–21 influenza season. *MMWR Recomm Rep*. 2020; 69(RR-8):1–24

2. Shope TR, Walker BH, Aird LD, Southward L, McCown JS, Martin JM. Pandemic influenza preparedness among child care center directors in 2008 and 2016. *Pediatrics*. 2017;139(6):e20163690
3. Garten R, Blanton L, Elal AIA, et al. Update: influenza activity in the United States during the 2017–18 season and composition of the 2018–19 influenza vaccine. *MMWR Morb Mortal Wkly Rep*. 2018;67(22):634–642
4. Centers for Disease Control and Prevention. Vaccine effectiveness tables for 2017-18 season. Available at: https://www.cdc.gov/flu/vaccines-work/2017-2018.html. Accessed May 31, 2019
5. Biggerstaff M, Kniss K, Jernigan DB, et al. Systematic assessment of multiple routine and near real-time indicators to classify the severity of influenza seasons and pandemic in the United States, 2003-2004 through 2015-2016. *Am J Epidemiol*. 2018;187(5):1040–1050
6. Dawood FS, Chung JR, Kim SS, et al. Interim estimates of 2019-20 seasonal influenza vaccine effectiveness–United States, February 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69(7):177–182
7. Xu X, Blanton L, Elal AIA, et al. Update: influenza activity in the United States during the 2018-19 season and composition of the 2019-20 influenza vaccine. *MMWR Morb Mortal Wkly Rep*. 2019;68(24):544–551
8. Centers for Disease Control and Prevention. Weekly US influenza surveillance report (FluView). Available at: https://www.cdc.gov/flu/weekly/. Accessed May 31, 2020
9. Centers for Disease Control and Prevention. Flu vaccination coverage, United States, 2018–19 influenza season. Available at: https://www.cdc.gov/flu/fluvaxview/coverage-1819estimates.htm. Accessed May 4, 2020
10. Centers for Disease Control and Prevention. COVIDView: a weekly surveillance study of U.S. COVID-19 activity. Available at: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview.html. Accessed May 4, 2020
11. Wang X, Li Y, O'Brien KL, et al; Respiratory Virus Global Epidemiology Network. Global burden of respiratory infections associated with seasonal influenza in children under 5 years in 2018: a systematic review and modelling study. *Lancet Glob Health*. 2020;8(4):e497–e510
12. Miyakawa R, Barreto NB, Kato RM, Neely MN, Russell CJ. Early use of anti-influenza medications in hospitalized children with tracheostomy. *Pediatrics*. 2019;143(3):e20182608
13. Centers for Disease Control and Prevention (CDC). Deaths related to 2009 pandemic influenza A (H1N1) among American Indian/Alaska Natives - 12 states, 2009. *MMWR Morb Mortal Wkly Rep*. 2009;58(48):1341–1344
14. Dee DL, Bensyl DM, Gindler J, et al. Racial and ethnic disparities in hospitalizations and deaths associated with 2009 pandemic Influenza A (H1N1) virus infections in the United States. *Ann Epidemiol*. 2011;21(8):623–630
15. Gounder PP, Callinan LS, Holman RC, et al. Influenza hospitalizations among american indian/alaska native people and in the United States general population. *Open Forum Infect Dis*. 2014;1(1):ofu031
16. Hennessy TW, Bruden D, Castrodale L, et al; Investigative Team. A case-control study of risk factors for death from 2009 pandemic influenza A(H1N1): is American Indian racial status an independent risk factor? *Epidemiol Infect*. 2016;144(2):315–324
17. Feldstein LR, Ogokeh C, Rha B, et al. Vaccine effectiveness against influenza hospitalization among children in the United States, 2015-2016 [published online ahead of print February 28, 2020]. *J Pediatr Infect Dis Soc*. doi: 10.1093/jpids/piaa017
18. Segaloff HE, Leventer-Roberts M, Riesel D, et al. Influenza vaccine effectiveness against hospitalization in fully and partially vaccinated children in Israel: 2015-2016, 2016-2017, and 2017-2018. *Clin Infect Dis*. 2019;69(12):2153–2161
19. Blyth CC, Cheng AC, Crawford NW, et al; Paediatric Active Enhanced Disease Surveillance (PAEDS), Influenza Complications Alert Network (FluCAN) Collaboration. The impact of new universal child influenza programs in Australia: vaccine coverage, effectiveness and disease epidemiology in hospitalised children in 2018. *Vaccine*. 2020;38(13):2779–2787
20. Pebody RG, Zhao H, Whitaker HJ, et al. Effectiveness of influenza vaccine in children in preventing influenza associated hospitalisation, 2018/19, England. *Vaccine*. 2020;38(2):158–164
21. Kalligeros M, Shehadeh F, Mylona EK, et al. Influenza vaccine effectiveness against influenza-associated hospitalization in children: a systematic review and meta-analysis. *Vaccine*. 2020;38(14):2893–2903
22. Chung JR, Rolfes MA, Flannery B, et al. Effects of influenza vaccination in the United States during the 2018-2019 influenza season [published online ahead of print January 6, 2020]. *Clin Infect Dis*. doi: 10.1093/cid/ciz1244
23. Flannery B, Reynolds SB, Blanton L, et al. Influenza vaccine effectiveness against pediatric deaths: 2010-2014. *Pediatrics*. 2017;139(5):e20164244
24. Ferdinands JM, Olsho LE, Agan AA, et al; Pediatric Acute Lung Injury and Sepsis Investigators (PALISI) Network. Effectiveness of influenza vaccine against life-threatening RT-PCR-confirmed influenza illness in US children, 2010-2012. *J Infect Dis*. 2014;210(5):674–683
25. Tran D, Vaudry W, Moore D, et al; members of the Canadian Immunization Monitoring Program Active. Hospitalization for influenza A versus B. *Pediatrics*. 2016;138(3):e20154643
26. World Health Organization. Recommended composition of influenza virus vaccine for use in the 2019-2020 northern hemisphere influenza season. Available at: https://www.who.int/influenza/vaccines/virus/recommendations/2019_20_north/en/. Accessed March 21, 2019
27. Vesikari T, Kirstein J, Devota Go G, et al. Efficacy, immunogenicity, and safety evaluation of an MF59-adjuvanted quadrivalent influenza virus vaccine compared with non-adjuvanted influenza vaccine in children: a multicentre, randomised controlled, observer-blinded, phase 3 trial. *Lancet Respir Med*. 2018;6(5):345–356
28. US Food and Drug Administration. Fluzone quadrivalent. 2018. Available at: https://www.fda.gov/vaccines-blood-

biologics/vaccines/fluzone-quadrivalent. Accessed June 24, 2019

29. Robertson CA, Mercer M, Selmani A, Klein NP, Jeanfreau R, Greenberg DP. Safety and immunogenicity of a full-dose, split-virion, inactivated, quadrivalent influenza vaccine in healthy children 6-35 months of age: a randomized controlled clinical trial. *Pediatr Infect Dis J*. 2019;38(3):323–328
30. Halasa NB, Gerber MA, Berry AA, et al. Safety and immunogenicity of full-dose trivalent inactivated influenza vaccine (TIV) compared with half-dose TIV administered to children 6 through 35 months of age. *J Pediatric Infect Dis Soc*. 2015;4(3):214–224
31. Claeys C, Zaman K, Dbaibo G, et al; Flu4VEC Study Group. Prevention of vaccine-matched and mismatched influenza in children aged 6-35 months: a multinational randomised trial across five influenza seasons. *Lancet Child Adolesc Health*. 2018;2(5):338–349
32. Jain VK, Domachowske JB, Wang L, et al. Time to change dosing of inactivated quadrivalent influenza vaccine in young children: evidence from a phase III, randomized, controlled trial. *J Pediatric Infect Dis Soc*. 2017;6(1):9–19
33. US Food and Drug Administration. Afluria quadrivalent. 2018. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/afluria-quadrivalent. Accessed June 24, 2019
34. Duffy J, Weintraub E, Hambidge SJ, et al; Vaccine Safety Datalink. Febrile seizure risk after vaccination in children 6 to 23 months. *Pediatrics*. 2016;138(1): e20160320
35. Thompson CA. Vaccine safety signal from spontaneous system not supported by active surveillance. *Am J Health Syst Pharm*. 2014;71(17): 1432–1433
36. Sentinel. Influenza vaccines and febrile seizures in the 2013-2014 and 2014-2015 influenza seasons. 2017. Available at: https://www.sentinelinitiative.org/sites/default/files/vaccines-blood-biologics/assessments/Influenza-Vaccines-Febrile-Seizures-Final-Report.pdf. Accessed June 24, 2019
37. Baker MA, Jankosky C, Yih WK, et al. The risk of febrile seizures following influenza and 13-valent pneumococcal conjugate vaccines. *Vaccine*. 2020;38(9): 2166–2171
38. Walter EB, Klein NP, Wodi AP, et al. Fever after influenza, diphtheria-tetanus-acellular pertussis, and pneumococcal vaccinations. *Pediatrics*. 2020;145(3): e20191909
39. Global advisory committee on vaccine safety, June 202. *Wkly Epidemiol Rec*. 2012;87(30):277–288
40. Grohskopf LA, Sokolow LZ, Fry AM, Walter EB, Jernigan DB. Update: ACIP recommendations for the use of quadrivalent live attenuated influenza vaccine (LAIV4) - United States, 2018-19 influenza season. *MMWR Morb Mortal Wkly Rep*. 2018;67(22):643–645
41. Mallory RM, Nyborg A, Kalyani RN, Yuan Y, Block SL, Dubovsky F. A study to evaluate the immunogenicity and shedding of live attenuated influenza vaccine strains in children 24-<48 months of age. *Vaccine*. 2020;38(5): 1001–1008
42. Pebody RG, Whitaker H, Ellis J, et al. End of season influenza vaccine effectiveness in primary care in adults and children in the United Kingdom in 2018/19. *Vaccine*. 2020;38(3):489–497
43. Centers for Disease Control and Prevention. US flu VE data for 2018-2019. Available at: https://www.cdc.gov/flu/vaccines-work/2018-2019.html. Accessed May 4, 2020
44. Nordin JD, Vazquez-Benitez G, Olsen A, Kuckler LC, Gao AY, Kharbanda EO. Safety of guidelines recommending live attenuated influenza vaccine for routine use in children and adolescents with asthma. *Vaccine*. 2019;37(30):4055–4060
45. Turner PJ, Fleming L, Saglani S, Southern J, Andrews NJ, Miller E; SNIFFLE-4 Study Investigators. Safety of live attenuated influenza vaccine (LAIV) in children with moderate to severe asthma. *J Allergy Clin Immunol*. 2020; 145(4):1157–1164.e6
46. Kelso JM, Greenhawt MJ, Li JT; Joint Task Force on Practice Parameters (JTFPP). Update on influenza vaccination of egg allergic patients. *Ann Allergy Asthma Immunol*. 2013;111(4): 301–302
47. Greenhawt M, Turner PJ, Kelso JM. Administration of influenza vaccines to egg allergic recipients: a practice parameter update 2017. *Ann Allergy Asthma Immunol*. 2018;120(1):49–52
48. American College of Obstetricians and Gynecologists. ACOG committee opinion No. 732: influenza vaccination during pregnancy. *Obstet Gynecol*. 2018;131(4): e109–e114
49. Robison SG, Osborn AW. The concordance of parent and child immunization. *Pediatrics*. 2017;139(5): e20162883
50. Zaman K, Roy E, Arifeen SE, et al. Effectiveness of maternal influenza immunization in mothers and infants. *N Engl J Med*. 2008;359(15):1555–1564
51. Tapia MD, Sow SO, Tamboura B, et al. Maternal immunisation with trivalent inactivated influenza vaccine for prevention of influenza in infants in Mali: a prospective, active-controlled, observer-blind, randomised phase 4 trial. *Lancet Infect Dis*. 2016;16(9): 1026–1035
52. Madhi SA, Cutland CL, Kuwanda L, et al; Maternal Flu Trial (Matflu) Team. Influenza vaccination of pregnant women and protection of their infants. *N Engl J Med*. 2014;371(10):918–931
53. Steinhoff MC, Katz J, Englund JA, et al. Year-round influenza immunisation during pregnancy in Nepal: a phase 4, randomised, placebo-controlled trial. *Lancet Infect Dis*. 2017;17(9):981–989
54. Shakib JH, Korgenski K, Presson AP, et al. Influenza in infants born to women vaccinated during pregnancy. *Pediatrics*. 2016;137(6):e20152360
55. Nunes MC, Madhi SA. Influenza vaccination during pregnancy for prevention of influenza confirmed illness in the infants: a systematic review and meta-analysis. *Hum Vaccin Immunother*. 2018;14(3):758–766
56. Thompson MG, Kwong JC, Regan AK, et al; PREVENT Workgroup. Influenza vaccine effectiveness in preventing influenza-associated hospitalizations during pregnancy: a multi-country retrospective test negative design study, 2010-2016. *Clin Infect Dis*. 2019; 68(9):1444–1453
57. Nunes MC, Madhi SA. Prevention of influenza-related illness in young infants by maternal vaccination during pregnancy. *F1000 Res*. 2018;7:122

58. Omer SB, Clark DR, Aqil AR, et al; BMGF Supported Maternal Influenza Immunization Trials Investigators Group. Maternal influenza immunization and prevention of severe clinical pneumonia in young infants: analysis of randomized controlled trials conducted in Nepal, Mali and South Africa. *Pediatr Infect Dis J*. 2018;37(5): 436–440

59. Munoz FM, Jackson LA, Swamy GK, et al. Safety and immunogenicity of seasonal trivalent inactivated influenza vaccines in pregnant women. *Vaccine*. 2018; 36(52):8054–8061

60. Sheffield JS, Greer LG, Rogers VL, et al. Effect of influenza vaccination in the first trimester of pregnancy. *Obstet Gynecol*. 2012;120(3):532–537

61. Polyzos KA, Konstantelias AA, Pitsa CE, Falagas ME. Maternal influenza vaccination and risk for congenital malformations: a systematic review and meta-analysis. *Obstet Gynecol*. 2015; 126(5):1075–1084

62. Chambers CD, Johnson D, Xu R, et al; OTIS Collaborative Research Group. Risks and safety of pandemic H1N1 influenza vaccine in pregnancy: birth defects, spontaneous abortion, preterm delivery, and small for gestational age infants. *Vaccine*. 2013;31(44):5026–5032

63. Nordin JD, Kharbanda EO, Vazquez Benitez G, Lipkind H, Vellozzi C, Destefano F; Vaccine Safety Datalink. Maternal influenza vaccine and risks for preterm or small for gestational age birth. *J Pediatr*. 2014;164(5): 1051–1057.e2

64. Chambers CD, Johnson DL, Xu R, et al; OTIS Collaborative Research Group. Safety of the 2010-11, 2011-12, 2012-13, and 2013-14 seasonal influenza vaccines in pregnancy: birth defects, spontaneous abortion, preterm delivery, and small for gestational age infants, a study from the cohort arm of VAMPSS. *Vaccine*. 2016;34(37): 4443–4449

65. Donahue JG, Kieke BA, King JP, et al. Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010-11 and 2011-12. *Vaccine*. 2017;35(40): 5314–5322

66. Donahue J. Inactivated influenza vaccine and spontaneous abortion in the Vaccine Safety Datalink in 2012-13, 2013-14, and 2014-15. *Vaccine*. 2019; 37(44):6673–6681

67. Schlaudecker EP, Steinhoff MC, Omer SB, et al. IgA and neutralizing antibodies to influenza a virus in human milk: a randomized trial of antenatal influenza immunization. *PLoS One*. 2013;8(8):e70867

68. Bradley JS, Blumer JL, Romero JR, et al. Intravenous zanamivir in hospitalized patients with influenza. *Pediatrics*. 2017;140(5):e20162727

69. Chan-Tack KM, Kim C, Moruf A, Birnkrant DB. Clinical experience with intravenous zanamivir under an Emergency IND program in the United States (2011-2014). *Antivir Ther*. 2015;20(5):561–564

70. Ferdinands JM, Fry AM, Reynolds S, et al. Intraseason waning of influenza vaccine protection: evidence from the US influenza vaccine effectiveness network, 2011-12 through 2014-15. *Clin Infect Dis*. 2017;64(5):544–550

71. Castilla J, Martínez-Baz I, Martínez-Artola V, et al; Primary Health Care Sentinel Network; Network for Influenza Surveillance in Hospitals of Navarre. Decline in influenza vaccine effectiveness with time after vaccination, Navarre, Spain, season 2011/12. *Euro Surveill*. 2013;18(5):20388

72. Kissling E, Valenciano M, Larrauri A, et al. Low and decreasing vaccine effectiveness against influenza A(H3) in 2011/12 among vaccination target groups in Europe: results from the I-MOVE multicentre case-control study. *Euro Surveill*. 2013;18(5):20390

73. Belongia EA, Sundaram ME, McClure DL, Meece JK, Ferdinands J, VanWormer JJ. Waning vaccine protection against influenza A (H3N2) illness in children and older adults during a single season. *Vaccine*. 2015;33(1):246–251

74. Radin JM, Hawksworth AW, Myers CA, Ricketts MN, Hansen EA, Brice GT. Influenza vaccine effectiveness: maintained protection throughout the duration of influenza seasons 2010-2011 through 2013-2014. *Vaccine*. 2016; 34(33):3907–3912

75. Puig-Barberà J, Mira-Iglesias A, Tortajada-Girbés M, et al; Valencia Hospital Network for the Study of Influenza and other Respiratory Viruses (VAHNSI, Spain). Waning protection of influenza vaccination during four influenza seasons, 2011/2012 to 2014/2015. *Vaccine*. 2017;35(43):5799–5807

76. Ray GT, Lewis N, Klein NP, Daley MF, Lipsitch M, Fireman B. Depletion-of-susceptibles Bias in Analyses of Intra-season waning of influenza vaccine effectiveness. *Clin Infect Dis*. 2020;70(7): 1484–1486

77. Kissling E, Nunes B, Robertson C, et al; I-MOVE case–control study team. I-MOVE multicentre case-control study 2010/11 to 2014/15: is there within-season waning of influenza type/subtype vaccine effectiveness with increasing time since vaccination? *Euro Surveill*. 2016;21(16)

78. Pebody R, Andrews N, McMenamin J, et al. Vaccine effectiveness of 2011/12 trivalent seasonal influenza vaccine in preventing laboratory-confirmed influenza in primary care in the United Kingdom: evidence of waning intra-seasonal protection. *Euro Surveill*. 2013; 18(5):20389

79. Petrie JG, Ohmit SE, Truscon R, et al. Modest waning of influenza vaccine efficacy and antibody titers during the 2007-2008 influenza season. *J Infect Dis*. 2016;214(8):1142–1149

80. Ray GT, Lewis N, Klein NP, et al. Intraseason waning of influenza vaccine effectiveness. *Clin Infect Dis*. 2019; 68(10):1623–1630

81. Ferdinands JM, Patel MM, Foppa IM, Fry AM. Influenza vaccine effectiveness. *Clin Infect Dis*. 2019;69(1):190–191

82. Centers for Disease Control and Prevention. Influenza vaccination coverage among health care personnel — United States, 2018–19 influenza season. Available at: https://www.cdc.gov/flu/fluvaxview/hcp-coverage_1819estimates.htm. Accessed May 4, 2020

83. Uyeki TM, Bernstein HH, Bradley JS, et al. Clinical practice guidelines by the Infectious Diseases Society of America: 2018 Update on diagnosis, treatment, chemoprophylaxis, and institutional outbreak management of seasonal influenza. *Clin Infect Dis*. 2019;68(6): e1–e47

84. Heo YA. Baloxavir: first global approval. *Drugs*. 2018;78(6):693–697

85. Dobson J, Whitley RJ, Pocock S, Monto AS. Oseltamivir treatment for influenza in adults: a meta-analysis of randomised controlled trials. *Lancet*. 2015;385(9979):1729–1737

86. Jefferson T, Jones MA, Doshi P, et al. Neuraminidase inhibitors for preventing and treating influenza in healthy adults and children. *Cochrane Database Syst Rev*. 2014;(4):CD008965

87. Malosh RE, Martin ET, Heikkinen T, Brooks WA, Whitley RJ, Monto AS. Efficacy and safety of oseltamivir in children: systematic review and individual patient data meta-analysis of randomized controlled trials. *Clin Infect Dis*. 2018;66(10):1492–1500

88. Uyeki TM. Oseltamivir treatment of influenza in children. *Clin Infect Dis*. 2018;66(10):1501–1503

89. Wang K, Shun-Shin M, Gill P, Perera R, Harnden A. Neuraminidase inhibitors for preventing and treating influenza in children (published trials only). *Cochrane Database Syst Rev*. 2012;(4): CD002744

90. Domínguez A, Romero-Tamarit A, Soldevila N, et al; Surveillance of Hospitalized Cases of Severe Influenza in Catalonia Working Group. Effectiveness of antiviral treatment in preventing death in severe hospitalised influenza cases over six seasons. *Epidemiol Infect*. 2018;146(7):799–808

91. Hsu J, Santesso N, Mustafa R, et al. Antivirals for treatment of influenza: a systematic review and meta-analysis of observational studies. *Ann Intern Med*. 2012;156(7):512–524

92. Muthuri SG, Venkatesan S, Myles PR, et al; PRIDE Consortium Investigators. Effectiveness of neuraminidase inhibitors in reducing mortality in patients admitted to hospital with influenza A H1N1pdm09 virus infection: a meta-analysis of individual participant data. *Lancet Respir Med*. 2014;2(5):395–404

93. Venkatesan S, Myles PR, Leonardi-Bee J, et al. Impact of outpatient neuraminidase inhibitor treatment in patients infected with influenza A(H1N1) pdm09 at high risk of hospitalization: an individual participant data metaanalysis. *Clin Infect Dis*. 2017; 64(10):1328–1334

94. Dawood FS, Jara J, Gonzalez R, et al. A randomized, double-blind, placebo-controlled trial evaluating the safety of early oseltamivir treatment among children 0-9 years of age hospitalized with influenza in El Salvador and Panama. *Antiviral Res*. 2016;133:85–94

95. Louie JK, Yang S, Samuel MC, Uyeki TM, Schechter R. Neuraminidase inhibitors for critically ill children with influenza. *Pediatrics*. 2013;132(6). Available at: www.pediatrics.org/cgi/content/full/132/6/e1539

96. Katzen J, Kohn R, Houk JL, Ison MG. Early oseltamivir after hospital admission is associated with shortened hospitalization: a 5-year analysis of oseltamivir timing and clinical outcomes. *Clin Infect Dis*. 2019;69(1): 52–58

97. Ramirez J, Peyrani P, Wiemken T, Chaves SS, Fry AM. A randomized study evaluating the effectiveness of oseltamivir initiated at the time of hospital admission in adults hospitalized with influenza-associated lower respiratory tract infections. *Clin Infect Dis*. 2018;67(5):736–742

98. Li L, Liu J, Qin K. Comparison of double-dose vs standard-dose oseltamivir in the treatment of influenza: a systematic review and meta-analysis [published online ahead of print June 4, 2020]. *J Clin Pharm Ther*. doi: 10.1111/jcpt.13203

99. Howard A, Uyeki TM, Fergie J. Influenza-associated acute necrotizing encephalopathy in siblings. *J Pediatric Infect Dis Soc*. 2018;7(3):e172–e177

100. Takeuchi S, Tetsuhashi M, Sato D. Oseltamivir phosphate-Lifting the restriction on its use to treat teenagers with influenza in Japan. *Pharmacoepidemiol Drug Saf*. 2019; 28(4):434–436

101. Koszalka P, Tilmanis D, Roe M, Vijaykrishna D, Hurt AC. Baloxavir marboxil susceptibility of influenza viruses from the Asia-Pacific, 2012-2018. *Antiviral Res*. 2019;164:91–96

102. Takashita E, Kawakami C, Morita H, et al; On Behalf Of The Influenza Virus Surveillance Group Of Japan. Detection of influenza A(H3N2) viruses exhibiting reduced susceptibility to the novel cap-dependent endonuclease inhibitor baloxavir in Japan, December 2018. *Euro Surveill*. 2019;24(3):1800698

103. Takashita E, Kawakami C, Ogawa R, et al. Influenza A(H3N2) virus exhibiting reduced susceptibility to baloxavir due to a polymerase acidic subunit I38T substitution detected from a hospitalised child without prior baloxavir treatment, Japan, January 2019. *Euro Surveill*. 2019;24(12):1900170

104. Hayden FG, Sugaya N, Hirotsu N, et al; Baloxavir Marboxil Investigators Group. Baloxavir marboxil for uncomplicated influenza in adults and adolescents. *N Engl J Med*. 2018; 379(10):913–923

105. Omoto S, Speranzini V, Hashimoto T, et al. Characterization of influenza virus variants induced by treatment with the endonuclease inhibitor baloxavir marboxil. *Sci Rep*. 2018;8(1):9633

106. Gubareva LV, Mishin VP, Patel MC, et al. Assessing baloxavir susceptibility of influenza viruses circulating in the United States during the 2016/17 and 2017/18 seasons. *Euro Surveill*. 2019; 24(3):1800666

107. Ince WL, Smith FB, O'Rear JJ, Thomson M. Treatment-emergent influenza virus PA substitutions independent of those at I38 associated with reduced baloxavir susceptibility and virus rebound in trials of baloxavir marboxil [published online ahead of print April 7, 2020]. *J Infect Dis*. doi: 10.1093/infdis/jiaa164

108. Takashita E, Daniels RS, Fujisaki S, et al. Global update on the susceptibilities of human influenza viruses to neuraminidase inhibitors and the cap-dependent endonuclease inhibitor baloxavir, 2017-2018. *Antiviral Res*. 2020; 175:104718

Recommended Childhood and Adolescent Immunization Schedule: United States, 2021

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Recommended Childhood and Adolescent Immunization Schedule: United States, 2021

COMMITTEE ON INFECTIOUS DISEASES

The 2021 recommended childhood and adolescent immunization schedules have been approved by the Centers for Disease Control and Prevention (CDC), American Academy of Pediatrics, American Academy of Family Physicians, American College of Obstetricians and Gynecologists, American College of Nurse-Midwives, American Academy of Physician Assistants, and National Association of Pediatric Nurse Practitioners. The schedules are revised annually to reflect current recommendations for the use of vaccines licensed by the US Food and Drug Administration.

The 2021 childhood and adolescent immunization schedule has been updated to ensure consistency between the format of the childhood and adolescent and adult immunization schedules. Similar to last year, the cover page includes a table with an alphabetical listing of vaccines, approved abbreviations for each vaccine, and vaccine trade names.

Table 1 contains the recommended immunization schedule from birth to 18 years of age.

Table 2 is the catch-up immunization schedule for persons 4 months to 18 years of age who start late or who are more than 1 month behind the recommended age for vaccine administration.

Table 3 lists the vaccines that may be indicated for children and adolescents 18 years of age or younger on the basis of medical conditions.

Similar to the 2021 schedule, the notes are presented in alphabetical order. The following changes to individual footnotes have been made to the 2021 schedule:

- For influenza vaccines:
  - Updated language about use of influenza vaccines in persons with an egg allergy with symptoms other than hives: if using an influenza vaccine other than Flublok or Flucelvax, administer in a medical setting under the supervision of a health care provider who can recognize and manage severe allergic reactions.

DOI: https://doi.org/10.1542/peds.2020-049775

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

To cite: COMMITTEE ON INFECTIOUS DISEASES. Recommended Childhood and Adolescent Immunization Schedule: United States, 2021. *Pediatrics*. 2021;147(3):e2020049775

- Added information regarding severe allergic reactions.
- Updated information about use of antiviral medications and administering quadrivalent live attenuated influenza vaccine (LAIV4): LAIV4 should not be used if one received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days.
- Added "Children younger than 2 years" to the situations in which LAIV4 should not be used[1] (Advisory Committee on Immunization Practices [ACIP] Meeting, June 24, 2020).

- For meningococcal serogroup A, C, W, and Y vaccines:
  - Added meningococcal groups A, C, W, and Y polysaccharide tetanus toxoid conjugate vaccine (MenACWY-TT) as an option for preventing disease attributed to the meningococcal serogroups A, C, W, and Y.
  - Added language for catch-up vaccination for infants who received 1 dose of meningococcal groups A, C, W, and Y oligosaccharide diphtheria CRM_{197} conjugate vaccine (MenACWY-CRM) at an age from 3 to 6 months[2] (ACIP Meeting, June 26–27, 2019).
- For the meningococcal B vaccine (MenB):
  - For persons aged ≥10 years with complement deficiency, complement inhibitor use, or asplenia or who are microbiologists: MenB booster dose 1 year after completion of a MenB primary series, followed by MenB booster doses every 2 to 3 years thereafter, for as long as an increased risk remains.
  - For persons aged ≥10 years determined by public health officials to be at an increased risk during an outbreak: One-time booster dose if it has been ≥1 year since completion of a MenB primary series. A booster dose interval of ≥6 months may be considered by public health officials, depending on the specific outbreak, vaccination strategy, and projected duration of elevated risk[2] (ACIP Meeting, June 26–27, 2019).
- For tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine (Tdap), ACIP recommendations have been updated to allow either the tetanus and diphtheria toxoids vaccine or Tdap to be used for the decennial tetanus and diphtheria toxoids booster, tetanus prophylaxis for wound management, and additional required doses in the catch-up immunization schedule, if a person has received at least 1 Tdap dose[3] (ACIP Meeting, October 23–24, 2019).

Other notable changes in the 2021 child and adolescent immunization schedule include the following:

- Cover page: changed the abbreviation LAIV to LAIV4; added MenACWT-TT (MenQuadfi) to list of meningococcal ACWY; added DTaP-IPV-Hib-HepB (Vaxelis) to list of combination vaccines.
- Table 1 (Recommended Child and Adolescent Immunization Schedule by Age): changed the abbreviation for live attenuated influenza vaccine (LAIV) to LAIV4. In the hepatitis B vaccine row, arrows were added to second dose.
- Table 3 (Recommended Child and Adolescent Immunization Schedule by Medical Condition): in the LAIV row, changed abbreviation to LAIV4. In the measles, mumps, and rubella (MMR) and varicella (VAR) rows, pregnancy column, an asterisk was added to indicate MMR and VAR vaccines should be administered after pregnancy. In the human papillomavirus (HPV) row, pregnancy column, the pink color for delay until after pregnancy has been replaced with red, which indicates not recommended and contraindicated; an asterisk was also added to indicate the HPV vaccine should be administered after pregnancy.
- Notes (Special Situations): clarifying edits were made to the notes to improve readability and the utility of the schedule for diphtheria and tetanus toxoids and acellular pertussis vaccination, *Haemophilus influenzae* type b vaccination, hepatitis A vaccination, hepatitis B vaccination, HPV vaccination, pneumococcal vaccination, and Tdap vaccination.
- A box within the notes section of the immunization schedules was included that states, "COVID-19 Vaccination- ACIP recommends use of COVID-19 vaccines within the scope of the Emergency Use Authorization or Biologics License Application for the particular vaccine. Interim ACIP recommendations for use of COVID-19 vaccines can be found at www.cdc.gov/vaccines/hcp/acip-recs" on the first page under "Additional Information."

The 2021 version of Tables 1 through 3 and the notes are available on the American Academy of Pediatrics Web site (https://redbook.solutions.aap.org/SS/Immunization_Schedules.aspx) and the CDC Web site (www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html). A parent-friendly vaccine schedule for children and adolescents is available at www.cdc.gov/vaccines/schedules/index.html. An adult immunization schedule is published in February of each year and is available at www.cdc.gov/vaccines/schedules/hcp/adult.html.

Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System. Guidance about how to obtain and complete a Vaccine Adverse Event Reporting

System form can be obtained at www.vaers.hhs.gov or by calling 800-822-7967. Additional information can be found in the *Red Book* and at *Red Book* Online (http://aapredbook.aappublications.org/). Statements from the ACIP and the CDC that contain detailed recommendations for individual vaccines, including recommendations for children with high-risk conditions, are available at www.cdc.gov/vaccines/hcp/acip-recs/index.html. Information on new vaccine releases, vaccine supplies, and interim recommendations resulting from vaccine shortages and statements on specific vaccines can be found at www.aapredbook.org/news/vaccstatus.shtml.

ABBREVIATIONS

ACIP: Advisory Committee on Immunization Practices
CDC: Centers for Disease Control and Prevention
HPV: human papillomavirus
LAIV: live attenuated influenza vaccine
LAIV4: quadrivalent live attenuated influenza vaccine
Tdap: tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine

REFERENCES

1. Grohskopf LA, Alyanak E, Broder KR, et al. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices - United States, 2020–21 influenza season. *MMWR Recomm Rep.* 2020;69(8):1–24
2. Mbaeyi SA, Bozio CH, Duffy J, et al. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. *MMWR Recomm Rep.* 2020;69(9):1–41
3. Havers FP, Moro PL, Hunter P, Hariri S, Bernstein H. Use of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccines: updated recommendations of the Advisory Committee on Immunization Practices — United States, 2019. *MMWR Morb Mortal Wkly Rep.* 2020;69(3):77–83

Resistance Training for Children and Adolescents

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Resistance Training for Children and Adolescents

Paul R. Stricker, MD, FAAP,[a] Avery D. Faigenbaum, EdD, FACSM, FNSCA,[b] Teri M. McCambridge, MD, FAAP,[c] COUNCIL ON SPORTS MEDICINE AND FITNESS

Resistance training is becoming more important as an integral part of comprehensive sport training regimens, school physical education classes, and after-school fitness programs. The increasing number of youth who are involved in sport activities, coupled with the health problems of inactivity and being overweight, have resulted in increased interest in resistance training. Secular declines in measures of muscular fitness in modern-day youth highlight the need for participation in youth resistance training for nonathletes as well as athletes. Parents often ask pediatricians to offer advice regarding the safety, benefits, and implementation of an effective resistance-training program. This report is a revision of the 2008 American Academy of Pediatrics policy statement and reviews current information and research on the benefits and risks of resistance training for children and adolescents.

KEY POINTS

1. Positive outcomes of improved strength in youth continue to be acknowledged, including improvements in health, fitness, rehabilitation of injuries, injury reduction, and physical literacy.
2. Resistance training is not limited to lifting weights but includes a wide array of body weight movements that can be implemented at young ages to improve declining measures of muscular fitness among children and adolescents.
3. Scientific research supports a wide acceptance that children and adolescents can gain strength with resistance training with low injury rates if the activities are performed with an emphasis on proper technique and are well supervised.
4. Gains in childhood strength are primarily attributed to the neurologic mechanism of increases in motor neuron recruitment, allowing for increases in strength without resultant muscle hypertrophy.

abstract

[a]Department of Orthopedics, Pediatric & Adolescent Sports Medicine, Scripps Clinic, San Diego, California; [b]Department of Health and Exercise Science, The College of New Jersey, Ewing, New Jersey; and [c]Department of Orthopedics, University of Maryland, College Park, Maryland

Drs Stricker, Faigenbaum, and McCambridge served as authors of the manuscript with substantial input into the content and revision; and all authors approved the final manuscript as submitted.

Clinical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, clinical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-1011

Address correspondence to Paul R. Stricker, MD, FAAP. E-mail: drpaul@drpaulstricker.com

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: Stricker PR, Faigenbaum AD, McCambridge TM, AAP COUNCIL ON SPORTS MEDICINE AND FITNESS. Resistance Training for Children and Adolescents. *Pediatrics*. 2020;145(6):e20201011

5. It is important to incorporate resistance training into physical education classes and youth sport programs to increase muscular strength, reduce the risk of overuse injuries, and spark an ongoing interest in this type of exercise.
6. Certain health situations require consultation with a medical professional before starting a program of resistance training.

BACKGROUND

Resistance training and strength training are synonymous terms used to denote a component of sport and exercise training that is designed to enhance muscular strength, muscular power, and local muscular endurance for general exercise or competitive sports. Resistance training is a specialized method of conditioning that involves the use of different modes of training with a wide range of resistive loads, from body weight to barbells. Resistance-training programs may include the use of free weights (barbells and dumbbells), weight machines, medicine balls, kettlebells, elastic tubing, or a person's own body weight to provide the resistance needed to increase strength.

Along with the extremes of inactivity and/or being overweight and the evolution of youth sports into more intense training at younger ages, there is also a change in the landscape of "strength" among children and adolescents. Evidence of decreasing measures of muscular fitness in youth over the years adds importance for involving youth in some form of resistance exercise regardless of whether they are involved in sports.[1–3] On the other hand, some adolescents are increasingly using resistance training in pursuit of muscularity without even being involved in sports.[4] The type, amount, and frequency of resistance exercises are dictated by the specific and unique goals of the sport and training program as well as the individual child's resistance training skill competency (RTSC) and accumulated time of formal resistance training (also referred to as "training age"). Table 1 defines an alphabetical list of common terms used in resistance training.

RESISTANCE-TRAINING BENEFITS

Performance Benefits

The many benefits of resistance training have been increasingly documented in the pediatric sports arena. Although building strength is often a primary goal, the positive sequelae of strength gains in youth continue to be recognized, including improvements in motor skill performance, gains in speed and power, developing physical literacy, reducing the risk of injury, and injury rehabilitation. Children and youth are entering competitive sports at younger ages, and their training programs are becoming more complex and can involve the use of private coaching, personal trainers, and sports psychologists in addition to their routine coaches and teams. Possessing adequate strength to keep up with these increased demands on the body is valuable to help reduce the risk of injury and optimize gains in performance.

TABLE 1 Definitions

Term	Definition
Bodybuilding	Lifting weights with the specific goal of increasing muscle size, symmetry, and definition with the possible goal of entering competitive events that are judged
Concentric muscle action	The muscle shortens during contraction (ie, lifting phase of bicep curl)
Core strengthening	Focusing a strength-building program on the muscles that stabilize the trunk and pelvis of the body; this training emphasizes strengthening the abdominal, low back, and gluteal muscles as well as flexibility of muscular attachments to the pelvis, such as the quadriceps and hamstring muscles
Eccentric muscle action	The muscle lengthens during contraction (ie, lowering phase of bicep curl)
Integrative neuromuscular training	Multimodal exercise program using different types of resistance training to target deficits in strength and motor control by improving both health- and skill-related components of physical fitness
Isokinetic muscle action	This exercise requires special equipment that maintains a fixed speed of muscle contraction throughout the range of motion
Muscular fitness	A global term that includes muscular strength, muscular power, and local muscular endurance
Physical literacy	Moving with confidence and competence in various activities and environments to benefit overall health
Plyometric exercises	Repeated, rapid, eccentric, and concentric muscle actions, such as side-to-side hops or squat jumps
Powerlifting	A competitive sport that involves maximum lifting ability; powerlifting includes the dead lift, back squat, and bench press
Prehabilitation	Strength, flexibility, and functional training aimed at preventing injuries before they happen or reducing the risk of a recurrent injury
Repetition (rep)	One complete movement of an exercise that typically involves lifting and lowering a load
Repetition maximum (RM)	The maximum amount of weight that can be lifted with proper exercise technique using a given resistance; a 1 RM is the maximum resistance that can be used for 1 complete repetition of an exercise, whereas a 10 RM is the maximum resistance that can be used for 10 complete repetitions of an exercise
Set	A group of repetitions performed continuously
Weightlifting	A sport that involves the performance of the snatch and clean-and-jerk exercises in competition
Weightlifting training	The use of weightlifting exercises, movements, and derivatives of these exercises incorporated into a training program

Health Benefits

Healthy lifestyles incorporate regular exercise that provides a balance of activities, including participating in strength-building programs. In addition to increasing muscular strength, muscular power, and local muscular endurance, resistance training has been shown to produce many health benefits, including improvements in cardiovascular fitness, body composition, bone mineral density, blood lipid profiles, insulin sensitivity in youth who are overweight, increased resistance to injury, and mental health.[5–14]

Programs involving resistance training provide positive options to engage children and adolescents with overweight or obesity in physical activity and may be more likely to create a positive and successful experience for these participants, who may have lower levels of physical fitness, poor exercise compliance, and reduced tolerance for aerobic training.[15–17] Evidence does show that participation in a resistance-training program helps increase daily levels of spontaneous activity in school-aged boys,[18,19] which suggests that resistance training may be a good place to start when trying to get inactive kids to be more active. Progressing into a combined program of resistance and aerobic training may generate added benefit because combined programs have shown favorable effects on the reduction of total body fat in youth.[20–22]

Additional Benefits

After years of research, it is now accepted that children and adolescents can increase strength with low injury rates if resistance training is well supervised with an emphasis on correct technique. Early studies successfully demonstrated significant strength gains in children and a lack of injury with proper technique and supervision.[5,7,12,23]

With a preponderance of studies showing positive gains from youth resistance training, perspectives are shifting regarding integrating resistance training into physical education, youth fitness, and injury-reduction programs.

Previous concerns regarding resistance training focused on what would happen if a child lifts weights, but more recent focus has turned toward what will happen if a child does not lift weights, especially in light of the secular declines in measures of muscular fitness over the years. Targeting strength deficits and building strength reserves will continue to be a valuable concept to address.[24,25] The available research supports resistance training in youth with a new perspective of acquiring and maintaining high strength reserves to enhance performance across a wide range of general and specific skills while reducing injury risk. There is a shift from the primary concern of injuries associated with resistance training to the concern of injury and other adverse events because of a lack of adequate strength to keep up with training demands.[14,26,27]

Resistance training is applicable to virtually all children and adolescents for contributions to muscular fitness, resistance to injury, and improved performance. Enhancing muscular strength is an important concept to embrace fully beyond the association with only lifting progressively heavier weights. This clarification may encourage girls and boys to engage in year-round resistance training to increase their strength reserves without fear of getting too muscular or impairing sports performance.

Numerous studies have shown that children and adolescents can gain strength with resistance-training programs involving technique-driven progression along with qualified supervision and instruction.[5,7,12,23,28–30] Adequate supervision may be variable depending on the goals of the resistance-training program, RTSC of the participants, and experience of the teacher, instructor, or coach. An experienced professional may be able to effectively guide a larger number of youth, whereas more individualized instruction may be appropriate for more advanced-level techniques. There are many different variables that contribute to a well-designed youth resistance-training program, including quality of instruction, training environment, training frequency, training age, type of resistance used, intensity of effort, number of sets and repetitions, rest interval between sets and exercises, and duration of training.[26]

Training and Detraining

Recent studies suggest that resistance-training programs lasting $>$23 weeks are most effective in attaining maximal strength gains.[30] Strength gains occur with different types of resistance training for a minimum duration of 8 weeks with a frequency of 2 to 3 times a week. In general, detraining effects can occur after 8 to 12 weeks without resistance training,[5,7,11,15,31,32] but detraining is a more complex process in youth because of developmental improvements in performance, which allows some skills to be retained better than others.[32] Children recover more quickly than adults from resistance-training fatigue; therefore, experts recommend 1 minute of rest between sets for beginners, increasing to 2 to 3 minutes of rest as the intensity of training increases (ie, incorporation of weightlifting movements or plyometric exercises).[33] Training exercises involving the core (abdominals, low back, and gluteal muscles) are foundationally important for sports participation and can provide benefit for sport-specific skill acquisition and postural control.[7,34,35]

One-Repetition Maximum

The one-repetition maximum (1 RM) (see Table 1 for definition) test can be administered by qualified professionals to assess maximal strength, determine an appropriate resistance-training intensity, and evaluate the effectiveness of a resistance-training program.[36] Previous American Academy of Pediatrics (AAP) policy statements have not recommended 1 RM testing in skeletally immature individuals. However, 1 RM testing that is properly administered has been found to be a valid and reliable measure of strength and power in children and adolescents.[36,37] Although 1 RM testing is used in pediatric research settings and youth sport facilities, alternative measures (handgrip strength, long jump, and vertical jump) correlate with 1 RM strength and may be used to evaluate muscular fitness in youth.[38] Research indicates that 1 RM testing in children and adolescents can be safe and efficacious when established testing protocols are followed by qualified professionals.[36,37,39,40]

Mechanisms of Strength Gains

Proper resistance training in children can enhance strength without resultant muscle hypertrophy. These strength gains are attributed primarily to a neurologic mechanism whereby training increases the number of motor neurons that are "recruited" to fire with each muscle contraction.[41,42] This mechanism accounts for the increase in strength in populations with low androgen concentrations, including girls and preadolescent boys. In contrast, resistance training during and after puberty augments muscle growth by actual muscle hypertrophy.[11] Early studies regarding resistance training involved nonathletic children, but an increasing number of studies are being conducted with competitive young athletes.[43,44] Further research is needed in the area of long-term strength improvements with resistance training programs in young athletes and the effect on the neurologic mechanism of motor unit recruitment.

Performance Enhancement and Other Uses of Resistance Training

Increases in strength with resistance programs have shown improvement in some performance measures, such as vertical jump, countermovement jumps, and sprint time[6,45–47] as well as improved maximal oxygen uptake with combined resistance and aerobic training programs.[48] Resistance training combined with aerobic training does not appear to impair strength gains in youth and may be more beneficial than single-mode training.[32,49] Translation of those improvements to overall athletic performance on the field or court may be more difficult because so many variables are involved with actual performance, making it challenging to separate the contribution from resistance training alone. However, positive results in the area of performance measures, along with other aspects of sport, such as injury rehabilitation and injury reduction, make resistance training a valuable piece of the training landscape and foundational to long-term athletic development.[50,51]

Prehabilitation

Preventive exercise (prehabilitation) uses resistance training to address and focus on joints that are commonly at risk for overuse injuries (ie, enhancing rotator cuff and scapular stabilization strength preventively to reduce shoulder injury in athletes who are involved in overhead sports, such as baseball, softball, tennis, volleyball, swimming, and water polo). Research in adolescent athletes has shown resistance training to contribute to decreased injuries.[5–7,14,52,53] Injury prevention programs may have greater effectiveness when started before the period of altered biomechanics that increase injury risk.[54–56]

Various prehabilitation studies are finding positive results in the reduction of anterior cruciate ligament injuries, especially when resistance training exercises are combined with plyometric exercises.[5–7,45,52,57] Plyometric training involves the use of rapid concentric and eccentric muscle actions to enhance muscle strength and power in a relatively short amount of time, such as squat jumps. Plyometric exercises may benefit performance[58–60] and reduce the risk of injury. When combined with proprioceptive training (ie, balance exercises), these programs have also been shown to be beneficial in rehabilitation and reduction of certain injuries, such as ankle sprains.[61]

RESISTANCE TRAINING RISKS

Injury rates in youth resistance training settings that adhere to qualified supervision and proper technique are lower than those occurring in other sports or general recess play at school.[4] On the basis of years of research in this area, there is less concern for injury from supervised, well-designed, and technique-driven resistance training and more concern for injuries that occur because of poor supervision, an inappropriate progression of training loads, or low strength reserves in youth who are not prepared for the demands of sports practice and competition.

Overtraining Risks

Resistance training has more of a place in injury reduction than in the cause of injury. However, prolonged training with heavy loads and resistance training without adequate rest and recovery between sessions have been correlated with increased injuries and illness,[62–64] thus requiring similar attention as with other sources of overtraining and

sensible incorporation into the yearly training schedule. It is important to account for time spent in resistance training as part of total training time to reduce the risk of overuse injuries. Resistance training can be incorporated into a year-round plan that varies in volume and intensity depending on the sport season (eg, preseason, in season, or off season).

The AAP recommends rest from competitive athletics, sport-specific training, and practice by taking at least 1 to 2 days off per week to allow for physical and psychological recovery.[65] Adequate fluid and caloric intake is necessary to provide the fuel to exercise, compete, recover, and grow.[66,67] Athletes participating in high levels of training volume who are underrecovered and undernourished are at risk for overtraining, injury, and illness.[68,69]

Skeletal Risks

Appropriately designed resistance training programs have no apparent negative effect on linear growth, physeal health, or the cardiovascular system.[7,22] Explosive contractions of the muscle-tendon attachment at apophyseal areas during active play, sports, or lifting weights may increase the risk of avulsion fracture until closer to skeletal maturity.[70,71] Resistance training safety is enhanced when teachers, coaches, and instructors ensure a safe training environment and use developmentally appropriate teaching strategies, focus on enhancing RTSC, and have an appropriate instructor/participant ratio. This ratio can vary on the basis of the expertise of the instructor, program design, and training age and RTSC of participants.

National Electronic Injury Surveillance System

Results of the US Consumer Product Safety Commission's National Electronic Injury Surveillance System (NEISS) have raised concerns about injuries from the use of weights and resistance training. The NEISS collects data on injuries related to strength training equipment but does not provide information on supervision, program design, or training experience. This system warrants mentioning in this report to reduce conflicting information among the general public who read NEISS information. Careful interpretation of NEISS data is needed because most injuries reported from resistance training occur on home gym equipment with unsafe behavior in unsupervised settings.[72] These data are in stark contrast to data from well-designed studies with appropriate supervision and technique, making education of parents necessary to reduce confusion about the risks associated with resistance training in the youth population.[12,73–75]

NEISS data suggest that muscle strains account for many of the reported injuries, and areas that are most commonly injured are the hand, low back, and upper trunk; recent NEISS data also suggest that hand injuries are particularly common in children $<$12 years old.[76,77] NEISS data neither specify the cause of the injury (ie, attempting to lift a heavy load with poor technique) nor separate recreational from competitive weightlifting or powerlifting injuries, but the data support the need for qualified supervision and equipment that are appropriate for the size and skill level of youth involved in resistance training.

Various intense metabolic conditioning programs incorporate different types of resistance training, running intervals, and repetitive body weight exercises, such as plyometrics, into training sessions. This type of high-intensity circuit training is typically characterized by the performance of a maximum number of repetitions of selected exercises for a predetermined time interval. In adult metabolic conditioning programs, the shoulder, knee, and low back are most commonly injured,[78] but safety in the pediatric population is undetermined because of a lack of current data. As with any type of resistance training, it is important to have proper exercise technique, qualified supervision, and adequate recovery between intense training sessions.

Medical Conditions

Certain health situations require special attention before beginning a resistance training regimen. Athletes with poorly controlled, preexisting hypertension require consultation with a medical professional because of the risk of marked elevation of blood pressure during resistance training with weights. Using one's own body weight is an acceptable alternative until a consultation can be obtained.[79,80] Consultation with a medical professional regarding resistance training is also required for young athletes with uncontrolled seizure disorders,[81] although resistance training has been determined to be safe in children with underlying seizures that are well controlled on medication.[81,82]

Some children and adolescents may be disqualified from participation in resistance training because of certain medical conditions. Counseling against resistance training is necessary for youngsters with hypertrophic cardiomyopathy who are at risk for worsening ventricular hypertrophy and restrictive cardiomyopathy or hemodynamic decompensation secondary to an acute increase in pulmonary hypertension.[83] Resistance training should be avoided in individuals with pulmonary hypertension because of a risk of acute decompensation during a sudden change in hemodynamics as well as those with Marfan syndrome.[83]

Although exercise interventions that include resistance training may be beneficial for youth with cancer,[84] certain chemotherapeutic agents require caution. Youth with a previous history of cancer treated with anthracycline chemotherapy are at increased risk for cardiotoxicity and acute congestive heart failure during resistance training, as evidenced by case reports associated with doxorubicin, daunomycin or daunorubicin, idarubicin, and possibly mitoxantrone.[85]

Misconceptions and Evidence

The health supervision visit is a good opportunity to explore the topic of resistance training, dispel the myths associated with this type of exercise (Table 2), and discuss the importance of staying physically active and strong. These visits can allow for the identification of risk factors for injury; discussion of family history, medical conditions, medications, previous injuries, as well as training goals; motivation for resistance training; discussion of experience; and discussion of expectations from both the child and parents. It is valuable for pediatricians to counsel families about the multiple health and fitness benefits of resistance training, including improvements in muscular strength, muscular power, sports performance, injury resistance, and long-term athletic development.

Performance-Enhancing Substances

The AAP strongly opposes the use of performance-enhancing substances and vigorously endorses efforts to eliminate their use among children and adolescents.[86] Information is available for health care providers to provide regarding the risks and health consequences of anabolic steroids and other performance-enhancing drugs as well as to discourage youth from considering their use. For instance, the AAP has a training simulation on addressing the use of performance-enhancing substances (available at www.aap.kognito.com).

Integrative Neuromuscular Training

In this era of sedentary pursuits of technology and social media, keeping children and adolescents active and optimally developing motor skills, muscular fitness, and physical literacy is challenging. No longer can it be assumed that children innately know how to run, hop, jump, and throw. Integrative neuromuscular training is a multimodal form of training that uses resistance exercises, dynamic stability, core exercises, and plyometric and agility training performed in short intervals with intermittent periods of rest.[26,87] Integrative neuromuscular training can improve muscular fitness in youth, enhance motor skill development, improve sports performance, and decrease sports injury risk.[12,87]

It is difficult to say at what age a child can begin resistance training because of developmental differences. If a child is able to begin participating in sports activities at 5 years of age, being able to begin some type of resistance training with body weight movements at that age is acceptable because strength gains can be made in ways other than lifting external loads. An age range of 5 to 7 years is when many children are often involved in sports participation, and it is reasonable that they can also benefit from the strength-building process with exercises such as frog jumps, bear crawls, crab walks, kangaroo hops, and one-leg hops.[88] The one-leg hop is a skill most 5-year-olds should be able to perform,[89] although the ability to perform more complex movements will be influenced by the amount of time youth have practiced basic skills and reinforced desired movement patterns. The combination of qualified instruction with technique-driven progression is likely to yield the greatest benefits for youth at any age.

Training Age

The more recent concepts of "training age" and RTSC can be used in the design of a resistance training program. Training age refers to the

TABLE 2 Misconceptions Versus Evidence

Misconceptions	Evidence
A child is unable to increase strength before puberty.	Prepubertal children are able to gain strength by an increase in neurologic recruitment of muscle fibers, and gains in strength can be made with low injury rates if resistance training programs are well supervised with an emphasis on proper technique.
Young boys and girls may get "muscle bound" if they resistance train.	Prepubertal strength gains occur by neurologic mechanisms, and pubertal gains may augment muscle growth by actual muscle hypertrophy enhanced by pubertal hormones.
Resistance training may decrease aerobic performance in youth.	Improvements in aerobic performance have been shown with combined aerobic and resistance training programs, and combined aerobic and resistance programs do not appear to impair strength gains in children.
Resistance training may stunt growth.	Well-designed resistance training programs have not been shown to have a negative effect on physeal (growth plate) health, linear growth, and cardiovascular health in youth.
Children are stronger now than ever before.	There is a need to target strength deficits and build strength reserves due to declining measures of muscular fitness in modern-day youth.
1 RM testing is unsafe for youth.	1 RM testing may be a safe method for assessing muscular strength in youth provided that qualified supervision is present and appropriate testing guidelines are followed.

cumulative amount of time spent in formalized training, and RTSC incorporates the quantity of weight lifted, the quality of the lifting movement, and the emotional maturity of the athlete.[26,90] As the athlete's RTSC advances, higher loads may be used in a technique-driven process, and a gradual progression of incorporating skills requiring higher degrees of technical ability may be included (ie, more advanced weightlifting movements and plyometric exercises).[7] Understanding training age and the importance of RTSC allows for developmentally appropriate, progressive training rather than relying on previous recommendations based solely on chronological age. With earlier participation in well-designed and properly supervised resistance training, a 10-year-old girl may already have 3 years of resistance-training experience versus a 14-year-old boy who is a beginner and has a resistance training age of 0.

Ways and Means of Improving Strength

Gains in strength can be acquired via various types of resistance training methods and equipment, including body weight, free weights, resistance bands, kettlebells, medicine balls, and child-size machines. Most fitness centers use equipment made for adult bodies and greater weight increments, but child-appropriate machines are available in some youth centers across the country. Dumbbells, kettlebells, and medicine balls require good balance control and technique while being small in size, portable, and allowing for sport-specific motions.

The Use of Weightlifting Movements

The competitive sport of weightlifting includes the snatch and the clean-and-jerk exercises, whereas weightlifting movements include derivatives of these exercises. Research has demonstrated that this type of weightlifting training is superior in improving countermovement jumps, horizontal jumps, and 5- and 20-m sprints over traditional resistance training.[47,91] Research has demonstrated that if light loads are used to learn these complex movements, and ongoing quality instruction is available for technique-driven progression, then weightlifting exercises and their derivatives can be incorporated into youth training programs safely.[7] Learning how to perform these multijoint lifts correctly requires considerable time and coaching expertise. Performing these multijoint movements in childhood can help youth gain competence and confidence in performing these skills. If weightlifting movements are going to be incorporated into a youth training program, the following guidelines are to be considered.

- Advance in a gradual fashion, learning the lifts with a wooden dowel then progressing to an unloaded, light barbell and finally to a weighted barbell, focusing on proper form throughout the technique-driven progression. These weightlifting movements can be incorporated into beginner programs but will depend on the goal of the program and quality of instruction available.
- Consider training age and RTSC level, which will vary individually on the basis of cumulative training and level of instruction.
- Perform under the guidance of a professional with requisite coaching certifications, such as a certified strength and conditioning specialist (National Strength and Conditioning Association), accredited strength and conditioning coach (UK Strength and Conditioning Association), or USA weightlifting coach (USA Weightlifting).

Competitive bodybuilding is the application of resistance training principles specifically for the appearance-related purposes of maximizing muscle mass, symmetry, and body definition. Endogenous anabolic hormones are necessary for the increased muscle mass that is the primary goal of bodybuilding. "Late bloomers" are often tempted to try to build muscle mass by increasing the intensity and volume of training; however, there is no substitute for the onset of puberty, and increased training does not hasten the biological clock. Concerns about abnormal eating behaviors, excessive focus on body image, or use of anabolic agents and other performance-enhancing substances warrant careful screening for these behaviors in any adolescent who pursues competitive bodybuilding.

Resistance Training Roadmap

Suggestions for youth who are engaged in a resistance training program are as follows.

- Qualified instructors with appropriate certifications who understand youth resistance-training principles and the physical and psychosocial uniqueness of youth should provide real-time feedback to ensure safe and correct movement development.
- Begin with 1 to 2 sets of 8 to 12 repetitions using a low resistance training intensity (ie, $\leq$60% 1 RM) as proper technique is developed. A low resistance training intensity allows for the completion of 8 to 12 repetitions of a variety of exercises without undue fatigue.
- As RTSC improves and can be demonstrated consistently, it is reasonable to increase weight in 5% to 10% increments and reduce the number of repetitions.
- The program can be progressed to 2 to 4 sets of 6 to 12 repetitions with a low to moderate training intensity ($\leq$80% 1 RM).
- Young athletes can be introduced to periodic phases of lower

repetition ranges (<6) at a higher training intensity (>80% 1 RM) provided that RTSC is high.[30]

- When performing more complex, multijoint exercises, such as weightlifting, the importance of completing all repetitions with proper technique is vital to achieve proper motor control development. During this type of resistance training, fewer repetitions (eg, 1–3) may be productive to aid in motor control development.
- Include all muscle groups, including core muscles, in a resistance training program.
- Perform the various exercises through the full range of motion with proper technique.
- Perform exercises in a particular sequence during training. In general, work large muscle groups before small muscle groups and complex, multijoint exercises before single-joint exercises.
- Achieving strength gains require sessions to be at least 20 to 30 minutes long and performed 2 to 3 times per week on nonconsecutive days while gradually increasing resistance training intensity and volume as strength and RTSC improve.
- Keep the resistance training stimulus effective and enjoyable by periodically varying the exercises, sets, and repetitions.
- Use dynamic warm-up exercises integrated into the training session followed by cool-down periods with appropriate stretching techniques.
- Youth resistance training programs should be technique driven and consistent with the needs, abilities, and maturity level of the participants.

Guidelines have been proposed by the National Strength and Conditioning Association[5] and the 2014 International Consensus position statement on youth resistance training.[7]

Resistance training is highly encouraged as part of a multifaceted approach to physical literacy, exercise, strength building, fitness, and athletic performance in youth. It is valuable to emphasize that combining aerobic training with resistance training also offers long-term benefits for general health and fitness. Important factors concerning child health are fueling the need for resistance training for all youth. Trends of decreasing muscular fitness in youth and the requirement of strength for competency in movement skill development are important and make it meaningful for families to be aware of the benefits of integrating strength-building activities into a well-rounded exercise program for general physical fitness, sports participation, and lifelong health and wellbeing. It is also important for youth who are involved in resistance training to be able to participate in a safe, supportive, and nonabusive environment. Health care providers, parents, and coaches who are interested in learning more are referred to the US Center for SafeSport (www.safesport.org) and the AAP clinical report on organized sports.[92]

RECOMMENDATIONS

The necessity and appropriateness of a youth resistance training program are determined on the basis of the program goals and RTSC of participants. Proper exercise technique and qualified supervision are necessary for youth resistance-training programs to be safe, effective, and enjoyable. With enthusiastic instruction, constructive feedback, and program variation, resistance training can become a lifetime activity. Recommendations for a youth resistance training program are as follows.

1. Obtain consultation with a medical professional before beginning a resistance training program in youth with uncontrolled hypertension, uncontrolled seizure disorders, specific cardiovascular conditions, or a history of treatment with an anthracycline chemotherapeutic agent.
2. Seek consultation with a pediatric cardiologist for children with complex congenital cardiac diseases for guidance on safety and possible modification of participation.
3. Integrate aerobic and resistance training along with other skill-related fitness components into developmentally appropriate exercise training (ie, integrative neuromuscular training) to create a comprehensive fitness program.
4. In youth with overweight or obesity, start with basic resistance exercises over a more aerobically based program to support and encourage successful physical activity both short- and long-term.
5. Include dynamic warm-up exercises in the training session and cool down with less intense stretching.
6. Encourage participants to have an adequate intake of fluids and proper nutrition because both are important for energy storage, recuperation, and competition. Proper fuel is beneficial for the caloric demands of exercise, performance, recovery, and growth.
7. Assess RTSC and provide real-time feedback on exercise technique to minimize risk and maximize benefit from resistance training. This can be achieved by the following.
    - Exercises should be performed initially with little or no load until RTSC improves and proper technique has been mastered.

- Incremental loads may then be added by using either body weight or other forms of resistance as long as proper form can be maintained.
- In youth with more advanced training age, higher loads and intensities will be necessary to increase muscular strength and power in preparation for sports.[30,43,44]
- 1 RM testing may be appropriate to develop an individualized resistance training program and monitor progress.

8. Address all major muscle groups of the upper and lower body along with the core and include multijoint activities, such as squats and weightlifting exercises, for a comprehensive program for building muscular strength and power. These exercises may be complemented by adding more focused exercises to address sport-specific goals.
9. Sensibly incorporate resistance training and account for time spent in resistance training as part of the total training plan to reduce the risk of overuse injuries. Monitoring time spent resistance training in school- and community-based programs in addition to other types of training is important to account for true total training volume.[93]
10. Evaluate any symptom of illness or sign of injury or overuse from resistance training or sport participation before allowing the exercise program to resume.
11. Incorporate weightlifting exercises and their derivatives into an exercise program under the direction of a qualified professional. Progress from a wooden dowel to an unloaded barbell as RTSC improves.
12. Educate athletes about the risks associated with the use of performance-enhancing substances and/or drugs and anabolic steroids to discourage the use of such substances.
13. Enhance resistance training safety by using professionals who are qualified, trained, and aware of the unique aspects of youth and possess a recognized strength and conditioning certification. Instructor/participant ratio is important and depends on the experience of the instructor as well as the training age and RTSC of participants. Licensed physical education teachers and certified fitness professionals with understanding and experience in training youth may provide safe and effective programs for children and adolescents, and young athletes may receive qualified instruction from their high school coaches or strength and conditioning specialists.[94]
14. Use proper technique and supervision by a qualified professional as necessary safety components in any resistance training program involving children and adolescents.

LEAD AUTHORS

Paul R. Stricker, MD, FAAP
Avery D. Faigenbaum, EdD, FACSM, FNSCA
Teri M. McCambridge, MD, FAAP

COUNCIL ON SPORTS MEDICINE AND FITNESS EXECUTIVE COMMITTEE, 2017–2018

Cynthia R. LaBella, MD, FAAP, Chairperson
M. Alison Brooks, MD, FAAP, Chairperson-Elect
Greg Canty, MD, FAAP
Alex B. Diamond, DO, FAAP
William Hennrikus, MD, FAAP
Kelsey Logan, MD, FAAP
Kody Moffatt, MD, FAAP
Blaise A. Nemeth, MD, MS, FAAP
K. Brooke Pengel MD, FAAP
Andrew R. Peterson MD, MSPH, FAAP
Paul R. Stricker, MD, FAAP

LIAISONS

Donald W. Bagnall – *National Athletic Trainers Association*
Mark E. Halstead, MD, FAAP – *American Medical Society for Sports Medicine*

CONSULTANTS

Michele LaBotz, MD, FAAP
Andrea Stracciolini, MD, FAAP

STAFF

Anjie Emanuel, MPH

ABBREVIATIONS

1 RM: 1-repetition maximum
AAP: American Academy of Pediatrics
NEISS: National Electronic Injury Surveillance System
RTSC: resistance training skill competency

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Laurson KR, Saint-Maurice PF, Welk GJ, Eisenmann JC. Reference curves for field tests of musculoskeletal fitness in U.S. children and adolescents: the 2012 NHANES national youth fitness survey. *J Strength Cond Res*. 2017;31(8): 2075–2082
2. Müllerová D, Langmajerová J, Sedláček P, et al. Dramatic decrease in muscular fitness in the Czech schoolchildren over the Last 20 years. *Cent Eur J Public Health*. 2015;23(suppl):S9–S13
3. Cohen DD, Voss C, Taylor MJ, Delextrat A, Ogunleye AA, Sandercock GR. Ten-year secular changes in muscular fitness in English children. *Acta Paediatr*. 2011; 100(10):e175–e177
4. Eisenberg ME, Wall M, Neumark-Sztainer D. Muscle-enhancing behaviors among adolescent girls and boys. *Pediatrics*. 2012;130(6):1019–1026
5. Faigenbaum AD, Kraemer WJ, Blimkie CJ, et al. Youth resistance training: updated position statement paper from the National Strength and Conditioning Association. *J Strength Cond Res*. 2009; 23(suppl 5):S60–S79
6. Myer GD, Faigenbaum AD, Chu DA, et al. Integrative training for children and adolescents: techniques and practices for reducing sports-related injuries and enhancing athletic performance. *Phys Sportsmed*. 2011;39(1):74–84
7. Lloyd RS, Faigenbaum AD, Stone MH, et al. Position statement on youth resistance training: the 2014 International Consensus. *Br J Sports Med*. 2014;48(7):498–505
8. Hind K, Burrows M. Weight-bearing exercise and bone mineral accrual in children and adolescents: a review of controlled trials. *Bone*. 2007;40(1): 14–27
9. Wang Q, Alén M, Nicholson P, et al. Weight-bearing, muscle loading and bone mineral accrual in pubertal girls--a 2-year longitudinal study. *Bone*. 2007; 40(5):1196–1202
10. Bernardoni B, Thein-Nissenbaum J, Fast J, et al. A school-based resistance intervention improves skeletal growth in adolescent females. *Osteoporos Int*. 2014;25(3):1025–1032
11. McCambridge TM, Stricker PR; American Academy of Pediatrics Council on Sports Medicine and Fitness. Strength training by children and adolescents. *Pediatrics*. 2008;121(4): 835–840
12. Faigenbaum AD, Myer GD. Resistance training among young athletes: safety, efficacy and injury prevention effects. *Br J Sports Med*. 2010;44(1):56–63
13. Ishikawa S, Kim Y, Kang M, Morgan DW. Effects of weight-bearing exercise on bone health in girls: a meta-analysis. *Sports Med*. 2013;43(9):875–892
14. Lauersen JB, Andersen TE, Andersen LB. Strength training as superior, dose-dependent and safe prevention of acute and overuse sports injuries: a systematic review, qualitative analysis and meta-analysis. *Br J Sports Med*. 2018;52(24):1557–1563
15. McGuigan MR, Tatasciore M, Newton RU, Pettigrew S. Eight weeks of resistance training can significantly alter body composition in children who are overweight or obese. *J Strength Cond Res*. 2009;23(1):80–85
16. Sothern MS, Loftin JM, Udall JN, et al. Safety, feasibility, and efficacy of a resistance training program in preadolescent obese children. *Am J Med Sci*. 2000;319(6):370–375
17. Sgro M, McGuigan MR, Pettigrew S, Newton RU. The effect of duration of resistance training interventions in children who are overweight or obese. *J Strength Cond Res*. 2009;23(4): 1263–1270
18. Meinhardt U, Witassek F, Petrò R, Fritz C, Eiholzer U. Strength training and physical activity in boys: a randomized trial. *Pediatrics*. 2013;132(6):1105–1111
19. Eiholzer U, Meinhardt U, Petrò R, Witassek F, Gutzwiller F, Gasser T. High-intensity training increases spontaneous physical activity in children: a randomized controlled study. *J Pediatr*. 2010;156(2):242–246
20. Alberga AS, Prud'homme D, Kenny GP, et al. Effects of aerobic and resistance training on abdominal fat, apolipoproteins and high-sensitivity C-reactive protein in adolescents with obesity: the HEARTY randomized clinical trial. *Int J Obes*. 2015;39(10):1494–1500
21. Jung HC, Jeon S, Lee NH, Kim K, Kang M, Lee S. Effects of exercise intervention on visceral fat in obese children and adolescents. *J Sports Med Phys Fitness*. 2019;59(6):1045–1057
22. Sigal RJ, Alberga AS, Goldfield GS, et al. Effects of aerobic training, resistance training, or both on percentage body fat and cardiometabolic risk markers in obese adolescents: the healthy eating aerobic and resistance training in youth randomized clinical trial. *JAMA Pediatr*. 2014;168(11):1006–1014
23. Malina RM. Weight training in youth-growth, maturation, and safety: an evidence-based review. *Clin J Sport Med*. 2006;16(6):478–487
24. Suchomel TJ, Nimphius S, Stone MH. The importance of muscular strength in athletic performance. *Sports Med*. 2016;46(10):1419–1449
25. Suchomel TJ, Nimphius S, Bellon CR, Stone MH. The importance of muscular strength: training considerations. *Sports Med*. 2018;48(4):765–785
26. Faigenbaum AD, Lloyd RS, MacDonald J, Myer GD. Citius, Altius, Fortius: beneficial effects of resistance training for young athletes: narrative review. *Br J Sports Med*. 2016;50(1):3–7
27. Fröberg A, Alricsson M, Ahnesjö J. Awareness of current recommendations and guidelines regarding strength training for youth. *Int J Adolesc Med Health*. 2014;26(4): 517–523
28. Moro T, Bianco A, Faigenbaum AD, Paoli A. [Pediatric resistance training: current issues and concerns]. *Minerva Pediatr*. 2014;66(3):217–227
29. Faigenbaum AD, Lloyd RS, Myer GD. Youth resistance training: past practices, new perspectives, and future directions. *Pediatr Exerc Sci*. 2013;25(4): 591–604
30. Lesinski M, Prieske O, Granacher U. Effects and dose-response relationships of resistance training on physical performance in youth athletes: a systematic review and meta-analysis. *Br J Sports Med*. 2016;50(13):781–795
31. Faigenbaum AD, Farrell AC, Fabiano M, et al. Effects of detraining on fitness performance in 7-year-old children.

J Strength Cond Res. 2013;27(2):323–330

32. Santos AP, Marinho DA, Costa AM, Izquierdo M, Marques MC. The effects of concurrent resistance and endurance training follow a detraining period in elementary school students. *J Strength Cond Res*. 2012;26(6):1708–1716
33. Faigenbaum AD, Ratamess NA, McFarland J, et al. Effect of rest interval length on bench press performance in boys, teens, and men. *Pediatr Exerc Sci*. 2008;20(4):457–469
34. Weston M, Hibbs AE, Thompson KG, Spears IR. Isolated core training improves sprint performance in national-level junior swimmers. *Int J Sports Physiol Perform*. 2015;10(2):204–210
35. Prieske O, Muehlbauer T, Borde R, et al. Neuromuscular and athletic performance following core strength training in elite youth soccer: role of instability. *Scand J Med Sci Sports*. 2016;26(1):48–56
36. Faigenbaum AD, Milliken LA, Westcott WL. Maximal strength testing in healthy children. *J Strength Cond Res*. 2003;17(1):162–166
37. Faigenbaum AD, McFarland JE, Herman RE, et al. Reliability of the one-repetition-maximum power clean test in adolescent athletes. *J Strength Cond Res*. 2012;26(2):432–437
38. Milliken LA, Faigenbaum AD, Loud RL, Westcott WL. Correlates of upper and lower body muscular strength in children. *J Strength Cond Res*. 2008;22(4):1339–1346
39. Castro-Piñero J, Ortega FB, Artero EG, et al. Assessing muscular strength in youth: usefulness of standing long jump as a general index of muscular fitness. *J Strength Cond Res*. 2010;24(7):1810–1817
40. Duhig S. Strength training for the young athlete. *J Aust Strength Cond*. 2013;21:5–13
41. Ramsay JA, Blimkie CJ, Smith K, Garner S, MacDougall JD, Sale DG. Strength training effects in prepubescent boys. *Med Sci Sports Exerc*. 1990;22(5):605–614
42. Ozmun JC, Mikesky AE, Surburg PR. Neuromuscular adaptations following prepubescent strength training. *Med Sci Sports Exerc*. 1994;26(4):510–514
43. Granacher U, Lesinski M, Büsch D, et al. Effects of resistance training in youth athletes on muscular fitness and athletic performance: a conceptual model for long-term athlete development. *Front Physiol*. 2016;7:164
44. Behm DG, Young JD, Whitten JHD, et al. Effectiveness of traditional strength vs. power training on muscle strength, power and speed with youth: a systematic review and meta-analysis. *Front Physiol*. 2017;8:423
45. Noyes FR, Barber-Westin SD, Tutalo Smith ST, Campbell T. A training program to improve neuromuscular and performance indices in female high school soccer players. *J Strength Cond Res*. 2013;27(2):340–351
46. de Hoyo M, Pozzo M, Sañudo B, et al. Effects of a 10-week in-season eccentric-overload training program on muscle-injury prevention and performance in junior elite soccer players. *Int J Sports Physiol Perform*. 2015;10(1):46–52
47. Chaouachi A, Hammami R, Kaabi S, Chamari K, Drinkwater EJ, Behm DG. Olympic weightlifting and plyometric training with children provides similar or greater performance improvements than traditional resistance training. *J Strength Cond Res*. 2014;28(6):1483–1496
48. Marta C, Marinho DA, Barbosa TM, Izquierdo M, Marques MC. Effects of concurrent training on explosive strength and VO(2max) in prepubescent children. *Int J Sports Med*. 2013;34(10):888–896
49. Gäbler M, Prieske O, Hortobágyi T, Granacher U. The effects of concurrent strength and endurance training on physical fitness and athletic performance in youth: a systematic review and meta-analysis. *Front Physiol*. 2018;9:1057
50. Lloyd RS, Cronin JB, Faigenbaum AD, et al. National Strength and Conditioning Association position statement on long-term athletic development. *J Strength Cond Res*. 2016;30(6):1491–1509
51. Bergeron MF, Mountjoy M, Armstrong N, et al. International Olympic Committee consensus statement on youth athletic development. *Br J Sports Med*. 2015;49(13):843–851
52. Sugimoto D, Myer GD, Foss KD, Hewett TE. Specific exercise effects of preventive neuromuscular training intervention on anterior cruciate ligament injury risk reduction in young females: meta-analysis and subgroup analysis. *Br J Sports Med*. 2015;49(5):282–289
53. Foss KDB, Thomas S, Khoury JC, Myer GD, Hewett TE. A school-based neuromuscular training program and sport-related injury incidence: a prospective randomized controlled clinical trial. *J Athl Train*. 2018;53(1):20–28
54. Myer GD, Sugimoto D, Thomas S, Hewett TE. The influence of age on the effectiveness of neuromuscular training to reduce anterior cruciate ligament injury in female athletes: a meta-analysis. *Am J Sports Med*. 2013;41(1):203–215
55. Rössler R, Junge A, Bizzini M, et al. A multinational cluster randomised controlled trial to assess the efficacy of '11+ Kids': a warm-up programme to prevent injuries in children's football. *Sports Med*. 2018;48(6):1493–1504
56. Ryman Augustsson S, Ageberg E. Weaker lower extremity muscle strength predicts traumatic knee injury in youth female but not male athletes. *BMJ Open Sport Exerc Med*. 2017;3(1):e000222
57. Renstrom P, Ljungqvist A, Arendt E, et al. Non-contact ACL injuries in female athletes: an International Olympic Committee current concepts statement. *Br J Sports Med*. 2008;42(6):394–412
58. Bedoya AA, Miltenberger MR, Lopez RM. Plyometric training effects on athletic performance in youth soccer athletes: a systematic review. *J Strength Cond Res*. 2015;29(8):2351–2360
59. Ramírez-Campillo R, Burgos CH, Henríquez-Olguín C, et al. Effect of unilateral, bilateral, and combined plyometric training on explosive and endurance performance of young soccer players. *J Strength Cond Res*. 2015;29(5):1317–1328
60. Asadi A, Arazi H, Ramirez-Campillo R, Moran J, Izquierdo M. Influence of

maturation stage on agility performance gains after plyometric training: a systematic review and meta-analysis. *J Strength Cond Res*. 2017; 31(9):2609–2617

61. Loudon JK, Santos MJ, Franks L, Liu W. The effectiveness of active exercise as an intervention for functional ankle instability: a systematic review. *Sports Med*. 2008;38(7):553–563
62. Boström A, Thulin K, Fredriksson M, Reese D, Rockborn P, Hammar ML. Risk factors for acute and overuse sport injuries in Swedish children 11 to 15 years old: what about resistance training with weights? *Scand J Med Sci Sports*. 2016;26(3):317–323
63. American Academy of Family Physicians; American Academy of Orthopaedic Surgeons; American College of Sports Medicine; American Orthopaedic Society for Sports Medicine; American Osteopathic Academy of Sports Medicine; American Medical Society for Sports Medicine. The team physician and strength and conditioning of athletes for sports: a consensus statement. *Med Sci Sports Exerc*. 2015;47(2):440–445
64. Gabbett TJ, Whyte DG, Hartwig TB, Wescombe H, Naughton GA. The relationship between workloads, physical performance, injury and illness in adolescent male football players. *Sports Med*. 2014;44(7): 989–1003
65. Brenner JS; American Academy of Pediatrics Council on Sports Medicine and Fitness. Overuse injuries, overtraining, and burnout in child and adolescent athletes. *Pediatrics*. 2007; 119(6):1242–1245
66. Petrie HJ, Stover EA, Horswill CA. Nutritional concerns for the child and adolescent competitor. *Nutrition*. 2004; 20(7–8):620–631
67. Cotunga N, Vickery CE, McBee S. Sports nutrition for young athletes. *J Sch Nurs*. 2005;21(6):323–328
68. Solomon ML, Weiss Kelly AK. Approach to the underperforming athlete. *Pediatr Ann*. 2016;45(3):e91–e96
69. Solomon ML, Briskin SM, Sabatina N, Steinhoff JE. The pediatric endurance athlete. *Curr Sports Med Rep*. 2017; 16(6):428–434
70. Calderazzi F, Nosenzo A, Galavotti C, Menozzi M, Pogliacomi F, Ceccarelli F. Apophyseal avulsion fractures of the pelvis. A review. *Acta Biomed*. 2018; 89(4):470–476
71. Browne TD, Yost RP, McCarron RF. Lumbar ring apophyseal fracture in an adolescent weight lifter. A case report. *Am J Sports Med*. 1990;18(5):533–535
72. US Consumer Product Safety Commission. National Electronic Injury Surveillance System. Available at: www.cpsc.gov/library/neiss.html. Accessed October 9, 2019
73. Hamill B. Relative safety of weightlifting and weight training. *J Strength Cond Res*. 1994;8(1):53–57
74. Byrd R, Pierce K, Rielly L, Brady J. Young weightlifters' performance across time. *Sports Biomech*. 2003;2(1):133–140
75. Harries SK, Lubans DR, Buxton A, MacDougall THJ, Callister R. Effects of 12-week resistance training on sprint and jump performances in competitive adolescent rugby union players. *J Strength Cond Res*. 2018;32(10): 2762–2769
76. Kerr ZY, Collins CL, Comstock RD. Epidemiology of weight training-related injuries presenting to United States emergency departments, 1990 to 2007. *Am J Sports Med*. 2010;38(4):765–771
77. Myer GD, Quatman CE, Khoury J, Wall EJ, Hewett TE. Youth versus adult "weightlifting" injuries presenting to United States emergency rooms: accidental versus nonaccidental injury mechanisms. *J Strength Cond Res*. 2009;23(7):2054–2060
78. Mehrab M, de Vos RJ, Kraan GA, Mathijssen NMC. Injury incidence and patterns among Dutch CrossFit athletes. *Orthop J Sports Med*. 2017; 5(12):2325967117745263
79. Rice SG; American Academy of Pediatrics Council on Sports Medicine and Fitness. Medical conditions affecting sports participation. *Pediatrics*. 2008;121(4):841–848
80. Black HR, Sica D, Ferdinand K, White WB. Eligibility and disqualification recommendations for competitive athletes with cardiovascular abnormalities: task force 6: hypertension: a scientific statement from the American Heart Association and the American College of Cardiology. *J Am Coll Cardiol*. 2015;66(21): 2393–2397
81. International League Against Epilepsy. ILAE Commission report. Restrictions for children with epilepsy. Commission of Pediatrics of the ILAE. *Epilepsia*. 1997; 38(9):1054–1056
82. Knowles BD, Pleacher MD. Athletes with seizure disorders. *Curr Sports Med Rep*. 2012;11(1):16–20
83. Maron BJ, Chaitman BR, Ackerman MJ, et al; Working Groups of the American Heart Association Committee on Exercise, Cardiac Rehabilitation, and Prevention; Councils on Clinical Cardiology and Cardiovascular Disease in the Young. Recommendations for physical activity and recreational sports participation for young patients with genetic cardiovascular diseases. *Circulation*. 2004;109(22):2807–2816
84. Fiuza-Luces C, Padilla JR, Soares-Miranda L, et al. Exercise intervention in pediatric patients with solid tumors: the physical activity in pediatric cancer trial. *Med Sci Sports Exerc*. 2017;49(2): 223–230
85. Steinherz LJ, Steinherz PG, Tan CT, Heller G, Murphy ML. Cardiac toxicity 4 to 20 years after completing anthracycline therapy. *JAMA*. 1991; 266(12):1672–1677
86. Gomez J; American Academy of Pediatrics Committee on Sports Medicine and Fitness. Use of performance-enhancing substances. *Pediatrics*. 2005;115(4):1103–1106
87. Myer GD, Faigenbaum AD, Ford KR, Best TM, Bergeron MF, Hewett TE. When to initiate integrative neuromuscular training to reduce sports-related injuries and enhance health in youth? *Curr Sports Med Rep*. 2011;10(3): 155–166
88. Faigenbaum A, Bruno L. A fundamental approach for treating pediatric dynapenia in kids. *ACSM's Health Fit J*. 2017;21:18–24
89. Kakebeeke TH, Locatelli I, Rousson V, Caflisch J, Jenni OG. Improvement in gross motor performance between 3 and 5 years of age. *Percept Mot Skills*. 2012;114(3):795–806
90. Smith JJ, DeMarco M, Kennedy SG, et al. Prevalence and correlates of resistance

training skill competence in adolescents. *J Sports Sci*. 2018;36(11):1241–1249

91. Hackett D, Davies T, Soomro N, Halaki M. Olympic weightlifting training improves vertical jump height in sportspeople: a systematic review with meta-analysis. *Br J Sports Med*. 2016;50(14):865–872
92. Logan K, Cuff S; Council on Sports Medicine and Fitness. Clinical report: organized sports for children, preadolescents, and adolescents. *Pediatrics*. 2019;143(6):e20190997
93. Gabbett TJ, Nassis GP, Oetter E, et al. The athlete monitoring cycle: a practical guide to interpreting and applying training monitoring data. *Br J Sports Med*. 2017;51(20):1451–1452
94. Coutts AJ, Murphy AJ, Dascombe BJ. Effect of direct supervision of a strength coach on measures of muscular strength and power in young rugby league players. *J Strength Cond Res*. 2004;18(2):316–323

Resources Recommended for the Care of Pediatric Patients in Hospitals

• *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Resources Recommended for the Care of Pediatric Patients in Hospitals

Kimberly D. Ernst, MD, MSMI, FAAP, COMMITTEE ON HOSPITAL CARE

It is crucial that all children are provided with high-quality and safe health care. Pediatric inpatient needs are unique in regard to policies, equipment, facilities, and personnel. The intent of this clinical report is to provide recommendations for the resources necessary to provide high-quality and safe pediatric inpatient medical care.

In 2016, there were 5.5 million hospitalizations of children 17 years and younger, with a mean length of stay of 4.0 days.[1] The primary indication for inpatient pediatric hospitalizations is respiratory illness, including pneumonia, acute bronchiolitis, and asthma.[2] Other common reasons for pediatric hospital admissions include appendicitis, seizures, infections, and dehydration.[2] Although many of these patients can be appropriately cared for in community settings, there must be a balance between family convenience, safe health care, and resource use. It is widely accepted that a minimum case volume is necessary to maintain competence and is associated with better outcomes; therefore, health care administrators and professionals need to evaluate their ability to care for the unique needs of the pediatric population and determine if they have the diagnostic and treatment capabilities, as well as the equipment and staffing, to provide high-quality and safe health care for these patients. Hospitals need to carefully evaluate their resources and may decide to be proactive in stabilizing and then transferring pediatric patients to facilities with higher pediatric inpatient volumes and more resources.

The intent of this clinical report is to provide recommendations for the resources (policies, equipment, facilities, and personnel) necessary to provide high-quality and safe pediatric inpatient medical care. Although all hospitals are obligated to provide emergency stabilization for children of all ages, including newly born infants,[3] this document's intent is specific to inpatient care after hospital admission, especially those hospitals with lower pediatric volumes that may need additional guidance. For pediatric emergency care, the American Academy of Pediatrics (AAP) provides detailed information in "Joint Policy Statement--Guidelines for Care of Children in the Emergency Department,"[4] and newborn care guidelines can be found in *Guidelines for Perinatal Care*.[5] For pediatric intensive care,

abstract

Section of Neonatal-Perinatal Medicine, Department of Pediatrics, College of Medicine, University of Oklahoma, Oklahoma City, Oklahoma

Dr Ernst was responsible for the literature review, writing the first draft, and revising the final draft with the input of all reviewers and approved the final manuscript as submitted.

Clinical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, clinical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2020-0204

Address correspondence to Kimberly D. Ernst, MD, MSMI, FAAP. E-mail: kimberly-ernst@ouhsc.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The author has indicated she has no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The author has indicated she has no potential conflicts of interest to disclose.

To cite: Ernst KD, AAP COMMITTEE ON HOSPITAL CARE. Resources Recommended for the Care of Pediatric Patients in Hospitals. *Pediatrics*. 2020;145(4):e20200204

the AAP and Society of Critical Care Medicine provide resources in "Criteria for Critical Care Infants and Children: PICU Admission, Discharge, and Triage Practice Statement and Levels of Care Guidance."[6]

POLICIES, PROCEDURES, AND PROTOCOLS

The care of the pediatric inpatient population is sufficiently different from that of the adult inpatient population, and these differences need to be taken into account when caring for this vulnerable population. Hospitals should electively admit only patients for whom they have appropriate resources, such as physical space, size-appropriate equipment, and qualified staff necessary for the unique needs of pediatric patients. In cases in which these resources are not available, policies to assist health care professionals with determining appropriate triage, consultation, and referral decisions are necessary. Hospitals that provide pediatric inpatient or outpatient services need both a plan in place (whether internally or through transport agreements) and resources available to provide urgent and emergent transfer to a facility with a higher level of care to best meet a patient's needs. These policies should address compliance with the Emergency Medical Treatment and Labor Act requirements.[3] A board-certified general pediatrician or pediatric medical subspecialist is strongly recommended to provide a leadership role to ensure all hospital policies, procedures, and protocols sufficiently address care for pediatric patients of all ages. If a pediatrician is not available, then a physician board certified in family or emergency medicine with current pediatric expertise could fulfill that role. Ideally, this physician would also be active in the evaluation of hospital-wide pediatric care and quality improvement efforts.

Regionalization and Interfacility Transfer

Hospitals and/or physicians providing care for children need well-established networks for timely consultation by subspecialists with pediatric expertise and, when necessary, for transfer of a patient to a facility that offers more advanced levels of care. Guidance for regionalization of care, the care of pediatric trauma patients, the care of pediatric critical care patients, and patient transfer has been published by the AAP, the American College of Surgeons, the Society of Critical Care Medicine, and the Emergency Medical Services for Children (EMSC) program.[6–10] Formal written interfacility transfer agreements should be in place for consultation and transport of a pediatric patient to a facility with a higher level of care.[10] These include access to air and ground transportation systems that are responsive and appropriately equipped and staffed on the basis of medical illness severity to care for children of all ages.[11] It is important for these referral relationships to be developed proactively and for protocols to be standardized to facilitate safe and efficient transports.

Regular multidisciplinary review of children transferred out of the facility as well as cases of deterioration can be conducted to reevaluate the hospital's admission, discharge, and transfer criteria. Ideally, this review would occur in collaboration with the regional referral facility. Such review may reveal minor modifications in equipment or training that would allow the facility to safely care for the higher-acuity patients it has previously transferred out, or alternatively, it may identify high-risk diagnoses that warrant immediate transfer on presentation. The goal is to ensure that all children in the facility receive the optimal care most appropriate for their medical and psychosocial needs.

Telehealth care may provide additional opportunities for collaboration between hospitals. In addition to direct patient interactions with pediatric medical subspecialists, tertiary centers may have outreach programs that can provide ongoing educational support for those practicing in the community.[12,13] One example of this model is Project ECHO (Extension for Community Healthcare Outcomes), a telementoring program designed to leverage widely available videoconferencing technology, clinical management tools, and case-based learning to increase workforce capacity by improving quality, reducing variety, and standardizing best practices within a multidisciplinary, team-based approach.[14] Establishing formalized relationships in advance can benefit both the referring hospital and the receiving tertiary care center by creating joint quality improvement teams to optimize patient care. Comprehensive information regarding the use of telehealth care can be found in "American Telemedicine Association Operating Procedures for Pediatric Telehealth."[15]

Patient Safety

The provision of care for hospitalized children should reflect an awareness of the unique patient safety concerns in the pediatric population:

- patient identification strategies that meet Joint Commission standards[16];
- the child's current weight in kilograms documented at admission and at regular intervals;
- a full set of vital signs documented in the medical record with a process for reporting abnormal age-specific vital sign values to the child's medical provider;

- all medication doses prescribed and dispensed by using weight-based dosing in kilograms with checks to ensure doses do not exceed the expected maximum dosages[17];
- precalculated medication dosages based on the child's weight in kilograms for common emergency medications[18];
- radiation safety procedures for imaging by using as low as reasonably achievable ionizing and shielding techniques[19]; and
- a rapid response team with at least 1 person having expertise in pediatric airway management as well as pediatric-specific criteria leading to activation of the team.[20]

The security of pediatric patients should be addressed within individual facilities. The Joint Commission standards require that the facility identifies and implements security procedures to address handling an infant or child abduction.[21] For younger children, the use of security bracelets or umbilical cord tags provide one layer of security, and locked units may provide security for older children. A risk assessment should be multidisciplinary, with each staff member providing input in his or her area of expertise to address actual and potential risks.[21] Not all pediatric patients will have family supervision, and the facility will be responsible for ensuring that children and adolescents do not leave the facility unattended or with a noncustodial parent or guardian. The physical layout, the number and arrangement of exits, the vulnerability of the patient population, intended level of guardian and/or visitor access, and community risk need to be addressed. Abduction and missing patient exercises are effective means to validate pediatric security effectiveness.[21] Facilities will need to address whole-hospital security measures to provide safety to patients, families, and staff in cases of active-shooter or other violent scenarios.[21]

Policies, procedures, and protocols should also be developed and implemented for all-hazards disaster preparedness.[4,22] Because of the complexities and need for advance planning, disaster preparedness is mentioned in this report to remind all facilities to address the issue. Hospital disaster plans are unique to each facility and community depending on the patient populations served as well as local, state, and regional resources and partners. The AAP has published additional information in "Ensuring the Health of Children in Disasters,"[22] and links to additional resources can be found on the AAP Disaster Preparedness Advisory Council and EMSC Web sites.[23,24] The EMSC program has prepared a checklist to assist facilities in incorporating pediatric preparedness into existing disaster policies.[25] Information for special populations, such as infants in the NICU and children with special health care needs, can be found in separate resources.[26,27]

Family-Centered Care

Facilities striving to provide patient- and family-centered care will include active family involvement in decision-making, medication safety processes, patient and family education, and discharge instruction.[28] It is important to address situations such as families with limited English proficiency and/or low general literacy, especially with regard to informed consent and family involvement and education.[29] Tailoring discussions with families by using the principles of health literacy universal precautions is critical for good communication.[30] Religious and cultural considerations may require adjustments to the child's care plan. Hospital policies allowing at least 1 caregiver to remain with the child at all times should be standard practice, especially with younger children. Ethical and legal guidelines for the care of adolescents need to be considered with regard to privacy and medical decision-making. Not only does consent need to be addressed but also assent on the basis of the child's age and developmental understanding.[29,31]

Policies should be developed that specify where children will be placed in the hospital once admitted. Single rooms provide better isolation for the common infectious diseases for which children are hospitalized and should also provide a space for caregivers to sleep and monitor care. If single rooms are not available, guidelines for appropriate age and sex cohorting should be established, taking into account adults who may be accompanying minors. Inviting families in the community to participate in policy making or design of a facility remodel can be a valuable resource for hospital leadership.

As the number of children with chronic illnesses increases, hospitals may care for more pediatric patients with life-limiting illnesses, even if only in an emergency situation. Processes should be in place for dealing with "do not resuscitate" or "allow natural death" orders with the understanding that individual situations require flexibility depending on the family and child's needs. The assessment and management of pain may be challenging because of the developmental and individual differences in experiencing and expressing pain. Several tools exist to provide improved pain control assessment and management.[32] The AAP statement "Patient- and Family-Centered Care and the Pediatrician's Role" can also act as a resource for facilities as they design their policies and processes.[28]

Policies regarding personnel and training will be addressed later in this report under Personnel and Training.

EQUIPMENT

Emergency Resuscitation Equipment

Essential equipment for care of the pediatric patient in hospitals includes resuscitation equipment for patients whose status has deteriorated since admission. All hospitals should be prepared for the emergency occurring in a pediatric patient, whether they routinely admit pediatric patients or not. A child who requires transfer to a facility with a higher level of pediatric care should be stabilized while transport is being arranged. The AAP policy statement "Joint Policy Statement--Guidelines for Care of Children in the Emergency Department" provides specific information for these situations.[33]

Separate pediatric emergency resuscitation carts are preferably located in or near areas such as the emergency department, pediatric inpatient unit, labor and delivery area, imaging area, and operating room. Supplies recommended for these carts include the following:

- inventory checklist;
- standardized code sheets with the medication dosages and Joules precalculated on the basis of weight in kilograms;
- pediatric backboard;
- personal protective equipment (gloves, gowns, masks);
- sharps container;
- cardiorespiratory and pulse oximetry monitors with appropriate alarm limits for pediatric patients;
- automated external defibrillators capable of treating pediatric patients with cardiac defibrillator paddles sized for infants and children;
- airway management equipment that fits children of all sizes (newborn to adolescents):
  - oxygen tanks;
  - pediatric oxygen masks;
  - bag-valve masks and manometers;
  - suctioning equipment;
  - laryngoscope blades;
  - oropharyngeal and nasoharyngeal airways;
  - endotracheal tubes (laryngeal masks are beneficial for health care professionals who rarely have the opportunity to intubate or rarely intubate children);
  - feeding tubes to provide gastric decompression during ventilation; and
  - chest tubes and large needles to evacuate pneumothoraces;
- vascular access devices and supplies:
  - skin preparation supplies and bandages;
  - small needle sizes, including butterfly needles;
  - various sizes of syringes;
  - umbilical line kits; and
  - intraosseous needles and drill;
- pediatric emergency medications, including fluids appropriate for pediatric patients (10% dextrose vials, 5% dextrose, and normal saline [NS] bags); and
- chemical mattress pads to provide warmth for infants.

Maintaining a code sheet with the medication dosages and Joules precalculated on the basis of the child's actual weight in kilograms is desirable in the patient's room (and, ideally, kept at all times with the patient during transport between departments or facilities). An extensive checklist of more specific supply items can be found in the resources and toolkit section on the EMSC Web site.[18]

Routine Hospital Equipment

Essential equipment is necessary to provide for the most common diagnoses seen in hospitals such as respiratory illness, appendicitis, seizure disorders, infections, and dehydration. This equipment should account for the wide differences observed in the pediatric population ranging from newborn infants to adolescents. The following list supplements standard adult equipment:

- infant, standing, and bed scales to measure patients in kilograms;
- appropriately sized respiratory equipment such as oxygen masks, nasal cannulas, bag-valve masks, artificial airways, and suctioning supplies;
- supplemental oxygen delivery systems, including low-flow meters;
- oximeter monitoring supplies that fit infants and small children;
- nebulizers and metered-dose inhalers with masks and spacers;
- "smart" infusion pumps designed for pediatric use with precise administration of low infusion rates with built-in libraries of the standard pediatric concentrations of medications;
- heel warmers to improve peripheral blood flow for sampling in infants;
- topical anesthetics for blood and spinal fluid sampling[34];
- pediatric lumbar puncture trays;
- sterile urine collection supplies in pediatric sizes;
- mercury-free thermometers with measurements in Celsius;
- pediatric-sized blood pressure cuffs;
- common pediatric fluids such as 10% dextrose vials, NS bags, 5% dextrose with 1/2 normal saline (D5-1/2NS), and 5% dextrose with normal saline (D5 NS);
- orogastric and nasogastric feeding tubes in sizes to fit children from newborn infants to adolescents;
- common infant formula types and bottles with nipples;
- pacifiers to provide newborn pain analgesia or soothing for neonatal abstinence;

- dedicated enteral pumps (these provide safety because they prevent inadvertent administration of enteral products via the intravenous route);
- electric breast pumps for mothers of young infants, including labels for storage and accessible storage facilities;
- incubators and/or warmers for infants and cribs with sleeping surfaces meeting safe-sleep guidelines[35];
- Various sizes of diapers;
- age-appropriate restraint devices, including soft wrist and leg restraints and arm and/or wrist immobilizers, to help preserve life-saving equipment such as endotracheal tubes, feeding tubes, and intravenous lines; and
- wheelchairs, crutches, slings, and splints in pediatric sizes.

Electronic Clinical Information Systems

Electronic clinical information systems play an important role in ensuring the safety and quality of pediatric care. A comprehensive AAP resource "Pediatric Aspects of Inpatient Health Information Technology Systems" provides guidance for facilities in understanding the unique aspects of safety, care, and documentation needs with regard to pediatric patients.[36] Although no dedicated pediatric inpatient clinical information system exists, some unique pediatric needs from this resource are highlighted below:

- anthropometric measurements (weight, length, head circumference) in metric units with automatic plotting on appropriate growth charts based on sex and age;
- storage of age-specific data, such as Apgar scores, pediatric pain scales, neonatal abstinence scores, pediatric mortality prediction scores, and ages in hours or days;
- ability to designate an indeterminate gender;
- configuration of access to adolescent patient data based on legal status and state confidentiality laws[37];
- ability to maintain continuity of access to health care information in cases in which children are mobile between various legal or physical custodians, for example, the foster care system;
- linking between infant and maternal medical charts and unlinking in cases of custodial loss or adoption;
- management of immunization data, including the ability to share administration data with the medical home and immunization registries;
- management of age-specific data for handoff reports including the transmission of the report to the medical home[38,39];
- ability to manage newborn screening and hearing screening data;
- availability of age-appropriate normal values for laboratory test results;
- ability to document developmental milestones;
- automated nutritional calculations;
- ability to manage the storage, tracking, and administration of human milk;
- electronic ordering of medications and infusions with weight-based calculations and alerts specific to the pediatric population;
- ability to preadmit patients likely to be admitted (preterm infant going to the NICU) so medications are readily available;
- medication dosing and drug interactions relative to pediatric patients;
- barcode scanning capabilities for medications, blood, and human milk as an additional layer of security for error prevention[40];
- discharge outpatient prescription prescribing with weight-based dosing, including total metric dose, as well as milliliters for liquid medications, name of medication, and reason for use; and
- ability to provide family education in their native language for medical issues as well as medications.

FACILITIES

Patient Care Area Facilities

The Joint Commission provides the *Comprehensive Accreditation Manual for Hospitals* that addresses the standards of hospital facilities to provide safe, quality health care.[41] These standards generally address the physical space and the features that protect patients, visitors, and staff. Caring for children requires additional considerations:

- single- or double-occupancy rooms that comply with guidelines for prevention of hospital-acquired infections (grouping pediatric rooms allows for efficient use of resources);
- pediatric beds allowing for bed rails to be raised;
- rooms with enough space to accommodate caregivers who stay with their children, including a sleeping space for at least 1 caregiver;
- adjustable privacy screens that allow convenient observation and supervision of patients;
- space to accommodate an accompanying adult in elevators and procedural rooms;
- a negative-pressure room for children admitted with suspected infectious illness that require that type of isolation;
- age-appropriate furniture, including cribs equipped with overhead safety devices and beds

having covered mechanical or electrical controls;
- high chairs for infant and toddler mealtimes;
- bookshelves or other large or bulky furniture anchored to the wall and that meet Consumer Product Safety Commission standards with a process in place to monitor for product recalls[42];
- specific safety products, such as electrical outlet covers, window locks, cabinet door safety latches, padding for sharp corners and edges, and toilet latches, for spaces in children's areas;
- cordless window coverings;
- cordless phones;
- magnet-free status communication boards;
- trash cans and sharps containers out of reach of toddlers and small children;
- alcohol-containing hand sanitizer dispensers not accessible to small children;
- age-appropriate spaces where children can feel safe from painful or scary medical procedures[43];
- a separate treatment room for procedures[43];
- entertainment consoles, computers, as well as educational and other age-appropriate activities help to keep children distracted; all toys, equipment, and play surfaces should be regularly cleaned with appropriate germicidal solutions;
- an indoor and/or secure outdoor playground area with equipment that has accommodations for those with impaired mobility;
- Internet access, with appropriate safeguards, available to all patients and families for entertainment, work, and education;
- facilities for families to safely store food and human milk and for personal hygiene (laundry, showers, etc) while they are staying with their children in the facility; and
- affordable or free parking for families with hospitalized children to encourage family involvement.

Although interior design and decor is beyond the scope of this document, additional information about child-friendly, developmentally appropriate environments may be obtained from the Institute for Patient- and Family-Centered Care Web site.[44]

Therapeutic and Diagnostic Facilities

The following therapeutic and diagnostic facilities are necessary, and 24-hour availability is strongly recommended:

- routine radiographic imaging, using techniques to reduce radiation exposure in children,[19] with a radiologist skilled in pediatric assessment available either on-site or by teleradiology for interpreting images;
- clinical laboratory with services appropriate for infant and pediatric needs, including hematologic profiles, blood chemistries (including serum bilirubin levels), blood gas studies, microbiology studies, common locally used antibiotic levels, and standard urine studies:
  - equipment to process all commonly ordered tests, such as complete blood cell counts and blood chemistry levels, by using samples of less than 1 mL ("micro" samples);
  - serum drug concentrations for aminoglycoside antibiotics, for example, known to cause ototoxicity and nephrotoxicity, with results available in a timely manner; send-out testing may not allow appropriate adjustments in dosing; and
  - standard laboratory regulations require appropriate critical reference values based on patient age[45];
- pharmacy services to provide age- and size-appropriate drug administration and dosing that includes both a weight-based dose and a final calculated amount[46]:
  - commonly used oral suspensions, including oral sucrose solutions to use for analgesia with painful procedures in young infants, quickly available[34];
  - supplies and expertise to safely create pediatric liquid formulations at nationally accepted standard concentrations[14];
  - orally administered liquid medications dispensed with metric dosing (milligrams, micrograms) on the label in small-volume milliliter-based dosing devices, such as syringes[47];
  - doses of medications calculated by using computer programs or calculations based on appropriate neonatal or pediatric pharmacokinetic models; and
  - medications for pediatrics stored in a separate location from adult formulations both within and outside of the pharmacy; and
- nutritional services to provide child-friendly meals:
  - common infant and toddler formulas, pediatric nutritional supplements, and rehydration formulas stocked in pediatric areas and readily retrieved for those in the emergency department or other areas where children are treated;
  - in cases in which the hospital cafeteria does not remain open 24 hours, prepackaged meals and patient nutritional supplies

stocked in the pediatric areas before the cafeteria closes for the night;
- nutritious meals and drinking water readily available for breastfeeding mothers; and
- donor human milk, which is becoming more widely available and is a consideration for hospitals treating infants who may benefit from this resource.

PERSONNEL AND TRAINING

Because respiratory illnesses are the most common pediatric diagnoses requiring inpatient admission, the need for health care facilities to have ready access to personnel skilled in airway management as well as specialized equipment in sizes appropriate for children from newborn infants to adolescents is imperative. Respiratory therapists with pediatric expertise are especially important for providing safe pediatric care because pediatric patients tend to experience respiratory arrest rather than the cardiac arrest seen in adults. Health care professionals with expertise in pediatric life support techniques should know the location of carts and equipment for cardiopulmonary resuscitation. Mock codes conducted on a regular basis with debriefings either by pediatric-trained internal staff or by using personnel from tertiary centers are strongly recommended. It is helpful if the multidisciplinary medical team trains together during life support courses so that the team functions optimally in times of emergency. This training complements, but does not replace, real-life experience in caring for hospitalized children. Education sessions, clinical training opportunities, and mock codes should be documented for review by hospital quality assurance committees and The Joint Commission.

Physicians and other health care professionals responsible for the care of inpatient pediatric patients should be licensed and have training in the care of hospitalized children either through a formal training program and/or through supervised experience consistent with the individual facility's bylaws for credentialing. Health care professionals need to maintain professional expertise through continuing education as well as maintenance of active life support credentials, including neonatal and pediatric advanced life support or equivalent training.[48] Those who are in charge of a pediatric patient's care may be either on-site or on-call, depending on the severity of a child's illness, and policies may address an acceptable response time for on-call professionals. Children who require intermediate- or higher-level care need a high-level health care professional who is in-house and readily available to respond to the patient immediately should the child's condition deteriorate.[49] The AAP and Society of Critical Care Medicine publication "Criteria for Critical Care Infants and Children: PICU Admission, Discharge, and Triage Practice Statement and Levels of Care Guidance" helps identify resource needs in those settings.[6] Facilities must have policies in place so that the responsible health care professional is known to all personnel caring for the child, whether it be the primary physician, on-call physician, or an in-house emergency department physician with abilities to care for pediatric patients. Procedures should be in place so that both families and the medical team are able to easily identify this person.

Because a child's age, as well as cognitive level, influences his or her ability to cooperate, sedation in children is often administered to relieve pain and anxiety as well as to provide immobility to allow the safe completion of a procedure. Health care professionals should have an in-depth knowledge of the agents they intend to use and their potential complications. It is important to be able to recognize the various levels of sedation in addition to possessing the skills and age- and size-appropriate equipment necessary to provide appropriate monitoring as well as cardiopulmonary support if needed.[50] Because normal vital sign values differ in younger age groups, instruction on the use of cardiorespiratory monitors and their alarms is necessary for all staff. Competencies and case volumes in pediatric sedation should be reviewed annually.[50] Children younger than 1 year are at a fourfold higher risk of anesthesia-related cardiac arrest than those between 1 and 18 years of age.[51] For this reason, for children younger than 2 years or older children with complex medical diseases, it is preferred that board-certified pediatric surgeons and anesthesiologists supervise all elective surgical procedures.[51] The AAP statement "Critical Elements for the Pediatric Perioperative Anesthesia Environment" has detailed information.[50]

Pediatric nursing experience and training is crucial in determining a facility's ability to provide high-quality and safe pediatric medical care. Because nurses spend more face-to-face time with the patient than any other member of the health care team, it is important that they are able to identify signs of decompensation and are able to intervene in an emergency. They should understand that normal laboratory values may differ in pediatric patients. Nurses must understand the behavioral differences that occur in children to modify their care on the basis of the child's understanding of the situation (eg, the use of age-appropriate pediatric pain scales)[34] or developmental differences in their ability to respond to a neurologic examination. Adolescents require a fine balance between guidance and autonomy, and pediatric nurses need skill in

recognizing signs of abuse or self-harm. In cases in which nurses have relatively low skill in obtaining intravenous access, it is preferable that the most experienced staff member attempt to obtain access to decrease the child's emotional and physical trauma. Although having a pediatric nursing educator is ideal, facilities lacking a pediatric educator should ensure they dedicate time to pediatric competencies. It is important for hospitals to anticipate pediatric personnel shortages or times of higher pediatric census by crosstraining nonpediatric staff, who should only be used after successfully demonstrating the essential duties of nurses caring for pediatric inpatients. If skilled pediatric staff are not available, consideration should be given to transfer of children to a facility that can meet the patients' needs. Baseline and annual evaluations that include age-specific and psychosocial competencies as well as the performance of essential pediatric skills should be verified by qualified personnel.

Similar to medical and nursing staff, pharmacists caring for pediatric patients need experience and specific training in their roles. Pediatric patients are at higher risk for medication error and may experience a more serious consequence should an error occur.[17] It is helpful for pharmacists with pediatric experience to participate in prospective order review, safety and technology committees, protocol development, staff education, quality improvement, and other high-impact patient care duties.[52] Pharmacy technicians who prepare pediatric medications, including parenteral solutions, need to maintain documented pediatric pharmacy competencies. Not all facilities will have a pediatric pharmacist on staff, and a liaison pediatric pharmacist from a children's hospital may be a beneficial resource to assist in minimizing the possibility of adverse consequences.

It is highly recommended that the following health care professionals be available on a routine basis to provide services to the inpatient pediatric patients: radiology technologists, nutritionists, lactation specialists, rehabilitation therapists, child life specialists, mental health specialists, social workers, and medical interpreters. Professionals providing these services should have adequate training and continuing education in the pediatric applications of their respective fields. Baseline and periodic competency evaluations should include competencies specific to the pediatric populations cared for in the individual facility. In many facilities, nurses often fill the role of providing lactation support to mother-infant dyads with common lactation issues. Staff who are asked to fill the gaps when other personnel are not available routinely should be provided continuing education opportunities to ensure competence in the roles they are performing. It is not acceptable to use family members as interpreters of health care information, and hospital staff should practice health literacy universal precautions. Only 12% of US adults are fluent in the language of health care, and the ability to absorb and use health information can be compromised by stress.[30] The Agency for Healthcare Research and Quality's *AHRQ Health Literacy Universal Precautions Toolkit, Second Edition*, can help facilities increase patient and family understanding of health information and enhance support for people of all health literacy levels.[30] Foreign and sign language assistance may be provided by a telephone or telehealth interpretive service, and educational materials may be translated by an off-site service if an interpreter is not available in-house. When it is not feasible to employ full-time personnel or crosstrain staff because of financial or staffing issues, facilities should maintain appropriate consultative relationships with tertiary hospital staff members. These points of contact may provide regular educational sessions, consultations for specific patients, and assistance with policy development.[8,9]

SPECIAL CONSIDERATIONS

Although all health care professionals who provide care to pediatric patients should be familiar with the unique and changing physical and psychosocial needs of children and the core concepts of patient- and family-centered care, having a child life specialist on staff is recommended.[28] If it is not feasible to maintain a dedicated child life specialist, facilities should consult one at a tertiary center to assist with ongoing education of the local hospital staff in the provision of psychosocial care and family- and child-friendly services.[43] The assessment of pain can be difficult in nonverbal children, and health care professionals need training in how to use age-appropriate pediatric pain scales appropriately. Staff may also need training on how to support children with intellectual disabilities or autism spectrum disorder, for example, who present with a medical illness needing treatment. Training in the physical as well as the emotional components of end-of-life situations and palliative care may be helpful for staff because many find it difficult to deal with a child's impending or actual death.

Hospitalized children, especially those with hospital stays anticipated to last more than a week, need a designated hospital liaison (nurse, social worker, discharge planner, child life specialist) to partner with the child's school to ensure the hospitalization does not cause interruption in the child's education endeavors. In some cases, having access to videoconferencing or online attendance at a child's school can keep the child from getting behind in his or her studies.

Children may be seen in the emergency department for medical disorders that can either present as or coexist with psychiatric or behavioral disorders needing appropriate triage. It is important to be sensitive to the needs of adolescent patients by asking nonprejudiced questions in private about sexual partners and substance use. Although toxic ingestions in toddlers may be accidental, those in adolescents may be a sign of suicidal intentions.[53] Sixteen percent of adolescents have seriously considered, and 8% have attempted, suicide in the past year.[54] Certain ethnic groups, those with a family or personal history of suicide attempts or behavioral disorders, and those who identify as a sexual minority are at higher risk.[55] Personnel should be able to recognize these issues and be familiar with the hospital's mental health resources and policies for appropriate triage.

Health care professionals responsible for the care of children should be trained in the recognition and initial management of child abuse, maltreatment, and neglect whether physical, sexual, emotional, or medical. They should be aware of the types of injuries that can occur at various ages and which ones are unlikely to have occurred in the manner in which they are described by the child or accompanying adult.[56,57] Children who have experienced physical or sexual abuse, children who have experienced violence in the home, or children who are diagnosed with a psychological disorder should have timely intervention with a child maltreatment team and/or mental health specialist. There should be policies in place to ensure proper reporting of allegations to authorities for further investigation as well as appropriate transfer to a facility with mental health services with expertise in pediatric care if not available locally. Guidance in the area of child maltreatment can be found on the AAP Council on Child Abuse and Neglect Web site.[58]

CONCLUSIONS

Inpatient facilities caring for the unique pediatric population should be well resourced to provide high-quality and safe health care by providing the appropriate policies, equipment, facilities, and personnel as outlined in this clinical report.

LEAD AUTHOR

Kimberly D. Ernst, MD, MSMI, FAAP

COMMITTEE ON HOSPITAL CARE, 2018–2019

Daniel A. Rauch, MD, FAAP, Chairperson
Kimberly D. Ernst, MD, MSMI, FAAP
Vanessa Lynn Hill, MD, FAAP
Melissa Marie Mauro-Small, MD, FAAP
Benson S. Hsu, MD, MBA, FAAP
Vinh Thuy Lam, MD, FAAP
Charles David Vinocur, MD, FAAP
Jennifer Ann Jewell, MD, FAAP, Former Chairperson

LIAISONS

Karen Castleberry – *Family Liaison*
Kristin Hittle Gigli, PhD, RN, CPNP-AC, CCRN – *National Association of Pediatric Nurse Practitioners*
Nancy Hanson – *Children's Hospital Association*
Michael S. Leonard, MD, MS, FAAP – *Representative to The Joint Commission*
Barbara Romito, MA, CCLS – *Association of Child Life Professionals*

STAFF

S. Niccole Alexander, MPP

ABBREVIATIONS

AAP: American Academy of Pediatrics
EMSC: Emergency Medical Services for Children
NS: normal saline

REFERENCES

1. Freeman WJ, Weiss AJ, Heslin KC. Overview of U.S. Hospital Stays in 2016: Variation by Geographic Region. Statistical Brief #246. Rockville, MD: Agency for Healthcare Research and Quality; 2018. Available at: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb246-Geographic-Variation-Hospital-Stays.pdf. Accessed March 30, 2019
2. Witt WP, Weiss AJ, Elixhauser A. Overview of Hospital Stays for Children in the United States, 2012. Statistical Brief #187. Rockville, MD: Agency for Healthcare Research and Quality; 2014. Available at: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb187-Hospital-Stays-Children-2012.pdf. Accessed March 30, 2019
3. Centers for Medicare and Medicaid Services. Emergency Medical Treatment and Labor Act (EMTALA). 2012. Available at: www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/. Accessed March 30, 2019
4. American Academy of Pediatrics, Committee on Pediatric Emergency Medicine; American College of Emergency Physicians, Pediatric Committee; Emergency Nurses Association, Pediatric Committee. Joint policy statement–Guidelines for care of children in the emergency department. *Pediatrics*. 2009;124(4):1233–1243. Reaffirmed February 2016
5. American Academy of Pediatrics, Committee on Fetus and Newborn; American College of Obstetricians and Gynecologists, Committee on Obstetric Practice. Guidelines for Perinatal Care. In: Riley LE, Stark AR, eds. 7th ed. Elk Grove Village, IL: American Academy of Pediatrics and Washington, DC: American College of Obstetricians and Gynecologists; 2012
6. Frankel LR, Hsu BS, Yeh TS, et al; Voting Panel. Criteria for critical care infants and children: PICU admission, discharge, and triage practice statement and levels of care guidance. *Pediatr Crit Care Med*. 2019;20(9):847–887
7. American Academy of Pediatrics, Section on Transport Medicine. Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients. In: Insoft RM, ed. 4th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2016
8. American College of Surgeons, Committee on Trauma. Resources for Optimal Care of the Injured Patient. 6th ed. Chicago, IL: American College of Surgeons; 2014

9. Committee on Pediatric Emergency Medicine, Council on Injury; Violence, and Poison Prevention, Section on Critical Care, Section on Orthopaedics, Section on Surgery, Section on Transport Medicine, Pediatric Trauma Society, and Society of Trauma Nurses Pediatric Committee. Management of pediatric trauma. *Pediatrics*. 2016; 138(2):e20161569
10. Emergency Nurses Association Pediatric Committee; Society of Trauma Nurses Pediatric Special Interest Group. Inter Facility Transfer Tool Kit for the Pediatric Patient. Houston, TX: Emergency Medical Services for Children Innovation and Improvement Center; 2017. Available at: https://emscimprovement.center/resources/toolboxes/interfacility-transfer-toolbox/. Accessed March 30, 2019
11. American Academy of Pediatrics; American College of Emergency Physicians; American College of Surgeons Committee on Trauma; Emergency Medical Services for Children; Emergency Nurses Association; National Association of EMS Physicians; National Association of State EMS Officials. Equipment for ground ambulances. *Pediatrics*. 2014; 134(3). Available at: www.pediatrics.org/cgi/content/full/134/3/e919
12. Marcin JP, Rimsza ME, Moskowitz WB; Committee on Pediatric Workforce. The use of telemedicine to address access and physician workforce shortages. *Pediatrics*. 2015;136(1):202–209
13. Burke BL Jr., Hall RW; Section on Telehealth Care. Telemedicine: pediatric applications. *Pediatrics*. 2015;136(1): e293–e308
14. American Academy of Pediatrics. AAP ECHO. Available at: www.aap.org/en-us/professional-resources/practice-transformation/echo/Pages/default.aspx. Accessed March 30, 2019
15. McSwain SD, Bernard J, Burke BL Jr., et al; American Telemedicine Association. American Telemedicine Association operating procedures for pediatric telehealth. *Telemed J E Health*. 2017;23(9):699–706
16. The Joint Commission. National Patient Safety Goals. Oakbrook Terrace, IL: The Joint Commission; 2015. Available at: www.jointcommission.org/assets/1/6/2015_NPSG_HAP.pdf. Accessed March 30, 2019
17. Levine SR, Cohen MR, Blanchard NR, et al. Guidelines for preventing medical errors in pediatrics. *J Pediatr Pharmacol Ther*. 2001;6:426–442
18. Emergency Medical Services for Children, Innovation and Improvement Center. Pediatric Disaster Preparedness Toolkit. 2009. Available at: https://emscimprovement.center/resources/publications/checklist-essential-for-every-hospitals-disaster-preparedness-policies/. Accessed March 30, 2019
19. Image Gently. Interventional Radiology - Step Lightly Resources. Available at: https://www.imagegently.org/Procedures/Interventional-Radiology/Image-Safely-Resources. Accessed March 30, 2019
20. Institute for Healthcare Improvement. Rapid response teams. Available at: www.ihi.org/Topics/RapidResponseTeams/Pages/default.aspx. Accessed March 30, 2019
21. US Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. *Incorporating Active Shooter Incident Planning Into Health Care Facility Emergency Operations Plans*. Washington, DC: US Department of Health and Human Services; 2014
22. Disaster Preparedness Advisory Council; Committee on Pediatric Emergency Medicine. Ensuring the health of children in disasters. *Pediatrics*. 2015;136(5). Available at: www.pediatrics.org/cgi/content/full/136/5/e1407
23. American Academy of Pediatrics, Disaster Preparedness Advisory Council. Children and disasters: disaster preparedness to meet children's needs. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Children-and-Disasters/Pages/default.aspx. Accessed March 30, 2019
24. Emergency Medical Services for Children Innovation and Improvement Center. Education & resources. Available at: https://emscimprovement.center/resources/. Accessed March 30, 2019
25. American Academy of Pediatrics; American College of Emergency Physicians; Emergency Nurses Association. Checklist of Essential Pediatric Domains and Considerations for Every Hospital's Disaster Preparedness Policies. Houston, TX: Emergency Medical Services for Children Innovation and Improvement Center; 2014. Available at: https://emscimprovement.center/documents/144/Checklist_HospitalDisasterPrepared2125.pdf. Accessed March 30, 2019
26. Barfield WD, Krug SE; Committee on Fetus and Newborn; Disaster Preparedness Advisory Council. Disaster preparedness in neonatal intensive care units. *Pediatrics*. 2017;139(5):e20170507
27. American Academy of Pediatrics; Committee on Pediatric Emergency Medicine and Council on Clinical Information Technology; American College of Emergency Physicians; Pediatric Emergency Medicine Committee. Policy statement–emergency information forms and emergency preparedness for children with special health care needs. *Pediatrics*. 2010;125(4):829–837. Reaffirmed October 2014
28. Committee on Hospital Care and Institute for Patient- and Family-Centered Care. Patient- and family-centered care and the pediatrician's role. *Pediatrics*. 2012;129(2):394–404
29. Committee on Pediatric Emergency Medicine; Committee on Bioethics. Consent for emergency medical services for children and adolescents. *Pediatrics*. 2011;128(2):427–433. Reaffirmed September 2015
30. Agency for Healthcare Research and Quality. AHRQ Health Literacy Universal Precautions Toolkit. Rockville, MD: Agency for Healthcare Research and Quality; 2018. Available at: www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/index.html. Accessed March 30, 2019
31. Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2):e20161484
32. American Academy of Pediatrics; American College of Emergency Physicians; Emergency Nurses Association. Pediatric Pain Management Toolkit. Houston, TX: Emergency Medical Services for Children Innovation and Improvement Center; 2017. Available at:

https://emscimprovement.center/resources/toolboxes/pediatric-pain-management-toolbox/. Accessed March 30, 2019

33. Fleisher GR, Ludwig S. Textbook of Pediatric Emergency Medicine. 6th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2010
34. Committee on Fetus and Newborn; Section on Anesthesiology and Pain Medicine. Prevention and management of procedural pain in the neonate: an update. *Pediatrics*. 2016;137(2):e20154271
35. Task Force on Sudden Infant Death Syndrome. SIDS and other sleep-related infant deaths: updated 2016 recommendations for a safe infant sleeping environment. *Pediatrics*. 2016; 138(5):e20162938
36. Lehmann CU; Council on Clinical Information Technology. Pediatric aspects of inpatient health information technology systems. *Pediatrics*. 2015; 135(3). Available at: www.pediatrics.org/cgi/content/full/135/3/e756
37. Committee on Adolescence. Achieving quality health services for adolescents. *Pediatrics*. 2016;138(2):e20161347
38. Jewell JA; Committee on Hospital Care. Standardization of inpatient handoff communication. *Pediatrics*. 2016;138(5): e2016281
39. Kuo DZ, Houtrow AJ; Council on Children with Disabilities. Recognition and management of medical complexity. *Pediatrics*. 2016;138(6):e20163021
40. Bates DW, Cohen M, Leape LL, Overhage JM, Shabot MM, Sheridan T. Reducing the frequency of errors in medicine using information technology. *J Am Med Inform Assoc*. 2001;8(4):299–308
41. The Joint Commission. Comprehensive Accreditation Manual for Hospitals. Oakbrook Terrace, IL: The Joint Commission; 2016
42. US Consumer Product Safety Commission. Regulations, laws & standards. Available at: www.cpsc.gov/Regulations-Laws–Standards. Accessed March 30, 2019
43. Committee on Hospital Care and Child Life Council. Child life services. *Pediatrics*. 2014;133(5). Available at: www.pediatrics.org/cgi/content/full/133/5/e1471
44. Institute for Patient- and Family-Centered Care. Resources. Available at: http://ipfcc.org/resources/index.html. Accessed March 30, 2019
45. Clinical and Laboratory Standards Institute. Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline [CLSI Document EP28-A3c]. 3rd ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2008
46. American Society of Health-System Pharmacists. ASHP compounded oral liquid version 1.01: finalized list July 2017. 2017. Available at: www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/s4s-ashp-oral-compound-liquids.ashx?la=en&hash=4C2E4F370B665C028981B61F6210335AD5D0D1D6. Accessed March 30, 2019
47. Committee on Drugs. Metric units and the preferred dosing of orally administered liquid medications. *Pediatrics*. 2015;135(4):784–787
48. Lye PS; American Academy of Pediatrics. Committee on Hospital Care and Section on Hospital Medicine. Clinical report–physicians' roles in coordinating care of hospitalized children. *Pediatrics*. 2010;126(4):829–832
49. Jaimovich DG; American Academy of Pediatrics Committee on Hospital Care and Section on Critical Care. Admission and discharge guidelines for the pediatric patient requiring intermediate care. *Pediatrics*. 2004; 113(5):1430–1433. Reaffirmed May 2017
50. Polaner DM, Houck CS; Section on Anesthesiology and Pain Medicine; American Academy of Pediatrics. Critical elements for the pediatric perioperative anesthesia environment. *Pediatrics*. 2015;136(6):1200–1205
51. Society for Pediatric Anesthesia. Society for Pediatric Anesthesia Policy Statement on Provision of Pediatric Anesthesia Care. Richmond, VA: Society for Pediatric Anesthesia; 2017. Available at: www.pedsanesthesia.org/about/provision-of-pediatric-anesthesia-care/. Accessed March 30, 2019
52. Boucher EA, Burke MM, Johnson PN, Klein KC, Miller JL; Advocacy Committee for the Pediatric Pharmacy Advocacy Group. Minimum requirements for core competency in pediatric pharmacy practice. *J Pediatr Pharmacol Ther*. 2015;20(6):481–484
53. Chun TH, Mace SE, Katz ER; American Academy of Pediatrics; Committee on Pediatric Emergency Medicine; American College of Emergency Physicians; Pediatric Emergency Medicine Committee. Evaluation and management of children and adolescents with acute mental health or behavioral problems. Part I: common clinical challenges of patients with mental health and/or behavioral emergencies. *Pediatrics*. 2016;138(3):e20161570
54. Shain B; Committee on Adolescence. Suicide and suicide attempts in adolescents. *Pediatrics*. 2016;138(1): e20161420
55. Eaton DK, Kann L, Kinchen S, et al; Centers for Disease Control and Prevention (CDC). Youth Risk Behavior Surveillance - United States, 2011. *MMWR Surveill Summ*. 2012;61(4):1–162
56. Flaherty EG, Perez-Rossello JM, Levine MA, Hennrikus WL; American Academy of Pediatrics Committee on Child Abuse and Neglect; Section on Radiology, American Academy of Pediatrics; Section on Endocrinology, American Academy of Pediatrics; Section on Orthopaedics, American Academy of Pediatrics; Society for Pediatric Radiology. Evaluating children with fractures for child physical abuse. *Pediatrics*. 2014; 133(2). Available at: www.pediatrics.org/cgi/content/full/133/2/e477
57. Christian CW; Committee on Child Abuse and Neglect, American Academy of Pediatrics. The evaluation of suspected child physical abuse. *Pediatrics*. 2015; 135(5). Available at: www.pediatrics.org/cgi/content/full/135/5/e1337
58. Flaherty EG, Stirling J; American Academy of Pediatrics, Committee on Child Abuse and Neglect. The pediatrician's role in child maltreatment prevention. *Pediatrics*. 2010;126(4):833–841. Reaffirmed May 2014

Routine Neuroimaging of the Preterm Brain

- *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Routine Neuroimaging of the Preterm Brain

Ivan L. Hand, MD, FAAP,[a] Renée A. Shellhaas, MD, MS, FAAP,[b] Sarah S. Milla, MD, FAAP,[c] COMMITTEE ON FETUS AND NEWBORN, SECTION ON NEUROLOGY, SECTION ON RADIOLOGY

Neuroimaging of the preterm infant is a common assessment performed in the NICU. Timely and focused studies can be used for diagnostic, therapeutic, and prognostic information. However, significant variability exists among neonatal units as to which modalities are used and when imaging studies are obtained. Appropriate timing and selection of neuroimaging studies can help identify neonates with brain injury who may require therapeutic intervention or who may be at risk for neurodevelopmental impairment. This clinical report reviews the different modalities of imaging broadly available to the clinician. Evidence-based indications for each modality, optimal timing of examinations, and prognostic value are discussed.

INTRODUCTION

Central to the assessment of the preterm infant is identifying the presence and extent of brain injury. Preterm infants are at significant risk of intraventricular hemorrhage (IVH), periventricular leukomalacia (PVL), posthemorrhagic ventricular dilatation, and other neurologic injuries that may or may not have imaging corollaries. Through neuroimaging, the neonatologist may initiate interventions and plan for supportive care and assess the risk of future neurologic impairment.

In 1968, Abraham Towbin[1] described the frequent finding of IVH at necropsy in preterm infants, with abnormalities almost universally present in those born at less than 28 weeks' gestation. Not until 10 years later did Papile at al[2] describe the computerized tomography (CT) findings of 46 consecutive very low birth weight (VLBW) infants and demonstrate a much higher incidence of IVH than was clinically suspected. That report described 4 separate grades of hemorrhage: "Grade I–subependymal hemorrhage, Grade II–intraventricular hemorrhage without ventricular dilatation, Grade III–intraventricular hemorrhage with ventricular dilatation, and Grade IV–intraventricular hemorrhage with parenchymal hemorrhage." Since the initial report, the Papile classification has been modified to grade I, indicating minimal IVH; grade II, with IVH occupying

abstract

[a]Department of Pediatrics, New York City Health + Hospitals/Kings County, State University of New York Downstate Medical Center, Brooklyn, New York; [b]Pediatric Neurology Division, Department of Pediatrics, Michigan Medicine, University of Michigan, Ann Arbor, Michigan; and [c]Departments of Radiology and Pediatrics, Emory University School of Medicine and Children's Healthcare of Atlanta, Atlanta, Georgia

Drs Hand, Shellhaas, and Milla researched, conceived, designed, analyzed, and interpreted data for this clinical report and drafted and revised this clinical report; and all authors approved the final manuscript as submitted.

DOI: https://doi.org/10.1542/peds.2020-029082

Address correspondence to Ivan L. Hand, MD, FAAP. E-mail: ivan.hand@nychhc.org

To cite: Hand IL, Milla SS, AAP COMMITTEE ON FETUS AND NEWBORN, SECTION ON NEUROLOGY, SECTION ON RADIOLOGY. Routine Neuroimaging of the Preterm Brain. *Pediatrics.* 2020;146(5):e2020029082

10% to 50% of the ventricular area; grade III, representing IVH with >50% of ventricular area; and last, parenchymal hemorrhage, most likely attributable to hemorrhagic venous infarction.[3]

These findings led to one of the earliest outcomes studies,[4] in which authors described the association of major developmental and neuromotor handicaps with the findings of more severe (grade III and IV) IVH on CT scan performed between 3 and 10 days of age. On the basis of these and other studies, the American Academy of Neurology (AAN) released practice parameters in 2002 suggesting universal cranial ultrasonographic screening for all infants born at less than 30 weeks' gestation.[5] The AAN also recommended that initial screening ultrasonography be performed at 7 to 14 days after birth and repeated at near term corrected age. In 2001, the Canadian Pediatric Society recommended screening all infants born at less than 32 weeks' gestation at 2 weeks after birth, with a repeat screening 6 weeks after birth.[6] Since the publication of those guidelines, cranial ultrasonography capabilities have evolved, and modern ultrasonography technology, along with the use of supplementary acoustic windows, can now provide good structural imaging of the preterm infant brain.[7]

Imaging the entire brain was once performed by using CT scanning. Use of head CT has given way to improved cranial ultrasonography as well as MRI, which yields better detail and avoids the use of ionizing radiation.[8] However, routine use of MRI for screening the preterm infant has been identified as being of questionable value in the Choosing Wisely campaign of the American Academy of Pediatrics.[9] The aim of this clinical report is to provide guidance to clinicians for an evidence-based approach to neuroimaging for the preterm infant.

INITIAL SCREENING EXAMINATIONS

The VLBW (ie, birth weight <1500 g) infant is at high risk for germinal matrix and IVH as well as ischemic white matter injury as identified by cranial ultrasonography. Risk of severe IVH is inversely related to gestational age, with infants born at less than 24 weeks' gestation at highest risk.[10] In 2017, the Vermont Oxford Network database demonstrated an overall 24.6% incidence of IVH and an 8.1% rate of severe IVH, defined as grade III or IV among more than 50 000 VLBW infants.[11] In a recently published survey of the California Perinatal Quality Care Collaborative, 63% of infants born at 22 to 23 6/7 weeks' gestation had IVH, with 36% demonstrating severe IVH.[12] This incidence decreased to 14% of infants whose gestational age at birth was 30 to 31 6/7 weeks having any IVH and 1.4% having a severe grade. Less severe grades of IVH (grades I and II) may have less prognostic influence on clinical outcomes. In a National Institute of Child Health and Development study of 1472 infants born at less than 27 weeks' gestational age,[13] there was no significant difference in neurodevelopmental outcomes at 18 to 22 months of those infants with and without these low-grade hemorrhages.

PVL is a disorder of the periventricular cerebral white matter that may be cystic or diffuse in nature. Most cystic PVL occurs in infants born between 26 and 30 weeks' gestation, initially appearing as periventricular increased echogenicity (eg, a blush or flare) with cystic evolution over the course of a few weeks. Periventricular hemorrhagic infarcts (PVHIs) (ie, formerly grade 4 IVH) occur mainly in infants born at <26 weeks' gestation[14] and occur infrequently in infants born beyond 30 weeks' gestation.[15] A PVHI is a parenchymal lesion usually associated with a large IVH and, on the basis of current understanding, believed to be caused by venous infarction. A PVHI is not, as once believed, an extension of the IVH into the parenchyma.

Severity of IVH in the most immature infants is consistent with the developmental changes of the subependymal germinal matrix as it decreases in size from 2.5 mm in the 24-week preterm infant to involution at about 36 weeks' gestational age.[3] For these and other reasons affecting vascular integrity, the more moderate and late preterm infants (those born between 32 and 36 6/7 weeks' gestation) are at less risk for significant intracranial injury. In a retrospective study of moderately preterm infants born between 29 and 33 weeks' gestation, 60% of a cohort of 7021 infants underwent cranial imaging, and 15% of these 4184 infants had ultrasonographic abnormalities.[16] The rates of severe IVH and cystic PVL were 1.7% and 2.6%, respectively, in this population.[15] The authors noted that low Apgar scores, maternal risk factors, lack of antenatal steroids, and vaginal delivery were associated with ultrasonographic abnormalities, including intracranial hemorrhage, PVL, and ventriculomegaly. The presence of risk factors such as abnormal neurologic examination, intrauterine growth restriction, abnormal head circumference, low Apgar scores, and need for ventilation or surfactant increased the chance of detecting an abnormality by fourfold in a group of more mature preterm infants born at 33 to 36 weeks' gestational age.[17] In a similar study, infants born at >30 weeks' gestation who were found to have significant ultrasonographic abnormalities typically had clinically significant events, such as placental abruption, seizures, hypotension, and hydrocephalus, which warranted the cranial ultrasonographic investigations.[18] Risk factors also play a role in the more immature preterm

infants as well. In a study of 303 infants born at <30 weeks' gestation, no asymptomatic infants required clinical intervention solely on the basis of screening ultrasonography performed at 7 to 14 days.[19] All infants who required clinical interventions had factors precipitating an ultrasonographic study, including anemia, metabolic acidosis, pulmonary hemorrhage, and hypotension. Similar results have been reported for infants born at <32 weeks' gestation with risk factors for severe IVH including lack of antenatal steroids, outborn status, asphyxia, significant acidosis, and/or hypotension.[10] Thus, the risk for severe IVH is associated with gestational age ≤30 weeks' gestation, with the highest risk in infants born at <24 weeks' gestation. Infants born at >30 weeks' gestation have a low risk of severe IVH unless they have additional clinical risk factors.

TIME OF IVH OCCURRENCE

The overwhelming majority of IVH in the preterm infant occurs within the first 3 days of life.[20–24] Of those, approximately 50% of hemorrhages occur within the first 5 hours, and approximately 70% occur within the first 24 hours of life. By 7 days, 95% of IVH will have occurred, with a small percentage appearing at 7 to 10 days.[21,22] In an analysis of infants requiring neurosurgical intervention for posthemorrhagic hydrocephalus, the average age of IVH development was 2 days, with ventriculomegaly apparent by 3 days of age.[24] In this study, temporizing neurosurgical procedures were performed 3 weeks after IVH development. Thus, frequent follow-up of significant IVH until resolution or stabilization will likely allow for early determination of ventricular dilation and the potential need for therapy.

REPEAT BRAIN IMAGING

PVL may initially be observed during the first week of life in the VLBW infant as increased echogenicity of the periventricular white matter, sometimes described as an echogenic "blush" or "flare." Because the periventricular white matter may normally have slight increased echogenicity, the echogenic choroid plexus can be used as an internal comparison for increased echogenicity.[25] Normal periventricular white matter should be less echogenic than the choroid plexus. These areas of white matter abnormality may become cystic on ultrasonography within 2 to 5 weeks and/or lead to ventriculomegaly from white matter volume loss, which can be visible on repeat ultrasonography at term equivalent age (TEA). In light of these findings, the Canadian Pediatric Society recommended screening at 6 weeks of age, whereas the AAN suggested a near term study.[5,6] These varying suggested time frames can lead to different timing of studies in the extremely preterm infant. Because 4- to 6-week screening is sensitive for identifying PVL and term equivalent cranial ultrasound findings are associated with adverse neurodevelopmental outcomes, we recommend screening during both time periods.

Sequential ultrasonography appears to have the best yield for identifying lesions associated with cerebral palsy. In infants with cerebral palsy, almost one third were found to have PVL on ultrasonography performed after 4 weeks of age.[26] Among 12 739 preterm infants who were screened at 4 weeks of age and again at near TEA, notably, 14% had cystic PVL that was only visible on the early imaging and had resolved by the time of the later study.[27] Subgroup analysis revealed that in infants born at <26 weeks' gestation, 18.5% of PVL cases were missed by a single ultrasonographic examination performed at TEA. However, a follow-up study demonstrated that infants who had cystic PVL at any time on ultrasonographic imaging had a significantly higher primary outcome of late death or neurodevelopmental impairment than those who never had such findings.[28] Thus, even if the findings were transient, infants with cystic PVL warrant close follow-up observation for neurodevelopmental impairment. Communication regarding neuroimaging results and follow-up plans are recommended between inpatient and outpatient providers.

STANDARD CRANIAL ULTRASOUND IMAGING TECHNIQUE

Cranial ultrasound imaging has traditionally made use of the anterior fontanelle as an acoustic window and should be performed by an American Registry for Diagnostic Medical Sonography board-certified sonographer. Images of the brain are taken in the coronal plane with anterior to posterior views and in the sagittal plane with appropriate angulation on the left and right.[7,29] Use of the posterior fontanelle may allow more detailed assessment of the periventricular white matter and occipital lobes. These views allow excellent visualization of supratentorial structures but limited views of the posterior fossa and cerebellum. The cerebellum has been shown to be a frequent site of injury, with significant hemorrhage occurring in as many as 9% of preterm infants with a diagnosis made by appropriately performed ultrasonography.[30,31] For this reason, additional imaging through the mastoid fontanelle is recommended. In cases of limited cerebellar hemorrhage, there was much better imaging sensitivity when mastoid views were obtained (86%) than when only the anterior fontanelle was assessed (16%).[32] However, mastoid views are unable to detect cerebellar microhemorrhages, which can only be visualized with MRI. Apart from hemorrhage, cerebellar hypoplasia is also associated with motor and

TABLE 1 Neuroimaging the Preterm Infant

Modality	Clinical Notes	Timing
Cranial ultrasonography	Routine anterior and mastoid fontanelle, optional posterior fontanelle, and vascular images	1. Initial scan within 7 d of age 2. Repeat scan at 4–6 wk of age 3. Scan near term or discharge
MRI	Ideally nonsedated	Optional, based on physician-family discussion; TEA
CT	Should be avoided in most instances	—

Preterm infants ≤30 wk or >30 wk with significant risk factors (see text). —, not applicable.

cognitive deficits.[31] Although most cases of cerebellar hypoplasia have been associated with cerebral white matter injury, other factors, including genetic and neurodegenerative syndromes, medications, infarction, and nutrition, play a role in cerebellar growth and affect neurologic outcomes. Thus, cerebellar imaging may have important diagnostic and prognostic value as part of the screening ultrasonographic examination. The addition of high-resolution linear color Doppler images obtained through the anterior fontanelle can be used to evaluate for patency of the superior sagittal sinus. If there is concern for venous sinus thrombosis, the posterior and mastoid windows can additionally help to evaluate the sagittal and transverse sinuses. Many centers are also measuring the resistive index of the anterior cerebral artery as a marker for vascular compliance and to document normal waveforms and diastolic flow.

MRI

MRI has become increasingly popular as a means of identifying brain injury in the preterm infant. MRI provides the most detailed imaging of the brain and avoids the radiation risks associated with CT.[33] Specific absorption rates (a measure of power of radiofrequency fields) in patients undergoing magnetic resonance procedures appear to be much lower in neonates than adults and within a safe and acceptable range.[34] MRI studies may be successfully performed in the preterm population at TEA without the use of any sedating medications.[35,36] Protocols that rely on feeding the infant 20 to 30 minutes before the scan and swaddling to limit movement have generally been successful in avoiding significant sedation in the majority of cases. With the use of nonsedated MRIs and the increasing availability of MRI-compatible equipment, this imaging has become more readily obtainable. Yet, controversy persists regarding which infants should receive MRI studies at TEA. Abnormal findings on MRIs performed at TEA in a group of infants born at <30 weeks' gestation have been shown to be predictive of psychomotor delay and cerebral palsy at 2 years of age.[37] The predictive value of MRI at TEA for school-aged neurocognitive outcomes is less clear. One study reported that abnormal brain MRI at TEA was predictive of adverse neurodevelopmental outcomes at 7 years of age.[38] This association with adverse neurodevelopmental outcome at 7 years of age was particularly striking for abnormalities in the white matter, deep gray matter, and cerebellum. However, other studies have reported[39,40] that adding MRI to early and late cranial ultrasonography did not improve prediction of severe intellectual disability or neurodevelopmental impairment at 6 to 7 years of age. Obtaining routine MRI has also not been shown to have a clinically significant effect on maternal anxiety or improve quality of life, although it may increase the cost of care.[41] As the Choosing Wisely[9] campaign identified, there is insufficient evidence that routine brain MRI at TEA improves long-term outcomes, and the effects the results may have on an individual family may not be predictable.[42,43]

RECOMMENDATIONS (TABLE 1)

- Infants born at a gestational age of ≤30 weeks and selected infants with a gestational age of >30 weeks who are believed to be at increased risk for brain injury on the basis of identified risk factors are recommended to be screened for IVH with appropriately performed cranial ultrasonography. These risk factors may include, but are not limited to, placental abruption, need for vigorous resuscitation, hypotension requiring pressor support, severe acidosis, prolonged mechanical ventilation, confirmed sepsis, or pneumothorax.
- Routine cranial ultrasonographic screening is recommended by 7 to 10 days of age for infants born at ≤30 weeks' gestational age. Screening before 7 days of age may be indicated for infants with clinical signs and symptoms suggestive of significant brain injury. Repeat cranial ultrasonographic screening is recommended to be performed at 4 to 6 weeks of age and at TEA or before hospital discharge.
- Infants with abnormal cranial ultrasonography findings are recommended to have repeat serial cranial ultrasonography as clinically indicated on the basis of chronological as well as gestational age.

- Standard cranial ultrasonographic screening includes views from the anterior and mastoid fontanelles. Additional posterior fontanelle and vascular imaging can be performed for additional information.
- CT is no longer considered a part of routine imaging techniques of the preterm brain.
- On the basis of available evidence, MRI for infants born at <30 weeks' gestational age is not indicated as a routine procedure. MRI may be offered at TEA to the high-risk infant after a conversation with the family regarding the limitations of this test for estimation of long-term prognosis. When possible, it is recommended that the brain MRI be performed without contrast in the nonsedated state by using a "feed and wrap" technique.

LEAD AUTHORS

Ivan L. Hand, MD, FAAP
Renée A. Shellhaas, MD, MS, FAAP
Sarah S. Milla, MD, FAAP

COMMITTEE ON FETUS AND NEWBORN, 2019–2020

James J. Cummings, MD, FAAP, Chairperson
Ira S. Adams-Chapman, MD, FAAP
Susan Wright Aucott, MD, FAAP
Jay P. Goldsmith, MD, FAAP
Ivan L. Hand, MD, FAAP
David Alan Kaufman, MD, FAAP
Camilia Rivera Martin, MD, FAAP
Karen M. Puopolo, MD, PhD, FAAP

LIAISONS

RADM Wanda D. Barfield, MD, MPH, FAAP – *Centers for Disease Control and Prevention*
Lisa Grisham, MS, NP – *National Association of Neonatal Nurses*
Tim Jancelewicz, MD – *Section on Surgery*
Russell Miller, MD – *American College of Obstetricians and Gynecologists*
Meredith Mowitz, MD, MS, FAAP – *Section on Neonatal-Perinatal Medicine*
Michael R. Narvey, MD, FAAP – *Canadian Paediatric Society*

STAFF

Jim Couto, MA

SECTION ON NEUROLOGY EXECUTIVE COMMITTEE, 2019–2020

Adam L. Hartman, MD, FAAP, Chairperson
Josh L. Bonkowsky, MD, PhD, FAAP
Jamie K. Capal, MD, FAAP
Timothy E. Lotze, MD, FAAP
Renée A. Shellhaas, MD, FAAP
David K. Urion, MD

LIAISON

Manuel A. Viamonte, MD – *Section on Pediatric Trainees*

STAFF

Paul Spire

SECTION ON RADIOLOGY EXECUTIVE COMMITTEE, 2019–2020

Sarah S. Milla, MD, FAAP, Chairperson
Adina L. Alazraki, MD, FAAP
Aparna Annam, DO, FAAP
Ellen Benya, MD, FAAP
Brandon P. Brown, MD, MA, FAAP
Hansel J. Otero, MD, FAAP
Edward Richer, MD, FAAP

STAFF

Laura Laskosz, MPH

ABBREVIATIONS

AAN: American Academy of Neurology
CT: computerized tomography
IVH: intraventricular hemorrhage
PVHI: periventricular hemorrhagic infarct
PVL: periventricular leukomalacia
TEA: term equivalent age
VLBW: very low birth weight

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Towbin A. Cerebral intraventricular hemorrhage and subependymal matrix infarction in the fetus and premature newborn. *Am J Pathol*. 1968;52(1):121–140
2. Papile LA, Burstein J, Burstein R, Koffler H. Incidence and evolution of subependymal and intraventricular hemorrhage: a study of infants with birth weights less than 1,500 gm. *J Pediatr*. 1978;92(4):529–534
3. Volpe JJ, Volpe JJ. *Volpe's Neurology of the Newborn*, 6th ed. Philadelphia, PA: Elsevier; 2018
4. Papile LA, Munsick-Bruno G, Schaefer A. Relationship of cerebral intraventricular hemorrhage and early childhood neurologic handicaps. *J Pediatr*. 1983;103(2):273–277
5. Ment LR, Bada HS, Barnes P, et al. Practice parameter: neuroimaging of the neonate: report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology*. 2002;58(12):1726–1738
6. Society CP. Routine screening cranial ultrasound examinations for the prediction of long term neurodevelopmental outcomes in

preterm infants. *Paediatr Child Health*. 2001;6(1):39–52

7. Meijler G. *Neonatal Cranial Ultrasonography*, 3rd ed. New York, NY: Springer Berlin Heidelberg; 2019
8. Kwon SH, Vasung L, Ment LR, Huppi PS. The role of neuroimaging in predicting neurodevelopmental outcomes of preterm neonates. *Clin Perinatol*. 2014; 41(1):257–283
9. Ho T, Dukhovny D, Zupancic JA, Goldmann DA, Horbar JD, Pursley DM. Choosing wisely in newborn medicine: five opportunities to increase value. *Pediatrics*. 2015;136(2). Available at: www.pediatrics.org/cgi/content/full/136/2/e482
10. Szpecht D, Szymankiewicz M, Nowak I, Gadzinowski J. Intraventricular hemorrhage in neonates born before 32 weeks of gestation-retrospective analysis of risk factors. *Childs Nerv Syst*. 2016;32(8):1399–1404
11. Nightingale Internet Reporting System. *Vermont Oxford Network Database of Very Low Birth Weight Infants Born in 2017*. Burlington, VT: Vermont Oxford Network; 2018
12. Handley SC, Passarella M, Lee HC, Lorch SA. Incidence trends and risk factor variation in severe intraventricular hemorrhage across a population based cohort. *J Pediatr*. 2018;200:24–29.e3
13. Payne AH, Hintz SR, Hibbs AM, et al.; Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Neurodevelopmental outcomes of extremely low-gestational-age neonates with low-grade periventricular-intraventricular hemorrhage. *JAMA Pediatr*. 2013;167(5): 451–459
14. Hamrick SE, Miller SP, Leonard C, et al. Trends in severe brain injury and neurodevelopmental outcome in premature newborn infants: the role of cystic periventricular leukomalacia. *J Pediatr*. 2004;145(5):593–599
15. Bassan H, Feldman HA, Limperopoulos C, et al. Periventricular hemorrhagic infarction: risk factors and neonatal outcome. *Pediatr Neurol*. 2006;35(2): 85–92
16. Natarajan G, Shankaran S, Saha S, et al. Antecedents and outcomes of abnormal cranial imaging in moderately preterm infants. *J Pediatr*. 2018;195:66–72.e3
17. Ballardini E, Tarocco A, Baldan A, Antoniazzi E, Garani G, Borgna-Pignatti C. Universal cranial ultrasound screening in preterm infants with gestational age 33-36 weeks. A retrospective analysis of 724 newborns. *Pediatr Neurol*. 2014;51(6):790–794
18. Harris NJ, Palacio D, Ginzel A, Richardson CJ, Swischuk L. Are routine cranial ultrasounds necessary in premature infants greater than 30 weeks gestation? *Am J Perinatol*. 2007;24(1):17–21
19. Heling AZ, Laughon MM, Price WA. Effect of routine, screening head ultrasounds on clinical interventions for premature infants. *Am J Perinatol*. 2018;35(10): 959–963
20. Dolfin T, Skidmore MB, Fong KW, Hoskins EM, Shennan AT. Incidence, severity, and timing of subependymal and intraventricular hemorrhages in preterm infants born in a perinatal unit as detected by serial real-time ultrasound. *Pediatrics*. 1983;71(4): 541–546
21. Paneth N, Pinto-Martin J, Gardiner J, et al. Incidence and timing of germinal matrix/intraventricular hemorrhage in low birth weight infants. *Am J Epidemiol*. 1993;137(11):1167–1176
22. Ment LR, Schneider KC, Ainley MA, Allan WC. Adaptive mechanisms of developing brain. The neuroradiologic assessment of the preterm infant. *Clin Perinatol*. 2000;27(2):303–323
23. Dani C, Bertini G, Pezzati M, et al.; IntraVentricular Ibuprofen Study Group. Prophylactic ibuprofen for the prevention of intraventricular hemorrhage among preterm infants: a multicenter, randomized study. *Pediatrics*. 2005;115(6):1529–1535
24. Han RH, Berger D, Gabir M, et al. Time-to-event analysis of surgically treated posthemorrhagic hydrocephalus in preterm infants: a single-institution retrospective study. *Childs Nerv Syst*. 2017;33(11):1917–1926
25. Rennie JM, Hagmann CF, Robertson NJ, Rennie JM. *Neonatal Cerebral Investigation*, 2nd ed. Cambridge, United Kingdom; New York: Cambridge University Press; 2008
26. De Vries LS, Van Haastert IL, Rademaker KJ, Koopman C, Groenendaal F. Ultrasound abnormalities preceding cerebral palsy in high-risk preterm infants. *J Pediatr*. 2004;144(6):815–820
27. Sarkar S, Shankaran S, Laptook AR, et al.; Generic Database Subcommittee of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Screening cranial imaging at multiple time points improves cystic periventricular leukomalacia detection. *Am J Perinatol*. 2015;32(10):973–979
28. Sarkar S, Shankaran S, Barks J, et al. Outcome of preterm infants with transient cystic periventricular leukomalacia on serial cranial imaging up to term equivalent age. *J Pediatr*. 2018;195:59–65.e3
29. American Institute of Ultrasound in Medicine. AIUM practice guideline for the performance of neurosonography in neonates and infants. *J Ultrasound Med*. 2010;29(1):151–156
30. Steggerda SJ, van Wezel-Meijler G. Cranial ultrasonography of the immature cerebellum: role and limitations. *Semin Fetal Neonatal Med*. 2016;21(5):295–304
31. Tam EWY. Cerebellar injury in preterm infants. *Handb Clin Neurol*. 2018;155: 49–59
32. Parodi A, Rossi A, Severino M, et al. Accuracy of ultrasound in assessing cerebellar haemorrhages in very low birthweight babies. *Arch Dis Child Fetal Neonatal Ed*. 2015;100(4):F289–F292
33. Smyser CD, Kidokoro H, Inder TE. Magnetic resonance imaging of the brain at term equivalent age in extremely premature neonates: to scan or not to scan? *J Paediatr Child Health*. 2012;48(9):794–800
34. Malik SJ, Beqiri A, Price AN, Teixeira JN, Hand JW, Hajnal JV. Specific absorption rate in neonates undergoing magnetic resonance procedures at 1.5 T and 3 T. *NMR Biomed*. 2015;28(3):344–352
35. Mathur AM, Neil JJ, McKinstry RC, Inder TE. Transport, monitoring, and successful brain MR imaging in unsedated neonates. *Pediatr Radiol*. 2008;38(3):260–264
36. Neubauer V, Griesmaier E, Baumgartner K, Mallouhi A, Keller M, Kiechl-

Kohlendorfer U. Feasibility of cerebral MRI in non-sedated preterm-born infants at term-equivalent age: report of a single centre. *Acta Paediatr*. 2011; 100(12):1544–1547

37. Woodward LJ, Anderson PJ, Austin NC, Howard K, Inder TE. Neonatal MRI to predict neurodevelopmental outcomes in preterm infants. *N Engl J Med*. 2006; 355(7):685–694

38. Anderson PJ, Treyvaud K, Neil JJ, et al. Associations of newborn brain magnetic resonance imaging with long-term neurodevelopmental impairments in very preterm children. *J Pediatr*. 2017;187:58–65.e1

39. Hintz SR, Barnes PD, Bulas D, et al; SUPPORT Study Group of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Neuroimaging and neurodevelopmental outcome in extremely preterm infants. *Pediatrics*. 2015;135(1). Available at: www.pediatrics.org/cgi/content/full/135/1/e32

40. Hintz SR, Vohr BR, Bann CM, et al.; SUPPORT study group of the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network. Preterm neuroimaging and school-age cognitive outcomes. *Pediatrics*. 2018;142(1): e20174058

41. Edwards AD, Redshaw ME, Kennea N, et al.; ePrime Investigators. Effect of MRI on preterm infants and their families: a randomised trial with nested diagnostic and economic evaluation. *Arch Dis Child Fetal Neonatal Ed*. 2018;103(1):F15–F21

42. Mann PC, Woodrum DE, Wilfond BS. Fuzzy images: ethical implications of using routine neuroimaging in premature neonates to predict neurologic outcomes. *J Pediatr*. 2013;163(2):587–592

43. Janvier A, Barrington K. Trying to predict the future of ex-preterm infants: who benefits from a brain MRI at term? *Acta Paediatr*. 2012;101(10): 1016–1017

Runaway Youth: Caring for the Nation's Largest Segment of Missing Children

• *Clinical Report*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Runaway Youth: Caring for the Nation's Largest Segment of Missing Children

Thresia B. Gambon, MD, MPH, MBA, FAAP,[a] Janna R. Gewirtz O'Brien, MD, FAAP,[b] COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH, COUNCIL ON COMMUNITY PEDIATRICS

The largest segment of missing children in the United States includes runaways, children who run away from home, and thrownaways, children who are told to leave or stay away from home by a household adult. Although estimates vary, as many as 1 in 20 youth run away from home annually. These unaccompanied youth have unique health needs, including high rates of trauma, mental illness, substance use, pregnancy, and sexually transmitted infections. While away, youth who run away are at high risk for additional trauma, victimization, and violence. Runaway and thrownaway youth have high unmet health care needs and limited access to care. Several populations are at particular high risk for runaway episodes, including victims of abuse and neglect; lesbian, gay, bisexual, transgender, and questioning youth; and youth in protective custody. Pediatricians and other health care professionals have a critical role to play in supporting runaway youth, addressing their unique health needs, fostering positive relationships within their families and with other supportive adults, and connecting them with available community resources. This report provides clinical guidance for pediatricians and other health care professionals regarding (1) the identification of adolescents who are at risk for running away or being thrown away and (2) the management of the unique medical, mental health, and social needs of these youth. In partnership with national, state, and local resources, pediatricians can significantly reduce risk and improve long-term outcomes for runaway youth.

INTRODUCTION

The largest segment of missing children in the United States includes runaways, children who run away from home, and thrownaways, children who are told to leave or stay away from home by a household adult.[1,2] This report aims to provide clinical guidance for pediatricians regarding (1) the identification of adolescents who are at risk for running away or being thrown away and (2) the management of the unique medical, mental health, and social needs of these youth.

abstract

[a]*Citrus Health Network, Miami, Florida; and* [b]*Department of Pediatrics, University of Minnesota, Minneapolis, Minnesota*

Clinical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, clinical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

Drs Gambon and Gewirtz O'Brien drafted, reviewed, and revised the manuscript, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2019-3752

Address correspondence to Thresia B. Gambon. E-mail: tbgambon@me.com

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

To cite: Gambon TB, Gewirtz O'Brien JR, AAP COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH, COUNCIL ON COMMUNITY PEDIATRICS. Runaway Youth: Caring for the Nation's Largest Segment of Missing Children. *Pediatrics.* 2020;145(2):e20193752

There has been a considerable amount of research conducted in the area of runaway and thrownaway youth since the 2004 publication of the previous clinical report "The Pediatrician's Role in the Prevention of Missing Children."[3] This clinical report expands on the previous report's discussion of youth who run away in the United States. Although estimates of the prevalence of running away vary depending on definitions, methodology, and population, the 2013 National Incidence Studies of Missing, Abducted, Runaway, and Thrownaway Children (NISMART-3), released by the US Office of Juvenile Justice and Delinquency Prevention in 2017, estimated that 413 000 children ran away or were thrown away in 2013, at a rate of 5.3 per 1000 children, comparable to previous NISMART cycles.[2,4] Other studies have estimated that between 5% and 8% of adolescents run away every year.[5–8] It is important that pediatricians understand this population so they can better serve these youth and families in clinical practice and in the community setting.

Unaccompanied adolescents who run away or who are asked to leave home have unique health needs. Before running away, many have learning disabilities, struggle with mental illness, experience school failure, or engage with peer groups who participate in high-risk behaviors.[9] Many have experienced abuse or neglect before running away.[10–13] While away, these unaccompanied minors are at high risk for victimization and violence; substance use; risky sexual behavior, including survival sex; further absenteeism from school; and other associated negative health consequences.[9–11,14–19]

DEFINITIONS

According to the Office of Juvenile Justice and Delinquency Prevention, a runaway episode occurs when a child leaves home without permission and stays away overnight for at least 1 night (for children younger than 15 years) or 2 nights (for children 15 years or older). A thrownaway episode occurs when a child is asked or told to leave the home by a household adult or is prevented from returning home by a household adult for at least 1 night when no adequate alternative care is arranged.[2]

Runaway and thrownaway episodes are grouped together because youth often fall into both categories. Information varies depending on who is interviewed regarding the circumstances; youth do not always view the circumstances the same way as the guardians and/or parents do.[20] Twenty-two percent of youth described the episode as a combination of running away and being thrown out.[20] In this report, the term "runaway" is used to refer to both categories, although the term "thrownaway" is occasionally used to be consistent with the data.

Runaways may not always be classified as missing children, making it difficult to quantify the problem. Many runaways are not considered missing because guardians and/or parents know the whereabouts of the youth. Youth who run away may stay with friends or other family members.[1,20] In addition, some runaways may not be reported missing because the guardians and/or parents are not looking for them. There is a small category of children who are permanently abandoned and are often not included in data because they may not be reported as missing.[1]

DEMOGRAPHICS

The total number of youth who run away is difficult to measure for a number of reasons, including inconsistent definitions and difficulty with sampling.[4] The data regarding the incidence of running away vary by state and by study population. As noted previously, NISMART-3 estimated a prevalence of running away of 5.3 per 1000 children.[2] In another study, published in 2006 on the basis of data from the 1996 wave of the National Longitudinal Study of Adolescent Health, authors reported that 6.4% of youth (nearly 850 000) had run away in the 12 months before the 1996 survey.[6] By using the data from the National Longitudinal Survey of Youth (1997 cohort), it was found that nearly 1 in 5 youth ran away before age 18. A school-based survey of Minnesota youth in grades 8 through 11 revealed that between 4% and 7% of students had run away at least once in the previous year.[7,8]

Each report of a missing child made to law enforcement is required by federal law to be entered into the Federal Bureau of Investigation National Crime Information Center (National Center for Missing and Exploited Children [NCMEC]).[21] Some of the reports may be regarding the same child because a report can be made each time a child is missing. In 2017, 464 000 reports were made into this database. One role of the NCMEC, the national clearinghouse and resource center for missing and exploited children, is to help with finding these children. In 2017, the NCMEC assisted with more than 27 000 cases, including 25 000 runaways (missingkids.org).[21]

The Runaway Safeline, (1–800-RUNAWAY), formerly known as the National Runaway Switchboard, is a federally funded national resource that provides services to youth and their families (https://www.1800runaway.org/). The Safeline allows runaway and homeless youth or their parents to call for assistance or guidance; attain 24-hour referrals to community resources, including shelter, food banks, legal assistance, and social services agencies; and seek crisis intervention counseling.[20] The Safeline handled more than 70 000 calls and electronic contacts in

2017.[22] Of those contacts, 31% of contacts were about youth who were contemplating running away, 16% were about youth who had run away, 5% were about youth asked to leave home or prevented from returning home (thrownaway), and 9% were about youth experiencing homelessness. Approximately three-fourths of the calls came from the affected youth.[22] Research compiled by the National Opinion Research Center found that more than 70% of youth left home on the spur of the moment, 36% of youth planned to run in advance, and 23% of youth who were thrown out said they expected to be thrown out.[20] This information was compiled from calls to the National Runaway Switchboard from 2000 to 2009, a comprehensive review of research on runaways, and new research conducted on youth in the streets and shelters in Chicago and Los Angeles between October 2008 and January 2010.[20] More than half of the adolescents reported that friends knew where they were, and 26% said that their parents knew their whereabouts. Only 13% of youth interviewed said that no one knew where they were.[20]

The NISMART-3 response rate was not high enough to be able to break down the characteristics of the runaway episodes.[2] Data from NISMART-2, conducted in 1999, reveal that 68% of runaways were between 15 and 17 years of age, 28% were 12 to 14 years of age, and 4% were 7 to 11 years of age.[1] Runaway episodes are most likely to occur during the summer; runaways usually go between 10 and 50 miles from home. Twenty-three percent traveled more than 50 miles from home. Most were gone from 24 hours to 1 week. Seven percent of runaways were missing for 1 to 6 months.[9]

The data regarding the distribution of runaway youth from racial and ethnic minority backgrounds are inconsistent.[1] Although racial and ethnic distributions have not been reported for NISMART-3, NISMART-2 data suggest that youth of color may be slightly overrepresented among runaway youth.[1,2] Research published in 2006 exploring the demographic profile of runaway youth in the United States using data from the National Longitudinal Study of Adolescent Health did not reveal significant differences in running away among racial and ethnic groups.[6] However, more recent data from the National Runaway Safeline reveal that youth of color seem to be overrepresented among runaway youth in crisis who are connecting with the Safeline; 23% of those youth connecting identify as black or African American, compared with 14% of the general population.[22] Morton et al[23] found similar results in 2018, revealing that black or African American youth were more likely to be homeless (including runaway episodes) than their peers. Although data on American Indian/Alaska Native youth who have run away are limited, an estimated 1 in every 130 American Indian/Alaska Native children go missing each year.[24] The number missing is likely to be higher, but estimates of American Indian/Alaska Native youth are limited because there is no centralized reporting system in tribal communities.[24]

The data regarding the gender distribution of runaway youth are also mixed but consistently reveal that girls run away more often than boys.[6] Sanchez et al[6] reported that female-identifying youth were more likely to have runaway. Data from the National Runaway Safeline reveal a similar trend. Among those youth connecting with the National Runaway Safeline in 2017, 69% identified as female, 29% identified as male, and 3% identified as either transgender or gender nonconforming.[22]

More than a decade of data suggest that lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth are disproportionately represented among runaway and thrownaway youth. An estimated 20% to 40% of teenagers who are homeless identify as LGBTQ, compared with 4% to 10% of nonhomeless peers.[25–28] In a 2015 study of 434 homeless youth in Texas, 25% of youth identified as lesbian, gay, bisexual, transgender, or something else.[25] The unique runaway experiences and health care needs of LGBTQ runaway youth are discussed in detail later in this report.

HEALTH IMPACTS

A generation of research reveals that runaways are at high risk for adverse health outcomes, including disease, crime (both as victims and perpetrators), injuries, alcohol use, illegal drug use and sales, and sexual contact including abuse and activity.[1,9,10,15–17,29] It is critical that pediatricians are aware of the health implications of runaway episodes so that they can better care for these children. Many, but not all, runaways are homeless while away. The American Academy of Pediatrics (AAP) policy statement "Providing Care for Children and Adolescents Facing Homelessness and Housing Insecurity" details the health risks associated with homelessness.[30] This section focuses on health risks associated with running away, although there is some overlap.

While away from home, youth are at high risk for poor sexual health outcomes, including pregnancy, sexually transmitted infections, and sexual exploitation and abuse.[17,31–35] Nearly half of female street youth and one-third of female youth living in emergency shelters report a history of pregnancy.[33,36] Although not the focus of this report, runaways may become involved in sex trafficking or exploitation, including survival sex, which is sex in exchange for food, clothing, or housing.[1,15] Readers are referred to the AAP policy "Child Sex

Trafficking and Commercial Sexual Exploitation: Health Care Needs of Victims" and other publications for additional information on this critical topic.[37,38] For youth who have been victims of abuse or neglect before running away or while away from home, pediatricians are mandated reporters. In states where sex trafficking is considered a form of abuse, pediatricians must make a formal report of suspected exploitation to law enforcement and to child protective services as well, if indicated.

Youth who run away are more likely to engage in substance use.[1,9] In addition to the health consequences associated with substance use alone, substance use increases the risk of sexual assault and mental health consequences dramatically for runaway adolescents.[38] In urban areas, these youth often join gangs or are involved in violent and/or drug-related criminal activity.[1,39] They have a high likelihood of being affected by violence while away from home.[1,11]

Youth who run away experience higher rates of mental illness, including anxiety, depression, and suicidality.[1,9,14,40] Edinburgh et al[14] showed that among runaway youth presenting to a child advocacy center, nearly a quarter had a history of a suicide attempt, compared with 13.7% of youth who had not run away. Older data from NISMART-2 revealed that 4% of endangered runaway and thrownaway youth had attempted suicide previously, but these data were not updated in NISMART-3.[1] A 2004 study measuring the prevalence of mental health disorders among runaway and homeless youth in small- to midsized cities in 4 Midwestern states revealed significantly higher rates of mental health disorders when compared with age-matched peers.[41]

Unfortunately, runaways frequently risk further trauma while away, including physical or sexual assault.[1,14,15,42] Poor mental health is believed to be associated with street victimization among homeless and runaway youth.[38] Running away puts youth at risk for exposure to additional trauma, further limits their social supports, and makes it difficult to access the necessary medical help for these disorders.[38]

There is a strong association between substance use and runaway episodes, although a causal link has not been established.[9,14,43] It is unclear whether the use of drugs and/or alcohol precipitates running away or being asked to leave home or whether the circumstances associated with the episodes lead to increased substance use, although longitudinal studies suggest that the association is likely bidirectional.[9] A 2013 study by Edinburgh et al[14] of youth presenting at a child advocacy center revealed that 1 in 3 runaway youth met criteria for problem substance use, whereas 1 in 10 nonrunaway youth met criteria. NISMART-2 data revealed that 17% of runaway youth reported using "hard drugs"; 18% were in the company of someone known to be using drugs while away, and 19% of runaway and thrownaway youth surveyed were substance dependent.[1]

Running away also has long-term effects on educational success. Youth who run away multiple times are 18% more likely to drop out of high school.[44] Youth who run away from home are less likely to graduate from high school. Seventy-five percent of runaway or homeless youth drop out of school.[19]

IDENTIFYING YOUTH WHO ARE AT RISK FOR RUNNING AWAY

There is no current, validated screening tool for runaway episodes, but practices should consider assessing for previous runaway episodes and risk factors for running away using a trauma-informed approach, which involves being aware of trauma and adverse childhood experiences that can affect health. "A trauma informed practice is defined as an organizational structure and treatment framework that involves understanding, recognizing, and responding to the effects of all types of trauma."[45] The AAP Trauma Toolbox for Primary Care contains resources on implementation for a primary care practice to become trauma informed.[45]

Many factors drive adolescents to run away or to be asked to leave home. The most common reason youth give for running away is fleeing a negative home environment.[9] In a study conducted by Tucker et al[9], several factors were found to be common in the runaway population. These factors included a perception of low parental support in the ninth grade, school disengagement, substance use, and depressive affect.[9] Disruption of the family structure and dysfunction and disorganization of homes are known risk factors for running away.[9,10]

Runaway behavior is more common in youth who have been exposed to violence, had a poor parent-child relationship, and/or had a history of delinquent behavior or depressive symptoms. Some studies have shown that economic problems in the home may lead to more youth running away.[19] Tyler and Bersani[46] noted that youth living in disadvantaged neighborhoods were also more likely to run away.

Disengagement from school is a significant risk factor for a child running away or becoming homeless. Tucker et al[9] reviewed an analysis of more than 15 000 youth in crisis shelters or transitional living programs and found that 47% had irregular school attendance and 22% had dropped out or been expelled.

Youth who are asked to leave home may include youth who are pushed out of their homes for different

reasons, some because the family cannot provide for their specific mental health or disability needs, some because parents cannot afford to provide care, and many because of poor relationships between parents and youth.[1,19]

Implementation of various screens during health care visits can assist to identify family stressors, school problems, and other social determinants of health that may increase the risk of running away. Screening tools such as the Well Child Care, Evaluation, Community Resources, Advocacy, Referral, Education survey instrument (WE CARE) and Safe Environment for Every Kid (SEEK) parent screening questionnaire screen families for problems related to education, housing, child maltreatment, domestic violence, and more. More information is available on the AAP Poverty and Child Health Web site.[47] For, adolescents, pediatricians should conduct a thorough, confidential psychosocial assessment, such as the HEEADSSS assessment (home environment, education and employment, eating, peer-related activities, drugs, sexuality, suicide/depression and safety).[48] Routine depression screening is also recommended for teenagers. Pediatricians should also assess for protective factors, including whether adolescents consider themselves to have several sources of support at home, at school, and in the community.[14]

When an adolescent at high risk for running away is identified, early intervention to prevent runaway episodes is recommended. Use of practice- and community-based resources to address any modifiable risk factors, support the psychological and behavioral health needs of the child and family, and ensure safety can be helpful. Pediatricians can share information regarding national resources for runaways and their families, including the National Runaway Safeline and the NCMEC (see Resources). Pediatricians can ask adolescents where they would go if they were to run away or be forced out, specifically assessing for other safe, supportive adults who might be able and willing to provide shelter and support in a crisis. Pediatricians can refer families to local resources for behavioral health, family therapy, and support and assistance with other issues.

Several high-risk populations deserve additional attention, including victims of abuse and neglect, LGBTQ youth, and youth in protective custody. Each of these populations is discussed in further detail in the sections that follow. Adolescents in these subgroups are at high risk for running away and may experience significant health effects while away.

VICTIMS OF ABUSE AND NEGLECT

Among runaway and thrownaway youth surveyed as part of NISMART-2, 21% (estimated 350 400) reported being physically or sexually abused at home in the year before the episode or were afraid of abuse if they returned.[1] Across multiple studies of homeless youth, rates of sexual abuse ranged from 17% to 35% and physical abuse ranged from 40% to 60%.[19,26] Approximately 20% of street youth have, at some point, been removed from their homes by authorities because of neglect or abuse.[32] Runaway youth consistently report family conflict as a primary reason for leaving the home.[32,49] Thrane et al[10] studied the impact of family abuse on running away, deviance, and street victimization and found that adolescents who had been exposed to neglect and sexual abuse ran away sooner and were more likely to be victimized on the street. Although most runaway youth are missing for less than 1 week and remain close to home, those who go missing for longer periods of time and who travel farther from home are more likely to have been abused previously.[10] As previously noted, while youth are away, they are at risk for further victimization.[14,38]

LGBTQ YOUTH

As noted previously, a decade of research suggests that an estimated 20% to 40% of teenagers who are homeless identify as LGBTQ, compared with 4% to 10% of nonhomeless peers.[25–28] In a 2012 survey of service providers for homeless youth and youth at risk for homelessness, Durso and Gates[50] explored reasons for homelessness among LGBTQ youth and found that nearly half (46%) of LGBTQ youth reported running away because of rejection relating to sexual orientation or gender identity, and 43% reported being forced out by parents because of sexual orientation or gender identity. Nearly one-third of these youth (32%) attributed their homelessness to physical, sexual, or verbal abuse at home.[50] To the authors' knowledge, there are no specific data that are focused on LGBTQ runaway youth; thus, the literature on LGBTQ homeless youth is used more generally in this discussion given the significant overlap in this population.

LGBTQ youth are more likely to be affected by the many health risks associated with homelessness.[41,50,51] LGBTQ youth who are homeless report higher rates of survival sex, substance use, and victimization when compared with non-LGBTQ homeless youth.[41,51–53] A survey by Cochran et al[51] comparing LGBT homeless youth and heterosexual homeless youth revealed that LGBT youth reported, on average, 7.4 more acts of sexual victimization than their heterosexual counterparts and had significantly higher rates of psychopathology.[50] LGBTQ youth also experience higher rates of depression and suicidality.[41,53,54] In a multistate single-day survey of homeless youth

by Van Leeuwen et al,[54] 62% of LGBTQ homeless youth reported a previous suicide attempt, compared with 29% of non-LGBTQ homeless youth.[54] In the same study, homeless LGBTQ youth had higher rates of sexually transmitted infections, including HIV, than heterosexual homeless youth.[54]

YOUTH IN PROTECTIVE CUSTODY

Data on runaway youth living in protective custody, including foster care, vary depending on the source of the data.[55–57] In 2017, 4734 (1.1%) of the 442 995 children in foster care in the United States ran away from their foster care placements, consistent with data reported by the US Department of Health and Human Services in 2016. Data from 2010 include all runaways in foster care from birth to 18 years of age, but because young children do not have the capability to run away, the estimate of children who run away increases with age, with approximately 30% of youth 12 years or older in out-of-home care placements having run away.[58,59] In 2013, Benoit-Bryan[59] reported that older youth in foster care were more than 2.5 times more likely to run away than youth who do not live in foster care. Lin[58] found that most foster youth who run away run to their family of origin and/or their friends out of a desire to maintain relationships with their community of origin.

One study from 2015 reported that youth in foster care who run away have often experienced emotional or psychological problems that began before entering foster care.[55] Experiences such as parental incarceration and personal history of substance use were associated with a higher number of runaway episodes.[55]

While in out-of-home care, children with developmental and cognitive disabilities were less likely to run away, whereas children with mental and behavioral health problems were more likely to run away.[57] Courtney and Zinn[57] found that some mental and/or behavioral disorders, such as schizophrenia and other psychoses, were associated with lower risk of running away, but alcohol- and other substance-related disorders were associated with increased risk. Data from the 2009 Adoption and Foster Care Analysis and Reporting System (AFCARS), a federally mandated data collection system that includes case-level information on (1) all children in foster care for whom child welfare agencies have responsibility for placement, care, and supervision and (2) children adopted through child welfare agencies, found that autism spectrum disorder was associated with a decreased incidence of running away.[55]

Child welfare system–related characteristics, including the type of placement, permanency plan while in care, reason for placement, number of placements, and the quality of care received in placements were also found to be factors associated with runaway behaviors.[58] The instability of foster care placements is a predictor of youth running away behavior, and multiple placements are related with an increased risk of running away.[58] Children who ran away experienced an average of 6 placement settings.[58] Stabilization of foster care placement is associated with fewer runaway episodes.[58] Placement type is also important; youth in foster homes, especially if placed with a relative, are less likely to run away than those placed in residential care.[57] In addition, children who are placed in the same foster home as a sibling are less likely to run away.[57] Youth who know they are unlikely to be reunified with family or relatives and/or be adopted are more likely to run away.[55] Of note, youth with a history of running away are 92% more likely to run away again.[58]

Children who run away from out-of-home care are at increased risk of negative consequences similar to all runaway youth, such as criminal victimization, sexual exploitation, and substance or alcohol use.[55]

For youth in protective custody, pediatricians should discuss stability of placement with the foster parent, case manager, and/or child, and a confidential discussion with the child should take place about how the child feels about where he or she is living and any concerns. For all children in foster care, it is critical that pediatricians recommend that their behavioral health needs be met. Pediatricians and other health care providers for youth in out-of-home custody can refer to the multiple resources available through the AAP on the Healthy Foster Care America Web page (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/healthy-foster-care-america/Pages/default.aspx).

ROLE OF TECHNOLOGY AND SOCIAL MEDIA

The rapid expansion of social media has influenced the experiences of runaway youth in several ways. Early data exploring the nature of Internet-initiated crimes suggest that online relationships may increase the risk of running away.[60] However, the evolving social media landscape makes the effects difficult to measure, and available follow-up data are limited. A study conducted from October 2001 to July 2002 of a random sample of law enforcement agencies described the characteristics of episodes in which juveniles became victims of sex crimes committed by people they met through the Internet.[61] This study revealed that victims in these crimes were primarily 13- to 15-year-old girls who met adult male offenders and developed romantic relationships with them for 1 month or longer. In most cases, offenders did not deceive victims regarding their age or sexual

motives. Of 129 cases studied, 5% involved violent offenses and 3% involved brief abductions in the setting of sexual assaults. Notably, 29% of the victims who attended face-to-face meetings were reported missing to police, with 24% being runaways and 5% who had misinformed parents regarding where they were going.[61] In a 2014 study of law enforcement perspectives on the role of technology in child sexual exploitation, investigators working on child sexual exploitation cases report that technology has played a significant role in the majority of cases.[62]

Recognizing the potential links between runaway youth, sexual exploitation, and technology, in April 2018, the Family and Youth Services Bureau added a tool titled "Online Recruitment of Youth Via Social Media and the Internet" to its "Human Trafficking and Runaway and Homeless Youth: Practical Tools for Grantees." This tool explores the role of social media trafficking recruitment, lists red flags, and recommends prevention strategies for youth-serving agencies.[63]

Innovative work has also emerged exploring the potential use of technology to improve health and access to services for homeless youth.[64–68] A 2016 study by Harpin et al[69] of homeless youth in Denver, Colorado, revealed that 71.9% of youth consistently used social media. Tyler and Schmitz[68] reported on using texting technology for data collection and explored potential opportunities for interventions leveraging technology. Buccieri and Molleson[64] explored the use of a youth-developed application for homeless youth. In their study of law enforcement, Mitchell and Boyd[62] discussed the potential opportunity for technology to be used to connect with difficult-to-reach populations that may be at risk for commercial sexual exploitation, including homeless and runway youth. Although much of this work has focused on homeless youth specifically, it has potential implications for runaway youth and requires further study.

MANAGEMENT OF RUNAWAY EPISODES

For children who have run away, pediatricians can conduct a thorough assessment of mental health concerns; substance use; previous history of abuse, violence, or victimization while away; exposure to trauma; and sexual and reproductive health needs and treat accordingly. Pediatricians should provide comprehensive care, including psychological and social support, to families who have a child or adolescent who has recently returned home after running away. Often, these children are targeted for punishment for the act of running away or for the associated misdeeds of substance use, theft, or prostitution when what is needed is medical and psychological treatment, family realignment, or placement in protective custody.[3]

Pediatricians can support and maintain awareness of programs that serve runaway youth and build connections with these programs through the medical home. Pediatricians may also consider sharing information regarding national resources for runaways and their families listed below, including the National Runaway Safeline and the NCMEC (see Resources).

OPPORTUNITIES FOR FUTURE RESEARCH AND ACTION

Additional research on the recognition, management, and prevention of runaway episodes is critical. Specifically, the development of well-validated screening tools for identifying children who are at high risk for running away or being thrown away would help pediatricians and other health care providers better identify this high-risk population of adolescents. Innovative, evidence-based interventions aimed at the prevention of runaway and thrownaway episodes in the clinical and community setting should also be developed and studied to guide practice- and community-based intervention.

Another potential area of study is the role of the Internet and social media in episodes of runaway youth, including further exploration of safe media use and applications of social media and technology to better support youth who have run away.

Finally, policies and programs that improve health care access for runaway youth are essential. Federal legislation supporting the Runaway and Homeless Youth Program, initially passed in the 1970s and revised as recently as 2017, recognizes this need and provides funding for services that support runaway and homeless youth. This legislation includes grant funding for programs that target mental and physical health among runaway youth and integrate health care into existing services for youth.[70,71] Shelter-based clinics, clinics for runaway youth, health care services for street youth, and free youth clinics all may serve as options to meet the health care needs of this population but must provide readily accessible, culturally competent, trauma-informed, and confidential care.[72–75] The Runaway Intervention Program in Minnesota represents an innovative nursing-led intervention targeting runaway youth with promising outcomes.[73,76,77] Community-based interventions that improve health care access and outcomes in a cost-effective manner should be studied and supported. Policy strategies are needed that improve access to health insurance and health care for runaway youth.

CONCLUSIONS

Runaway and thrownaway youth, the largest category of missing children, require ongoing support and

continued engagement with pediatricians and other health care providers and community resources to prevent recurrence and address their unique health needs.

RECOMMENDATIONS FOR CLINICAL PRACTICE

- Identify youth who are at high risk for running away or being thrown away.
  - Conduct a thorough, confidential social history and home environment, education and employment, eating, peer-related activities, drugs, sexuality, suicide and/or depression, and safety (HEEADSSS) assessment for all adolescents, including surveillance for risk factors known to be associated with running away.[48] Routine depression screening is recommended for children 12 and up by using standardized tools such as the Patient Health Questionnaire for Adolescents (PHQ-A) and the primary care version of the Beck Depression Inventory (BDI).[78]
  - Assess whether adolescents consider themselves to have sources of support, including the pediatrician, so that they do not need to resort to running away. Ask them to identify an adult they feel comfortable confiding in and recommend they go to that adult if they are having any issues.
- Consider posting and sharing information regarding national resources for runaways and their families in waiting or examination rooms.
- If an adolescent is believed to be at high risk for running away or has run away before, discuss a safety plan for future runaway episodes, including a plan for accessing safe housing. Review potential health and behavioral risks associated with running away and provide necessary health care to mitigate risk, such as reliable contraception and access to mental health care.
- If risk factors are identified, intervene early to prevent runaway episodes by using practice- and community-based resources to address any modifiable risk factors, support the psychological and behavioral health needs of the child and family, and ensure safety.
- Consider counseling special populations as follows:
  - Victims of abuse and neglect: For children with a known or suspected history of abuse or neglect, confirm that they feel safe in their current living situation.
  - LGBTQ youth: Help support sexual minority children and youth and their families, particularly about the process of coming out regarding nonconforming gender expression or sexual orientation.
  - Youth in protective custody: For youth in protective custody, discuss stability of placement with the foster parent, case manager, and/or child. Discuss with the child how he or she feels about where he or she is living and any concerns.
  - Youth with mental health and/or substance use issues: Recommend appropriate ongoing mental health support and services. For substance use, consider using the screening, brief intervention, and referral to treatment (SBIRT) outlined in the AAP policy statement and clinical report.[79,80]
- Support and maintain awareness of programs that serve youth who have run away or are homeless, including hotlines, shelters, and other resources to provide for basic needs while youth are away (see Resources).
- For youth who have run away, conduct a thorough assessment of mental health concerns; substance use; previous history of abuse, violence, or victimization while away; exposure to trauma; and sexual and reproductive health needs and treat accordingly. Youth who have run away may run away again. Refer at-risk youth to programs that are focused on self-empowerment, healthy sexuality, and relationships and safety planning with the goal of increasing youth resilience.
- Provide comprehensive care through a trauma-informed lens, including psychological and social support, to families who have a child or adolescent who has recently returned home after running away.
- Although the prevention of runaway episodes has not been well studied, prevention likely depends on the development of strong, nurturing, reciprocal relationships from early childhood. Building on existing approaches within Bright Futures for health supervision visits and validated community programs, the AAP supports efforts to promote positive relationships and positive parenting strategies early on.
- In states where sex trafficking is considered a form of abuse, pediatricians must make a formal report of suspected exploitation to law enforcement and to child protective services as well, if indicated.

RESOURCES

- The National Runaway Safeline, formerly known as the National Runaway Switchboard (1–800-RUNAWAY; https://www.1800runaway.org/), serves as a hotline for children considering running away and those who have run away.
- NCMEC (www.missingkids.com): If a child runs away, the parent or

guardian should contact the NCMEC at 1-800-THE-LOST in addition to reporting the incident to law enforcement. Any information about a missing child or suspected sexual exploitation should be reported to NCMEC.

- Strengthening Families (www.strengtheningfamilies.net) provides resources for building resilience in parents and children.
- National Network for Youth (www.nn4youth.org) is a public education and policy advocacy organization dedicated to the prevention and eradication of youth homelessness.

LEAD AUTHORS

Thresia B. Gambon, MD, MPH, MBA, FAAP
Janna R. Gewirtz O'Brien, MD, FAAP

COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH, 2019–2020

Arthur Lavin, MD, FAAP, Chairperson
George LaMonte Askew, MD, FAAP
Rebecca Baum, MD, FAAP
Evelyn Berger-Jenkins, MD, FAAP
Tiffani Johnson, MD, FAAP
Douglas Jutte, MD, MPH, FAAP
Arwa Nasir, MBBS, MSc, MPH, FAAP

FORMER COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH MEMBERS

Michael W. Yogman, MD, FAAP, Former Chairperson
Nerissa S. Bauer, MD, MPH, FAAP
Thresia B. Gambon, MD, FAAP
Keith M. Lemmon, MD, FAAP
Jason Richard Rafferty, MD, MPH, EdM, FAAP
Lawrence Sagin Wissow, MD, MPH, FAAP

LIAISONS

Sharon Berry, PhD, ABPP, LP – *Society of Pediatric Psychology*
Edward R. Christophersen, PhD, ABPP, FAAP – *Society of Pediatric Psychology*
Kathleen Davis, LSW – *Family Liaison*
Norah L. Johnson, PhD, RN, CPNP-BC – *National Association of Pediatric Nurse Practitioners*
Rachel Shana Segal, MD – *Section on Pediatric Trainees*
Abigail Boden Schlesinger, MD – *American Academy of Child and Adolescent Psychiatry*
Amy Starin, PhD, LCSW – *National Association of Social Workers*

STAFF

Carolyn McCarty, PhD

COUNCIL ON COMMUNITY PEDIATRICS, 2019–2020

James Duffee, MD, MPH, FAAP, Chairperson
Kimberley J. Dilley, MD, MPH, FAAP
Andrea E. Green, MD, FAAP
Joyce Javier, MD, MPH, MS, FAAP
Madhulika Mathur, MD, MPH, FAAP
Gerri Mattson, MD, FAAP
Kimberly G. Montez, MD, MPH, FAAP
Jacqueline L. Nelson, MD, FAAP
Christopher B. Peltier, MD, FAAP

FORMER COUNCIL ON COMMUNITY PEDIATRICS MEMBERS

Benjamin A. Gitterman, MD, FAAP
Thresia B. Gambon, MD, MPH, MBA, FAAP
Janna R. Gewirtz O'Brien, MD, FAAP
Virginia Keane, MD, FAAP

LIAISONS

Donene Feist
Zheyi Teoh, MD

STAFF

Dana Bennett-Tejes, MA
Jean Davis, MPP

ABBREVIATIONS

AAP: American Academy of Pediatrics
LGBT: lesbian, gay, bisexual, and transgender
LGBTQ: lesbian, gay, bisexual, transgender, and questioning
NCMEC: National Center for Missing and Exploited Children
NISMART-2: 1999 National Incidence Studies of Missing, Abducted, Runaway, and Thrownaway Children
NISMART-3: 2013 National Incidence Studies of Missing, Abducted, Runaway, and Thrownaway Children

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Hammer H, Finkelhor D, Sedlak AJ. *Runaway/Thrownaway Children: National Estimates and Characteristics*. Washington, DC: US Department of Justice, Office of Justice Programs, Office of Juvenile Justice and Delinquency Prevention; 2002. Available at: https://www.ncjrs.gov/pdffiles1/ojjdp/196469.pdf. Accessed March 1, 2017
2. Sedlak AJ, Finkelhor D, Brick JM; Office of Juvenile Justice and Delinquency Prevention. National estimates of missing children: updated findings from a survey of parents and other primary caretakers. 2017. Available at: https://www.ojjdp.gov/pubs/250089.pdf. Accessed June 11, 2019
3. Howard BJ, Broughton DD; American Academy of Pediatrics Committee on Psychosocial Aspects of Child and Family Health. The pediatrician's role in the prevention of missing children. *Pediatrics*. 2004;114(4):1100–1105. Reaffirmed January 2015
4. Greene JM, Sanchez R, Harris J, Cignetti C, Akin D, Wheeless S. Incidence and

prevalence of homeless and runaway youth. 2003. Available at: https://www.acf.hhs.gov/sites/default/files/opre/incidence.pdf. Accessed March 2017

5. Ringwalt CL, Greene JM, Robertson M, McPheeters M. The prevalence of homelessness among adolescents in the United States. *Am J Public Health*. 1998;88(9):1325–1329
6. Sanchez RP, Waller MW, Greene JM. Who runs? A demographic profile of runaway youth in the United States. *J Adolesc Health*. 2006;39(5):778–781
7. Minnesota Student Survey Interagency Team. Minnesota Student Survey 2013. Roseville, MN: Minnesota Department of Education; 2013. Available at: http://w20.education.state.mn.us/MDEAnalytics/DataTopic.jsp?TOPICID=242. Accessed January 21, 2019
8. Minnesota Student Survey Interagency Team. Minnesota Student Survey 2016. Roseville, MN: Minnesota Department of Education; 2016. Available at: http://w20.education.state.mn.us/MDEAnalytics/DataTopic.jsp?TOPICID=242. Accessed January 21, 2019
9. Tucker JS, Edelen MO, Ellickson PL, Klein DJ. Running away from home: a longitudinal study of adolescent risk factors and young adult outcomes. *J Youth Adolesc*. 2011;40(5):507–518
10. Thrane LE, Hoyt DR, Whitbeck LB, Yoder KA. Impact of family abuse on running away, deviance, and street victimization among homeless rural and urban youth. *Child Abuse Negl*. 2006;30(10):1117–1128
11. Tyler KA, Gervais SJ, Davidson MM. The relationship between victimization and substance use among homeless and runaway female adolescents. *J Interpers Violence*. 2013;28(3):474–493
12. Tyler KA, Johnson KA. A longitudinal study of the effects of early abuse on later victimization among high-risk adolescents [published correction appears in *Violence Vict*. 2006;21(4): preceding 403]. *Violence Vict*. 2006;21(3):287–306
13. Whitbeck LB, Hoyt DR, Ackley KA. Families of homeless and runaway adolescents: a comparison of parent/caretaker and adolescent perspectives on parenting, family violence, and adolescent conduct. *Child Abuse Negl*. 1997;21(6):517–528
14. Edinburgh LD, Harpin SB, Garcia CM, Saewyc EM. Differences in abuse and related risk and protective factors by runaway status for adolescents seen at a U.S. Child Advocacy Centre. *Int J Child Adolesc Resil*. 2013;1(1):4–16
15. Edinburgh L, Pape-Blabolil J, Harpin SB, Saewyc E. Assessing exploitation experiences of girls and boys seen at a Child Advocacy Center. *Child Abuse Negl*. 2015;46:47–59
16. Edinburgh L, Saewyc E, Thao T, Levitt C. Sexual exploitation of very young Hmong girls. *J Adolesc Health*. 2006;39(1):111–118
17. Lacoursiere T, Fontenot HB. The impact of running away on teen girls' sexual health. *Nurs Womens Health*. 2012;16(5):411–417
18. Meltzer H, Ford T, Bebbington P, Vostanis P. Children who run away from home: risks for suicidal behavior and substance misuse. *J Adolesc Health*. 2012;51(5):415–421
19. National Conference of State Legislatures. Homeless and runaway youth. Available at: http://www.ncsl.org/research/human-services/homeless-and-runaway-youth.aspx. Accessed March 20, 2017
20. Pergamit M, Ernst M, Benoit-Bryan J, Kessel J; National Runaway Switchboard. Why they run: an in-depth look at America's runaway youth. 2010. Available at: http://www.missingkids.org/footer/media/keyfacts. Accessed February 3, 2018
21. The National Center for Missing and Exploited Children. Key facts. Available at: www.missingkids.com. Accessed March 17, 2018
22. National Runaway Safeline; US Department of Health and Human Services. National trends on youth in crisis in the United States: an analysis of trends in crisis connections to the National Runaway Safeline over the past decade (2007–2017). 2018. Available at: https://www.1800runaway.org/wp-content/uploads/2018/11/NRS-2018-Trend-Report_Final.pdf. Accessed January 21, 2019
23. Morton MH, Dworsky A, Matjasko JL, et al. Prevalence and correlates of youth homelessness in the United States. *J Adolesc Health*. 2018;62(1):14–21
24. US Department of Justice. National vs. native missing youth statistics. Available at: https://amber-ic.org/wp-content/uploads/2017/11/NationalvsNativeMissingYouth.pdf. Accessed August 2, 2019
25. Narendorf SC, Santa Maria DM, Cooper JA. Youth Count 2.0!: full report of findings 2015. Available at: https://www.uh.edu/socialwork/_docs/Research/FINAL%20REPORT%20YOUTH%20COUNT%202.0.pdf. Accessed April 28, 2019
26. Cray A, Miller K, Durso LE; Center for American Progress. Seeking shelter: the experiences and unmet needs of LGBT homeless youth. 2013. Available at: https://www.americanprogress.org/issues/lgbt/reports/2013/09/26/75746/seeking-shelter-the-experiences-and-unmet-needs-of-lgbt-homeless-youth/. Accessed April 28, 2019
27. Corliss HL, Goodenow CS, Nichols L, Austin SB. High burden of homelessness among sexual-minority adolescents: findings from a representative Massachusetts high school sample. *Am J Public Health*. 2011;101(9):1683–1689
28. Cunningham M, Pergamit M, Astone N, Luna J; Urban Institute. Homeless LGBTQ youth. 2014. Available at: www.urban.org/research/publication/homeless-lgbtq-youth. Accessed April 28, 2019
29. Yates GL, MacKenzie R, Pennbridge J, Cohen E. A risk profile comparison of runaway and non-runaway youth. *Am J Public Health*. 1988;78(7):820–821
30. Council on Community Pediatrics. Providing care for children and adolescents facing homelessness and housing insecurity. *Pediatrics*. 2013;131(6):1206–1210. Reaffirmed October 2016
31. Thrane LE, Chen X. Impact of running away on girls' pregnancy. *J Adolesc*. 2012;35(2):443–449
32. Robertson MJ, Toro PA. Homeless youth: research, intervention, and policy. In: Fosburg LB, Dennis DL, eds. *Practical Lessons: The 1998 National Symposium on Homelessness Research*. Washington, DC: US Department of

Housing and Urban Development, US Department of Health and Human Services; 1999:77–108

33. Thompson SJ, Bender KA, Lewis CM, Watkins R. Runaway and pregnant: risk factors associated with pregnancy in a national sample of runaway/homeless female adolescents. *J Adolesc Health*. 2008;43(2):125–132
34. Thompson SJ, Pillai VK. Determinants of runaway episodes among adolescents using crisis shelter services. *Int J Soc Welf*. 2006;15(2):142–149
35. Thompson SJ. Risk/protective factors associated with substance use among runaway/homeless youth utilizing emergency shelter services nationwide. *Subst Abus*. 2004;25(3):13–26
36. Greene JM, Ringwalt CL. Pregnancy among three national samples of runaway and homeless youth. *J Adolesc Health*. 1998;23(6):370–377
37. Greenbaum J, Crawford-Jukubiak JE; Committee on Child Abuse and Neglect. Child sex trafficking and commercial sexual exploitation: health care needs of victims. *Pediatrics*. 2015;135(3):566–574
38. Thrane LE, Yoder KA, Chen X. The influence of running away on the risk of female sexual assault in the subsequent year. *Violence Vict*. 2011;26(6):816–829
39. Crawford DM, Whitbeck LB, Hoyt DR. Propensity for violence among homeless and runaway adolescents: an event history analysis. *Crime Delinq*. 2011;57(6):950–968
40. Lim C, Rice E, Rhoades H. Depressive symptoms and their association with adverse environmental factors and substance use in runaway and homeless youths. *J Res Adolesc*. 2016;26(3):403–417
41. Whitbeck LB, Johnson KD, Hoyt DR, Cauce AM. Mental disorder and comorbidity among runaway and homeless adolescents. *J Adolesc Health*. 2004;35(2):132–140
42. Bender K, Brown SM, Thompson SJ, Ferguson KM, Langenderfer L. Multiple victimizations before and after leaving home associated with PTSD, depression, and substance use disorder among homeless youth. *Child Maltreat*. 2015;20(2):115–124
43. Holliday SB, Edelen MO, Tucker JS. Family functioning and predictors of runaway behavior among at-risk youth. *Child Adolesc Social Work J*. 2017;34(3):247–258
44. Aratani Y, Cooper JL. The effects of runaway-homeless episodes on high school dropout. *Youth Soc*. 2015;47(2):173–198
45. American Academy of Pediatrics. Trauma toolbox for primary care. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/resilience/Pages/Becoming-a-Trauma-Informed-Practice.aspx. Accessed October 3, 2019
46. Tyler KA, Bersani BE. A longitudinal study of early adolescent precursors to running away. *J Early Adolesc*. 2008;28(2):230–251
47. American Academy of Pediatrics. Poverty and child health toolkit. Available at: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/poverty/Pages/home.aspx. Accessed June 27, 2019
48. American Academy of Pediatrics. Bright Futures. Performing preventative services: a bright futures handbook. Available at: https://brightfutures.aap.org/Bright%20Futures%20Documents/History,%200bservation,%20and%20Surveillance.pdf. Accessed July 23, 2019
49. National Runaway Safeline. NRS call statistics. Available at: https://www.1800runaway.org/trendreport2017/. Accessed November 15, 2018
50. Durso LE, Gates GJ. *Serving Our Youth: Findings from a National Survey of Service Providers Working with Lesbian, Gay, Bisexual and Transgender Youth Who Are Homeless or At Risk of Becoming Homeless*. Los Angeles, CA: The Williams Institute with True Colors Fund, The Palette Fund; 2012. Available at: https://williamsinstitute.law.ucla.edu/research/safe-schools-and-youth/serving-our-youth-july-2012/. Accessed January 31, 2019
51. Cochran BN, Stewart AJ, Ginzler JA, Cauce AM. Challenges faced by homeless sexual minorities: comparison of gay, lesbian, bisexual, and transgender homeless adolescents with their heterosexual counterparts. *Am J Public Health*. 2002;92(5):773–777
52. Rice E, Barman-Adhikari A, Rhoades H, et al. Homelessness experiences, sexual orientation, and sexual risk taking among high school students in Los Angeles. *J Adolesc Health*. 2013;52(6):773–778
53. Keuroghlian AS, Shtasel D, Bassuk EL. Out on the street: a public health and policy agenda for lesbian, gay, bisexual, and transgender youth who are homeless. *Am J Orthopsychiatry*. 2014;84(1):66–72
54. Van Leeuwen JM, Boyle S, Salomonsen-Sautel S, et al. Lesbian, gay, and bisexual homeless youth: an eight-city public health perspective. *Child Welfare*. 2006;85(2):151–170
55. Kim H, Chenot D, Lee S. Running away from out-of-home care: a multilevel analysis. *Child Soc*. 2015;29(2):109–121
56. Finkelstein M, Wamsley M, Currie D, Miranda D; Vera Institute of Justice. Youth who chronically AWOL from foster care. 2004. Available at: https://www.vera.org/publications/youth-who-chronically-awol-from-foster-care-why-they-run-where-they-go-and-what-can-be-done. Accessed February 4, 2018
57. Courtney ME, Zinn A. Predictors of running away from out-of-home care. *Child Youth Serv Rev*. 2009;31(12):1298–1306
58. Lin C-H. Children who run away from foster care: who are the children and what are the risk factors? *Child Youth Serv Rev*. 2012;34(4):807–813
59. Benoit-Bryan J. Family characteristics and runaway youth. 2013. Available at: https://www.1800runaway.org/wp-content/uploads/2015/05/Family-Characteristics-and-Runaway-Behavior-final2.pdf. Accessed July 22, 2019
60. Wolak J, Finkelhor D, Mitchell KJ, Ybarra ML. Online "predators" and their victims: myths, realities, and implications for prevention and treatment. *Am Psychol*. 2008;63(2):111–128
61. Wolak J, Finkelhor D, Mitchell K. Internet-initiated sex crimes against minors: implications for prevention based on findings from a national study. *J Adolesc Health*. 2004;35(5):424.e11-424.e20
62. Mitchell KJ, Boyd D. *Understanding the Role of Technology in the Commercial*

Sexual Exploitation of Children: The Perspective of Law Enforcement. Durham, NH: Crimes Against Children Research Center, University of New Hampshire; 2014. Available at: https://scholars.unh.edu/ccrc/37/. Accessed April 28, 2019

63. Family and Youth Services Bureau. *Human Trafficking and Runaway and Homeless Youth: Practical Tools for Grantees. Online Recruitment of Youth Via Social Media and the Internet Youth Social Media Use*. Washington, DC: Family and Youth Services Bureau; 2018. Available at: https://rhyttac.memberclicks.net/assets/docs/Resources/RHY%20HT%20Social%20Media.pdf. Accessed April 28, 2019
64. Buccieri K, Molleson G. Empowering homeless youth: building capacity through the development of mobile technology. *J Community Pract*. 2015;23(2):238–254
65. Rice E, Barman-Adhikari A. Internet and social media use as a resource among homeless youth. *J Comput Mediat Commun*. 2014;19(2):232–247
66. Stott TC, MacEachron A, Gustavsson N. Social media and child welfare: policy, training, and the risks and benefits from the administrator's perspective. *Adv Soc Work*. 2017;17(2):221–234
67. Tyler KA, Olson K. Examining the feasibility of ecological momentary assessment using short message service surveying with homeless youth. *Field Methods*. 2018;30(2):91–104
68. Tyler KA, Schmitz RM. Using cell phones for data collection: benefits, outcomes, and intervention possibilities with homeless youth. *Child Youth Serv Rev*. 2017;76:59–64
69. Harpin S, Davis J, Low H, Gilroy C. Mobile phone and social media use of homeless youth in Denver, Colorado. *J Community Health Nurs*. 2016;33(2):90–97
70. Family and Youth Services Bureau. Runaway and Homeless Youth Program authorizing legislation. 2018. Available at: https://www.acf.hhs.gov/fysb/resource/rhy-act. Accessed January 21, 2019
71. Cooper EF; Congressional Research Service. The Runaway and Homeless Youth Program: administration, funding, and legislative actions. 2006. Available at: https://digital.library.unt.edu/ark:/67531/metacrs9962/m1/1/high_res_d/RL31933_2006Mar23.pdf. Accessed April 5, 2019
72. Klein JD, Woods AH, Wilson KM, Prospero M, Greene J, Ringwalt C. Homeless and runaway youths' access to health care. *J Adolesc Health*. 2000;27(5):331–339
73. Edinburgh LD, Saewyc EM. A novel, intensive home-visiting intervention for runaway, sexually exploited girls. *J Spec Pediatr Nurs*. 2009;14(1):41–48
74. English A. Runaway and street youth at risk for HIV infection: legal and ethical issues in access to care. *J Adolesc Health*. 1991;12(7):504–510
75. Hudson AL, Nyamathi A, Greengold B, et al. Health-seeking challenges among homeless youth. *Nurs Res*. 2010;59(3):212–218
76. Bounds D, Edinburgh L, Fogg L, Saewyc E. The Minnesota Runaway Intervention Program's influence on sexually exploited youth's trauma responses. *J Adolesc Health*. 2017;60(2):S22–S23
77. Saewyc EM, Edinburgh LD. Restoring healthy developmental trajectories for sexually exploited young runaway girls: fostering protective factors and reducing risk behaviors. *J Adolesc Health*. 2010;46(2):180–188
78. Siu AL; US Preventive Services Task Force. Screening for depression in children and adolescents: US Preventive Services Task Force recommendation statement. *Pediatrics*. 2016;137(3):e20154467
79. Levy SJ, Williams JF; Committee on Substance Use and Prevention. Substance use screening, brief intervention, and referral to treatment. *Pediatrics*. 2016;138(1):e20161211
80. Committee on Substance Use and Prevention. Substance use screening, brief intervention, and referral to treatment. *Pediatrics*. 2016;138(1):e20161210

Truth, Reconciliation, and Transformation: Continuing on the Path to Equity

- *Policy Statement*

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of all Children

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

Truth, Reconciliation, and Transformation: Continuing on the Path to Equity

American Academy of Pediatrics Board of Directors

One year ago, the American Academy of Pediatrics (AAP) published a landmark policy statement identifying racism as a core social determinant of health and a driver of health inequities.[1] Seventy-five years ago, the AAP admitted its first Black members, Drs Alonzo deGrate Smith and Roland Boyd Scott. As the AAP continues to evolve its equity agenda, it is essential that the tortuous experiences of Drs deGrate Smith and Scott on their pathway to AAP membership be truthfully acknowledged and reckoned with.

At the time of their initially rejected applications in 1939, both Drs deGrate Smith and Scott were busy clinicians and well-established leaders in the pediatric academic community as faculty at the Howard University College of Medicine in Washington, DC. Dr deGrate Smith, through the practice pathway, and Dr Scott, via examination, were among the earliest pediatricians to achieve certification under the Advisory Board of Medical Specialties (ABMS) when the American Board of Pediatrics (ABP) was established in 1933. However, the ABMS required American Medical Association (AMA) membership to honor certification, and the local AMA chapter, the Medical Society of the District of Columbia, was segregated.[2] According to the oral history interview of Dr Melvin E. Jenkins Jr, advocacy on the part of the inaugural ABP president, Dr Borden Veeder, was necessary to permanently eliminate this exclusionary barrier and to make certification possible for all eligible candidates regardless of race or ethnicity.[3] Drs deGrate Smith and Scott faced other systemic barriers, including the inability to gain admitting privileges to care for even their own patients at local hospitals in the District of Columbia. This was a hurdle that Dr Scott was not able to overcome until 1955, fully 6 years after he had already been appointed Chair of Pediatrics at Howard University.[4]

Although AAP bylaws did not explicitly prohibit physicians of color from membership, and Drs deGrate Smith and Scott were finally admitted in 1945, it is clear that the AAP Executive Board struggled with unbiased consideration of their applications. The characterizations related to Drs deGrate Smith and Scott in the following passages excerpted directly from meeting transcripts of AAP Executive Board meetings in November 1939,

DOI: https://doi.org/10.1542/peds.2020-019794

Address correspondence to President@aap.org.

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

To cite: American Academy of Pediatrics Board of Directors. Truth, Reconciliation, and Transformation: Continuing on the Path to Equity. *Pediatrics*. 2020;146(3): e2020019794

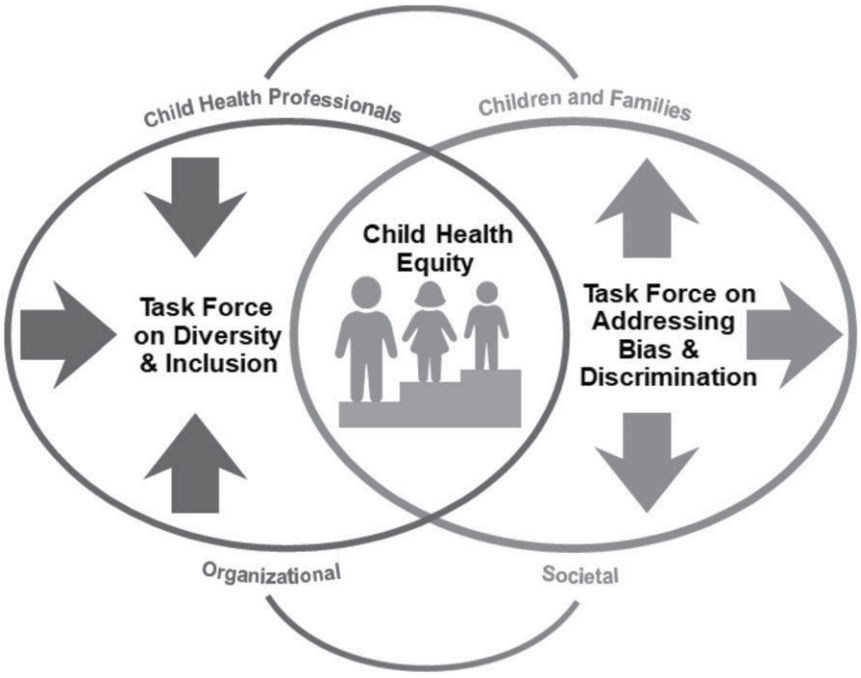


FIGURE 1
AAP Equity Agenda.

November 1944, and June 1945 are elucidating, instructive, and painful to read. The verbatim dialogue and proceedings highlight the racist attitudes and beliefs from which early AAP leaders were clearly not immune.

November 1939—American Academy of Pediatrics Executive Board

[Region I Chairman] then presented the application of Dr Alfred [sic] deGrate Smith. Motion made by [Region I Chairman] that this application not be accepted and that a letter be sent to his sponsor outlining the educational advancements being outlined by the American Academy of Pediatrics for negro physicians; motion seconded by [Region I Associate Chairman] and carried.[5]

[Region III Chairman] moved that all of these [Region III] applications, with the exception of Dr Scott, be accepted into membership; motion duly seconded and carried. Motion made by [Region I Chairman] that the same action be taken on Dr Scott as had been taken on Dr Smith; motion seconded and carried.[5]

November 1944—American Academy of Pediatrics Executive Board

"I know Smith and he is a very nice fellow. Scott has for a year or two attended the Sunday morning clinical conferences at Children's Hospital. He has taken part in the discussion of cases at Freedman's Hospital. I think the local men in Washington would like to have something to say about men taken into the Academy from that particular location. I think they would rather resent an effort being made to put these men in. I would like to hear what [Region II Chairman] has to say."[5]

"We allow negroes to come to our meeting and we fix a separate place for them to sit. They do not become members. If they became members they would want to come and eat with you at the table. You cannot hold them down."[5]

June 1945—American Academy of Pediatrics Executive Board

"We talked with them for about a half hour and they conducted themselves as gentlemen. They said their only interest in wishing to join the Academy was for educational purposes. They said they would not attend any meetings held South of the Mason and Dixon line. They would attend meetings in other parts of the country, but under no circumstances enter into the social side for the reason that they did not want to get hurt themselves. I impressed upon them the importance should they be elected, of their being leaders and not pushers, and their acceptance in the Academy would be guidance for those who would come at a later time."[6]

"I think the problem is of much more concern to us than it needs to be. In the first place, we have a definite responsibility to these negro representatives and to the negro population of the country. The only trouble is the social implication. The burden lies much heavier upon Smith and Scott than upon us. As the President (of the Academy) says, we have the authority to say who will not be admitted. In the event that either of these men transgress the social lines, they completely stop the advancement of the negro."[6]

In the United States there is a tendency to be ahistorical when it comes to race. The lack of acknowledgment, or worse, the intentional whitewashing of history and the longitudinal relationship of 400 years of oppression on the present-day expression of racism is not uncommon. As the AAP turns the corner toward the 2030 centennial anniversary of its founding, we cannot do so without authentically acknowledging, owning, and reconciling past discriminatory transgressions like the shameful gauntlet to membership experienced by Drs Alonzo deGrate Smith and Roland Boyd Scott.

In honoring the memory of these two trailblazers and their contributions to pediatrics and the AAP,[7] be it resolved that, we, the Board of Directors of the AAP:

1) Apologize for the racism that contributed to the inequities that Drs deGrate Smith, Scott, and other pediatricians have endured, and;
2) Commit to a bylaws referendum to explicitly codify that AAP membership does not discriminate on the basis of race, ethnicity, religion, sex, sexual orientation, gender identity, disability, or national origin.

The AAP as an organization is on a firm pathway to broadly establishing an equity agenda through meaningful diversity and inclusion and a societal commitment to combating bias and discrimination

in all its forms, including structural and systemic anti-Black racism (Fig 1). This country is already majority represented by children of color when it comes to the pediatric population.

Embracing racial and ethnic socialization is critical for *all* children and families as well as for the pediatricians who care for them. Healing starts at home with truth, reckoning, and honest reconciliation.

The AAP is proud to transparently acknowledge, proud to publicly reconcile, and proud to continue to lead on behalf of the best interests of children, adolescents, and young adults and the people who care for them.

REFERENCES

1. Trent M, Dooley DG, Dougé J; Section on Adolescent Health; Council on Community Pediatrics; Committee on Adolescence. The impact of racism on child and adolescent health. *Pediatrics*. 2019;144(2):e20191765
2. Negro doctor addresses DC medical society. *Jet*. April 16, 1953
3. Interview of Melvin E. Jenkins Jr, MD. American Academy of Pediatrics Oral History Project, August 12, 2008
4. DC hospital admits 3 Negro physicians. *Jet*. March 10, 1955
5. AAP Gartner Pediatric History Center. Archived Executive Board Meeting Minutes. Accessed June 28, 2020
6. Wyckoff AS. First Black AAP members rose in prominence but faced scrutiny. *AAP News*. 2019. Available at: https://www.aappublications.org/news/2019/02/04/dyk020419. Accessed July 13, 2020
7. Parrott RH, Jenkins ME. Howland Award presentation to Roland B. Scott. *Pediatr Res*. 1991;30(6):626–627

SECTION 4

Current Policies

From the American Academy of Pediatrics

(Through December 31, 2020)

- *Policy Statements*
  ORGANIZATIONAL PRINCIPLES TO GUIDE AND DEFINE THE CHILD HEALTH CARE SYSTEM AND TO IMPROVE THE HEALTH OF ALL CHILDREN

- *Clinical Reports*
  GUIDANCE FOR THE CLINICIAN IN RENDERING PEDIATRIC CARE

- *Technical Reports*
  BACKGROUND INFORMATION TO SUPPORT AMERICAN ACADEMY OF PEDIATRICS POLICY

American Academy of Pediatrics

Policy Statements, Clinical Reports, Technical Reports

Current through December 31, 2020
The companion *Pediatric Clinical Practice Guidelines & Policies* eBook
points to the full text of all titles listed herein.

2020 RECOMMENDATIONS FOR PREVENTIVE PEDIATRIC HEALTH CARE

Committee on Practice and Ambulatory Medicine and Bright Futures Periodicity Schedule Workgroup

ABSTRACT. The 2020 Recommendations for Preventive Pediatric Health Care (Periodicity Schedule) have been approved by the American Academy of Pediatrics (AAP) and represents a consensus of the AAP and the Bright Futures Periodicity Schedule Workgroup. Each child and family is unique; therefore, these recommendations are designed for the care of children who are receiving competent parenting, have no manifestations of any important health problems, and are growing and developing in a satisfactory fashion. Developmental, psychosocial, and chronic disease issues for children and adolescents may require frequent counseling and treatment visits separate from preventive care visits. Additional visits also may become necessary if circumstances suggest variations from the normal. (2/20)

See full text on page 545.

https://pediatrics.aappublications.org/content/145/3/e20200013

AAP DIVERSITY AND INCLUSION STATEMENT

American Academy of Pediatrics

ABSTRACT. The vision of the American Academy of Pediatrics (AAP) is that all children have optimal health and well-being and are valued by society and that AAP members practice the highest quality health care and experience professional satisfaction and personal well-being. From the founding of the AAP, pursuing this vision has included treasuring the uniqueness of each child and fostering a profession, health care system, and communities that celebrate all aspects of the diversity of each child and family. (3/18)

http://pediatrics.aappublications.org/content/141/4/e20180193

ABUSIVE HEAD TRAUMA IN INFANTS AND CHILDREN

Sandeep K. Narang, MD, JD, FAAP; Amanda Fingarson, DO, FAAP; James Lukefahr, MD, FAAP; and Council on Child Abuse and Neglect

ABSTRACT. Abusive head trauma (AHT) remains a significant cause of morbidity and mortality in the pediatric population, especially in young infants. In the past decade, advancements in research have refined medical understanding of the epidemiological, clinical, biomechanical, and pathologic factors comprising the diagnosis, thereby enhancing clinical detection of a challenging diagnostic entity. Failure to recognize AHT and respond appropriately at any step in the process, from medical diagnosis to child protection and legal decision-making, can place children at risk. The American Academy of Pediatrics revises the 2009 policy statement on AHT to incorporate the growing body of knowledge on the topic. Although this statement incorporates some of that growing body of knowledge, it is not a comprehensive exposition of the science. This statement aims to provide pediatric practitioners with general guidance on a complex subject. The Academy recommends that pediatric practitioners remain vigilant for the signs and symptoms of AHT, conduct thorough medical evaluations, consult with pediatric medical subspecialists when necessary, and embrace the challenges and need for strong advocacy on the subject. (3/20)

See full text on page 549.

https://pediatrics.aappublications.org/content/145/4/e20200203

ACCESS TO OPTIMAL EMERGENCY CARE FOR CHILDREN

Committee on Pediatric Emergency Medicine

ABSTRACT. Millions of pediatric patients require some level of emergency care annually, and significant barriers limit access to appropriate services for large numbers of children. The American Academy of Pediatrics has a strong commitment to identifying barriers to access to emergency care, working to surmount these obstacles, and encouraging, through education and system changes, improved levels of emergency care available to all children. (1/07, reaffirmed 8/10, 7/14)

http://pediatrics.aappublications.org/content/119/1/161

ACHIEVING QUALITY HEALTH SERVICES FOR ADOLESCENTS

Committee on Adolescence

ABSTRACT. This update of the 2008 statement from the American Academy of Pediatrics redirects the discussion of quality health care from the theoretical to the practical within the medical home. This statement reviews the evolution of the medical home concept and challenges the provision of quality adolescent health care within the patient-centered medical home. Areas of attention for quality adolescent health care are reviewed, including developmentally appropriate care, confidentiality, location of adolescent care, providers who offer such care, the role of research in advancing care, and the transition to adult care. (7/16)

http://pediatrics.aappublications.org/content/138/2/e20161347

ACHIEVING THE PEDIATRIC MENTAL HEALTH COMPETENCIES (TECHNICAL REPORT)

Cori M. Green, MD, MS, FAAP; Jane Meschan Foy, MD, FAAP; Marian F. Earls, MD, FAAP; Committee on Psychosocial Aspects of Child and Family Health; and Mental Health Leadership Work Group

ABSTRACT. Mental health disorders affect 1 in 5 children; however, the majority of affected children do not receive appropriate services, leading to adverse adult outcomes. To meet the needs of children, pediatricians need to take on a larger role in addressing mental health problems. The accompanying policy statement, "Mental Health Competencies for Pediatric Practice," articulates mental health competencies pediatricians could achieve to improve the mental health care of children; yet, the majority of pediatricians do not feel prepared to do so. In this technical report, we summarize current initiatives and resources that exist for trainees and practicing pediatricians across the training continuum. We also identify gaps in mental health clinical experience and training and suggest areas in which education can be strengthened. With this report, we aim to stimulate efforts to address gaps by summarizing educational strategies that have been applied and could be applied to undergraduate medical education, residency and fellowship training,

continuing medical education, maintenance of certification, and practice quality improvement activities to achieve the pediatric mental health competencies. In this report, we also articulate the research questions important to the future of pediatric mental health training and practice. (10/19)
https://pediatrics.aappublications.org/content/144/5/e20192758

ADDRESSING EARLY CHILDHOOD EMOTIONAL AND BEHAVIORAL PROBLEMS

Council on Early Childhood, Committee on Psychosocial Aspects of Child and Family Health, and Section on Developmental and Behavioral Pediatrics

ABSTRACT. Emotional, behavioral, and relationship problems can develop in very young children, especially those living in high-risk families or communities. These early problems interfere with the normative activities of young children and their families and predict long-lasting problems across multiple domains. A growing evidence base demonstrates the efficacy of specific family-focused therapies in reducing the symptoms of emotional, behavioral, and relationship symptoms, with effects lasting years after the therapy has ended. Pediatricians are usually the primary health care providers for children with emotional or behavioral difficulties, and awareness of emerging research about evidence-based treatments will enhance this care. In most communities, access to these interventions is insufficient. Pediatricians can improve the care of young children with emotional, behavioral, and relationship problems by calling for the following: increased access to care; increased research identifying alternative approaches, including primary care delivery of treatments; adequate payment for pediatric providers who serve these young children; and improved education for pediatric providers about the principles of evidence-based interventions. (11/16)
http://pediatrics.aappublications.org/content/138/6/e20163023

ADDRESSING EARLY CHILDHOOD EMOTIONAL AND BEHAVIORAL PROBLEMS (TECHNICAL REPORT)

Mary Margaret Gleason, MD, FAAP; Edward Goldson, MD, FAAP; Michael W. Yogman, MD, FAAP; Council on Early Childhood; Committee on Psychosocial Aspects of Child and Family Health; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. More than 10% of young children experience clinically significant mental health problems, with rates of impairment and persistence comparable to those seen in older children. For many of these clinical disorders, effective treatments supported by rigorous data are available. On the other hand, rigorous support for psychopharmacologic interventions is limited to 2 large randomized controlled trials. Access to psychotherapeutic interventions is limited. The pediatrician has a critical role as the leader of the medical home to promote well-being that includes emotional, behavioral, and relationship health. To be effective in this role, pediatricians promote the use of safe and effective treatments and recognize the limitations of psychopharmacologic interventions. This technical report reviews the data supporting treatments for young children with emotional, behavioral, and relationship problems and supports the policy statement of the same name. (11/16)
http://pediatrics.aappublications.org/content/138/6/e20163025

ADMISSION AND DISCHARGE GUIDELINES FOR THE PEDIATRIC PATIENT REQUIRING INTERMEDIATE CARE (CLINICAL REPORT)

Committee on Hospital Care and Section on Critical Care (joint with Society of Critical Care Medicine)

ABSTRACT. During the past 3 decades, the specialty of pediatric critical care medicine has grown rapidly, leading to a number of pediatric intensive care units opening across the country. Many patients who are admitted to the hospital require a higher level of care than routine inpatient general pediatric care, yet not to the degree of intensity of pediatric critical care; therefore, an intermediate care level has been developed in institutions providing multidisciplinary subspecialty pediatric care. These patients may require frequent monitoring of vital signs and nursing interventions, but usually they do not require invasive monitoring. The admission of the pediatric intermediate care patient is guided by physiologic parameters depending on the respective organ system involved relative to an institution's resources and capacity to care for a patient in a general care environment. This report provides admission and discharge guidelines for intermediate pediatric care. Intermediate care promotes greater flexibility in patient triage and provides a cost-effective alternative to admission to a pediatric intensive care unit. This level of care may enhance the efficiency of care and make health care more affordable for patients receiving intermediate care. (5/04, reaffirmed 2/08, 5/17, 2/20)
http://pediatrics.aappublications.org/content/113/5/1430

ADOLESCENT AND YOUNG ADULT TATTOOING, PIERCING, AND SCARIFICATION (CLINICAL REPORT)

Cora C. Breuner, MD, MPH; David A. Levine, MD; and Committee on Adolescence

ABSTRACT. Tattoos, piercing, and scarification are now commonplace among adolescents and young adults. This first clinical report from the American Academy of Pediatrics on voluntary body modification will review the methods used to perform the modifications. Complications resulting from body modification methods, although not common, are discussed to provide the pediatrician with management information. Body modification will be contrasted with nonsuicidal self-injury. When available, information also is presented on societal perceptions of body modification. (9/17)
http://pediatrics.aappublications.org/content/140/4/e20163494

ADOLESCENT DRUG TESTING POLICIES IN SCHOOLS

Sharon Levy, MD, MPH, FAAP; Miriam Schizer, MD, MPH, FAAP; and Committee on Substance Abuse

ABSTRACT. School-based drug testing is a controversial approach to preventing substance use by students. Although school drug testing has hypothetical benefits, and studies have noted modest reductions in self-reported student drug use, the American Academy of Pediatrics opposes widespread implementation of these programs because of the lack of solid evidence for their effectiveness. (3/15)
http://pediatrics.aappublications.org/content/135/4/782

ADOLESCENT DRUG TESTING POLICIES IN SCHOOLS (TECHNICAL REPORT)

Sharon Levy, MD, MPH, FAAP; Miriam Schizer, MD, MPH, FAAP; and Committee on Substance Abuse

ABSTRACT. More than a decade after the US Supreme Court established the legality of school-based drug testing, these programs remain controversial, and the evidence evaluating efficacy and risks is inconclusive. The objective of this technical report is to review the relevant literature that explores the benefits, risks, and costs of these programs. (3/15)
http://pediatrics.aappublications.org/content/135/4/e1107

ADOLESCENT PREGNANCY: CURRENT TRENDS AND ISSUES (CLINICAL REPORT)

Jonathan D. Klein, MD, MPH, and Committee on Adolescence

ABSTRACT. The prevention of unintended adolescent pregnancy is an important goal of the American Academy of Pediatrics and our society. Although adolescent pregnancy and birth rates have been steadily decreasing, many adolescents still become pregnant. Since the last statement on adolescent pregnancy was issued by the Academy in 1998, efforts to prevent

adolescent pregnancy have increased, and new observations, technologies, and prevention effectiveness data have emerged. The purpose of this clinical report is to review current trends and issues related to adolescent pregnancy, update practitioners on this topic, and review legal and policy implications of concern to pediatricians. (7/05)
http://pediatrics.aappublications.org/content/116/1/281

ADOLESCENT PREGNANCY: CURRENT TRENDS AND ISSUES—ADDENDUM

Committee on Adolescence

INTRODUCTION. The purpose of this addendum is to update pediatricians and other professionals on recent research and data regarding adolescent sexuality, contraceptive use, and childbearing since publication of the original 2005 clinical report, "Adolescent Pregnancy: Current Trends and Issues." There has been a trend of decreasing sexual activity and teen births and pregnancies since 1991, except between the years of 2005 and 2007, when there was a 5% increase in birth rates. Currently, teen birth rates in the United States are at a record low secondary to increased use of contraception at first intercourse and use of dual methods of condoms and hormonal contraception among sexually active teenagers. Despite these data, the United States continues to lead other industrialized countries in having unacceptably high rates of adolescent pregnancy, with over 700 000 pregnancies per year, the direct health consequence of unprotected intercourse. Importantly, the 2006–2010 National Survey of Family Growth (NSFG) revealed that less than one-third of 15- to 19-year-old female subjects consistently used contraceptive methods at last intercourse. (4/14)
http://pediatrics.aappublications.org/content/133/5/954

ADOLESCENTS AND HIV INFECTION: THE PEDIATRICIAN'S ROLE IN PROMOTING ROUTINE TESTING

Committee on Pediatric AIDS

ABSTRACT. Pediatricians can play a key role in preventing and controlling HIV infection by promoting risk-reduction counseling and offering routine HIV testing to adolescent and young adult patients. Most sexually active youth do not feel that they are at risk of contracting HIV and have never been tested. Obtaining a sexual history and creating an atmosphere that promotes nonjudgmental risk counseling is a key component of the adolescent visit. In light of increasing numbers of people with HIV/AIDS and missed opportunities for HIV testing, the Centers for Disease Control and Prevention recommends universal and routine HIV testing for all patients seen in health care settings who are 13 to 64 years of age. There are advances in diagnostics and treatment that help support this recommendation. This policy statement reviews the epidemiologic data and recommends that routine screening be offered to all adolescents at least once by 16 to 18 years of age in health care settings when the prevalence of HIV in the patient population is more than 0.1%. In areas of lower community HIV prevalence, routine HIV testing is encouraged for all sexually active adolescents and those with other risk factors for HIV. This statement addresses many of the real and perceived barriers that pediatricians face in promoting routine HIV testing for their patients. (10/11, reaffirmed 9/15)
http://pediatrics.aappublications.org/content/128/5/1023

THE ADOLESCENT'S RIGHT TO CONFIDENTIAL CARE WHEN CONSIDERING ABORTION

Committee on Adolescence

ABSTRACT. In this statement, the American Academy of Pediatrics reaffirms its position that the rights of adolescents to confidential care when considering abortion should be protected. Adolescents should be encouraged to involve their parents and other trusted adults in decisions regarding pregnancy termination, and most do so voluntarily. The majority of states require that minors have parental consent for an abortion. However, legislation mandating parental involvement does not achieve the intended benefit of promoting family communication, and it increases the risk of harm to the adolescent by delaying access to appropriate medical care. This statement presents a summary of pertinent current information related to the benefits and risks of legislation requiring mandatory parental involvement in an adolescent's decision to obtain an abortion. (1/17)
http://pediatrics.aappublications.org/content/139/2/e20163861

ADVANCED PRACTICE IN NEONATAL NURSING

Committee on Fetus and Newborn

ABSTRACT. The participation of advanced practice registered nurses in neonatal care continues to be accepted and supported by the American Academy of Pediatrics. Recognized categories of advanced practice neonatal nursing are the neonatal clinical nurse specialist and the neonatal nurse practitioner. (5/09, reaffirmed 1/14)
http://pediatrics.aappublications.org/content/123/6/1606

ADVOCACY AND COLLABORATIVE HEALTH CARE FOR JUSTICE-INVOLVED YOUTH

Mikah C. Owen, MD, MPH, FAAP; Stephenie B. Wallace, MD, MSPH, FAAP; and Committee on Adolescence

ABSTRACT. Children and adolescents who become involved with the justice system often do so with complex medical, mental health, developmental, social, and legal needs. Most have been exposed to childhood trauma or adversity, which both contribute to their involvement with the justice system and negatively impact their health and well-being. Whether youth are held in confinement or in their home communities, pediatricians play a critical role in promoting the health and well-being of justice-involved youth. Having a working knowledge of the juvenile justice system and common issues facing justice-involved youth may help pediatricians enhance their clinical care and advocacy efforts. This policy statement is a revision of the 2011 policy "Health Care for Youth in the Juvenile Justice System." It provides an overview of the juvenile justice system, describes racial bias and overrepresentation of youth of color in the justice system, reviews the health and mental health status of justice-involved youth, and identifies advocacy opportunities for juvenile justice reform. (6/20)
See full text on page 559.
https://pediatrics.aappublications.org/content/146/1/e20201755

ADVOCACY FOR IMPROVING NUTRITION IN THE FIRST 1000 DAYS TO SUPPORT CHILDHOOD DEVELOPMENT AND ADULT HEALTH

Sarah Jane Schwarzenberg, MD, FAAP; Michael K. Georgieff, MD, FAAP; and Committee on Nutrition

ABSTRACT. Maternal prenatal nutrition and the child's nutrition in the first 2 years of life (1000 days) are crucial factors in a child's neurodevelopment and lifelong mental health. Child and adult health risks, including obesity, hypertension, and diabetes, may be programmed by nutritional status during this period. Calories are essential for growth of both fetus and child but are not sufficient for normal brain development. Although all nutrients are necessary for brain growth, key nutrients that support neurodevelopment include protein; zinc; iron; choline; folate; iodine; vitamins A, D, B_6, and B_{12}; and long-chain polyunsaturated fatty acids. Failure to provide key nutrients during this critical period of brain development may result in lifelong deficits in brain function despite subsequent nutrient repletion. Understanding the complex interplay of micro- and macronutrients and neurodevelopment is key to moving beyond simply recommending a "good diet" to optimizing nutrient delivery for the developing child. Leaders in pediatric health and policy

makers must be aware of this research given its implications for public policy at the federal and state level. Pediatricians should refer to existing services for nutrition support for pregnant and breastfeeding women, infants, and toddlers. Finally, all providers caring for children can advocate for healthy diets for mothers, infants, and young children in the first 1000 days. Prioritizing public policies that ensure the provision of adequate nutrients and healthy eating during this crucial time would ensure that all children have an early foundation for optimal neurodevelopment, a key factor in long-term health. (1/18)
http://pediatrics.aappublications.org/content/141/2/e20173716

ADVOCATING FOR LIFE SUPPORT TRAINING OF CHILDREN, PARENTS, CAREGIVERS, SCHOOL PERSONNEL, AND THE PUBLIC

James M. Callahan, MD, FAAP; Susan M. Fuchs, MD, FAAP; and Committee on Pediatric Emergency Medicine

ABSTRACT. Out-of-hospital cardiac arrest occurs frequently among people of all ages, including more than 6000 children annually. Pediatric cardiac arrest in the out-of-hospital setting is a stressful event for family, friends, caregivers, classmates, school personnel, and witnesses. Immediate bystander cardiopulmonary resuscitation and the use of automated external defibrillators are associated with improved survival in adults. There is some evidence in which improved survival in children who receive immediate bystander cardiopulmonary resuscitation is shown. Pediatricians, in their role as advocates to improve the health of all children, are uniquely positioned to strongly encourage the training of children, parents, caregivers, school personnel, and the lay public in the provision of basic life support, including pediatric basic life support, as well as the appropriate use of automated external defibrillators. (5/18)
http://pediatrics.aappublications.org/content/141/6/e20180704

ADVOCATING FOR LIFE SUPPORT TRAINING OF CHILDREN, PARENTS, CAREGIVERS, SCHOOL PERSONNEL, AND THE PUBLIC (TECHNICAL REPORT)

Susan M. Fuchs, MD, FAAP, and Committee on Pediatric Emergency Medicine

ABSTRACT. Pediatric cardiac arrest in the out-of-hospital setting is a traumatic event for family, friends, caregivers, classmates, and school personnel. Immediate bystander cardiopulmonary resuscitation and the use of automatic external defibrillators have been shown to improve survival in adults. There is some evidence to show improved survival in children who receive immediate bystander cardiopulmonary resuscitation. Pediatricians, in their role as advocates to improve the health of all children, are uniquely positioned to strongly encourage the training of children, parents, caregivers, school personnel, and the lay public in the provision of basic life support, including pediatric basic life support, as well as the appropriate use of automated external defibrillators. (5/18)
http://pediatrics.aappublications.org/content/141/6/e20180705

AGE LIMIT OF PEDIATRICS

Amy Peykoff Hardin, MD, FAAP; Jesse M. Hackell, MD, FAAP; and Committee on Practice and Ambulatory Medicine

ABSTRACT. Pediatrics is a multifaceted specialty that encompasses children's physical, psychosocial, developmental, and mental health. Pediatric care may begin periconceptionally and continues through gestation, infancy, childhood, adolescence, and young adulthood. Although adolescence and young adulthood are recognizable phases of life, an upper age limit is not easily demarcated and varies depending on the individual patient. The establishment of arbitrary age limits on pediatric care by health care providers should be discouraged. The decision to continue care with a pediatrician or pediatric medical or surgical subspecialist should be made solely by the patient (and family, when appropriate) and the physician and must take into account the physical and psychosocial needs of the patient and the abilities of the pediatric provider to meet these needs. (8/17)
http://pediatrics.aappublications.org/content/140/3/e20172151

AGE TERMINOLOGY DURING THE PERINATAL PERIOD

Committee on Fetus and Newborn

ABSTRACT. Consistent definitions to describe the length of gestation and age in neonates are needed to compare neurodevelopmental, medical, and growth outcomes. The purposes of this policy statement are to review conventional definitions of age during the perinatal period and to recommend use of standard terminology including gestational age, postmenstrual age, chronological age, corrected age, adjusted age, and estimated date of delivery. (11/04, reaffirmed 10/07, 11/08, 7/14)
http://pediatrics.aappublications.org/content/114/5/1362

ALCOHOL USE BY YOUTH

Joanna Quigley, MD, FAAP, and Committee on Substance Use and Prevention

ABSTRACT. Alcohol use continues to be problematic for youth and young adults in the United States. Understanding of neurobiology and neuroplasticity continues to highlight the potential adverse impact of underage drinking on the developing brain. This policy statement provides the position of the American Academy of Pediatrics on the issue of alcohol and is supported by an accompanying technical report. (6/19)
https://pediatrics.aappublications.org/content/144/1/e20191356

ALCOHOL USE BY YOUTH (TECHNICAL REPORT)

Sheryl A. Ryan, MD, FAAP; Patricia Kokotailo, MD, MPH, FAAP; and Committee on Substance Use and Prevention

ABSTRACT. Alcohol use continues to be a major concern from preadolescence through young adulthood in the United States. Results of recent neuroscience research have helped to elucidate neurobiological models of addiction, substantiated the deleterious effects of alcohol on adolescent brain development, and added additional evidence to support the call to prevent and reduce underage drinking. This technical report reviews the relevant literature and supports the accompanying policy statement in this issue of *Pediatrics.* (6/19)
https://pediatrics.aappublications.org/content/144/1/e20191357

ALLERGY TESTING IN CHILDHOOD: USING ALLERGEN-SPECIFIC IGE TESTS (CLINICAL REPORT)

Scott H. Sicherer, MD; Robert A. Wood, MD; and Section on Allergy and Immunology

ABSTRACT. A variety of triggers can induce common pediatric allergic diseases which include asthma, allergic rhinitis, atopic dermatitis, food allergy, and anaphylaxis. Allergy testing serves to confirm an allergic trigger suspected on the basis of history. Tests for allergen-specific immunoglobulin E (IgE) are performed by in vitro assays or skin tests. The tests are excellent for identifying a sensitized state in which allergen-specific IgE is present, and may identify triggers to be eliminated and help guide immunotherapy treatment. However, a positive test result does not always equate with clinical allergy. Newer enzymatic assays based on anti-IgE antibodies have supplanted the radioallergosorbent test (RAST). This clinical report focuses on allergen-specific IgE testing, emphasizing that the medical history and knowledge of disease characteristics are crucial for rational test selection and interpretation. (12/11)
http://pediatrics.aappublications.org/content/129/1/193

ALL-TERRAIN VEHICLE INJURY PREVENTION: TWO-, THREE-, AND FOUR-WHEELED UNLICENSED MOTOR VEHICLES

Committee on Injury and Poison Prevention

ABSTRACT. Since 1987, the American Academy of Pediatrics (AAP) has had a policy about the use of motorized cycles and all-terrain vehicles (ATVs) by children. The purpose of this policy statement is to update and strengthen previous policy. This statement describes the various kinds of motorized cycles and ATVs and outlines the epidemiologic characteristics of deaths and injuries related to their use by children in light of the 1987 consent decrees entered into by the US Consumer Product Safety Commission and the manufacturers of ATVs. Recommendations are made for public, patient, and parent education by pediatricians; equipment modifications; the use of safety equipment; and the development and improvement of safer off-road trails and responsive emergency medical systems. In addition, the AAP strengthens its recommendation for passage of legislation in all states prohibiting the use of 2- and 4-wheeled off-road vehicles by children younger than 16 years, as well as a ban on the sale of new and used 3-wheeled ATVs, with a recall of all used 3-wheeled ATVs. (6/00, reaffirmed 5/04, 1/07, 5/13, 11/19)

http://pediatrics.aappublications.org/content/105/6/1352

ALUMINUM EFFECTS IN INFANTS AND CHILDREN

Mark R. Corkins, MD, FAAP, and Committee on Nutrition

ABSTRACT. Aluminum has no known biological function; however, it is a contaminant present in most foods and medications. Aluminum is excreted by the renal system, and patients with renal diseases should avoid aluminum-containing medications. Studies demonstrating long-term toxicity from the aluminum content in parenteral nutrition components led the US Food and Drug Administration to implement rules for these solutions. Large-volume ingredients were required to reduce the aluminum concentration, and small-volume components were required to be labeled with the aluminum concentration. Despite these rules, the total aluminum concentration from some components continues to be above the recommended final concentration. The concerns about toxicity from the aluminum present in infant formulas and antiperspirants have not been substantiated but require more research. Aluminum is one of the most effective adjuvants used in vaccines, and a large number of studies have documented minimal adverse effects from this use. Long-term, high-concentration exposure to aluminum has been linked in meta-analyses with the development of Alzheimer disease. (11/19)

https://pediatrics.aappublications.org/content/144/6/e20193148

AMBIENT AIR POLLUTION: HEALTH HAZARDS TO CHILDREN

Committee on Environmental Health

ABSTRACT. Ambient (outdoor) air pollution is now recognized as an important problem, both nationally and worldwide. Our scientific understanding of the spectrum of health effects of air pollution has increased, and numerous studies are finding important health effects from air pollution at levels once considered safe. Children and infants are among the most susceptible to many of the air pollutants. In addition to associations between air pollution and respiratory symptoms, asthma exacerbations, and asthma hospitalizations, recent studies have found links between air pollution and preterm birth, infant mortality, deficits in lung growth, and possibly, development of asthma. This policy statement summarizes the recent literature linking ambient air pollution to adverse health outcomes in children and includes a perspective on the current regulatory process. The statement provides advice to pediatricians on how to integrate issues regarding air quality and health into patient education and children's environmental health advocacy and concludes with recommendations to the government on promotion of effective air-pollution policies to ensure protection of children's health. (12/04, reaffirmed 4/09)

http://pediatrics.aappublications.org/content/114/6/1699

ANTENATAL COUNSELING REGARDING RESUSCITATION AND INTENSIVE CARE BEFORE 25 WEEKS OF GESTATION (CLINICAL REPORT)

James Cummings, MD, FAAP, and Committee on Fetus and Newborn

ABSTRACT. The anticipated birth of an extremely low gestational age (<25 weeks) infant presents many difficult questions, and variations in practice continue to exist. Decisions regarding care of periviable infants should ideally be well informed, ethically sound, consistent within medical teams, and consonant with the parents' wishes. Each health care institution should consider having policies and procedures for antenatal counseling in these situations. Family counseling may be aided by the use of visual materials, which should take into consideration the intellectual, cultural, and other characteristics of the family members. Although general recommendations can guide practice, each situation is unique; thus, decision-making should be individualized. In most cases, the approach should be shared decision-making with the family, guided by considering both the likelihood of death or morbidity and the parents' desires for their unborn child. If a decision is made not to resuscitate, providing comfort care, encouraging family bonding, and palliative care support are appropriate. (8/15)

http://pediatrics.aappublications.org/content/136/3/588

ANTERIOR CRUCIATE LIGAMENT INJURIES: DIAGNOSIS, TREATMENT, AND PREVENTION (CLINICAL REPORT)

Cynthia R. LaBella, MD, FAAP; William Hennrikus, MD, FAAP; Timothy E. Hewett, PhD, FACSM; Council on Sports Medicine and Fitness; and Section on Orthopaedics

ABSTRACT. The number of anterior cruciate ligament (ACL) injuries reported in athletes younger than 18 years has increased over the past 2 decades. Reasons for the increasing ACL injury rate include the growing number of children and adolescents participating in organized sports, intensive sports training at an earlier age, and greater rate of diagnosis because of increased awareness and greater use of advanced medical imaging. ACL injury rates are low in young children and increase sharply during puberty, especially for girls, who have higher rates of noncontact ACL injuries than boys do in similar sports. Intrinsic risk factors for ACL injury include higher BMI, subtalar joint overpronation, generalized ligamentous laxity, and decreased neuromuscular control of knee motion. ACL injuries often require surgery and/or many months of rehabilitation and substantial time lost from school and sports participation. Unfortunately, regardless of treatment, athletes with ACL injuries are up to 10 times more likely to develop degenerative arthritis of the knee. Safe and effective surgical techniques for children and adolescents continue to evolve. Neuromuscular training can reduce risk of ACL injury in adolescent girls. This report outlines the current state of knowledge on epidemiology, diagnosis, treatment, and prevention of ACL injuries in children and adolescents. (4/14, reaffirmed 7/18)

http://pediatrics.aappublications.org/content/133/5/e1437

THE APGAR SCORE

Committee on Fetus and Newborn (joint with American College of Obstetricians and Gynecologists Committee on Obstetric Practice)

ABSTRACT. The Apgar score provides an accepted and convenient method for reporting the status of the newborn infant immediately after birth and the response to resuscitation if needed. The Apgar score alone cannot be considered as evidence

of, or a consequence of, asphyxia; does not predict individual neonatal mortality or neurologic outcome; and should not be used for that purpose. An Apgar score assigned during resuscitation is not equivalent to a score assigned to a spontaneously breathing infant. The American Academy of Pediatrics and the American College of Obstetricians and Gynecologists encourage use of an expanded Apgar score reporting form that accounts for concurrent resuscitative interventions. (9/15)
http://pediatrics.aappublications.org/content/136/4/819

APNEA OF PREMATURITY (CLINICAL REPORT)

Eric C. Eichenwald, MD, FAAP, and Committee on Fetus and Newborn

ABSTRACT. Apnea of prematurity is one of the most common diagnoses in the NICU. Despite the frequency of apnea of prematurity, it is unknown whether recurrent apnea, bradycardia, and hypoxemia in preterm infants are harmful. Research into the development of respiratory control in immature animals and preterm infants has facilitated our understanding of the pathogenesis and treatment of apnea of prematurity. However, the lack of consistent definitions, monitoring practices, and consensus about clinical significance leads to significant variation in practice. The purpose of this clinical report is to review the evidence basis for the definition, epidemiology, and treatment of apnea of prematurity as well as discharge recommendations for preterm infants diagnosed with recurrent apneic events. (12/15)
http://pediatrics.aappublications.org/content/137/1/e20153757

ASSESSMENT AND MANAGEMENT OF INGUINAL HERNIA IN INFANTS (CLINICAL REPORT)

Kasper S. Wang, MD; Committee on Fetus and Newborn; and Section on Surgery

ABSTRACT. Inguinal hernia repair in infants is a routine surgical procedure. However, numerous issues, including timing of the repair, the need to explore the contralateral groin, use of laparoscopy, and anesthetic approach, remain unsettled. Given the lack of compelling data, consideration should be given to large, prospective, randomized controlled trials to determine best practices for the management of inguinal hernias in infants. (9/12)
http://pediatrics.aappublications.org/content/130/4/768

ATOPIC DERMATITIS: SKIN-DIRECTED MANAGEMENT (CLINICAL REPORT)

Megha M. Tollefson, MD; Anna L. Bruckner, MD, FAAP; and Section on Dermatology

ABSTRACT. Atopic dermatitis is a common inflammatory skin condition characterized by relapsing eczematous lesions in a typical distribution. It can be frustrating for pediatric patients, parents, and health care providers alike. The pediatrician will treat the majority of children with atopic dermatitis as many patients will not have access to a pediatric medical subspecialist, such as a pediatric dermatologist or pediatric allergist. This report provides up-to-date information regarding the disease and its impact, pathogenesis, treatment options, and potential complications. The goal of this report is to assist pediatricians with accurate and useful information that will improve the care of patients with atopic dermatitis. (11/14)
http://pediatrics.aappublications.org/content/134/6/e1735

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER AND SUBSTANCE ABUSE (CLINICAL REPORT)

Elizabeth Harstad, MD, MPH, FAAP; Sharon Levy, MD, MPH, FAAP; and Committee on Substance Abuse

ABSTRACT. Attention-deficit/hyperactivity disorder (ADHD) and substance use disorders are inextricably intertwined. Children with ADHD are more likely than peers to develop substance use disorders. Treatment with stimulants may reduce the risk of substance use disorders, but stimulants are a class of medication with significant abuse and diversion potential. The objectives of this clinical report were to present practical strategies for reducing the risk of substance use disorders in patients with ADHD and suggestions for safe stimulant prescribing. (6/14, reaffirmed 10/20)
http://pediatrics.aappublications.org/content/134/1/e293

BARRIER PROTECTION USE BY ADOLESCENTS DURING SEXUAL ACTIVITY

Laura K. Grubb, MD, MPH, FAAP, and Committee on Adolescence

ABSTRACT. Rates of sexual activity, pregnancies, and births among adolescents have continued to decline during the past decade to historic lows. Despite these positive trends, many adolescents remain at risk for unintended pregnancy and sexually transmitted infections (STIs). When used consistently and correctly, latex and synthetic barrier methods reduce the risk of many STIs, including HIV, and pregnancy. This update of the 2013 policy statement is intended to assist pediatricians in understanding and supporting the use of barrier methods by their patients to prevent unintended pregnancies and STIs and address obstacles to their use. (7/20)
See full text on page 581.
https://pediatrics.aappublications.org/content/146/2/e2020007237

BARRIER PROTECTION USE BY ADOLESCENTS DURING SEXUAL ACTIVITY (TECHNICAL REPORT)

Laura K. Grubb, MD, MPH, FAAP, and Committee on Adolescence

ABSTRACT. Rates of sexual activity, pregnancies, and births among adolescents have continued to decline during the past decade to historic lows. Despite these positive trends, many adolescents remain at risk for unintended pregnancy and sexually transmitted infections (STIs). This technical report discusses the new data and trends in adolescent sexual behavior and barrier protection use. Since 2017, STI rates have increased and use of barrier methods, specifically external condom use, has declined among adolescents and young adults. Interventions that increase availability of or accessibility to barrier methods are most efficacious when combined with additional individual, small-group, or community-level activities that include messages about safer sex. Continued research informs public health interventions for adolescents that increase the consistent and correct use of barrier methods and promote dual protection of barrier methods for STI prevention together with other effective methods of contraception. (7/20)
See full text on page 587.
https://pediatrics.aappublications.org/content/146/2/e2020007245

BEST PRACTICES FOR IMPROVING FLOW AND CARE OF PEDIATRIC PATIENTS IN THE EMERGENCY DEPARTMENT (TECHNICAL REPORT)

Isabel A. Barata, MD, FACEP; Kathleen M. Brown, MD, FACEP; Laura Fitzmaurice, MD, FACEP, FAAP; Elizabeth Stone Griffin, RN; Sally K. Snow, BSN, RN; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. This report provides a summary of best practices for improving flow, reducing waiting times, and improving the quality of care of pediatric patients in the emergency department. (12/14, reaffirmed 7/20)
http://pediatrics.aappublications.org/content/135/1/e273

BICYCLE HELMETS

Committee on Injury and Poison Prevention

ABSTRACT. Bicycling remains one of the most popular recreational sports among children in America and is the leading cause of recreational sports injuries treated in emergency departments. An estimated 23 000 children younger than 21 years sus-

tained head injuries (excluding the face) while bicycling in 1998. The bicycle helmet is a very effective device that can prevent the occurrence of up to 88% of serious brain injuries. Despite this, most children do not wear a helmet each time they ride a bicycle, and adolescents are particularly resistant to helmet use. Recently, a group of national experts and government agencies renewed the call for all bicyclists to wear helmets. This policy statement describes the role of the pediatrician in helping attain universal helmet use among children and teens for each bicycle ride. (10/01, reaffirmed 1/05, 2/08, 11/11)
http://pediatrics.aappublications.org/content/108/4/1030

BINGE DRINKING (CLINICAL REPORT)

Lorena Siqueira, MD, MSPH, FAAP; Vincent C. Smith, MD, MPH, FAAP; and Committee on Substance Abuse

ABSTRACT. Alcohol is the substance most frequently abused by children and adolescents in the United States, and its use is associated with the leading causes of death and serious injury at this age (ie, motor vehicle accidents, homicides, and suicides). Among youth who drink, the proportion who drink heavily is higher than among adult drinkers, increasing from approximately 50% in those 12 to 14 years of age to 72% among those 18 to 20 years of age. In this clinical report, the definition, epidemiology, and risk factors for binge drinking; the neurobiology of intoxication, blackouts, and hangovers; genetic considerations; and adverse outcomes are discussed. The report offers guidance for the pediatrician. As with any high-risk behavior, prevention plays a more important role than later intervention and has been shown to be more effective. In the pediatric office setting, it is important to ask every adolescent about alcohol use. (8/15)
http://pediatrics.aappublications.org/content/136/3/e718

BONE DENSITOMETRY IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Laura K. Bachrach, MD; Catherine M. Gordon, MD, MS; and Section on Endocrinology

ABSTRACT. Concerns about bone health and potential fragility in children and adolescents have led to a high interest in bone densitometry. Pediatric patients with genetic and acquired chronic diseases, immobility, and inadequate nutrition may fail to achieve expected gains in bone size, mass, and strength, leaving them vulnerable to fracture. In older adults, bone densitometry has been shown to predict fracture risk and reflect response to therapy. The role of densitometry in the management of children at risk of bone fragility is less clear. This clinical report summarizes current knowledge about bone densitometry in the pediatric population, including indications for its use, interpretation of results, and risks and costs. The report emphasizes updated consensus statements generated at the 2013 Pediatric Position Development Conference of the International Society of Clinical Densitometry by an international panel of bone experts. Some of these recommendations are evidence-based, whereas others reflect expert opinion, because data are sparse on many topics. The statements from this and other expert panels provide general guidance to the pediatrician, but decisions about ordering and interpreting bone densitometry still require clinical judgment. The interpretation of bone densitometry results in children differs from that in older adults. The terms "osteopenia" and "osteoporosis" based on bone densitometry findings alone should not be used in younger patients; instead, bone mineral content or density that falls >2 SDs below expected is labeled "low for age." Pediatric osteoporosis is defined by the Pediatric Position Development Conference by using 1 of the following criteria: ≥1 vertebral fractures occurring in the absence of local disease or high-energy trauma (without or with densitometry measurements) or low bone density for age and a significant fracture history (defined as ≥2 long bone fractures before 10 years of age or ≥3 long bone fractures before 19 years of age). Ongoing research will help define the indications and best methods for assessing bone strength in children and the clinical factors that contribute to fracture risk. The Pediatric Endocrine Society affirms the educational value of this publication. (9/16)
http://pediatrics.aappublications.org/content/138/4/e20162398

BOXING PARTICIPATION BY CHILDREN AND ADOLESCENTS

Council on Sports Medicine and Fitness (joint with Canadian Paediatric Society Healthy Active Living and Sports Medicine Committee)

ABSTRACT. Thousands of boys and girls younger than 19 years participate in boxing in North America. Although boxing provides benefits for participants, including exercise, self-discipline, and self-confidence, the sport of boxing encourages and rewards deliberate blows to the head and face. Participants in boxing are at risk of head, face, and neck injuries, including chronic and even fatal neurologic injuries. Concussions are one of the most common injuries that occur with boxing. Because of the risk of head and facial injuries, the American Academy of Pediatrics and the Canadian Paediatric Society oppose boxing as a sport for children and adolescents. These organizations recommend that physicians vigorously oppose boxing in youth and encourage patients to participate in alternative sports in which intentional head blows are not central to the sport. (8/11, reaffirmed 2/15, 3/20)
http://pediatrics.aappublications.org/content/128/3/617

BREASTFEEDING AND THE USE OF HUMAN MILK

Section on Breastfeeding

ABSTRACT. Breastfeeding and human milk are the normative standards for infant feeding and nutrition. Given the documented short- and long-term medical and neurodevelopmental advantages of breastfeeding, infant nutrition should be considered a public health issue and not only a lifestyle choice. The American Academy of Pediatrics reaffirms its recommendation of exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant. Medical contraindications to breastfeeding are rare. Infant growth should be monitored with the World Health Organization (WHO) Growth Curve Standards to avoid mislabeling infants as underweight or failing to thrive. Hospital routines to encourage and support the initiation and sustaining of exclusive breastfeeding should be based on the American Academy of Pediatrics-endorsed WHO/UNICEF "Ten Steps to Successful Breastfeeding." National strategies supported by the US Surgeon General's Call to Action, the Centers for Disease Control and Prevention, and The Joint Commission are involved to facilitate breastfeeding practices in US hospitals and communities. Pediatricians play a critical role in their practices and communities as advocates of breastfeeding and thus should be knowledgeable about the health risks of not breastfeeding, the economic benefits to society of breastfeeding, and the techniques for managing and supporting the breastfeeding dyad. The "Business Case for Breastfeeding" details how mothers can maintain lactation in the workplace and the benefits to employers who facilitate this practice. (2/12)
http://pediatrics.aappublications.org/content/129/3/e827

THE BREASTFEEDING-FRIENDLY PEDIATRIC OFFICE PRACTICE (CLINICAL REPORT)

Joan Younger Meek, MD, MS, RD, FAAP, IBCLC; Amy J. Hatcher, MD, FAAP; and Section on Breastfeeding

ABSTRACT. The landscape of breastfeeding has changed over the past several decades as more women initiate breastfeeding in the postpartum period and more hospitals are designated as Baby-Friendly Hospitals by following the evidence-based Ten

Steps to Successful Breastfeeding. The number of births in such facilities has increased more than sixfold over the past decade. With more women breastfeeding and stays in the maternity facilities lasting only a few days, the vast majority of continued breastfeeding support occurs in the community. Pediatric care providers evaluate breastfeeding infants and their mothers in the office setting frequently during the first year of life. The office setting should be conducive to providing ongoing breastfeeding support. Likewise, the office practice should avoid creating barriers for breastfeeding mothers and families or unduly promoting infant formula. This clinical report aims to review practices shown to support breastfeeding that can be implemented in the outpatient setting, with the ultimate goal of increasing the duration of exclusive breastfeeding and the continuation of any breastfeeding. (4/17)
http://pediatrics.aappublications.org/content/139/5/e20170647

THE BUILT ENVIRONMENT: DESIGNING COMMUNITIES TO PROMOTE PHYSICAL ACTIVITY IN CHILDREN

Committee on Environmental Health

ABSTRACT. An estimated 32% of American children are overweight, and physical inactivity contributes to this high prevalence of overweight. This policy statement highlights how the built environment of a community affects children's opportunities for physical activity. Neighborhoods and communities can provide opportunities for recreational physical activity with parks and open spaces, and policies must support this capacity. Children can engage in physical activity as a part of their daily lives, such as on their travel to school. Factors such as school location have played a significant role in the decreased rates of walking to school, and changes in policy may help to increase the number of children who are able to walk to school. Environment modification that addresses risks associated with automobile traffic is likely to be conducive to more walking and biking among children. Actions that reduce parental perception and fear of crime may promote outdoor physical activity. Policies that promote more active lifestyles among children and adolescents will enable them to achieve the recommended 60 minutes of daily physical activity. By working with community partners, pediatricians can participate in establishing communities designed for activity and health. (5/09, reaffirmed 1/13)
http://pediatrics.aappublications.org/content/123/6/1591

CALCIUM AND VITAMIN D REQUIREMENTS OF ENTERALLY FED PRETERM INFANTS (CLINICAL REPORT)

Steven A. Abrams, MD, and Committee on Nutrition

ABSTRACT. Bone health is a critical concern in managing preterm infants. Key nutrients of importance are calcium, vitamin D, and phosphorus. Although human milk is critical for the health of preterm infants, it is low in these nutrients relative to the needs of the infants during growth. Strategies should be in place to fortify human milk for preterm infants with birth weight <1800 to 2000 g and to ensure adequate mineral intake during hospitalization and after hospital discharge. Biochemical monitoring of very low birth weight infants should be performed during their hospitalization. Vitamin D should be provided at 200 to 400 IU/day both during hospitalization and after discharge from the hospital. Infants with radiologic evidence of rickets should have efforts made to maximize calcium and phosphorus intake by using available commercial products and, if needed, direct supplementation with these minerals. (4/13)
http://pediatrics.aappublications.org/content/131/5/e1676

CARDIOVASCULAR MONITORING AND STIMULANT DRUGS FOR ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

James M. Perrin, MD; Richard A. Friedman, MD; Timothy K. Knilans, MD; Black Box Working Group; and Section on Cardiology and Cardiac Surgery

ABSTRACT. A recent American Heart Association (AHA) statement recommended electrocardiograms (ECGs) routinely for children before they start medications to treat attention-deficit/hyperactivity disorder (ADHD). The AHA statement reflected the thoughtful work of a group committed to improving the health of children with heart disease. However, the recommendation to obtain an ECG before starting medications for treating ADHD contradicts the carefully considered and evidence-based recommendations of the American Academy of Child and Adolescent Psychiatry and the American Academy of Pediatrics (AAP). These organizations have concluded that sudden cardiac death (SCD) in persons taking medications for ADHD is a very rare event, occurring at rates no higher than those in the general population of children and adolescents. Both of these groups also noted the lack of any evidence that the routine use of ECG screening before beginning medication for ADHD treatment would prevent sudden death. The AHA statement pointed out the importance of detecting silent but clinically important cardiac conditions in children and adolescents, which is a goal that the AAP shares. The primary purpose of the AHA statement is to prevent cases of SCD that may be related to stimulant medications. The recommendations of the AAP and the rationale for these recommendations are the subject of this statement. (8/08)
http://pediatrics.aappublications.org/content/122/2/451

CARE OF ADOLESCENT PARENTS AND THEIR CHILDREN (CLINICAL REPORT)

Jorge L. Pinzon, MD; Veronnie F. Jones, MD; Committee on Adolescence; and Committee on Early Childhood

ABSTRACT. Teen pregnancy and parenting remain an important public health issue in the United States and the world, and many children live with their adolescent parents alone or as part of an extended family. A significant proportion of teen parents reside with their family of origin, significantly affecting the multigenerational family structure. Repeated births to teen parents are also common. This clinical report updates a previous policy statement on care of the adolescent parent and their children and addresses medical and psychosocial risks specific to this population. Challenges unique to teen parents and their children are reviewed, along with suggestions for the pediatrician on models for intervention and care. (11/12, reaffirmed 7/16)
http://pediatrics.aappublications.org/content/130/6/e1743

THE CARE OF CHILDREN WITH CONGENITAL HEART DISEASE IN THEIR PRIMARY MEDICAL HOME

M. Regina Lantin-Hermoso, MD, FAAP, FACC; Stuart Berger, MD, FAAP; Ami B. Bhatt, MD, FACC; Julia E. Richerson, MD, FAAP; Robert Morrow, MD, FAAP; Michael D. Freed, MD, FAAP, FACC; Robert H. Beekman III, MD, FAAP, FACC; and Section on Cardiology and Cardiac Surgery

ABSTRACT. Congenital heart disease (CHD) is the most common birth anomaly. With advances in repair and palliation of these complex lesions, more and more patients are surviving and are discharged from the hospital to return to their families. Patients with CHD have complex health care needs that often must be provided for or coordinated for by the primary care provider (PCP) and medical home. This policy statement aims to provide the PCP with general guidelines for the care of the child with congenital heart defects and outlines anticipated problems, serving as a repository of current knowledge in a practical, read-

ily accessible format. A timeline approach is used, emphasizing the role of the PCP and medical home in the management of patients with CHD in their various life stages. (10/17)
http://pediatrics.aappublications.org/content/140/5/e20172607

CARE OF THE ADOLESCENT AFTER AN ACUTE SEXUAL ASSAULT (CLINICAL REPORT)

James E. Crawford-Jakubiak, MD, FAAP; Elizabeth M. Alderman, MD, FAAP, SAHM; John M. Leventhal, MD, FAAP; Committee on Child Abuse and Neglect; and Committee on Adolescence

ABSTRACT. Sexual violence is a broad term that encompasses a wide range of sexual victimizations. Since the American Academy of Pediatrics published its last policy statement on sexual assault in 2008, additional information and data have emerged about sexual violence affecting adolescents and the treatment and management of the adolescent who has been a victim of sexual assault. This report provides new information to update physicians and focuses on the acute assessment and care of adolescent victims who have experienced a recent sexual assault. Follow-up of the acute assault, as well as prevention of sexual assault, are also discussed. (2/17)
http://pediatrics.aappublications.org/content/139/3/e20164243

CAREGIVER-FABRICATED ILLNESS IN A CHILD: A MANIFESTATION OF CHILD MALTREATMENT (CLINICAL REPORT)

Emalee G. Flaherty, MD, FAAP; Harriet L. MacMillan, MD; and Committee on Child Abuse and Neglect

ABSTRACT. Caregiver-fabricated illness in a child is a form of child maltreatment caused by a caregiver who falsifies and/or induces a child's illness, leading to unnecessary and potentially harmful medical investigations and/or treatment. This condition can result in significant morbidity and mortality. Although caregiver-fabricated illness in a child has been widely known as Munchausen syndrome by proxy, there is ongoing discussion about alternative names, including pediatric condition falsification, factitious disorder (illness) by proxy, child abuse in the medical setting, and medical child abuse. Because it is a relatively uncommon form of maltreatment, pediatricians need to have a high index of suspicion when faced with a persistent or recurrent illness that cannot be explained and that results in multiple medical procedures or when there are discrepancies between the history, physical examination, and health of a child. This report updates the previous clinical report "Beyond Munchausen Syndrome by Proxy: Identification and Treatment of Child Abuse in the Medical Setting." The authors discuss the need to agree on appropriate terminology, provide an update on published reports of new manifestations of fabricated medical conditions, and discuss approaches to assessment, diagnosis, and management, including how best to protect the child from further harm. (8/13, reaffirmed 8/18)
http://pediatrics.aappublications.org/content/132/3/590

CHEERLEADING INJURIES: EPIDEMIOLOGY AND RECOMMENDATIONS FOR PREVENTION

Council on Sports Medicine and Fitness

ABSTRACT. Over the last 30 years, cheerleading has increased dramatically in popularity and has evolved from leading the crowd in cheers at sporting events into a competitive, year-round sport involving complex acrobatic stunts and tumbling. Consequently, cheerleading injuries have steadily increased over the years in both number and severity. Sprains and strains to the lower extremities are the most common injuries. Although the overall injury rate remains relatively low, cheerleading has accounted for approximately 66% of all catastrophic injuries in high school girl athletes over the past 25 years. Risk factors for injuries in cheerleading include higher BMI, previous injury, cheering on harder surfaces, performing stunts, and supervision by a coach with low level of training and experience. This policy statement describes the epidemiology of cheerleading injuries and provides recommendations for injury prevention. (10/12, reaffirmed 7/15)
http://pediatrics.aappublications.org/content/130/5/966

CHEMICAL-BIOLOGICAL TERRORISM AND ITS IMPACT ON CHILDREN

Sarita Chung, MD, FAAP; Carl R. Baum, MD, FACMT, FAAP; Ann-Christine Nyquist, MD, MSPH, FAAP; Disaster Preparedness Advisory Council; Council on Environmental Health; and Committee on Infectious Diseases

ABSTRACT. Chemical and biological events (including infectious disease outbreaks) may affect children disproportionately, and the threat of a chemical or biological attack remains in the United States and worldwide. Although federal programs and funding support a broad range of federal initiatives for public health preparedness and response, funding at the state and local levels has been flat or is decreasing, potentially leaving communities vulnerable. Consequently, pediatricians need to prepare and be ready to care for children in their communities before, during, and after a chemical or biological event, including during long-term recovery. Some medical countermeasures for particular chemical and biological agents have not been adequately studied or approved for children. The American Academy of Pediatrics provides resources and education on disaster preparedness and response, including information on the pediatrician's role in disasters, pediatric medical countermeasures, and mental health after an event as well as individual and family preparedness. This policy statement addresses the steps that clinicians and policy makers can take to protect children and mitigate the effects of a chemical or biological attack. (1/20)
See full text on page 603.
https://pediatrics.aappublications.org/content/145/2/e20193749

CHEMICAL-BIOLOGICAL TERRORISM AND ITS IMPACT ON CHILDREN (TECHNICAL REPORT)

Sarita Chung, MD, FAAP; Carl R. Baum, MD, FACMT, FAAP; Ann-Christine Nyquist, MD, MSPH, FAAP; Disaster Preparedness Advisory Council; Council on Environmental Health; and Committee on Infectious Diseases

ABSTRACT. Children are potential victims of chemical or biological terrorism. In recent years, children have been victims of terrorist acts such as the chemical attacks (2017–2018) in Syria. Consequently, it is necessary to prepare for and respond to the needs of children after a chemical or biological attack. A broad range of public health initiatives have occurred since the terrorist attacks of September 11, 2001. However, in many cases, these initiatives have not ensured the protection of children. Since 2001, public health preparedness has broadened to an all-hazards approach, in which response plans for terrorism are blended with those for unintentional disasters or outbreaks (eg, natural events such as earthquakes or pandemic influenza or man-made catastrophes such as a hazardous-materials spill). In response to new principles and programs that have evolved over the last decade, this technical report supports the accompanying update of the American Academy of Pediatrics 2006 policy statement "Chemical-Biological Terrorism and its Impact on Children." The roles of the pediatrician and public health agencies continue to evolve, and only their coordinated readiness and response efforts will ensure that the medical and mental health needs of children will be met successfully. In this document, we will address chemical and biological incidents. Radiation disasters are addressed separately. (1/20)
See full text on page 613.
https://pediatrics.aappublications.org/content/145/2/e20193750

CHEMICAL-MANAGEMENT POLICY: PRIORITIZING CHILDREN'S HEALTH

Council on Environmental Health

ABSTRACT. The American Academy of Pediatrics recommends that chemical-management policy in the United States be revised to protect children and pregnant women and to better protect other populations. The Toxic Substance Control Act (TSCA) was passed in 1976. It is widely recognized to have been ineffective in protecting children, pregnant women, and the general population from hazardous chemicals in the marketplace. It does not take into account the special vulnerabilities of children in attempting to protect the population from chemical hazards. Its processes are so cumbersome that in its more than 30 years of existence, the TSCA has been used to regulate only 5 chemicals or chemical classes of the tens of thousands of chemicals that are in commerce. Under the TSCA, chemical companies have no responsibility to perform premarket testing or postmarket follow-up of the products that they produce; in fact, the TSCA contains disincentives for the companies to produce such data. Voluntary programs have been inadequate in resolving problems. Therefore, chemical-management policy needs to be rewritten in the United States. Manufacturers must be responsible for developing information about chemicals before marketing. The US Environmental Protection Agency must have the authority to demand additional safety data about a chemical and to limit or stop the marketing of a chemical when there is a high degree of suspicion that the chemical might be harmful to children, pregnant women, or other populations. (4/11, reaffirmed 9/16)

http://pediatrics.aappublications.org/content/127/5/983

CHILD ABUSE, CONFIDENTIALITY, AND THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

Committee on Child Abuse and Neglect

ABSTRACT. The federal Health Insurance Portability and Accountability Act (HIPAA) of 1996 has significantly affected clinical practice, particularly with regard to how patient information is shared. HIPAA addresses the security and privacy of patient health data, ensuring that information is released appropriately with patient or guardian consent and knowledge. However, when child abuse or neglect is suspected in a clinical setting, the physician may determine that release of information without consent is necessary to ensure the health and safety of the child. This policy statement provides an overview of HIPAA regulations with regard to the role of the pediatrician in releasing or reviewing patient health information when the patient is a child who is a suspected victim of abuse or neglect. This statement is based on the most current regulations provided by the US Department of Health and Human Services and is subject to future changes and clarifications as updates are provided. (12/09, reaffirmed 1/14)

http://pediatrics.aappublications.org/content/125/1/197

CHILD FATALITY REVIEW

Cindy W. Christian, MD; Robert D. Sege, MD, PhD; Committee on Child Abuse and Neglect; Committee on Injury, Violence, and Poison Prevention; and Council on Community Pediatrics

ABSTRACT. Injury remains the leading cause of pediatric mortality and requires public health approaches to reduce preventable deaths. Child fatality review teams, first established to review suspicious child deaths involving abuse or neglect, have expanded toward a public health model of prevention of child fatality through systematic review of child deaths from birth through adolescence. Approximately half of all states report reviewing child deaths from all causes, and the process of fatality review has identified effective local and state prevention strategies for reducing child deaths. This expanded approach can be a powerful tool in understanding the epidemiology and preventability of child death locally, regionally, and nationally; improving accuracy of vital statistics data; and identifying public health and legislative strategies for reducing preventable child fatalities. The American Academy of Pediatrics supports the development of federal and state legislation to enhance the child fatality review process and recommends that pediatricians become involved in local and state child death reviews. (8/10, reaffirmed 5/14, 12/19)

http://pediatrics.aappublications.org/content/126/3/592

CHILD LIFE SERVICES

Committee on Hospital Care and Child Life Council

ABSTRACT. Child life programs are an important component of pediatric hospital–based care to address the psychosocial concerns that accompany hospitalization and other health care experiences. Child life specialists focus on the optimal development and well-being of infants, children, adolescents, and young adults while promoting coping skills and minimizing the adverse effects of hospitalization, health care, and/or other potentially stressful experiences. Using therapeutic play, expressive modalities, and psychological preparation as primary tools, in collaboration with the entire health care team and family, child life interventions facilitate coping and adjustment at times and under circumstances that might otherwise prove overwhelming for the child. Play and developmentally appropriate communication are used to: (1) promote optimal development; (2) educate children and families about health conditions; (3) prepare children and families for medical events or procedures; (4) plan and rehearse useful coping and pain management strategies; (5) help children work through feelings about past or impending experiences; and (6) establish therapeutic relationships with patients, siblings, and parents to support family involvement in each child's care. (4/14, reaffirmed 2/18)

http://pediatrics.aappublications.org/content/133/5/e1471

CHILD PASSENGER SAFETY

Dennis R. Durbin, MD, MSCE, FAAP; Benjamin D. Hoffman, MD, FAAP; and Council on Injury, Violence, and Poison Prevention

ABSTRACT. Child passenger safety has dramatically evolved over the past decade; however, motor vehicle crashes continue to be the leading cause of death for children 4 years and older. This policy statement provides 4 evidence-based recommendations for best practices in the choice of a child restraint system to optimize safety in passenger vehicles for children from birth through adolescence: (1) rear-facing car safety seats as long as possible; (2) forward-facing car safety seats from the time they outgrow rear-facing seats for most children through at least 4 years of age; (3) belt-positioning booster seats from the time they outgrow forward-facing seats for most children through at least 8 years of age; and (4) lap and shoulder seat belts for all who have outgrown booster seats. In addition, a fifth evidence-based recommendation is for all children younger than 13 years to ride in the rear seats of vehicles. It is important to note that every transition is associated with some decrease in protection; therefore, parents should be encouraged to delay these transitions for as long as possible. These recommendations are presented in the form of an algorithm that is intended to facilitate implementation of the recommendations by pediatricians to their patients and families and should cover most situations that pediatricians will encounter in practice. The American Academy of Pediatrics urges all pediatricians to know and promote these recommendations as part of child passenger safety anticipatory guidance at every health supervision visit. (10/18)

http://pediatrics.aappublications.org/content/142/5/e20182460

CHILD PASSENGER SAFETY (TECHNICAL REPORT)

Dennis R. Durbin, MD, MSCE, FAAP; Benjamin D. Hoffman, MD, FAAP; and Council on Injury, Violence, and Poison Prevention

ABSTRACT. Despite significant reductions in the number of children killed in motor vehicle crashes over the past decade, crashes continue to be the leading cause of death to children 4 years and older. Therefore, the American Academy of Pediatrics continues to recommend the inclusion of child passenger safety anticipatory guidance at every health supervision visit. This technical report provides a summary of the evidence in support of 5 recommendations for best practices to optimize safety in passenger vehicles for children from birth through adolescence that all pediatricians should know and promote in their routine practice. These recommendations are presented in the revised policy statement on child passenger safety in the form of an algorithm that is intended to facilitate their implementation by pediatricians with their patients and families. The algorithm is designed to cover the majority of situations that pediatricians will encounter in practice. In addition, a summary of evidence on a number of additional issues affecting the safety of children in motor vehicles, including the proper use and installation of child restraints, exposure to air bags, travel in pickup trucks, children left in or around vehicles, and the importance of restraint laws, is provided. Finally, this technical report provides pediatricians with a number of resources for additional information to use when providing anticipatory guidance to families. (10/18)

http://pediatrics.aappublications.org/content/142/5/e20182461

CHILD SEX TRAFFICKING AND COMMERCIAL SEXUAL EXPLOITATION: HEALTH CARE NEEDS OF VICTIMS (CLINICAL REPORT)

Jordan Greenbaum, MD; James E. Crawford-Jakubiak, MD, FAAP; and Committee on Child Abuse and Neglect

ABSTRACT. Child sex trafficking and commercial sexual exploitation of children (CSEC) are major public health problems in the United States and throughout the world. Despite large numbers of American and foreign youth affected and a plethora of serious physical and mental health problems associated with CSEC, there is limited information available to pediatricians regarding the nature and scope of human trafficking and how pediatricians and other health care providers may help protect children. Knowledge of risk factors, recruitment practices, possible indicators of CSEC, and common medical and behavioral health problems experienced by victims will help pediatricians recognize potential victims and respond appropriately. As health care providers, educators, and leaders in child advocacy, pediatricians play an essential role in addressing the public health issues faced by child victims of CSEC. Their roles can include working to increase recognition of CSEC, providing direct care and anticipatory guidance related to CSEC, engaging in collaborative efforts with medical and nonmedical colleagues to provide for the complex needs of youth, and educating child-serving professionals and the public. (2/15, reaffirmed 10/20)

http://pediatrics.aappublications.org/content/135/3/566

THE CHILD WITNESS IN THE COURTROOM

Robert H. Pantell, MD, FAAP, and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Beginning in the 1980s, children have increasingly served as witnesses in the criminal, civil, and family courts; currently, >100 000 children appear in court each year. This statement updates the 1992 American Academy of Pediatrics (AAP) policy statement "The Child as a Witness" and the subsequent 1999 "The Child in Court: A Subject Review." It also builds on existing AAP policy on adverse life events affecting children and resources developed to understand and address childhood trauma. The purpose of this policy statement is to provide background information on some of the legal issues involving children testifying in court, including the accuracy and psychological impact of child testimony; to provide suggestions for how pediatricians can support patients who will testify in court; and to make recommendations for policy improvements to minimize the adverse psychological consequences for child witnesses. These recommendations are, for the most part, based on studies on the psychological and physiologic consequences of children witnessing and experiencing violence, as well as appearing in court, that have emerged since the previous AAP publications on the subject. The goal is to reduce the secondary traumatization of and long-term consequences for children providing testimony about violence they have experienced or witnessed. This statement primarily addresses children appearing in court as victims of physical or sexual abuse or as witnesses of violent acts; most of the scientific literature addresses these specific situations. It may apply, in certain situations, to children required to provide testimony in custody disputes, child welfare proceedings, or immigration court. It does not address children appearing in court as offenders or as part of juvenile justice proceedings. (2/17)

http://pediatrics.aappublications.org/content/139/3/e20164008

CHILDREN, ADOLESCENTS, AND THE MEDIA

Council on Communications and Media

ABSTRACT. Media, from television to the "new media" (including cell phones, iPads, and social media), are a dominant force in children's lives. Although television is still the predominant medium for children and adolescents, new technologies are increasingly popular. The American Academy of Pediatrics continues to be concerned by evidence about the potential harmful effects of media messages and images; however, important positive and prosocial effects of media use should also be recognized. Pediatricians are encouraged to take a media history and ask 2 media questions at every well-child visit: How much recreational screen time does your child or teenager consume daily? Is there a television set or Internet-connected device in the child's bedroom? Parents are encouraged to establish a family home use plan for all media. Media influences on children and teenagers should be recognized by schools, policymakers, product advertisers, and entertainment producers. (10/13)

http://pediatrics.aappublications.org/content/132/5/958

CHILDREN AND ADOLESCENTS AND DIGITAL MEDIA (TECHNICAL REPORT)

Yolanda (Linda) Reid Chassiakos, MD, FAAP; Jenny Radesky, MD, FAAP; Dimitri Christakis, MD, FAAP; Megan A. Moreno, MD, MSEd, MPH, FAAP; Corinn Cross, MD, FAAP; and Council on Communications and Media

ABSTRACT. Today's children and adolescents are immersed in both traditional and new forms of digital media. Research on traditional media, such as television, has identified health concerns and negative outcomes that correlate with the duration and content of viewing. Over the past decade, the use of digital media, including interactive and social media, has grown, and research evidence suggests that these newer media offer both benefits and risks to the health of children and teenagers. Evidence-based benefits identified from the use of digital and social media include early learning, exposure to new ideas and knowledge, increased opportunities for social contact and support, and new opportunities to access health promotion messages and information. Risks of such media include negative health effects on sleep, attention, and learning; a higher incidence of obesity and depression; exposure to inaccurate, inappropriate, or unsafe content and contacts; and compromised privacy and confidentiality. This technical report reviews the literature regarding these opportunities and risks, framed around clinical questions, for

children from birth to adulthood. To promote health and wellness in children and adolescents, it is important to maintain adequate physical activity, healthy nutrition, good sleep hygiene, and a nurturing social environment. A healthy Family Media Use Plan (www.healthychildren.org/MediaUsePlan) that is individualized for a specific child, teenager, or family can identify an appropriate balance between screen time/online time and other activities, set boundaries for accessing content, guide displays of personal information, encourage age-appropriate critical thinking and digital literacy, and support open family communication and implementation of consistent rules about media use. (10/16)
http://pediatrics.aappublications.org/content/138/5/e20162593

CHILDREN EXPOSED TO MALTREATMENT: ASSESSMENT AND THE ROLE OF PSYCHOTROPIC MEDICATION (CLINICAL REPORT)

Brooks Keeshin, MD, FAAP; Heather C. Forkey, MD, FAAP; George Fouras, MD, DFAACAP; Harriet L. MacMillan, CM, MD, MSc, FRCPC; Council on Child Abuse and Neglect; and Council on Foster Care, Adoption, and Kinship Care (joint with American Academy of Child and Adolescent Psychiatry Committee on Child Maltreatment and Violence and Committee on Adoption and Foster Care)

ABSTRACT. Pediatricians regularly care for children who have experienced child maltreatment. Child maltreatment is a risk factor for a broad range of mental health problems. Issues specific to child maltreatment make addressing emotional and behavioral challenges among maltreated children difficult. This clinical report focuses on 2 key issues necessary for the care of maltreated children and adolescents in pediatric settings: trauma-informed assessments and the role of pharmacotherapy in maltreated children and adolescents. Specific to assessment, current or past involvement of the child in the child welfare system can hinder obtaining necessary information or access to appropriate treatments. Furthermore, trauma-informed assessments can help identify the need for specific interventions. Finally, it is important to take both child welfare system and trauma-informed assessment approaches into account when considering the use of psychotropic agents because there are critical diagnostic and systemic issues that affect the prescribing and discontinuing of psychiatric medications among children with a history of child maltreatment. (1/20)

See full text on page 635.

https://pediatrics.aappublications.org/content/145/2/e20193751

CHILDREN WITH INTELLECTUAL AND DEVELOPMENTAL DISABILITIES AS ORGAN TRANSPLANTATION RECIPIENTS

Mindy B. Statter, MD, MBE; Garey Noritz, MD; Committee on Bioethics; and Council on Children With Disabilities

ABSTRACT. The demand for transplantable solid organs far exceeds the supply of deceased donor organs. Patient selection criteria are determined by individual transplant programs; given the scarcity of solid organs for transplant, allocation to those most likely to benefit takes into consideration both medical and psychosocial factors. Children with intellectual and developmental disabilities have historically been excluded as potential recipients of organ transplants. When a transplant is likely to provide significant health benefits, denying a transplant to otherwise eligible children with disabilities may constitute illegal and unjustified discrimination. Children with intellectual and developmental disabilities should not be excluded from the potential pool of recipients and should be referred for evaluation as recipients of solid organ transplants. (4/20)

See full text on page 653.

https://pediatrics.aappublications.org/content/145/5/e20200625

CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP): ACCOMPLISHMENTS, CHALLENGES, AND POLICY RECOMMENDATIONS

Committee on Child Health Financing

ABSTRACT. Sixteen years ago, the 105th Congress, responding to the needs of 10 million children in the United States who lacked health insurance, created the State Children's Health Insurance Program (SCHIP) as part of the Balanced Budget Act of 1997. Enacted as Title XXI of the Social Security Act, the Children's Health Insurance Program (CHIP; or SCHIP as it has been known at some points) provided states with federal assistance to create programs specifically designed for children from families with incomes that exceeded Medicaid thresholds but that were insufficient to enable them to afford private health insurance. Congress provided $40 billion in block grants over 10 years for states to expand their existing Medicaid programs to cover the intended populations, to erect new stand-alone SCHIP programs for these children, or to effect some combination of both options. Congress reauthorized CHIP once in 2009 under the Children's Health Insurance Program Reauthorization Act and extended its life further within provisions of the Patient Protection and Affordable Care Act of 2010. The purpose of this statement is to review the features of CHIP as it has evolved over the 16 years of its existence; to summarize what is known about the effects that the program has had on coverage, access, health status, and disparities among participants; to identify challenges that remain with respect to insuring this group of vulnerable children, including the impact that provisions of the new Affordable Care Act will have on the issue of health insurance coverage for near-poor children after 2015; and to offer recommendations on how to expand and strengthen the national commitment to provide health insurance to all children regardless of means. (2/14, reaffirmed 8/20)
http://pediatrics.aappublications.org/content/133/3/e784

CIRCUMCISION POLICY STATEMENT

Task Force on Circumcision

ABSTRACT. Male circumcision is a common procedure, generally performed during the newborn period in the United States. In 2007, the American Academy of Pediatrics (AAP) formed a multidisciplinary task force of AAP members and other stakeholders to evaluate the recent evidence on male circumcision and update the Academy's 1999 recommendations in this area. Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks and that the procedure's benefits justify access to this procedure for families who choose it. Specific benefits identified included prevention of urinary tract infections, penile cancer, and transmission of some sexually transmitted infections, including HIV. The American College of Obstetricians and Gynecologists has endorsed this statement. (8/12)
http://pediatrics.aappublications.org/content/130/3/585

CLIMATIC HEAT STRESS AND EXERCISING CHILDREN AND ADOLESCENTS

Council on Sports Medicine and Fitness and Council on School Health

ABSTRACT. Results of new research indicate that, contrary to previous thinking, youth do not have less effective thermoregulatory ability, insufficient cardiovascular capacity, or lower physical exertion tolerance compared with adults during exercise in the heat when adequate hydration is maintained. Accordingly, besides poor hydration status, the primary determinants of reduced performance and exertional heat-illness risk in youth during sports and other physical activities in a hot environment include undue physical exertion, insufficient recovery between repeated exercise bouts or closely scheduled same-day training sessions or rounds of sports competition, and inappropriately

wearing clothing, uniforms, and protective equipment that play a role in excessive heat retention. Because these known contributing risk factors are modifiable, exertional heat illness is usually preventable. With appropriate preparation, modifications, and monitoring, most healthy children and adolescents can safely participate in outdoor sports and other physical activities through a wide range of challenging warm to hot climatic conditions. (8/11, reaffirmed 2/15)
http://pediatrics.aappublications.org/content/128/3/e741

CLINICAL CONSIDERATIONS RELATED TO THE BEHAVIORAL MANIFESTATIONS OF CHILD MALTREATMENT (CLINICAL REPORT)

Robert D. Sege, MD, PhD, FAAP; Lisa Amaya-Jackson, MD, MPH, FAACAP; Committee on Child Abuse and Neglect; and Council on Foster Care, Adoption, and Kinship Care (joint with American Academy of Child and Adolescent Psychiatry Committee on Child Maltreatment and Violence and National Center for Child Traumatic Stress)

ABSTRACT. Children who have suffered early abuse or neglect may later present with significant health and behavior problems that may persist long after the abusive or neglectful environment has been remediated. Neurobiological research suggests that early maltreatment may result in an altered psychological and physiologic response to stressful stimuli, a response that deleteriously affects the child's subsequent development. Pediatricians can assist caregivers by helping them recognize the abused or neglected child's emotional and behavioral responses associated with child maltreatment and guide them in the use of positive parenting strategies, referring the children and families to evidence-based therapeutic treatment and mobilizing available community resources. (3/17)
http://pediatrics.aappublications.org/content/139/4/e20170100

CLINICAL GENETIC EVALUATION OF THE CHILD WITH MENTAL RETARDATION OR DEVELOPMENTAL DELAYS (CLINICAL REPORT)

John B. Moeschler, MD; Michael Shevell, MD; and Committee on Genetics

ABSTRACT. This clinical report describes the clinical genetic evaluation of the child with developmental delays or mental retardation. The purpose of this report is to describe the optimal clinical genetics diagnostic evaluation to assist pediatricians in providing a medical home for children with developmental delays or mental retardation and their families. The literature supports the benefit of expert clinical judgment by a consulting clinical geneticist in the diagnostic evaluation. However, it is recognized that local factors may preclude this particular option. No single approach to the diagnostic process is supported by the literature. This report addresses the diagnostic importance of clinical history, 3-generation family history, dysmorphologic examination, neurologic examination, chromosome analysis (≥650 bands), fragile X molecular genetic testing, fluorescence in situ hybridization studies for subtelomere chromosome rearrangements, molecular genetic testing for typical and atypical presentations of known syndromes, computed tomography and/or magnetic resonance brain imaging, and targeted studies for metabolic disorders. (6/06, reaffirmed 5/12)
http://pediatrics.aappublications.org/content/117/6/2304

CLINICAL PRACTICE POLICY TO PROTECT CHILDREN FROM TOBACCO, NICOTINE, AND TOBACCO SMOKE

Section on Tobacco Control

ABSTRACT. Tobacco dependence starts in childhood. Tobacco exposure of children is common and causes illness and premature death in children and adults, with adverse effects starting in the womb. There is no safe level of tobacco smoke exposure. Pediatricians should screen for use of tobacco and other nicotine delivery devices and provide anticipatory guidance to prevent smoking initiation and reduce tobacco smoke exposure. Pediatricians need to be aware of the different nicotine delivery systems marketed and available.

Parents and caregivers are important sources of children's tobacco smoke exposure. Because tobacco dependence is a severe addiction, to protect children's health, caregiver tobacco dependence treatment should be offered or referral for treatment should be provided (such as referral to the national smoker's quitline at 1-800-QUIT-NOW). If the source of tobacco exposure cannot be eliminated, counseling about reducing exposure to children should be provided.

Health care delivery systems should facilitate the effective prevention, identification, and treatment of tobacco dependence in children and adolescents, their parents, and other caregivers. Health care facilities should protect children from tobacco smoke exposure and tobacco promotion. Tobacco dependence prevention and treatment should be part of medical education, with knowledge assessed as part of board certification examinations. (10/15, reaffirmed 6/20)
http://pediatrics.aappublications.org/content/136/5/1008

CLINICAL TOOLS TO ASSESS ASTHMA CONTROL IN CHILDREN (CLINICAL REPORT)

Chitra Dinakar, MD, FAAP; Bradley E. Chipps, MD, FAAP; Section on Allergy and Immunology; and Section on Pediatric Pulmonology and Sleep Medicine

ABSTRACT. Asthma affects an estimated 7 million children and causes significant health care and disease burden. The most recent iteration of the National Heart, Lung and Blood Institute asthma guidelines, the Expert Panel Report 3, emphasizes the assessment and monitoring of asthma control in the management of asthma. Asthma control refers to the degree to which the manifestations of asthma are minimized by therapeutic interventions and the goals of therapy are met. Although assessment of asthma severity is used to guide initiation of therapy, monitoring of asthma control helps determine whether therapy should be maintained or adjusted. The nuances of estimation of asthma control include understanding concepts of current impairment and future risk and incorporating their measurement into clinical practice. Impairment is assessed on the basis of frequency and intensity of symptoms, variations in lung function, and limitations of daily activities. "Risk" refers to the likelihood of exacerbations, progressive loss of lung function, or adverse effects from medications. Currently available ambulatory tools to measure asthma control range are subjective measures, such as patient-reported composite asthma control score instruments or objective measures of lung function, airway hyperreactivity, and biomarkers. Because asthma control exhibits short- and long-term variability, health care providers need to be vigilant regarding the fluctuations in the factors that can create discordance between subjective and objective assessment of asthma control. Familiarity with the properties, application, and relative value of these measures will enable health care providers to choose the optimal set of measures that will adhere to national standards of care and ensure delivery of high-quality care customized to their patients. (12/16)
http://pediatrics.aappublications.org/content/139/1/e20163438

COCHLEAR IMPLANTS IN CHILDREN: SURGICAL SITE INFECTIONS AND PREVENTION AND TREATMENT OF ACUTE OTITIS MEDIA AND MENINGITIS

Lorry G. Rubin, MD; Blake Papsin, MD; Committee on Infectious Diseases; and Section on Otolaryngology—Head and Neck Surgery

ABSTRACT. The use of cochlear implants is increasingly common, particularly in children younger than 3 years. Bacterial meningitis, often with associated acute otitis media, is more

common in children with cochlear implants than in groups of control children. Children with profound deafness who are candidates for cochlear implants should receive all age-appropriate doses of pneumococcal conjugate and Haemophilus influenzae type b conjugate vaccines and appropriate annual immunization against influenza. In addition, starting at 24 months of age, a single dose of 23-valent pneumococcal polysaccharide vaccine should be administered. Before implant surgery, primary care providers and cochlear implant teams should ensure that immunizations are up-to-date, preferably with completion of indicated vaccines at least 2 weeks before implant surgery. Imaging of the temporal bone/inner ear should be performed before cochlear implantation in all children with congenital deafness and all patients with profound hearing impairment and a history of bacterial meningitis to identify those with inner-ear malformations/cerebrospinal fluid fistulas or ossification of the cochlea. During the initial months after cochlear implantation, the risk of complications of acute otitis media may be higher than during subsequent time periods. Therefore, it is recommended that acute otitis media diagnosed during the first 2 months after implantation be initially treated with a parenteral antibiotic (eg, ceftriaxone or cefotaxime). Episodes occurring 2 months or longer after implantation can be treated with a trial of an oral antimicrobial agent (eg, amoxicillin or amoxicillin/clavulanate at a dose of approximately 90 mg/kg per day of amoxicillin component), provided the child does not appear toxic and the implant does not have a spacer/positioner, a wedge that rests in the cochlea next to the electrodes present in certain implant models available between 1999 and 2002. "Watchful waiting" without antimicrobial therapy is inappropriate for children with implants with acute otitis media. If feasible, tympanocentesis should be performed for acute otitis media, and the material should be sent for culture, but performance of this procedure should not result in an undue delay in initiating antimicrobial therapy. For patients with suspected meningitis, cerebrospinal fluid as well as middle-ear fluid, if present, should be sent for culture. Empiric antimicrobial therapy for meningitis occurring within 2 months of implantation should include an agent with broad activity against Gram-negative bacilli (eg, meropenem) plus vancomycin. For meningitis occurring 2 months or longer after implantation, standard empiric antimicrobial therapy for meningitis (eg, ceftriaxone plus vancomycin) is indicated. For patients with meningitis, urgent evaluation by an otolaryngologist is indicated for consideration of imaging and surgical exploration. (7/10, reaffirmed 1/18)

http://pediatrics.aappublications.org/content/126/2/381

CODEINE: TIME TO SAY "NO" (CLINICAL REPORT)

Joseph D. Tobias, MD, FAAP; Thomas P. Green, MD, FAAP; Charles J. Coté, MD, FAAP; Section on Anesthesiology and Pain Medicine; and Committee on Drugs

ABSTRACT. Codeine has been prescribed to pediatric patients for many decades as both an analgesic and an antitussive agent. Codeine is a prodrug with little inherent pharmacologic activity and must be metabolized in the liver into morphine, which is responsible for codeine's analgesic effects. However, there is substantial genetic variability in the activity of the responsible hepatic enzyme, *CYP2D6,* and, as a consequence, individual patient response to codeine varies from no effect to high sensitivity. Drug surveillance has documented the occurrence of unanticipated respiratory depression and death after receiving codeine in children, many of whom have been shown to be ultrarapid metabolizers. Patients with documented or suspected obstructive sleep apnea appear to be at particular risk because of opioid sensitivity, compounding the danger among rapid metabolizers in this group. Recently, various organizations and regulatory bodies, including the World Health Organization, the US Food and Drug Administration, and the European Medicines Agency, have promulgated stern warnings regarding the occurrence of adverse effects of codeine in children. These and other groups have or are considering a declaration of a contraindication for the use of codeine for children as either an analgesic or an antitussive. Additional clinical research must extend the understanding of the risks and benefits of both opioid and nonopioid alternatives for orally administered, effective agents for acute and chronic pain. (9/16)

http://pediatrics.aappublications.org/content/138/4/e20162396

COLLABORATIVE ROLE OF THE PEDIATRICIAN IN THE DIAGNOSIS AND MANAGEMENT OF BIPOLAR DISORDER IN ADOLESCENTS (CLINICAL REPORT)

Benjamin N. Shain, MD, PhD, and Committee on Adolescence

ABSTRACT. Despite the complexity of diagnosis and management, pediatricians have an important collaborative role in referring and partnering in the management of adolescents with bipolar disorder. This report presents the classification of bipolar disorder as well as interviewing and diagnostic guidelines. Treatment options are described, particularly focusing on medication management and rationale for the common practice of multiple, simultaneous medications. Medication adverse effects may be problematic and better managed with collaboration between mental health professionals and pediatricians. Case examples illustrate a number of common diagnostic and management issues. (11/12)

http://pediatrics.aappublications.org/content/130/6/e1725

COMMUNICATING WITH CHILDREN AND FAMILIES: FROM EVERYDAY INTERACTIONS TO SKILL IN CONVEYING DISTRESSING INFORMATION (TECHNICAL REPORT)

Marcia Levetown, MD, and Committee on Bioethics

ABSTRACT. Health care communication is a skill that is critical to safe and effective medical practice; it can and must be taught. Communication skill influences patient disclosure, treatment adherence and outcome, adaptation to illness, and bereavement. This article provides a review of the evidence regarding clinical communication in the pediatric setting, covering the spectrum from outpatient primary care consultation to death notification, and provides practical suggestions to improve communication with patients and families, enabling more effective, efficient, and empathic pediatric health care. (5/08, reaffirmed 12/16)

http://pediatrics.aappublications.org/content/121/5/e1441

COMMUNITY PEDIATRICS: NAVIGATING THE INTERSECTION OF MEDICINE, PUBLIC HEALTH, AND SOCIAL DETERMINANTS OF CHILDREN'S HEALTH

Council on Community Pediatrics

ABSTRACT. This policy statement provides a framework for the pediatrician's role in promoting the health and well-being of all children in the context of their families and communities. It offers pediatricians a definition of community pediatrics, emphasizes the importance of recognizing social determinants of health, and delineates the need to partner with public health to address population-based child health issues. It also recognizes the importance of pediatric involvement in child advocacy at local, state, and federal levels to ensure all children have access to a high-quality medical home and to eliminate child health disparities. This statement provides a set of specific recommendations that underscore the critical nature of this dimension of pediatric practice, teaching, and research. (2/13, reaffirmed 10/16)

http://pediatrics.aappublications.org/content/131/3/623

COMPREHENSIVE EVALUATION OF THE CHILD WITH INTELLECTUAL DISABILITY OR GLOBAL DEVELOPMENTAL DELAYS (CLINICAL REPORT)

John B. Moeschler, MD, MS, FAAP, FACMG; Michael Shevell, MDCM, FRCP; and Committee on Genetics

ABSTRACT. Global developmental delay and intellectual disability are relatively common pediatric conditions. This report describes the recommended clinical genetics diagnostic approach. The report is based on a review of published reports, most consisting of medium to large case series of diagnostic tests used, and the proportion of those that led to a diagnosis in such patients. Chromosome microarray is designated as a first-line test and replaces the standard karyotype and fluorescent in situ hybridization subtelomere tests for the child with intellectual disability of unknown etiology. Fragile X testing remains an important first-line test. The importance of considering testing for inborn errors of metabolism in this population is supported by a recent systematic review of the literature and several case series recently published. The role of brain MRI remains important in certain patients. There is also a discussion of the emerging literature on the use of whole-exome sequencing as a diagnostic test in this population. Finally, the importance of intentional comanagement among families, the medical home, and the clinical genetics specialty clinic is discussed. (8/14, reaffirmed 10/19)

http://pediatrics.aappublications.org/content/134/3/e903

COMPREHENSIVE HEALTH EVALUATION OF THE NEWLY ADOPTED CHILD (CLINICAL REPORT)

Veronnie Faye Jones, MD, PhD, MSPH, FAAP; Elaine E. Schulte, MD, MPH, FAAP; and Council on Foster Care, Adoption, and Kinship Care

ABSTRACT. Children who join families through the process of adoption, whether through a domestic or international route, often have multiple health care needs. Pediatricians and other health care personnel are in a unique position to guide families in achieving optimal health for the adopted children as families establish a medical home. Shortly after placement in an adoptive home, it is recommended that children have a timely comprehensive health evaluation to provide care for known medical needs and identify health issues that are unknown. It is important to begin this evaluation with a review of all available medical records and pertinent verbal history. A complete physical examination then follows. The evaluation should also include diagnostic testing based on findings from the history and physical examination as well as the risks presented by the child's previous living conditions. Age-appropriate screenings may include, but are not limited to, newborn screening panels and hearing, vision, dental, and formal behavioral and/or developmental screenings. The comprehensive assessment may occur at the time of the initial visit to the physician after adoptive placement or can take place over several visits. Adopted children can be referred to other medical specialists as deemed appropriate. The Council on Adoption, Foster Care, and Kinship Care is a resource within the American Academy of Pediatrics for physicians providing care for children who are being adopted. (4/19)

https://pediatrics.aappublications.org/content/143/5/e20190657

CONFLICTS BETWEEN RELIGIOUS OR SPIRITUAL BELIEFS AND PEDIATRIC CARE: INFORMED REFUSAL, EXEMPTIONS, AND PUBLIC FUNDING

Committee on Bioethics

ABSTRACT. Although respect for parents' decision-making authority is an important principle, pediatricians should report suspected cases of medical neglect, and the state should, at times, intervene to require medical treatment of children. Some parents' reasons for refusing medical treatment are based on their religious or spiritual beliefs. In cases in which treatment is likely to prevent death or serious disability or relieve severe pain, children's health and future autonomy should be protected. Because religious exemptions to child abuse and neglect laws do not equally protect all children and may harm some children by causing confusion about the duty to provide medical treatment, these exemptions should be repealed. Furthermore, public health care funds should not cover alternative unproven religious or spiritual healing practices. Such payments may inappropriately legitimize these practices as appropriate medical treatment. (10/13, reaffirmed 12/16, 11/17)

http://pediatrics.aappublications.org/content/132/5/962

CONGENITAL BRAIN AND SPINAL CORD MALFORMATIONS AND THEIR ASSOCIATED CUTANEOUS MARKERS (CLINICAL REPORT)

Mark Dias, MD, FAANS, FAAP; Michael Partington, MD, FAANS, FAAP; and Section on Neurologic Surgery

ABSTRACT. The brain, spinal cord, and skin are all derived from the embryonic ectoderm; this common derivation leads to a high association between central nervous system dysraphic malformations and abnormalities of the overlying skin. A myelomeningocele is an obvious open malformation, the identification of which is not usually difficult. However, the relationship between congenital spinal cord malformations and other cutaneous malformations, such as dimples, vascular anomalies (including infantile hemangiomata and other vascular malformations), congenital pigmented nevi or other hamartomata, or midline hairy patches may be less obvious but no less important. Pediatricians should be aware of these associations, recognize the cutaneous markers associated with congenital central nervous system malformations, and refer children with such markers to the appropriate specialist in a timely fashion for further evaluation and treatment. (9/15)

http://pediatrics.aappublications.org/content/136/4/e1105

CONSENT BY PROXY FOR NONURGENT PEDIATRIC CARE (CLINICAL REPORT)

Jonathan M. Fanaroff, MD, JD, FAAP, FCLM, and Committee on Medical Liability and Risk Management

ABSTRACT. Minor-aged patients are often brought to the pediatrician for nonurgent acute medical care, physical examinations, or health supervision visits by someone other than their legally authorized representative, which, in most situations, is a parent. These surrogates or proxies can be members of the child's extended family, such as a grandparent, adult sibling, or aunt/uncle; a noncustodial parent or stepparent in cases of divorce and remarriage; an adult who lives in the home but is not biologically or legally related to the child; or even a child care provider (eg, au pair, nanny, private-duty nurse/nurse's aide, group home supervisor). This report identifies common situations in which pediatricians may encounter "consent by proxy" for nonurgent medical care for minors, including physical examinations, and explains the potential for liability exposure associated with these circumstances. The report suggests practical steps that balance the need to minimize the physician's liability exposure with the patient's access to health care. Key issues to be considered when creating or updating office policies for obtaining and documenting consent by proxy are offered. (1/17)

http://pediatrics.aappublications.org/content/139/2/e20163911

CONSENT FOR EMERGENCY MEDICAL SERVICES FOR CHILDREN AND ADOLESCENTS

Committee on Pediatric Emergency Medicine and Committee on Bioethics

ABSTRACT. Parental consent generally is required for the medical evaluation and treatment of minor children. However, children and adolescents might require evaluation of and treatment for emergency medical conditions in situations in which a parent or legal guardian is not available to provide consent or

conditions under which an adolescent patient might possess the legal authority to provide consent. In general, a medical screening examination and any medical care necessary and likely to prevent imminent and significant harm to the pediatric patient with an emergency medical condition should not be withheld or delayed because of problems obtaining consent. The purpose of this policy statement is to provide guidance in those situations in which parental consent is not readily available, in which parental consent is not necessary, or in which parental refusal of consent places a child at risk of significant harm. (7/11, reaffirmed 9/15)
http://pediatrics.aappublications.org/content/128/2/427

CONSUMPTION OF RAW OR UNPASTEURIZED MILK AND MILK PRODUCTS BY PREGNANT WOMEN AND CHILDREN

Committee on Infectious Diseases and Committee on Nutrition

ABSTRACT. Sales of raw or unpasteurized milk and milk products are still legal in at least 30 states in the United States. Raw milk and milk products from cows, goats, and sheep continue to be a source of bacterial infections attributable to a number of virulent pathogens, including *Listeria monocytogenes, Campylobacter jejuni, Salmonella* species, *Brucella* species, and *Escherichia coli* O157. These infections can occur in both healthy and immunocompromised individuals, including older adults, infants, young children, and pregnant women and their unborn fetuses, in whom life-threatening infections and fetal miscarriage can occur. Efforts to limit the sale of raw milk products have met with opposition from those who are proponents of the purported health benefits of consuming raw milk products, which contain natural or unprocessed factors not inactivated by pasteurization. However, the benefits of these natural factors have not been clearly demonstrated in evidence-based studies and, therefore, do not outweigh the risks of raw milk consumption. Substantial data suggest that pasteurized milk confers equivalent health benefits compared with raw milk, without the additional risk of bacterial infections. The purpose of this policy statement was to review the risks of raw milk consumption in the United States and to provide evidence of the risks of infectious complications associated with consumption of unpasteurized milk and milk products, especially among pregnant women, infants, and children. (12/13, reaffirmed 11/19)
http://pediatrics.aappublications.org/content/133/1/175

CONTRACEPTION FOR ADOLESCENTS

Committee on Adolescence

ABSTRACT. Contraception is a pillar in reducing adolescent pregnancy rates. The American Academy of Pediatrics recommends that pediatricians develop a working knowledge of contraception to help adolescents reduce risks of and negative health consequences related to unintended pregnancy. Over the past 10 years, a number of new contraceptive methods have become available to adolescents, newer guidance has been issued on existing contraceptive methods, and the evidence base for contraception for special populations (adolescents who have disabilities, are obese, are recipients of solid organ transplants, or are HIV infected) has expanded. The Academy has addressed contraception since 1980, and this policy statement updates the 2007 statement on contraception and adolescents. It provides the pediatrician with a description and rationale for best practices in counseling and prescribing contraception for adolescents. It is supported by an accompanying technical report. (9/14)
http://pediatrics.aappublications.org/content/134/4/e1244

CONTRACEPTION FOR ADOLESCENTS (TECHNICAL REPORT)

Mary A. Ott, MD, MA, FAAP; Gina S. Sucato, MD, MPH, FAAP; and Committee on Adolescence

ABSTRACT. A working knowledge of contraception will assist the pediatrician in both sexual health promotion as well as treatment of common adolescent gynecologic problems. Best practices in adolescent anticipatory guidance and screening include a sexual health history, screening for pregnancy and sexually transmitted infections, counseling, and if indicated, providing access to contraceptives. Pediatricians' long-term relationships with adolescents and families allow them to help promote healthy sexual decision-making, including abstinence and contraceptive use. Additionally, medical indications for contraception, such as acne, dysmenorrhea, and heavy menstrual bleeding, are frequently uncovered during adolescent visits. This technical report provides an evidence base for the accompanying policy statement and addresses key aspects of adolescent contraceptive use, including the following: (1) sexual history taking, confidentiality, and counseling; (2) adolescent data on the use and side effects of newer contraceptive methods; (3) new data on older contraceptive methods; and (4) evidence supporting the use of contraceptives in adolescent patients with complex medical conditions. (9/14)
http://pediatrics.aappublications.org/content/134/4/e1257

CONTRACEPTION FOR HIV-INFECTED ADOLESCENTS (CLINICAL REPORT)

Athena P. Kourtis, MD, PhD, MPH, FAAP; Ayesha Mirza, MD, FAAP; and Committee on Pediatric AIDS

ABSTRACT. Access to high-quality reproductive health care is important for adolescents and young adults with HIV infection to prevent unintended pregnancies, sexually transmitted infections, and secondary transmission of HIV to partners and children. As perinatally HIV-infected children mature into adolescence and adulthood and new HIV infections among adolescents and young adults continue to occur in the United States, medical providers taking care of such individuals often face issues related to sexual and reproductive health. Challenges including drug interactions between several hormonal methods and antiretroviral agents make decisions regarding contraceptive options more complex for these adolescents. Dual protection, defined as the use of an effective contraceptive along with condoms, should be central to ongoing discussions with HIV-infected young women and couples wishing to avoid pregnancy. Last, reproductive health discussions need to be integrated with discussions on HIV care, because a reduction in plasma HIV viral load below the level of detection (an "undetectable viral load") is essential for the individual's health as well as for a reduction in HIV transmission to partners and children. (8/16)
http://pediatrics.aappublications.org/content/138/3/e20161892

CONTROVERSIES CONCERNING VITAMIN K AND THE NEWBORN

Committee on Fetus and Newborn

ABSTRACT. Prevention of early vitamin K deficiency bleeding (VKDB) of the newborn, with onset at birth to 2 weeks of age (formerly known as classic hemorrhagic disease of the newborn), by oral or parenteral administration of vitamin K is accepted practice. In contrast, late VKDB, with onset from 2 to 12 weeks of age, is most effectively prevented by parenteral administration of vitamin K. Earlier concern regarding a possible causal association between parenteral vitamin K and childhood cancer has not been substantiated. This revised statement presents updated recommendations for the use of vitamin K in the prevention of early and late VKDB. (7/03, reaffirmed 5/06, 5/09, 9/14, 2/20)
http://pediatrics.aappublications.org/content/112/1/191

CORD BLOOD BANKING FOR POTENTIAL FUTURE TRANSPLANTATION

William T. Shearer, MD, PhD, FAAP; Bertram H. Lubin, MD, FAAP; Mitchell S. Cairo, MD, FAAP; Luigi D. Notarangelo, MD; Section on Hematology/Oncology; and Section on Allergy and Immunology

ABSTRACT. This policy statement is intended to provide information to guide pediatricians, obstetricians, and other medical specialists and health care providers in responding to parents' questions about cord blood donation and banking as well as the types (public versus private) and quality of cord blood banks. Cord blood is an excellent source of stem cells for hematopoietic stem cell transplantation in children with some fatal diseases. Cord blood transplantation offers another method of definitive therapy for infants, children, and adults with certain hematologic malignancies, hemoglobinopathies, severe forms of T-lymphocyte and other immunodeficiencies, and metabolic diseases. The development of universal screening for severe immunodeficiency assay in a growing number of states is likely to increase the number of cord blood transplants. Both public and private cord blood banks worldwide hold hundreds of thousands of cord blood units designated for the treatment of fatal or debilitating illnesses. The procurement, characterization, and cryopreservation of cord blood is free for families who choose public banking. However, the family cost for private banking is significant and not covered by insurance, and the unit may never be used. Quality-assessment reviews by several national and international accrediting bodies show private cord blood banks to be underused for treatment, less regulated for quality control, and more expensive for the family than public cord blood banks. There is an unquestionable need to study the use of cord blood banking to make new and important alternative means of reconstituting the hematopoietic blood system in patients with malignancies and blood disorders and possibly regenerating tissue systems in the future. Recommendations regarding appropriate ethical and operational standards (including informed consent policies, financial disclosures, and conflict-of-interest policies) are provided for physicians, institutions, and organizations that operate or have a relationship with cord blood banking programs. The information on all aspects of cord blood banking gathered in this policy statement will facilitate parental choice for public or private cord blood banking. (10/17)
http://pediatrics.aappublications.org/content/140/5/e20172695

CORPORAL PUNISHMENT IN SCHOOLS

Committee on School Health

ABSTRACT. The American Academy of Pediatrics recommends that corporal punishment in schools be abolished in all states by law and that alternative forms of student behavior management be used. (8/00, reaffirmed 6/03, 5/06, 2/12, 12/18)
http://pediatrics.aappublications.org/content/106/2/343

COUNSELING IN PEDIATRIC POPULATIONS AT RISK FOR INFERTILITY AND/OR SEXUAL FUNCTION CONCERNS (CLINICAL REPORT)

Leena Nahata, MD, FAAP; Gwendolyn P. Quinn, PhD; Amy C. Tishelman, PhD; and Section on Endocrinology

ABSTRACT. Reproductive health is an important yet often overlooked topic in pediatric health care; when addressed, the focus is generally on prevention of sexually transmitted infections and unwanted pregnancy. Two aspects of reproductive health counseling that have received minimal attention in pediatrics are fertility and sexual function for at-risk pediatric populations, and youth across many disciplines are affected. Although professional organizations, such as the American Academy of Pediatrics and the American Society of Clinical Oncology, have published recommendations about fertility preservation discussions, none of these guidelines address how to have ongoing conversations with at-risk youth and their families about the potential for future infertility and sexual dysfunction in developmentally appropriate ways. Researchers suggest many pediatric patients at risk for reproductive problems remain uncertain and confused about their fertility or sexual function status well into young adulthood. Potential infertility may cause distress and anxiety, has been shown to affect formation of romantic relationships, and may lead to unplanned pregnancy in those who incorrectly assumed they were infertile. Sexual dysfunction is also common and may lead to problems with intimacy and self-esteem; survivors of pediatric conditions consistently report inadequate guidance from clinicians in this area. Health care providers and parents report challenges in knowing how and when to discuss these issues. In this context, the goal of this clinical report is to review evidence and considerations for providers related to information sharing about impaired fertility and sexual function in pediatric patients attributable to congenital and acquired conditions or treatments. (7/18)
http://pediatrics.aappublications.org/content/142/2/e20181435

COUNSELING PARENTS AND TEENS ABOUT MARIJUANA USE IN THE ERA OF LEGALIZATION OF MARIJUANA (CLINICAL REPORT)

Sheryl A. Ryan, MD, FAAP; Seth D. Ammerman, MD, FAAP; and Committee on Substance Use and Prevention

ABSTRACT. Many states have recently made significant changes to their legislation making recreational and/or medical marijuana use by adults legal. Although these laws, for the most part, have not targeted the adolescent population, they have created an environment in which marijuana increasingly is seen as acceptable, safe, and therapeutic. This clinical report offers guidance to the practicing pediatrician based on existing evidence and expert opinion/consensus of the American Academy of Pediatrics regarding anticipatory guidance and counseling to teenagers and their parents about marijuana and its use. The recently published technical report provides the detailed evidence and references regarding the research on which the information in this clinical report is based. (2/17)
http://pediatrics.aappublications.org/content/139/3/e20164069

COUNTERING VACCINE HESITANCY (CLINICAL REPORT)

Kathryn M. Edwards, MD, FAAP; Jesse M. Hackell, MD, FAAP; Committee on Infectious Diseases; and Committee on Practice and Ambulatory Medicine

ABSTRACT. Immunizations have led to a significant decrease in rates of vaccine-preventable diseases and have made a significant impact on the health of children. However, some parents express concerns about vaccine safety and the necessity of vaccines. The concerns of parents range from hesitancy about some immunizations to refusal of all vaccines. This clinical report provides information about addressing parental concerns about vaccination. (8/16)
http://pediatrics.aappublications.org/content/138/3/e20162146

CRITICAL ELEMENTS FOR THE PEDIATRIC PERIOPERATIVE ANESTHESIA ENVIRONMENT

Section on Anesthesiology and Pain Medicine

ABSTRACT. The American Academy of Pediatrics proposes guidance for the pediatric perioperative anesthesia environment. Essential components are identified to optimize the perioperative environment for the anesthetic care of infants and children. Such an environment promotes the safety and well-being of infants and children by reducing the risk of adverse events. (11/15)
http://pediatrics.aappublications.org/content/136/6/1200

THE CRUCIAL ROLE OF RECESS IN SCHOOL

Council on School Health

ABSTRACT. Recess is at the heart of a vigorous debate over the role of schools in promoting the optimal development of the whole child. A growing trend toward reallocating time in school to accentuate the more academic subjects has put this important facet of a child's school day at risk. Recess serves as a necessary break from the rigors of concentrated, academic challenges in the

classroom. But equally important is the fact that safe and well-supervised recess offers cognitive, social, emotional, and physical benefits that may not be fully appreciated when a decision is made to diminish it. Recess is unique from, and a complement to, physical education—not a substitute for it. The American Academy of Pediatrics believes that recess is a crucial and necessary component of a child's development and, as such, it should not be withheld for punitive or academic reasons. (12/12, reaffirmed 8/16)
http://pediatrics.aappublications.org/content/131/1/183

DEALING WITH THE CARETAKER WHOSE JUDGMENT IS IMPAIRED BY ALCOHOL OR DRUGS: LEGAL AND ETHICAL CONSIDERATIONS (CLINICAL REPORT)

Steven A. Bondi, JD, MD, FAAP; James Scibilia, MD, FAAP; and Committee on Medical Liability and Risk Management

ABSTRACT. An estimated 8.7 million children live in a household with a substance-using parent or guardian. Substance-using caretakers may have impaired judgment that can negatively affect their child's well-being, including his or her ability to receive appropriate medical care. Although the physician-patient relationship exists between the pediatrician and the child, obligations related to safety and confidentiality should be considered as well. In managing encounters with impaired caretakers who may become disruptive or dangerous, pediatricians should be aware of their responsibilities before acting. In addition to fulfilling the duty involved with an established physician-patient relationship, the pediatrician should take reasonable care to safeguard patient confidentiality; protect the safety of their patient, other patients in the facility, visitors, and employees; and comply with reporting mandates. This clinical report identifies and discusses the legal and ethical concepts related to these circumstances. The report offers implementation suggestions when establishing anticipatory procedures and training programs for staff in such situations to maximize the patient's well-being and safety and minimize the liability of the pediatrician. (11/19)
https://pediatrics.aappublications.org/content/144/6/e20193153

DEATH OF A CHILD IN THE EMERGENCY DEPARTMENT

Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. The American Academy of Pediatrics, American College of Emergency Physicians, and Emergency Nurses Association have collaborated to identify practices and principles to guide the care of children, families, and staff in the challenging and uncommon event of the death of a child in the emergency department in this policy statement and in an accompanying technical report. (6/14, reaffirmed 9/19)
http://pediatrics.aappublications.org/content/134/1/198

DEATH OF A CHILD IN THE EMERGENCY DEPARTMENT (TECHNICAL REPORT)

Patricia J. O'Malley, MD, FAAP; Isabel A. Barata, MD, FACEP, FAAP; Sally K. Snow, RN, BSN, CPEN, FAEN; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. The death of a child in the emergency department (ED) is one of the most challenging problems facing ED clinicians. This revised technical report and accompanying policy statement reaffirm principles of patient- and family-centered care. Recent literature is examined regarding family presence, termination of resuscitation, bereavement responsibilities of ED clinicians, support of child fatality review efforts, and other issues inherent in caring for the patient, family, and staff when a child dies in the ED. Appendices are provided that offer an approach to bereavement activities in the ED, carrying out forensic responsibilities while providing compassionate care, communicating the news of the death of a child in the acute setting, providing a closing ritual at the time of terminating resuscitation efforts, and managing the child with a terminal condition who presents near death in the ED. (6/14, reaffirmed 9/19)
http://pediatrics.aappublications.org/content/134/1/e313

DEFINITION OF A PEDIATRICIAN

Committee on Pediatric Workforce

POLICY. The American Academy of Pediatrics (AAP) has developed the following definition of pediatrics and a pediatrician:

Pediatrics is the specialty of medical science concerned with the physical, mental, and social health of children from birth to young adulthood. Pediatric care encompasses a broad spectrum of health services ranging from preventive health care to the diagnosis and treatment of acute and chronic diseases.

Pediatrics is a discipline that deals with biological, social, and environmental influences on the developing child and with the impact of disease and dysfunction on development. Children differ from adults anatomically, physiologically, immunologically, psychologically, developmentally, and metabolically.

The pediatrician, a term that includes primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists, understands this constantly changing functional status of his or her patients' incident to growth and development and the consequent changing standards of "normal" for age. A pediatrician is a physician who is concerned primarily with the health, welfare, and development of children and is uniquely qualified for these endeavors by virtue of interest and initial training. This training includes 4 years of medical school education, plus an additional year or years (usually at least 3) of intensive training devoted solely to all aspects of medical care for children, adolescents, and young adults. Maintenance of these competencies is achieved by experience, training, continuous education, self-assessment, and practice improvement.

A pediatrician is able to define accurately the child's health status and to serve as a consultant and make use of other specialists as consultants as needed, ideally in the context of, or in conjunction with, the physician-led medical home. Because the child's welfare is heavily dependent on the home and family, the pediatrician supports efforts to create a nurturing environment. Such support includes education about healthful living and anticipatory guidance for both patients and parents.

A pediatrician participates at the community level in preventing or solving problems in child health care and publicly advocates the causes of children. (3/15, reaffirmed 12/19)
http://pediatrics.aappublications.org/content/135/4/780

DETENTION OF IMMIGRANT CHILDREN

Julie M. Linton, MD, FAAP; Marsha Griffin, MD, FAAP; Alan J. Shapiro, MD, FAAP; and Council on Community Pediatrics

ABSTRACT. Immigrant children seeking safe haven in the United States, whether arriving unaccompanied or in family units, face a complicated evaluation and legal process from the point of arrival through permanent resettlement in communities. The conditions in which children are detained and the support services that are available to them are of great concern to pediatricians and other advocates for children. In accordance with internationally accepted rights of the child, immigrant and refugee children should be treated with dignity and respect and should not be exposed to conditions that may harm or traumatize them. The Department of Homeland Security facilities do not meet the basic standards for the care of children in residential settings. The recommendations in this statement call for limited exposure of any child to current Department of Homeland Security facilities (ie, Customs and Border Protection and Immigration and Customs Enforcement facilities) and for

longitudinal evaluation of the health consequences of detention of immigrant children in the United States. From the moment children are in the custody of the United States, they deserve health care that meets guideline-based standards, treatment that mitigates harm or traumatization, and services that support their health and well-being. This policy statement also provides specific recommendations regarding postrelease services once a child is released into communities across the country, including a coordinated system that facilitates access to a medical home and consistent access to education, child care, interpretation services, and legal services. (4/17)

http://pediatrics.aappublications.org/content/139/5/e20170483

DEVELOPMENTAL DYSPLASIA OF THE HIP PRACTICE GUIDELINE (TECHNICAL REPORT)

Harold P. Lehmann, MD, PhD; Richard Hinton, MD, MPH; Paola Morello, MD; Jeanne Santoli, MD; in conjunction with Steering Committee on Quality Improvement and Subcommittee on Developmental Dysplasia of the Hip

ABSTRACT. *Objective.* To create a recommendation for pediatricians and other primary care providers about their role as screeners for detecting developmental dysplasia of the hip (DDH) in children.

Patients. Theoretical cohorts of newborns.

Method. Model-based approach using decision analysis as the foundation. Components of the approach include the following:

Perspective: Primary care provider.

Outcomes: DDH, avascular necrosis of the hip (AVN).

Options: Newborn screening by pediatric examination; orthopaedic examination; ultrasonographic examination; orthopaedic or ultrasonographic examination by risk factors. Intercurrent health supervision-based screening.

Preferences: 0 for bad outcomes, 1 for best outcomes.

Model: Influence diagram assessed by the Subcommittee and by the methodology team, with critical feedback from the Subcommittee.

Evidence Sources: Medline and EMBASE search of the research literature through June 1996. Hand search of sentinel journals from June 1996 through March 1997. Ancestor search of accepted articles.

Evidence Quality: Assessed on a custom subjective scale, based primarily on the fit of the evidence to the decision model.

Results. After discussion, explicit modeling, and critique, an influence diagram of 31 nodes was created. The computer-based and the hand literature searches found 534 articles, 101 of which were reviewed by 2 or more readers. Ancestor searches of these yielded a further 17 articles for evidence abstraction. Articles came from around the globe, although primarily Europe, British Isles, Scandinavia, and their descendants. There were 5 controlled trials, each with a sample size less than 40. The remainder were case series. Evidence was available for 17 of the desired 30 probabilities. Evidence quality ranged primarily between one third and two thirds of the maximum attainable score (median: 10–21; interquartile range: 8–14).

Based on the raw evidence and Bayesian hierarchical meta-analyses, our estimate for the incidence of DDH revealed by physical examination performed by pediatricians is 8.6 per 1000; for orthopaedic screening, 11.5; for ultrasonography, 25. The odds ratio for DDH, given breech delivery, is 5.5; for female sex, 4.1; for positive family history, 1.7, although this last factor is not statistically significant. Postneonatal cases of DDH were divided into mid-term (younger than 6 months of age) and late-term (older than 6 months of age). Our estimates for the mid-term rate for screening by pediatricians is 0.34/1000 children screened; for orthopaedists, 0.1; and for ultrasonography, 0.28. Our estimates for late-term DDH rates are 0.21/1000 newborns screened by pediatricians; 0.08, by orthopaedists; and 0.2 for ultrasonography. The rates of AVN for children referred before 6 months of age is estimated at 2.5/1000 infants referred. For those referred after 6 months of age, our estimate is 109/1000 referred infants.

The decision model (reduced, based on available evidence) suggests that orthopaedic screening is optimal, but because orthopaedists in the published studies and in practice would differ, the supply of orthopaedists is relatively limited, and the difference between orthopaedists and pediatricians is statistically insignificant, we conclude that pediatric screening is to be recommended. The place of ultrasonography in the screening process remains to be defined because there are too few data about postneonatal diagnosis by ultrasonographic screening to permit definitive recommendations. These data could be used by others to refine the conclusions based on costs, parental preferences, or physician style. Areas for research are well defined by our model-based approach. (4/00)

http://pediatrics.aappublications.org/content/105/4/e57

DIAGNOSIS, EVALUATION, AND MANAGEMENT OF HIGH BLOOD PRESSURE IN CHILDREN AND ADOLESCENTS (TECHNICAL REPORT)

Carissa M. Baker-Smith, MD, MS, MPH, FAAP, FAHA; Susan K. Flinn, MA; Joseph T. Flynn, MD, MS, FAAP; David C. Kaelber, MD, PhD, MPH, FAAP, FACP, FACMI; Douglas Blowey, MD; Aaron E. Carroll, MD, MS, FAAP; Stephen R. Daniels, MD, PhD, FAAP; Sarah D. de Ferranti, MD, MPH, FAAP; Janis M. Dionne, MD, FRCPC; Bonita Falkner, MD; Samuel S. Gidding, MD; Celeste Goodwin; Michael G. Leu, MD, MS, MHS, FAAP; Makia E. Powers, MD, MPH, FAAP; Corinna Rea, MD, MPH, FAAP; Joshua Samuels, MD, MPH, FAAP; Madeline Simasek, MD, MSCP, FAAP; Vidhu V. Thaker, MD, FAAP; Elaine M. Urbina, MD, MS, FAAP; and Subcommittee on Screening and Management of High Blood Pressure in Children

ABSTRACT. Systemic hypertension is a major cause of morbidity and mortality in adulthood. High blood pressure (HBP) and repeated measures of HBP, hypertension (HTN), begin in youth. Knowledge of how best to diagnose, manage, and treat systemic HTN in children and adolescents is important for primary and subspecialty care providers.

Objectives: To provide a technical summary of the methodology used to generate the 2017 "Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents," an update to the 2004 "Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents."

Data Sources: Medline, Cochrane Central Register of Controlled Trials, and Excerpta Medica Database references published between January 2003 and July 2015 followed by an additional search between August 2015 and July 2016.

Study Selection: English-language observational studies and randomized trials.

Methods: Key action statements (KASs) and additional recommendations regarding the diagnosis, management, and treatment of HBP in youth were the product of a detailed systematic review of the literature. A content outline establishing the breadth and depth was followed by the generation of 4 patient, intervention, comparison, outcome, time questions. Key questions addressed: (1) diagnosis of systemic HTN, (2) recommended work-up of systemic HTN, (3) optimal blood pressure (BP) goals, and (4) impact of high BP on indirect markers of cardiovascular disease in youth. Once selected, references were subjected to a 2-person review of the abstract and title followed by a separate 2-person full-text review. Full citation information, population data, findings, benefits and harms of the findings, as well as other key reference information were archived. Selected primary references were then used for KAS generation. Level of

evidence (LOE) scoring was assigned for each reference and then in aggregate. Appropriate language was used to generate each KAS based on the LOE and the balance of benefit versus harm of the findings. Topics that could not be researched via the stated approach were (1) definition of HTN in youth, and (2) definition of left ventricular hypertrophy. KASs related to these stated topics were generated via expert opinion.

Results: Nearly 15 000 references were identified during an initial literature search. After a deduplication process, 14 382 references were available for title and abstract review, and 1379 underwent full text review. One hundred twenty-four experimental and observational studies published between 2003 and 2016 were selected as primary references for KAS generation, followed by an additional 269 primary references selected between August 2015 and July 2016. The LOE for the majority of references was C. In total, 30 KASs and 27 additional recommendations were generated; 12 were related to the diagnosis of HTN, 13 were related to management and additional diagnostic testing, 3 to treatment goals, and 2 to treatment options. Finally, special additions to the clinical practice guideline included creation of new BP tables based on BP values obtained solely from children with normal weight, creation of a simplified table to enhance screening and recognition of abnormal BP, and a revision of the criteria for diagnosing left ventricular hypertrophy.

Conclusions: An extensive and detailed systematic approach was used to generate evidence-based guidelines for the diagnosis, management, and treatment of youth with systemic HTN. (8/18)

http://pediatrics.aappublications.org/content/142/3/e20182096

DIAGNOSIS, MANAGEMENT, AND TREATMENT OF FEMALE GENITAL MUTILATION OR CUTTING IN GIRLS (CLINICAL REPORT)

Janine Young, MD, FAAP; Nawal M. Nour, MD, MPH, FACOG; Robert C. Macauley, MD, FAAP; Sandeep K. Narang, MD, JD, FAAP; Crista Johnson-Agbakwu, MD, MSc, FACOG; Section on Global Health; Committee on Medical Liability and Risk Management; and Committee on Bioethics

ABSTRACT. Female genital mutilation or cutting (FGM/C) involves medically unnecessary cutting of parts or all of the external female genitalia. It is outlawed in the United States and much of the world but is still known to occur in more than 30 countries. FGM/C most often is performed on children, from infancy to adolescence, and has significant morbidity and mortality. In 2018, an estimated 200 million girls and women alive at that time had undergone FGM/C worldwide. Some estimate that more than 500 000 girls and women in the United States have had or are at risk for having FGM/C. However, pediatric prevalence of FGM/C is only estimated given that most pediatric cases remain undiagnosed both in countries of origin and in the Western world, including in the United States. It is a cultural practice not directly tied to any specific religion, ethnicity, or race and has occurred in the United States. Although it is mostly a pediatric practice, currently there is no standard FGM/C teaching required for health care providers who care for children, including pediatricians, family physicians, child abuse pediatricians, pediatric urologists, and pediatric urogynecologists. This clinical report is the first comprehensive summary of FGM/C in children and includes education regarding a standard-of-care approach for examination of external female genitalia at all health supervision examinations, diagnosis, complications, management, treatment, culturally sensitive discussion and counseling approaches, and legal and ethical considerations. (7/20)

See full text on page 665.

https://pediatrics.aappublications.org/content/146/2/e20201012

DIAGNOSIS, TREATMENT, AND PREVENTION OF CONGENITAL TOXOPLASMOSIS IN THE UNITED STATES (TECHNICAL REPORT)

Yvonne A. Maldonado, MD, FAAP; Jennifer S. Read, MD, MS, MPH, DTM&H, FAAP; and Committee on Infectious Diseases

ABSTRACT. Congenital toxoplasmosis (CT) is a parasitic disease that can cause significant fetal and neonatal harm. Coordinated efforts by pregnant women, researchers, physicians, and health policy makers regarding potential primary and secondary preventive measures for CT and their implementation may lead to a lower incidence of CT as well as lower morbidity and mortality rates associated with CT. The purpose of this technical report is to summarize available information regarding the diagnosis, treatment, and prevention of CT. (1/17)

http://pediatrics.aappublications.org/content/139/2/e20163860

DIAGNOSIS AND MANAGEMENT OF AN INITIAL UTI IN FEBRILE INFANTS AND YOUNG CHILDREN (TECHNICAL REPORT)

S. Maria E. Finnell, MD, MS; Aaron E. Carroll, MD, MS; Stephen M. Downs, MD, MS; Steering Committee on Quality Improvement and Management; and Subcommittee on Urinary Tract Infection

ABSTRACT. *Objectives.* The diagnosis and management of urinary tract infections (UTIs) in young children are clinically challenging. This report was developed to inform the revised, evidence-based, clinical guideline regarding the diagnosis and management of initial UTIs in febrile infants and young children, 2 to 24 months of age, from the American Academy of Pediatrics Subcommittee on Urinary Tract Infection.

Methods. The conceptual model presented in the 1999 technical report was updated after a comprehensive review of published literature. Studies with potentially new information or with evidence that reinforced the 1999 technical report were retained. Meta-analyses on the effectiveness of antimicrobial prophylaxis to prevent recurrent UTI were performed.

Results. Review of recent literature revealed new evidence in the following areas. Certain clinical findings and new urinalysis methods can help clinicians identify febrile children at very low risk of UTI. Oral antimicrobial therapy is as effective as parenteral therapy in treating UTI. Data from published, randomized controlled trials do not support antimicrobial prophylaxis to prevent febrile UTI when vesicoureteral reflux is found through voiding cystourethrography. Ultrasonography of the urinary tract after the first UTI has poor sensitivity. Early antimicrobial treatment may decrease the risk of renal damage from UTI.

Conclusions. Recent literature agrees with most of the evidence presented in the 1999 technical report, but meta-analyses of data from recent, randomized controlled trials do not support antimicrobial prophylaxis to prevent febrile UTI. This finding argues against voiding cystourethrography after the first UTI. (8/11)

http://pediatrics.aappublications.org/content/128/3/e749

DIAGNOSIS AND MANAGEMENT OF CHILDHOOD OBSTRUCTIVE SLEEP APNEA SYNDROME (TECHNICAL REPORT)

Carole L. Marcus, MBBCh; Lee J. Brooks, MD; Sally Davidson Ward, MD; Kari A. Draper, MD; David Gozal, MD; Ann C. Halbower, MD; Jacqueline Jones, MD; Christopher Lehmann, MD; Michael S. Schechter, MD, MPH; Stephen Sheldon, MD; Richard N. Shiffman, MD, MCIS; Karen Spruyt, PhD; Steering Committee on Quality Improvement and Management; and Subcommittee on Obstructive Sleep Apnea Syndrome

ABSTRACT. *Objective.* This technical report describes the procedures involved in developing recommendations on the management of childhood obstructive sleep apnea syndrome (OSAS).

Methods. The literature from 1999 through 2011 was evaluated.

Results and Conclusions. A total of 3166 titles were reviewed, of which 350 provided relevant data. Most articles were level II through IV. The prevalence of OSAS ranged from 0% to 5.7%, with obesity being an independent risk factor. OSAS was associated with cardiovascular, growth, and neurobehavioral abnormalities and possibly inflammation. Most diagnostic screening tests had low sensitivity and specificity. Treatment of OSAS resulted in improvements in behavior and attention and likely improvement in cognitive abilities. Primary treatment is adenotonsillectomy (AT). Data were insufficient to recommend specific surgical techniques; however, children undergoing partial tonsillectomy should be monitored for possible recurrence of OSAS. Although OSAS improved postoperatively, the proportion of patients who had residual OSAS ranged from 13% to 29% in low-risk populations to 73% when obese children were included and stricter polysomnographic criteria were used. Nevertheless, OSAS may improve after AT even in obese children, thus supporting surgery as a reasonable initial treatment. A significant number of obese patients required intubation or continuous positive airway pressure (CPAP) postoperatively, which reinforces the need for inpatient observation. CPAP was effective in the treatment of OSAS, but adherence is a major barrier. For this reason, CPAP is not recommended as first-line therapy for OSAS when AT is an option. Intranasal steroids may ameliorate mild OSAS, but follow-up is needed. Data were insufficient to recommend rapid maxillary expansion. (8/12)
http://pediatrics.aappublications.org/content/130/3/e714

DIAGNOSIS AND MANAGEMENT OF GASTROESOPHAGEAL REFLUX IN PRETERM INFANTS (CLINICAL REPORT)

Eric C. Eichenwald, MD, FAAP, and Committee on Fetus and Newborn

ABSTRACT. Gastroesophageal reflux (GER), generally defined as the passage of gastric contents into the esophagus, is an almost universal phenomenon in preterm infants. It is a common diagnosis in the NICU; however, there is large variation in its treatment across NICU sites. In this clinical report, the physiology, diagnosis, and symptomatology in preterm infants as well as currently used treatment strategies in the NICU are examined. Conservative measures to control reflux, such as left lateral body position, head elevation, and feeding regimen manipulation, have not been shown to reduce clinically assessed signs of GER in the preterm infant. In addition, preterm infants with clinically diagnosed GER are often treated with pharmacologic agents; however, a lack of evidence of efficacy together with emerging evidence of significant harm (particularly with gastric acid blockade) strongly suggest that these agents should be used sparingly, if at all, in preterm infants. (6/18)
http://pediatrics.aappublications.org/content/142/1/e20181061

DIAGNOSIS AND MANAGEMENT OF INFANTILE HEMANGIOMA (CLINICAL REPORT)

David H. Darrow, MD, DDS; Arin K. Greene, MD; Anthony J. Mancini, MD; Amy J. Nopper, MD; Section on Dermatology; Section on Otolaryngology—Head & Neck Surgery; and Section on Plastic Surgery

ABSTRACT. Infantile hemangiomas (IHs) are the most common tumors of childhood. Unlike other tumors, they have the unique ability to involute after proliferation, often leading primary care providers to assume they will resolve without intervention or consequence. Unfortunately, a subset of IHs rapidly develop complications, resulting in pain, functional impairment, or permanent disfigurement. As a result, the primary clinician has the task of determining which lesions require early consultation with a specialist. Although several recent reviews have been published, this clinical report is the first based on input from individuals representing the many specialties involved in the treatment of IH. Its purpose is to update the pediatric community regarding recent discoveries in IH pathogenesis, treatment, and clinical associations and to provide a basis for clinical decision-making in the management of IH. (9/15)
http://pediatrics.aappublications.org/content/136/4/e1060

DIAGNOSIS AND MANAGEMENT OF INFANTILE HEMANGIOMA: EXECUTIVE SUMMARY

David H. Darrow, MD, DDS, FAAP; Arin K. Greene, MD, FAAP; Anthony J. Mancini, MD, FAAP; Amy J. Nopper, MD, FAAP; Section on Dermatology; Section on Otolaryngology—Head & Neck Surgery; and Section on Plastic Surgery

ABSTRACT. Infantile hemangiomas (IHs) are the most common tumors of childhood. Unlike other tumors, they have the capacity to involute after proliferation, often leading primary care providers to assume they will resolve without intervention or consequence. However, a subset of IHs may be associated with complications, resulting in pain, functional impairment, or permanent disfigurement. As a result, the primary care provider is often called on to decide which lesions should be referred for early consultation with a specialist.

This document provides a summary of the guidance contained in the clinical report "Diagnosis and Management of Infantile Hemangioma," published concurrently in the online version of *Pediatrics* (*Pediatrics.* 2015;136[4]:e1060–e1104, available at: www.pediatrics.org/content/136/4/e1060). The report is uniquely based on input from the many specialties involved in the treatment of IH. Its purpose is to update the pediatric community about recent discoveries in IH pathogenesis, clinical associations, and treatment and to provide a knowledge base and framework for clinical decision-making in the management of IH. (9/15)
http://pediatrics.aappublications.org/content/136/4/786

DIAGNOSIS AND PREVENTION OF IRON DEFICIENCY AND IRON-DEFICIENCY ANEMIA IN INFANTS AND YOUNG CHILDREN (0–3 YEARS OF AGE) (CLINICAL REPORT)

Robert D. Baker, MD, PhD; Frank R. Greer, MD; and Committee on Nutrition

ABSTRACT. This clinical report covers diagnosis and prevention of iron deficiency and iron-deficiency anemia in infants (both breastfed and formula fed) and toddlers from birth through 3 years of age. Results of recent basic research support the concerns that iron-deficiency anemia and iron deficiency without anemia during infancy and childhood can have long-lasting detrimental effects on neurodevelopment. Therefore, pediatricians and other health care providers should strive to eliminate iron deficiency and iron-deficiency anemia. Appropriate iron intakes for infants and toddlers as well as methods for screening for iron deficiency and iron-deficiency anemia are presented. (10/10)
http://pediatrics.aappublications.org/content/126/5/1040

DIAGNOSIS OF HIV-1 INFECTION IN CHILDREN YOUNGER THAN 18 MONTHS IN THE UNITED STATES (TECHNICAL REPORT)

Jennifer S. Read, MD, MS, MPH, DTM&H, and Committee on Pediatric AIDS

ABSTRACT. The objectives of this technical report are to describe methods of diagnosis of HIV-1 infection in children younger than 18 months in the United States and to review important issues that must be considered by clinicians who care for infants and young children born to HIV-1–infected women. Appropriate HIV-1 diagnostic testing for infants and children younger than 18 months differs from that for older children, adolescents, and adults because of passively transferred maternal HIV-1 antibodies, which may be detectable in the child's bloodstream until 18 months of age. Therefore, routine serologic testing of these infants and young children is generally only informative before the age of 18 months if the test result is negative. Virologic assays, including HIV-1 DNA or RNA assays, represent the gold

standard for diagnostic testing of infants and children younger than 18 months. With such testing, the diagnosis of HIV-1 infection (as well as the presumptive exclusion of HIV-1 infection) can be established within the first several weeks of life among nonbreastfed infants. Important factors that must be considered when selecting HIV-1 diagnostic assays for pediatric patients and when choosing the timing of such assays include the age of the child, potential timing of infection of the child, whether the infection status of the child's mother is known or unknown, the antiretroviral exposure history of the mother and of the child, and characteristics of the virus. If the mother's HIV-1 serostatus is unknown, rapid HIV-1 antibody testing of the newborn infant to identify HIV-1 exposure is essential so that antiretroviral prophylaxis can be initiated within the first 12 hours of life if test results are positive. For HIV-1–exposed infants (identified by positive maternal test results or positive antibody results for the infant shortly after birth), it has been recommended that diagnostic testing with HIV-1 DNA or RNA assays be performed within the first 14 days of life, at 1 to 2 months of age, and at 3 to 6 months of age. If any of these test results are positive, repeat testing is recommended to confirm the diagnosis of HIV-1 infection. A diagnosis of HIV-1 infection can be made on the basis of 2 positive HIV-1 DNA or RNA assay results. In nonbreastfeeding children younger than 18 months with no positive HIV-1 virologic test results, presumptive exclusion of HIV-1 infection can be based on 2 negative virologic test results (1 obtained at ≥2 weeks and 1 obtained at ≥4 weeks of age); 1 negative virologic test result obtained at ≥8 weeks of age; or 1 negative HIV-1 antibody test result obtained at ≥6 months of age. Alternatively, presumptive exclusion of HIV-1 infection can be based on 1 positive HIV-1 virologic test with at least 2 subsequent negative virologic test results (at least 1 of which is performed at ≥8 weeks of age) or negative HIV-1 antibody test results (at least 1 of which is performed at ≥6 months of age). Definitive exclusion of HIV-1 infection is based on 2 negative virologic test results, 1 obtained at ≥1 month of age and 1 obtained at ≥4 months of age, or 2 negative HIV-1 antibody test results from separate specimens obtained at ≥6 months of age. For both presumptive and definitive exclusion of infection, the child should have no other laboratory (eg, no positive virologic test results) or clinical (eg, no AIDS-defining conditions) evidence of HIV-1 infection. Many clinicians confirm the absence of HIV-1 infection with a negative HIV-1 antibody assay result at 12 to 18 months of age. For breastfeeding infants, a similar testing algorithm can be followed, with timing of testing starting from the date of complete cessation of breastfeeding instead of the date of birth. (12/07, reaffirmed 4/10, 2/15)

http://pediatrics.aappublications.org/content/120/6/e1547

DIAGNOSIS OF PREGNANCY AND PROVIDING OPTIONS COUNSELING FOR THE ADOLESCENT PATIENT (CLINICAL REPORT)

Laurie L. Hornberger, MD, MPH, FAAP, and Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics policy statement "Options Counseling for the Pregnant Adolescent Patient" recommends the basic content of the pediatrician's counseling for an adolescent facing a new diagnosis of pregnancy. However, options counseling is just one aspect of what may be one of the more challenging scenarios in the pediatric office. Pediatricians must remain alert to the possibility of pregnancy among their adolescent female patients. When discovering symptoms suggestive of pregnancy, pediatricians must obtain a relevant history, perform diagnostic testing and properly interpret the results, and understand the significance of the results from the patient perspective and reveal them to the patient in a sensitive manner. If the patient is indeed pregnant, the pediatrician, in addition to providing comprehensive options counseling, may need to help recruit adult support for the patient and should offer continued assistance to the adolescent and her family after the office visit. All pediatricians should be aware of the legal aspects of adolescent reproductive care and the resources for pregnant adolescents in their communities. This clinical report presents a more comprehensive view of the evaluation and management of pregnancy in the adolescent patient and a context for options counseling. (8/17)

http://pediatrics.aappublications.org/content/140/3/e20172273

DIAGNOSTIC IMAGING OF CHILD ABUSE

Section on Radiology

ABSTRACT. The role of imaging in cases of child abuse is to identify the extent of physical injury when abuse is present and to elucidate all imaging findings that point to alternative diagnoses. Effective diagnostic imaging of child abuse rests on high-quality technology as well as a full appreciation of the clinical and pathologic alterations occurring in abused children. This statement is a revision of the previous policy published in 2000. (4/09)

http://pediatrics.aappublications.org/content/123/5/1430

DIGITAL ADVERTISING TO CHILDREN

Jenny Radesky, MD, FAAP; Yolanda (Linda) Reid Chassiakos, MD, FAAP, FACP; Nusheen Ameenuddin, MD, MPH, MPA, FAAP; Dipesh Navsaria, MPH, MSLIS, MD, FAAP; and Council on Communication and Media

ABSTRACT. Advertising to children and teenagers is a multibillion-dollar industry. This policy statement reviews the forms of advertising that children and teenagers encounter, including newer forms of digital marketing, such as sponsored content, influencers, data collection, persuasive design, and personalized behavioral marketing driven by machine learning. Parents and pediatric health care providers need to be aware of the ways different marketing messages reach children and teenagers, including Internet sites, social media, and mobile apps. Evidence suggests that exposure to advertising is associated with unhealthy behaviors, such as intake of high-calorie, low-nutrient food and beverages; use of tobacco products and electronic cigarettes; use of alcohol and marijuana; and indoor tanning. Children are uniquely vulnerable to the persuasive effects of advertising because of immature critical thinking skills and impulse inhibition. School-aged children and teenagers may be able to recognize advertising but often are not able to resist it when it is embedded within trusted social networks, encouraged by celebrity influencers, or delivered next to personalized content. This policy statement expresses concern about the practice of tracking and using children's digital behavior to inform targeted marketing campaigns, which may contribute to health disparities among vulnerable children or populations. Pediatricians should guide parents and children to develop digital literacy skills to prevent or mitigate negative outcomes, but it is equally important that policy makers and technology companies embrace digital design, data collection, and marketing practices within today's broad digital environment that support healthier decision-making and outcomes. (6/20)

See full text on page 699.

https://pediatrics.aappublications.org/content/146/1/e20201681

DISASTER PREPAREDNESS IN NEONATAL INTENSIVE CARE UNITS (CLINICAL REPORT)

Wanda D. Barfield, MD, MPH, FAAP, RADM USPHS; Steven E. Krug, MD, FAAP; Committee on Fetus and Newborn; and Disaster Preparedness Council

ABSTRACT. Disasters disproportionally affect vulnerable, technology-dependent people, including preterm and critically ill newborn infants. It is important for health care providers to be aware of and prepared for the potential consequences of disasters for the NICU. Neonatal intensive care personnel can

provide specialized expertise for their hospital, community, and regional emergency preparedness plans and can help develop institutional surge capacity for mass critical care, including equipment, medications, personnel, and facility resources. (4/17)
http://pediatrics.aappublications.org/content/139/5/e20170507

DISCLOSURE OF ADVERSE EVENTS IN PEDIATRICS

Committee on Medical Liability and Risk Management and Council on Quality Improvement and Patient Safety

ABSTRACT. Despite increasing attention to issues of patient safety, preventable adverse events (AEs) continue to occur, causing direct and consequential injuries to patients, families, and health care providers. Pediatricians generally agree that there is an ethical obligation to inform patients and families about preventable AEs and medical errors. Nonetheless, barriers, such as fear of liability, interfere with disclosure regarding preventable AEs. Changes to the legal system, improved communications skills, and carefully developed disclosure policies and programs can improve the quality and frequency of appropriate AE disclosure communications. (11/16)
http://pediatrics.aappublications.org/content/138/6/e20163215

DISPENSING MEDICATIONS AT THE HOSPITAL UPON DISCHARGE FROM AN EMERGENCY DEPARTMENT (TECHNICAL REPORT)

Loren G. Yamamoto, MD, MPH, MBA; Shannon Manzi, PharmD; and Committee on Pediatric Emergency Medicine

ABSTRACT. Although most health care services can and should be provided by their medical home, children will be referred or require visits to the emergency department (ED) for emergent clinical conditions or injuries. Continuation of medical care after discharge from an ED is dependent on parents or caregivers' understanding of and compliance with follow-up instructions and on adherence to medication recommendations. ED visits often occur at times when the majority of pharmacies are not open and caregivers are concerned with getting their ill or injured child directly home. Approximately one-third of patients fail to obtain priority medications from a pharmacy after discharge from an ED. The option of judiciously dispensing ED discharge medications from the ED's outpatient pharmacy within the facility is a major convenience that overcomes this obstacle, improving the likelihood of medication adherence. Emergency care encounters should be routinely followed up with primary care provider medical homes to ensure complete and comprehensive care. (1/12, reaffirmed 9/15, 7/19)
http://pediatrics.aappublications.org/content/129/2/e562

DISTINGUISHING SUDDEN INFANT DEATH SYNDROME FROM CHILD ABUSE FATALITIES (CLINICAL REPORT)

Kent P. Hymel, MD, and Committee on Child Abuse and Neglect (joint with National Association of Medical Examiners)

ABSTRACT. Fatal child abuse has been mistaken for sudden infant death syndrome. When a healthy infant younger than 1 year dies suddenly and unexpectedly, the cause of death may be certified as sudden infant death syndrome. Sudden infant death syndrome is more common than infanticide. Parents of sudden infant death syndrome victims typically are anxious to provide unlimited information to professionals involved in death investigation or research. They also want and deserve to be approached in a nonaccusatory manner. This clinical report provides professionals with information and suggestions for procedures to help avoid stigmatizing families of sudden infant death syndrome victims while allowing accumulation of appropriate evidence in potential cases of infanticide. This clinical report addresses deficiencies and updates recommendations in the 2001 American Academy of Pediatrics policy statement of the same name. (7/06, reaffirmed 4/09, 3/13, 7/17)
http://pediatrics.aappublications.org/content/118/1/421

DONOR HUMAN MILK FOR THE HIGH-RISK INFANT: PREPARATION, SAFETY, AND USAGE OPTIONS IN THE UNITED STATES

Committee on Nutrition, Section on Breastfeeding, and Committee on Fetus and Newborn

ABSTRACT. The use of donor human milk is increasing for high-risk infants, primarily for infants born weighing <1500 g or those who have severe intestinal disorders. Pasteurized donor milk may be considered in situations in which the supply of maternal milk is insufficient. The use of pasteurized donor milk is safe when appropriate measures are used to screen donors and collect, store, and pasteurize the milk and then distribute it through established human milk banks. The use of nonpasteurized donor milk and other forms of direct, Internet-based, or informal human milk sharing does not involve this level of safety and is not recommended. It is important that health care providers counsel families considering milk sharing about the risks of bacterial or viral contamination of nonpasteurized human milk and about the possibilities of exposure to medications, drugs, or herbs in human milk. Currently, the use of pasteurized donor milk is limited by its availability and affordability. The development of public policy to improve and expand access to pasteurized donor milk, including policies that support improved governmental and private financial support for donor milk banks and the use of donor milk, is important. (12/16)
http://pediatrics.aappublications.org/content/139/1/e20163440

DRINKING WATER FROM PRIVATE WELLS AND RISKS TO CHILDREN

Committee on Environmental Health and Committee on Infectious Diseases

ABSTRACT. Drinking water for approximately one sixth of US households is obtained from private wells. These wells can become contaminated by pollutant chemicals or pathogenic organisms and cause illness. Although the US Environmental Protection Agency and all states offer guidance for construction, maintenance, and testing of private wells, there is little regulation. With few exceptions, well owners are responsible for their own wells. Children may also drink well water at child care or when traveling. Illness resulting from children's ingestion of contaminated water can be severe. This policy statement provides recommendations for inspection, testing, and remediation for wells providing drinking water for children. (5/09, reaffirmed 1/13, 9/19)
http://pediatrics.aappublications.org/content/123/6/1599

DRINKING WATER FROM PRIVATE WELLS AND RISKS TO CHILDREN (TECHNICAL REPORT)

Walter J. Rogan, MD; Michael T. Brady, MD; Committee on Environmental Health; and Committee on Infectious Diseases

ABSTRACT. Drinking water for approximately one sixth of US households is obtained from private wells. These wells can become contaminated by pollutant chemicals or pathogenic organisms, leading to significant illness. Although the US Environmental Protection Agency and all states offer guidance for construction, maintenance, and testing of private wells, there is little regulation, and with few exceptions, well owners are responsible for their own wells. Children may also drink well water at child care or when traveling. Illness resulting from children's ingestion of contaminated water can be severe. This report reviews relevant aspects of groundwater and wells; describes the common chemical and microbiologic contaminants; gives an algorithm with recommendations for inspection, testing, and remediation for wells providing drinking water for children; reviews the definitions and uses of various bottled waters; provides current estimates of costs for well testing; and provides

federal, national, state, and, where appropriate, tribal contacts for more information. (5/09, reaffirmed 1/13, 9/19)
http://pediatrics.aappublications.org/content/123/6/e1123

DRUGS USED TO TREAT PEDIATRIC EMERGENCIES (CLINICAL REPORT)

Rohit P. Shenoi, MD, FAAP; Nathan Timm, MD, FAAP; Committee on Drugs; and Committee on Pediatric Emergency Medicine

ABSTRACT. This clinical report is a revision of "Preparing for Pediatric Emergencies: Drugs to Consider." It updates the list, indications, and dosages of medications used to treat pediatric emergencies in the prehospital, pediatric clinic, and emergency department settings. Although it is not an all-inclusive list of medications that may be used in all emergencies, this resource will be helpful when treating a vast majority of pediatric medical emergencies. Dosage recommendations are consistent with current emergency references such as the Advanced Pediatric Life Support and Pediatric Advanced Life Support textbooks and American Heart Association resuscitation guidelines. (12/19)
See full text on page 709.
https://pediatrics.aappublications.org/content/145/1/e20193450

E-CIGARETTES AND SIMILAR DEVICES

Brian P. Jenssen, MD, MSHP, FAAP; Susan C. Walley, MD, FAAP; and Section on Tobacco Control

ABSTRACT. Electronic cigarettes (e-cigarettes) are the most commonly used tobacco product among youth. The 2016 US Surgeon General's Report on e-cigarette use among youth and young adults concluded that e-cigarettes are unsafe for children and adolescents. Furthermore, strong and consistent evidence finds that children and adolescents who use e-cigarettes are significantly more likely to go on to use traditional cigarettes—a product that kills half its long-term users. E-cigarette manufacturers target children with enticing candy and fruit flavors and use marketing strategies that have been previously successful with traditional cigarettes to attract youth to these products. Numerous toxicants and carcinogens have been found in e-cigarette solutions. Nonusers are involuntarily exposed to the emissions of these devices with secondhand and thirdhand aerosol. To prevent children, adolescents, and young adults from transitioning from e-cigarettes to traditional cigarettes and minimize the potential public health harm from e-cigarette use, there is a critical need for e-cigarette regulation, legislative action, and counterpromotion to protect youth. (1/19)
https://pediatrics.aappublications.org/content/143/2/e20183652

EARLY CHILDHOOD ADVERSITY, TOXIC STRESS, AND THE ROLE OF THE PEDIATRICIAN: TRANSLATING DEVELOPMENTAL SCIENCE INTO LIFELONG HEALTH

Committee on Psychosocial Aspects of Child and Family Health; Committee on Early Childhood, Adoption, and Dependent Care; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. Advances in a wide range of biological, behavioral, and social sciences are expanding our understanding of how early environmental influences (the ecology) and genetic predispositions (the biologic program) affect learning capacities, adaptive behaviors, lifelong physical and mental health, and adult productivity. A supporting technical report from the American Academy of Pediatrics (AAP) presents an integrated ecobiodevelopmental framework to assist in translating these dramatic advances in developmental science into improved health across the life span. Pediatricians are now armed with new information about the adverse effects of toxic stress on brain development, as well as a deeper understanding of the early life origins of many adult diseases. As trusted authorities in child health and development, pediatric providers must now complement the early identification of developmental concerns with a greater focus on those interventions and community investments that reduce external threats to healthy brain growth. To this end, AAP endorses a developing leadership role for the entire pediatric community—one that mobilizes the scientific expertise of both basic and clinical researchers, the family-centered care of the pediatric medical home, and the public influence of AAP and its state chapters—to catalyze fundamental change in early childhood policy and services. AAP is committed to leveraging science to inform the development of innovative strategies to reduce the precipitants of toxic stress in young children and to mitigate their negative effects on the course of development and health across the life span. (12/11, reaffirmed 7/16)
http://pediatrics.aappublications.org/content/129/1/e224

EARLY CHILDHOOD CARIES IN INDIGENOUS COMMUNITIES

Committee on Native American Child Health (joint with Canadian Paediatric Society First Nations, Inuit, and Métis Committee)

ABSTRACT. The oral health of Indigenous children of Canada (First Nations, Inuit, and Métis) and the United States (American Indian, Alaska Native) is a major child health issue: there is a high prevalence of early childhood caries (ECC) and resulting adverse health effects in this community, as well as high rates and costs of restorative and surgical treatments under general anesthesia. ECC is an infectious disease that is influenced by multiple factors, including socioeconomic determinants, and requires a combination of approaches for improvement. This statement includes recommendations for preventive oral health and clinical care for young infants and pregnant women by primary health care providers, community-based health-promotion initiatives, oral health workforce and access issues, and advocacy for community water fluoridation and fluoride-varnish program access. Further community-based research on the epidemiology, prevention, management, and microbiology of ECC in Indigenous communities would be beneficial. (5/11, reaffirmed 10/16)
http://pediatrics.aappublications.org/content/127/6/1190

EARLY CHILDHOOD HOME VISITING

James H. Duffee, MD, MPH, FAAP; Alan L. Mendelsohn, MD, FAAP; Alice A. Kuo, MD, PhD, FAAP; Lori A. Legano, MD, FAAP; Marian F. Earls, MD, MTS, FAAP; Council on Community Pediatrics; Council on Early Childhood; and Committee on Child Abuse and Neglect

ABSTRACT. High-quality home-visiting services for infants and young children can improve family relationships, advance school readiness, reduce child maltreatment, improve maternal-infant health outcomes, and increase family economic self-sufficiency. The American Academy of Pediatrics supports unwavering federal funding of state home-visiting initiatives, the expansion of evidence-based programs, and a robust, coordinated national evaluation designed to confirm best practices and cost-efficiency. Community home visiting is most effective as a component of a comprehensive early childhood system that actively includes and enhances a family-centered medical home. (8/17)
http://pediatrics.aappublications.org/content/140/3/e20172150

EARLY INTERVENTION, IDEA PART C SERVICES, AND THE MEDICAL HOME: COLLABORATION FOR BEST PRACTICE AND BEST OUTCOMES (CLINICAL REPORT)

Richard C. Adams, MD; Carl Tapia, MD; and Council on Children With Disabilities

ABSTRACT. The medical home and the Individuals With Disabilities Education Act Part C Early Intervention Program share many common purposes for infants and children ages 0 to 3 years, not the least of which is a family-centered focus. Professionals in pediatric medical home practices see substantial numbers of infants and toddlers with developmental delays

and/or complex chronic conditions. Economic, health, and family-focused data each underscore the critical role of timely referral for relationship-based, individualized, accessible early intervention services and the need for collaborative partnerships in care. The medical home process and Individuals With Disabilities Education Act Part C policy both support nurturing relationships and family-centered care; both offer clear value in terms of economic and health outcomes. Best practice models for early intervention services incorporate learning in the natural environment and coaching models. Proactive medical homes provide strategies for effective developmental surveillance, family-centered resources, and tools to support high-risk groups, and comanagement of infants with special health care needs, including the monitoring of services provided and outcomes achieved. (9/13, reaffirmed 5/17)
http://pediatrics.aappublications.org/content/132/4/e1073

ECHOCARDIOGRAPHY IN INFANTS AND CHILDREN

Section on Cardiology

ABSTRACT. It is the intent of this statement to inform pediatric providers on the appropriate use of echocardiography. Although on-site consultation may be impossible, methods should be established to ensure timely review of echocardiograms by a pediatric cardiologist. With advances in data transmission, echocardiography information can be exchanged, in some cases eliminating the need for a costly patient transfer. By cooperating through training, education, and referral, complete and cost-effective echocardiographic services can be provided to all children. (6/97, reaffirmed 3/03, 3/07)
http://pediatrics.aappublications.org/content/99/6/921

EFFECTIVE DISCIPLINE TO RAISE HEALTHY CHILDREN

Robert D. Sege, MD, PhD, FAAP; Benjamin S. Siegel, MD, FAAP; Council on Child Abuse and Neglect; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Pediatricians are a source of advice for parents and guardians concerning the management of child behavior, including discipline strategies that are used to teach appropriate behavior and protect their children and others from the adverse effects of challenging behavior. Aversive disciplinary strategies, including all forms of corporal punishment and yelling at or shaming children, are minimally effective in the short-term and not effective in the long-term. With new evidence, researchers link corporal punishment to an increased risk of negative behavioral, cognitive, psychosocial, and emotional outcomes for children. In this Policy Statement, the American Academy of Pediatrics provides guidance for pediatricians and other child health care providers on educating parents about positive and effective parenting strategies of discipline for children at each stage of development as well as references to educational materials. This statement supports the need for adults to avoid physical punishment and verbal abuse of children. (11/18)
http://pediatrics.aappublications.org/content/142/6/e20183112

THE EFFECTS OF ARMED CONFLICT ON CHILDREN

Sherry Shenoda, MD, FAAP; Ayesha Kadir, MD, MSc, FAAP; Shelly Pitterman, PhD; Jeffrey Goldhagen, MD, MPH, FAAP; and Section on International Child Health

ABSTRACT. Children are increasingly exposed to armed conflict and targeted by governmental and nongovernmental combatants. Armed conflict directly and indirectly affects children's physical, mental, and behavioral health. It can affect every organ system, and its impact can persist throughout the life course. In addition, children are disproportionately impacted by morbidity and mortality associated with armed conflict. A children's rights–based approach provides a framework for collaboration by the American Academy of Pediatrics, child health professionals, and national and international partners to respond in the domains of clinical care, systems development, and policy formulation. The American Academy of Pediatrics and child health professionals have critical and synergistic roles to play in the global response to the impact of armed conflict on children. (11/18)
http://pediatrics.aappublications.org/content/142/6/e20182585

THE EFFECTS OF ARMED CONFLICT ON CHILDREN (TECHNICAL REPORT)

Ayesha Kadir, MD, MSc, FAAP; Sherry Shenoda, MD, FAAP; Jeffrey Goldhagen, MD, MPH, FAAP; Shelly Pitterman, PhD; and Section on International Child Health

ABSTRACT. More than 1 in 10 children worldwide are affected by armed conflict. The effects are both direct and indirect and are associated with immediate and long-term harm. The direct effects of conflict include death, physical and psychological trauma, and displacement. Indirect effects are related to a large number of factors, including inadequate and unsafe living conditions, environmental hazards, caregiver mental health, separation from family, displacement-related health risks, and the destruction of health, public health, education, and economic infrastructure. Children and health workers are targeted by combatants during attacks, and children are recruited or forced to take part in combat in a variety of ways. Armed conflict is both a toxic stress and a significant social determinant of child health. In this Technical Report, we review the available knowledge on the effects of armed conflict on children and support the recommendations in the accompanying Policy Statement on children and armed conflict. (11/18)
http://pediatrics.aappublications.org/content/142/6/e20182586

THE EFFECTS OF EARLY NUTRITIONAL INTERVENTIONS ON THE DEVELOPMENT OF ATOPIC DISEASE IN INFANTS AND CHILDREN: THE ROLE OF MATERNAL DIETARY RESTRICTION, BREASTFEEDING, HYDROLYZED FORMULAS, AND TIMING OF INTRODUCTION OF ALLERGENIC COMPLEMENTARY FOODS (CLINICAL REPORT)

Frank R. Greer, MD, FAAP; Scott H. Sicherer, MD, FAAP; A. Wesley Burks, MD, FAAP; Committee on Nutrition; and Section on Allergy and Immunology

ABSTRACT. This clinical report updates and replaces a 2008 clinical report from the American Academy of Pediatrics, which addressed the roles of maternal and early infant diet on the prevention of atopic disease, including atopic dermatitis, asthma, and food allergy. As with the previous report, the available data still limit the ability to draw firm conclusions about various aspects of atopy prevention through early dietary interventions. Current evidence does not support a role for maternal dietary restrictions during pregnancy or lactation. Although there is evidence that exclusive breastfeeding for 3 to 4 months decreases the incidence of eczema in the first 2 years of life, there are no short- or long-term advantages for exclusive breastfeeding beyond 3 to 4 months for prevention of atopic disease. The evidence now suggests that any duration of breastfeeding ≥3 to 4 months is protective against wheezing in the first 2 years of life, and some evidence suggests that longer duration of any breastfeeding protects against asthma even after 5 years of age. No conclusions can be made about the role of breastfeeding in either preventing or delaying the onset of specific food allergies. There is a lack of evidence that partially or extensively hydrolyzed formula prevents atopic disease. There is no evidence that delaying the introduction of allergenic foods, including peanuts, eggs, and fish, beyond 4 to 6 months prevents atopic disease. There is now evidence that early introduction of peanuts may prevent peanut allergy. (3/19)
https://pediatrics.aappublications.org/content/143/4/e20190281

ELECTRONIC COMMUNICATION OF THE HEALTH RECORD AND INFORMATION WITH PEDIATRIC PATIENTS AND THEIR GUARDIANS

Emily C. Webber, MD, FAAP, FAMIA; David Brick, MD, FAAP; James P. Scibilia, MD, FAAP; Peter Dehnel, MD, FAAP; Council on Clinical Information Technology; Committee on Medical Liability and Risk Management; and Section on Telehealth Care

ABSTRACT. Communication of health data has evolved rapidly with the widespread adoption of electronic health records (EHRs) and communication technology. What used to be sent to patients via paper mail, fax, or e-mail may now be accessed by patients via their EHRs, and patients may also communicate securely with their medical team via certified technology. Although EHR technologies have great potential, their most effective applications and uses for communication between pediatric and adolescent patients, guardians, and medical teams has not been realized. There are wide variations in available technologies, guiding policies, and practices; some physicians and patients are successful in using certified tools but others are forced to limit their patients' access to e-health data and associated communication altogether. In general, pediatric and adolescent patients are less likely than adult patients to have electronic access and the ability to exchange health data. There are several reasons for these limitations, including inconsistent standards and recommendations regarding the recommended age for independent access, lack of routine EHR support for the ability to filter or proxy such access, and conflicting laws about patients' and physicians' rights to access EHRs and ability to communicate electronically. Effective, safe electronic exchange of health data requires active collaboration between physicians, patients, policy makers, and health information technology vendors. This policy statement addresses current best practices for these stakeholders and delineates the continued gaps and how to address them. (6/19)

https://pediatrics.aappublications.org/content/144/1/e20191359

ELECTRONIC DOCUMENTATION IN PEDIATRICS: THE RATIONALE AND FUNCTIONALITY REQUIREMENTS

Heather C. O'Donnell, MD, MSc, FAAP; Srinivasan Suresh, MD, MBA, FAAP; and Council on Clinical Information Technology

ABSTRACT. Clinical documentation is a fundamental component of the practice of medicine. It has significantly evolved over the past decade, largely because of the growth of health information technology and electronic health records. Although government agencies and other professional organizations have published position statements on the structure and use of electronic documentation, few have specifically addressed the documentation needs for the care of children. A policy statement on electronic documentation of clinical care by general pediatric and subspecialist providers by the American Academy of Pediatrics is needed. This statement provides insight on the unmet needs of key stakeholders to direct future research and development of the electronic media necessary to enhance the wellness of children and improve health care delivery. It also addresses the challenges and opportunities for efficient and effective clinical documentation in pediatrics. (6/20)

See full text on page 717.

https://pediatrics.aappublications.org/content/146/1/e20201682

ELECTRONIC DOCUMENTATION IN PEDIATRICS: THE RATIONALE AND FUNCTIONALITY REQUIREMENTS (TECHNICAL REPORT)

Heather C. O'Donnell, MD, MSc, FAAP; Srinivasan Suresh, MD, MBA, FAAP; and Council on Clinical Information Technology

ABSTRACT. Clinical documentation has dramatically changed since the implementation and use of electronic health records and electronic provider documentation. The purpose of this report is to review these changes and promote the development of standards and best practices for electronic documentation for pediatric patients. In this report, we evaluate the unique aspects of clinical documentation for pediatric care, including specialized information needs and stakeholders specific to the care of children. Additionally, we explore new models of documentation, such as shared documentation, in which patients may be both authors and consumers, and among care teams while still maintaining the ability to clearly define care and services provided to patients in a given day or encounter. Finally, we describe alternative documentation techniques and newer technologies that could improve provider efficiency and the reuse of clinical data. (6/20)

See full text on page 725.

https://pediatrics.aappublications.org/content/146/1/00

ELECTRONIC PRESCRIBING IN PEDIATRICS: TOWARD SAFER AND MORE EFFECTIVE MEDICATION MANAGEMENT

Council on Clinical Information Technology

ABSTRACT. This policy statement identifies the potential value of electronic prescribing (e-prescribing) systems in improving quality and reducing harm in pediatric health care. On the basis of limited but positive pediatric data and on the basis of federal statutes that provide incentives for the use of e-prescribing systems, the American Academy of Pediatrics recommends the adoption of e-prescribing systems with pediatric functionality. The American Academy of Pediatrics also recommends a set of functions that technology vendors should provide when e-prescribing systems are used in environments in which children receive care. (3/13, reaffirmed 12/18)

http://pediatrics.aappublications.org/content/131/4/824

ELECTRONIC PRESCRIBING IN PEDIATRICS: TOWARD SAFER AND MORE EFFECTIVE MEDICATION MANAGEMENT (TECHNICAL REPORT)

Kevin B. Johnson, MD, MS; Christoph U. Lehmann, MD; and Council on Clinical Information Technology

ABSRACT. This technical report discusses recent advances in electronic prescribing (e-prescribing) systems, including the evidence base supporting their limitations and potential benefits. Specifically, this report acknowledges that there are limited but positive pediatric data supporting the role of e-prescribing in mitigating medication errors, improving communication with dispensing pharmacists, and improving medication adherence. On the basis of these data and on the basis of federal statutes that provide incentives for the use of e-prescribing systems, the American Academy of Pediatrics recommends the adoption of e-prescribing systems with pediatric functionality. This report supports the accompanying policy statement from the American Academy of Pediatrics recommending the adoption of e-prescribing by pediatric health care providers. (3/13, reaffirmed 12/18)

http://pediatrics.aappublications.org/content/131/4/e1350

ELIMINATION OF PERINATAL HEPATITIS B: PROVIDING THE FIRST VACCINE DOSE WITHIN 24 HOURS OF BIRTH

Committee on Infectious Diseases and Committee on Fetus and Newborn

ABSTRACT. After the introduction of the hepatitis B vaccine in the United States in 1982, a greater than 90% reduction in new infections was achieved. However, approximately 1000 new cases of perinatal hepatitis B infection are still identified annually in the United States. Prevention of perinatal hepatitis B relies on the proper and timely identification of infants born to mothers who are hepatitis B surface antigen positive and to mothers with unknown status to ensure administration of appropriate postexposure immunoprophylaxis with hepatitis B vaccine and immune globulin. To reduce the incidence of perinatal hepatitis

B transmission further, the American Academy of Pediatrics endorses the recommendation of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention that all newborn infants with a birth weight of greater than or equal to 2000 g receive hepatitis B vaccine by 24 hours of age. (8/17)
http://pediatrics.aappublications.org/content/140/3/e20171870

EMERGENCY CONTRACEPTION

Krishna K. Upadhya, MD, MPH, FAAP, and Committee on Adolescence

ABSTRACT. Despite significant declines over the past 2 decades, the United States continues to experience birth rates among teenagers that are significantly higher than other high-income nations. Use of emergency contraception (EC) within 120 hours after unprotected or underprotected intercourse can reduce the risk of pregnancy. Emergency contraceptive methods include oral medications labeled and dedicated for use as EC by the US Food and Drug Administration (ulipristal and levonorgestrel), the "off-label" use of combined oral contraceptives, and insertion of a copper intrauterine device. Indications for the use of EC include intercourse without use of contraception; condom breakage or slippage; missed or late doses of contraceptives, including the oral contraceptive pill, contraceptive patch, contraceptive ring, and injectable contraception; vomiting after use of oral contraceptives; and sexual assault. Our aim in this updated policy statement is to (1) educate pediatricians and other physicians on available emergency contraceptive methods; (2) provide current data on the safety, efficacy, and use of EC in teenagers; and (3) encourage routine counseling and advance EC prescription as 1 public health strategy to reduce teenaged pregnancy. (11/19)
https://pediatrics.aappublications.org/content/144/6/e20193149

EMERGENCY INFORMATION FORMS AND EMERGENCY PREPAREDNESS FOR CHILDREN WITH SPECIAL HEALTH CARE NEEDS

Committee on Pediatric Emergency Medicine and Council on Clinical Information Technology (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee)

ABSTRACT. Children with chronic medical conditions rely on complex management plans for problems that cause them to be at increased risk for suboptimal outcomes in emergency situations. The emergency information form (EIF) is a medical summary that describes medical condition(s), medications, and special health care needs to inform health care providers of a child's special health conditions and needs so that optimal emergency medical care can be provided. This statement describes updates to EIFs, including computerization of the EIF, expanding the potential benefits of the EIF, quality-improvement programs using the EIF, the EIF as a central repository, and facilitating emergency preparedness in disaster management and drills by using the EIF. (3/10, reaffirmed 7/14, 10/14)
http://pediatrics.aappublications.org/content/125/4/829

EMERGING ISSUES IN MALE ADOLESCENT SEXUAL AND REPRODUCTIVE HEALTH CARE (CLINICAL REPORT)

Laura K. Grubb, MD, MPH, FAAP; Makia Powers, MD, MPH, MSc, FAAP; and Committee on Adolescence

ABSTRACT. Pediatricians are encouraged to address male adolescent sexual and reproductive health on a regular basis, including taking a sexual history, discussing healthy sexuality, performing an appropriate physical examination, providing patient-centered and age-appropriate anticipatory guidance, and administering appropriate vaccinations. These services can be provided to male adolescent patients in a confidential and culturally appropriate manner, can promote healthy sexual relationships and responsibility, can and involve parents in age-appropriate discussions about sexual health. (4/20)
See full text on page 739.
https://pediatrics.aappublications.org/content/145/5/e20200627

ENDORSEMENT OF HEALTH AND HUMAN SERVICES RECOMMENDATION FOR PULSE OXIMETRY SCREENING FOR CRITICAL CONGENITAL HEART DISEASE

Section on Cardiology and Cardiac Surgery Executive Committee

ABSTRACT. Incorporation of pulse oximetry to the assessment of the newborn infant can enhance detection of critical congenital heart disease (CCHD). Recently, the Secretary of Health and Human Services (HHS) recommended that screening for CCHD be added to the uniform screening panel. The American Academy of Pediatrics (AAP) has been a strong advocate of early detection of CCHD and fully supports the decision of the Secretary of HHS.

The AAP has published strategies for the implementation of pulse oximetry screening, which addressed critical issues such as necessary equipment, personnel, and training, and also provided specific recommendations for assessment of saturation by using pulse oximetry as well as appropriate management of a positive screening result. The AAP is committed to the safe and effective implementation of pulse oximetry screening and is working with other advocacy groups and governmental agencies to promote pulse oximetry and to support widespread surveillance for CCHD.

Going forward, AAP chapters will partner with state health departments to implement the new screening strategy for CCHD and will work to ensure that there is an adequate system for referral for echocardiographic/pediatric cardiac evaluation after a positive screening result. It is imperative that AAP members engage their respective policy makers in adopting and funding the recommendations made by the Secretary of HHS. (12/11)
http://pediatrics.aappublications.org/content/129/1/190

ENHANCING PEDIATRIC WORKFORCE DIVERSITY AND PROVIDING CULTURALLY EFFECTIVE PEDIATRIC CARE: IMPLICATIONS FOR PRACTICE, EDUCATION, AND POLICY MAKING

Committee on Pediatric Workforce

ABSTRACT. This policy statement serves to combine and update 2 previously independent but overlapping statements from the American Academy of Pediatrics (AAP) on culturally effective health care (CEHC) and workforce diversity. The AAP has long recognized that with the ever-increasing diversity of the pediatric population in the United States, the health of all children depends on the ability of all pediatricians to practice culturally effective care. CEHC can be defined as the delivery of care within the context of appropriate physician knowledge, understanding, and appreciation of all cultural distinctions, leading to optimal health outcomes. The AAP believes that CEHC is a critical social value and that the knowledge and skills necessary for providing CEHC can be taught and acquired through focused curricula across the spectrum of lifelong learning.

This statement also addresses workforce diversity, health disparities, and affirmative action. The discussion of diversity is broadened to include not only race, ethnicity, and language but also cultural attributes such as gender, religious beliefs, sexual orientation, and disability, which may affect the quality of health care. The AAP believes that efforts must be supported through health policy and advocacy initiatives to promote the delivery of CEHC and to overcome educational, organizational, and other barriers to improving workforce diversity. (9/13, reaffirmed 10/15)
http://pediatrics.aappublications.org/content/132/4/e1105

ENSURING COMPREHENSIVE CARE AND SUPPORT FOR TRANSGENDER AND GENDER-DIVERSE CHILDREN AND ADOLESCENTS

Jason Rafferty, MD, MPH, EdM, FAAP; Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; and Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness

ABSTRACT. As a traditionally underserved population that faces numerous health disparities, youth who identify as transgender and gender diverse (TGD) and their families are increasingly presenting to pediatric providers for education, care, and referrals. The need for more formal training, standardized treatment, and research on safety and medical outcomes often leaves providers feeling ill equipped to support and care for patients that identify as TGD and families. In this policy statement, we review relevant concepts and challenges and provide suggestions for pediatric providers that are focused on promoting the health and positive development of youth that identify as TGD while eliminating discrimination and stigma. (9/18)

http://pediatrics.aappublications.org/content/142/4/e20182162

ENSURING THE HEALTH OF CHILDREN IN DISASTERS

Disaster Preparedness Advisory Council and Committee on Pediatric Emergency Medicine

ABSTRACT. Infants, children, adolescents, and young adults have unique physical, mental, behavioral, developmental, communication, therapeutic, and social needs that must be addressed and met in all aspects of disaster preparedness, response, and recovery. Pediatricians, including primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists, have key roles to play in preparing and treating families in cases of disasters. Pediatricians should attend to the continuity of practice operations to provide services in time of need and stay abreast of disaster and public health developments to be active participants in community planning efforts. Federal, state, tribal, local, and regional institutions and agencies that serve children should collaborate with pediatricians to ensure the health and well-being of children in disasters. (10/15)

http://pediatrics.aappublications.org/content/136/5/e1407

EPIDEMIOLOGY AND DIAGNOSIS OF HEALTH CARE–ASSOCIATED INFECTIONS IN THE NICU (TECHNICAL REPORT)

Committee on Fetus and Newborn and Committee on Infectious Diseases

ABSTRACT. Health care–associated infections in the NICU are a major clinical problem resulting in increased morbidity and mortality, prolonged length of hospital stays, and increased medical costs. Neonates are at high risk for health care–associated infections because of impaired host defense mechanisms, limited amounts of protective endogenous flora on skin and mucosal surfaces at time of birth, reduced barrier function of neonatal skin, the use of invasive procedures and devices, and frequent exposure to broad-spectrum antibiotics. This statement will review the epidemiology and diagnosis of health care–associated infections in newborn infants. (3/12, reaffirmed 2/16)

http://pediatrics.aappublications.org/content/129/4/e1104

EPINEPHRINE FOR FIRST-AID MANAGEMENT OF ANAPHYLAXIS (CLINICAL REPORT)

Scott H. Sicherer, MD, FAAP; F. Estelle R. Simons, MD, FAAP; and Section on Allergy and Immunology

ABSTRACT. Anaphylaxis is a severe, generalized allergic or hypersensitivity reaction that is rapid in onset and may cause death. Epinephrine (adrenaline) can be life-saving when administered as rapidly as possible once anaphylaxis is recognized. This clinical report from the American Academy of Pediatrics is an update of the 2007 clinical report on this topic. It provides information to help clinicians identify patients at risk of anaphylaxis and new information about epinephrine and epinephrine autoinjectors (EAs). The report also highlights the importance of patient and family education about the recognition and management of anaphylaxis in the community. Key points emphasized include the following: (1) validated clinical criteria are available to facilitate prompt diagnosis of anaphylaxis; (2) prompt intramuscular epinephrine injection in the mid-outer thigh reduces hospitalizations, morbidity, and mortality; (3) prescribing EAs facilitates timely epinephrine injection in community settings for patients with a history of anaphylaxis and, if specific circumstances warrant, for some high-risk patients who have not previously experienced anaphylaxis; (4) prescribing epinephrine for infants and young children weighing <15 kg, especially those who weigh 7.5 kg and under, currently presents a dilemma, because the lowest dose available in EAs, 0.15 mg, is a high dose for many infants and some young children; (5) effective management of anaphylaxis in the community requires a comprehensive approach involving children, families, preschools, schools, camps, and sports organizations; and (6) prevention of anaphylaxis recurrences involves confirmation of the trigger, discussion of specific allergen avoidance, allergen immunotherapy (eg, with stinging insect venom, if relevant), and a written, personalized anaphylaxis emergency action plan; and (7) the management of anaphylaxis also involves education of children and supervising adults about anaphylaxis recognition and first-aid treatment. (2/17)

http://pediatrics.aappublications.org/content/139/3/e20164006

EQUIPMENT FOR GROUND AMBULANCES

American Academy of Pediatrics (joint with American College of Emergency Physicians, American College of Surgeons Committee on Trauma, Emergency Medical Services for Children, Emergency Nurses Association, National Association of EMS Physicians, and National Association of State EMS Officials)

On January 1, 2014, the American Academy of Pediatrics, American College of Emergency Physicians, American College of Surgeons Committee on Trauma, Emergency Medical Services for Children, Emergency Nurses Association, National Association of EMS Physicians, and National Association of State EMS Officials coauthored a joint policy statement, "Equipment for Ground Ambulances" (*Prehosp Emerg Care.* 2014;19[1]:92–97). The full text of the joint policy statement is available at: http://informahealthcare.com/doi/full/10.3109/10903127.2013.851312. (8/14, reaffirmed 1/20)

http://pediatrics.aappublications.org/content/134/3/e919

ERADICATING POLIO: HOW THE WORLD'S PEDIATRICIANS CAN HELP STOP THIS CRIPPLING ILLNESS FOREVER (CLINICAL REPORT)

Walter A. Orenstein, MD, FAAP, and Committee on Infectious Diseases

ABSTRACT. The American Academy of Pediatrics strongly supports the Polio Eradication and Endgame Strategic Plan of the Global Polio Eradication Initiative. This plan was endorsed in November 2012 by the Strategic Advisory Group of Experts on Immunization of the World Health Organization and published by the World Health Organization in April 2013. As a key component of the plan, it will be necessary to stop oral polio vaccine (OPV) use globally to achieve eradication, because the attenuated viruses in the vaccine rarely can cause polio. The plan includes procedures for elimination of vaccine-associated paralytic polio and circulating vaccine-derived polioviruses (cVDPVs). cVDPVs can proliferate when vaccine viruses are transmitted among susceptible people, resulting in mutations conferring both the neurovirulence and transmissibility characteristics of wild polioviruses. Although there are 3 different types of wild poliovirus strains, the polio eradication effort has already

resulted in the global elimination of type 2 poliovirus for more than a decade. Type 3 poliovirus may be eliminated because the wild type 3 poliovirus was last detected in 2012. Thus, of the 3 wild types, only wild type 1 poliovirus is still known to be circulating and causing disease. OPV remains the key vaccine for eradicating wild polioviruses in polio-infected countries because it induces high levels of systemic immunity to prevent paralysis and intestinal immunity to reduce transmission. However, OPV is a rare cause of paralysis and the substantial decrease in wild-type disease has resulted in estimates that the vaccine is causing more polio-related paralysis annually in recent years than the wild virus. The new endgame strategic plan calls for stepwise removal of the type 2 poliovirus component from trivalent oral vaccines, because type 2 wild poliovirus appears to have been eradicated (since 1999) and yet is the main cause of cVDPV outbreaks and approximately 40% of vaccine-associated paralytic polio cases. The Endgame and Strategic Plan will be accomplished by shifting from trivalent OPV to bivalent OPV (containing types 1 and 3 poliovirus only). It will be necessary to introduce trivalent inactivated poliovirus vaccine (IPV) into routine immunization programs in all countries using OPV to provide population immunity to type 2 before the switch from trivalent OPV to bivalent OPV. The Global Polio Eradication Initiative hopes to achieve global eradication of polio by 2018 with this strategy, after which all OPV use will be stopped. Challenges expected for adding IPV into routine immunization schedules include higher cost of IPV compared with OPV, cold-chain capacity limits, more complex administration of vaccine because IPV requires injections as opposed to oral administration, and inferior intestinal immunity conferred by IPV. The goal of this report is to help pediatricians understand the change in strategy and outline ways that pediatricians can help global polio eradication efforts, including advocating for the resources needed to accomplish polio eradication and for incorporation of IPV into routine immunization programs in all countries. (12/14, reaffirmed 5/19)

http://pediatrics.aappublications.org/content/135/1/196

ESSENTIAL CONTRACTUAL LANGUAGE FOR MEDICAL NECESSITY IN CHILDREN

Committee on Child Health Financing

ABSTRACT. The previous policy statement from the American Academy of Pediatrics, "Model Language for Medical Necessity in Children," was published in July 2005. Since that time, there have been new and emerging delivery and payment models. The relationship established between health care providers and health plans should promote arrangements that are beneficial to all who are affected by these contractual arrangements. Pediatricians play an important role in ensuring that the needs of children are addressed in these emerging systems. It is important to recognize that health care plans designed for adults may not meet the needs of children. Language in health care contracts should reflect the health care needs of children and families. Informed pediatricians can make a difference in the care of children and influence the role of primary care physicians in the new paradigms. This policy highlights many of the important elements pediatricians should assess as providers develop a role in emerging care models. (7/13, reaffirmed 9/17)

http://pediatrics.aappublications.org/content/132/2/398

ESTABLISHING A STANDARD PROTOCOL FOR THE VOIDING CYSTOURETHROGRAPHY (CLINICAL REPORT)

Dominic Frimberger, MD; Maria-Gisela Mercado-Deane, MD, FAAP; Section on Urology; and Section on Radiology

ABSTRACT. The voiding cystourethrogram (VCUG) is a frequently performed test to diagnose a variety of urologic conditions, such as vesicoureteral reflux. The test results determine whether continued observation or an interventional procedure is indicated. VCUGs are ordered by many specialists and primary care providers, including pediatricians, family practitioners, nephrologists, hospitalists, emergency department physicians, and urologists. Current protocols for performing and interpreting a VCUG are based on the International Reflux Study in 1985. However, more recent information provided by many national and international institutions suggests a need to refine those recommendations. The lead author of the 1985 study, R.L. Lebowitz, agreed to and participated in the current protocol. In addition, a recent survey directed to the chairpersons of pediatric radiology of 65 children's hospitals throughout the United States and Canada showed that VCUG protocols vary substantially. Recent guidelines from the American Academy of Pediatrics (AAP) recommend a VCUG for children between 2 and 24 months of age with urinary tract infections but did not specify how this test should be performed. To improve patient safety and to standardize the data obtained when a VCUG is performed, the AAP Section on Radiology and the AAP Section on Urology initiated the current VCUG protocol to create a consensus on how to perform this test. (10/16)

http://pediatrics.aappublications.org/content/138/5/e20162590

ETHICAL AND POLICY ISSUES IN GENETIC TESTING AND SCREENING OF CHILDREN

Committee on Bioethics and Committee on Genetics (joint with American College of Medical Genetics and Genomics)

ABSTRACT. The genetic testing and genetic screening of children are commonplace. Decisions about whether to offer genetic testing and screening should be driven by the best interest of the child. The growing literature on the psychosocial and clinical effects of such testing and screening can help inform best practices. This policy statement represents recommendations developed collaboratively by the American Academy of Pediatrics and the American College of Medical Genetics and Genomics with respect to many of the scenarios in which genetic testing and screening can occur. (2/13, reaffirmed 6/18)

http://pediatrics.aappublications.org/content/131/3/620

ETHICAL CONSIDERATIONS IN RESEARCH WITH SOCIALLY IDENTIFIABLE POPULATIONS

Committee on Native American Child Health and Committee on Community Health Services

ABSTRACT. Community-based research raises ethical issues not normally encountered in research conducted in academic settings. In particular, conventional risk-benefits assessments frequently fail to recognize harms that can occur in socially identifiable populations as a result of research participation. Furthermore, many such communities require more stringent measures of beneficence that must be applied directly to the participating communities. In this statement, the American Academy of Pediatrics sets forth recommendations for minimizing harms that may result from community-based research by emphasizing community involvement in the research process. (1/04, reaffirmed 10/07, 1/13)

http://pediatrics.aappublications.org/content/113/1/148

ETHICAL CONTROVERSIES IN ORGAN DONATION AFTER CIRCULATORY DEATH

Committee on Bioethics

ABSTRACT. The persistent mismatch between the supply of and need for transplantable organs has led to efforts to increase the supply, including controlled donation after circulatory death (DCD). Controlled DCD involves organ recovery after the planned withdrawal of life-sustaining treatment and the declaration of death according to the cardiorespiratory criteria. Two central ethical issues in DCD are when organ recovery can begin and how to manage conflicts of interests. The "dead donor rule" should be maintained, and donors in cases of DCD should

only be declared dead after the permanent cessation of circulatory function. Permanence is generally established by a 2- to 5-minute waiting period. Given ongoing controversy over whether the cessation must also be irreversible, physicians should not be required to participate in DCD. Because the preparation for organ recovery in DCD begins before the declaration of death, there are potential conflicts between the donor's and recipient's interests. These conflicts can be managed in a variety of ways, including informed consent and separating the various participants' roles. For example, informed consent should be sought for premortem interventions to improve organ viability, and organ procurement organization personnel and members of the transplant team should not be involved in the discontinuation of life-sustaining treatment or the declaration of death. It is also important to emphasize that potential donors in cases of DCD should receive integrated interdisciplinary palliative care, including sedation and analgesia. (4/13, reaffirmed 12/16)
http://pediatrics.aappublications.org/content/131/5/1021

EVALUATING CHILDREN WITH FRACTURES FOR CHILD PHYSICAL ABUSE (CLINICAL REPORT)

Emalee G. Flaherty, MD, FAAP; Jeannette M. Perez-Rossello, MD; Michael A. Levine, MD; William L. Hennrikus, MD; Committee on Child Abuse and Neglect; Section on Radiology; Section on Endocrinology; and Section on Orthopaedics (joint with Society for Pediatric Radiology)

ABSTRACT. Fractures are common injuries caused by child abuse. Although the consequences of failing to diagnose an abusive injury in a child can be grave, incorrectly diagnosing child abuse in a child whose fractures have another etiology can be distressing for a family. The aim of this report is to review recent advances in the understanding of fracture specificity, the mechanism of fractures, and other medical diseases that predispose to fractures in infants and children. This clinical report will aid physicians in developing an evidence-based differential diagnosis and performing the appropriate evaluation when assessing a child with fractures. (1/14)
http://pediatrics.aappublications.org/content/133/2/e477

EVALUATING FOR SUSPECTED CHILD ABUSE: CONDITIONS THAT PREDISPOSE TO BLEEDING (TECHNICAL REPORT)

Shannon L. Carpenter, MD, MS; Thomas C. Abshire, MD; James D. Anderst, MD, MS; Section on Hematology/Oncology; and Committee on Child Abuse and Neglect

ABSTRACT. Child abuse might be suspected when children present with cutaneous bruising, intracranial hemorrhage, or other manifestations of bleeding. In these cases, it is necessary to consider medical conditions that predispose to easy bleeding/bruising. When evaluating for the possibility of bleeding disorders and other conditions that predispose to hemorrhage, the pediatrician must consider the child's presenting history, medical history, and physical examination findings before initiating a laboratory investigation. Many medical conditions can predispose to easy bleeding. Before ordering laboratory tests for a disease, it is useful to understand the biochemical basis and clinical presentation of the disorder, condition prevalence, and test characteristics. This technical report reviews the major medical conditions that predispose to bruising/bleeding and should be considered when evaluating for abusive injury. (3/13, reaffirmed 7/16)
http://pediatrics.aappublications.org/content/131/4/e1357

EVALUATION AND MANAGEMENT OF CHILDREN AND ADOLESCENTS WITH ACUTE MENTAL HEALTH OR BEHAVIORAL PROBLEMS. PART I: COMMON CLINICAL CHALLENGES OF PATIENTS WITH MENTAL HEALTH AND/OR BEHAVIORAL EMERGENCIES (CLINICAL REPORT)

Thomas H. Chun, MD, MPH, FAAP; Sharon E. Mace, MD, FAAP, FACEP; Emily R. Katz, MD, FAAP; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee)

INTRODUCTION. Mental health problems are among the leading contributors to the global burden of disease. Unfortunately, pediatric populations are not spared of mental health problems. In the United States, 21% to 23% of children and adolescents have a diagnosable mental health or substance use disorder. Among patients of emergency departments (EDs), 70% screen positive for at least 1 mental health disorder, 23% meet criteria for 2 or more mental health concerns, 45% have a mental health problem resulting in impaired psychosocial functioning, and 10% of adolescents endorse significant levels of psychiatric distress at the time of their ED visit. In pediatric primary care settings, the reported prevalence of mental health and behavioral disorders is between 12% to 22% of children and adolescents.

Although the American Academy of Pediatrics (AAP) has published a policy statement on mental health competencies and a Mental Health Toolkit for pediatric primary care providers, no such guidelines or resources exist for clinicians who care for pediatric mental health emergencies. This clinical report supports the 2006 joint policy statement of the AAP and American College of Emergency Physicians (ACEP) on pediatric mental health emergencies, with the goal of addressing the knowledge gaps in this area. The report is written primarily from the perspective of ED clinicians, but it is intended for all clinicians who care for children and adolescents with acute mental health and behavioral problems.

Recent epidemiologic studies of mental health visits have revealed a rapid burgeoning of both ED and primary care visits. An especially problematic trend is the increase in "boarding" of psychiatric patients in the ED and inpatient pediatric beds (ie, extended stays lasting days or even weeks). Although investigation of boarding practices is still in its infancy, the ACEP and the American Medical Association have both expressed concern about it, because it significantly taxes the functioning and efficiency of both the ED and hospital, and mental health services may not be available in the ED.

In addition, compared with other pediatric care settings, ED patients are known to be at higher risk of mental health disorders, including depression, anxiety, posttraumatic stress disorder, and substance abuse. These mental health conditions may be unrecognized not only by treating clinicians but also by the child/adolescent and his or her parents. A similar phenomenon has been described with suicidal patients. Individuals who have committed suicide frequently visited a health care provider in the months preceding their death. Although a minority of suicidal patients present with some form of self-harm, many have vague somatic complaints (eg, headache, gastrointestinal tract distress, back pain, concern for a sexually transmitted infection) masking their underlying mental health condition.

Despite studies demonstrating moderate agreement between emergency physicians and psychiatrists in the assessment and management of patients with mental health problems, ED clinicians frequently cite lack of training and confidence in their abilities as barriers to caring for patients with mental health emergencies. Another study of emergency medicine and pediatric emergency medicine training programs found that formal training in psychiatric problems is not required nor offered by most programs. Pediatric primary care providers report similar barriers to caring for their patients with mental health problems.

Part I of this clinical report focuses on the issues relevant to patients presenting to the ED with a mental health chief complaint and covers the following topics:

- Medical clearance of pediatric psychiatric patients
- Suicidal ideation and suicide attempts
- Involuntary hospitalization
- Restraint of the agitated patient
  - — Verbal restraint
  - — Chemical restraint
  - — Physical restraint
- Coordination with the medical home

Part II discusses challenging patients with primarily medical or indeterminate presentations, in which the contribution of an underlying mental health condition may be unclear or a complicating factor, including:

- Somatic symptom and related disorders
- Adverse effects to psychiatric medications
  - — Antipsychotic adverse effects
  - — Neuroleptic malignant syndrome
  - — Serotonin syndrome
- Children with special needs in the ED (autism spectrum and developmental disorders)
- Mental health screening in the ED

An executive summary of this clinical report can be found at www.pediatrics.org/cgi/doi/10.1542/peds.2016-1571. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20161570

EVALUATION AND MANAGEMENT OF CHILDREN AND ADOLESCENTS WITH ACUTE MENTAL HEALTH OR BEHAVIORAL PROBLEMS. PART I: COMMON CLINICAL CHALLENGES OF PATIENTS WITH MENTAL HEALTH AND/OR BEHAVIORAL EMERGENCIES—EXECUTIVE SUMMARY (CLINICAL REPORT)

Thomas H. Chun, MD, MPH, FAAP; Sharon E. Mace, MD, FAAP, FACEP; Emily R. Katz, MD, FAAP; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee)

ABSTRACT. The number of children and adolescents seen in emergency departments (EDs) and primary care settings for mental health problems has skyrocketed in recent years, with up to 23% of patients in both settings having diagnosable mental health conditions. Even when a mental health problem is not the focus of an ED or primary care visit, mental health conditions, both known and occult, may challenge the treating clinician and complicate the patient's care.

Although the American Academy of Pediatrics has published a policy statement on mental health competencies and a Mental Health Toolkit for pediatric primary care providers, no such guidelines or resources exist for clinicians who care for pediatric mental health emergencies. Many ED and primary care physicians report a paucity of training and lack of confidence in caring for pediatric psychiatry patients. The 2 clinical reports (www.pediatrics.org/cgi/doi/10.1542/peds.2016-1570 and www.pediatrics.org/cgi/doi/10.1542/peds.2016-1573) support the 2006 joint policy statement of the American Academy of Pediatrics and the American College of Emergency Physicians on pediatric mental health emergencies, with the goal of addressing the knowledge gaps in this area. Although written primarily from the perspective of ED clinicians, they are intended for all clinicians who care for children and adolescents with acute mental health and behavioral problems.

The clinical reports are organized around the common clinical challenges pediatric caregivers face, both when a child or adolescent presents with a psychiatric chief complaint or emergency (part I) and also when a mental health condition may be an unclear or complicating factor in a non–mental health clinical presentation (part II). Part II of the clinical reports (www.pediatrics.org/cgi/doi/10.1542/peds.2016-1573) includes discussions of somatic symptom and related disorders, adverse effects of psychiatric medications including neuroleptic malignant syndrome and serotonin syndrome, caring for children with special needs such as autism and developmental disorders, and mental health screening. This executive summary is an overview of part I of the clinical reports. The full text of the below topics can be accessed online at (www.pediatrics.org/cgi/doi/10.1542/peds.2016-1570). (8/16)

http://pediatrics.aappublications.org/content/138/3/e20161571

EVALUATION AND MANAGEMENT OF CHILDREN WITH ACUTE MENTAL HEALTH OR BEHAVIORAL PROBLEMS. PART II: RECOGNITION OF CLINICALLY CHALLENGING MENTAL HEALTH RELATED CONDITIONS PRESENTING WITH MEDICAL OR UNCERTAIN SYMPTOMS (CLINICAL REPORT)

Thomas H. Chun, MD, MPH, FAAP; Sharon E. Mace, MD, FAAP, FACEP; Emily R. Katz, MD, FAAP; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee)

INTRODUCTION. Part I of this clinical report (http://www.pediatrics.org/cgi/doi/10.1542/peds.2016-1570) discusses the common clinical issues that may be encountered in caring for children and adolescents presenting to the emergency department (ED) or primary care setting with a mental health condition or emergency and includes the following:

- Medical clearance of pediatric psychiatric patients
- Suicidal ideation and suicide attempts
- Involuntary hospitalization
- Restraint of the agitated patient
  - — Verbal restraint
  - — Chemical restraint
  - — Physical restraint
- Coordination with the medical home

Part II discusses the challenges a pediatric clinician may face when evaluating patients with a mental health condition, which may be contributing to or a complicating factor for a medical or indeterminate clinical presentation. Topics covered include the following:

- Somatic symptom and related disorders
- Adverse effects of psychiatric medications
  - — Antipsychotic adverse effects
  - — Neuroleptic malignant syndrome
  - — Serotonin syndrome
- Children with special needs (autism spectrum disorders [ASDs] and developmental disorders [DDs])
- Mental health screening

The report is written primarily from the perspective of ED clinicians, but it is intended for all clinicians who care for children and adolescents with acute mental health and behavioral problems. An executive summary of this clinical report can be found at http://www.pediatrics.org/cgi/doi/10.1542/peds.2016-1574. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20161573

EVALUATION AND MANAGEMENT OF CHILDREN WITH ACUTE MENTAL HEALTH OR BEHAVIORAL PROBLEMS. PART II: RECOGNITION OF CLINICALLY CHALLENGING MENTAL HEALTH RELATED CONDITIONS PRESENTING WITH MEDICAL OR UNCERTAIN SYMPTOMS—EXECUTIVE SUMMARY (CLINICAL REPORT)

Thomas H. Chun, MD, MPH, FAAP; Sharon E. Mace, MD, FAAP, FACEP; Emily R. Katz, MD, FAAP; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee)

ABSTRACT. The number of children and adolescents seen in emergency departments (EDs) and primary care settings for mental health problems has skyrocketed in recent years, with up to 23% of patients in both settings having diagnosable mental health conditions. Even when a mental health problem is not the focus of an ED or primary care visit, mental health conditions, both known and occult, may challenge the treating clinician and complicate the patient's care.

Although the American Academy of Pediatrics (AAP) has published a policy statement on mental health competencies and a Mental Health Toolkit for pediatric primary care providers, no such guidelines or resources exist for clinicians who care for pediatric mental health emergencies. Many ED and primary care physicians report paucity of training and lack of confidence in caring for pediatric psychiatry patients. The 2 clinical reports support the 2006 joint policy statement of the AAP and the American College of Emergency Physicians on pediatric mental health emergencies, with the goal of addressing the knowledge gaps in this area. Although written primarily from the perspective of ED clinicians, it is intended for all clinicians who care for children and adolescents with acute mental health and behavioral problems. They are organized around the common clinical challenges pediatric caregivers face, both when a child or adolescent presents with a psychiatric chief complaint or emergency (part I) and when a mental health condition may be an unclear or complicating factor in a non-mental health ED presentation (part II). Part I of the clinical reports includes discussions of Medical Clearance of Pediatric Psychiatric Patients; Suicide and Suicidal Ideation; Restraint of the Agitated Patient Including Verbal, Chemical, and Physical Restraint; and Coordination of Care With the Medical Home, and it can be accessed online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-1570. This executive summary is an overview of part II of the clinical reports. Full text of the following topics can be accessed online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-1573. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20161574

EVALUATION AND MANAGEMENT OF THE INFANT EXPOSED TO HIV IN THE UNITED STATES (CLINICAL REPORT)

Ellen Gould Chadwick, MD, FAAP; Echezona Edozie Ezeanolue, MD, MPH, FAAP; and Committee on Pediatric AIDS

ABSTRACT. Pediatricians play a crucial role in optimizing the prevention of perinatal transmission of HIV infection. Pediatricians provide antiretroviral prophylaxis to infants born to women with HIV type 1 (HIV) infection during pregnancy and to those whose mother's status was first identified during labor or delivery. Infants whose mothers have an undetermined HIV status should be tested for HIV infection within the boundaries of state laws and receive presumptive HIV therapy if the results are positive. Pediatricians promote avoidance of postnatal HIV transmission by advising mothers with HIV not to breastfeed. Pediatricians test the infant exposed to HIV for determination of HIV infection and monitor possible short- and long-term toxicity from antiretroviral exposure. Finally, pediatricians support families living with HIV by providing counseling to parents or caregivers as an important component of care. (10/20)

See full text on page 757.

https://pediatrics.aappublications.org/content/146/5/e2020029058

EVALUATION AND REFERRAL FOR DEVELOPMENTAL DYSPLASIA OF THE HIP IN INFANTS (CLINICAL REPORT)

Brian A. Shaw, MD, FAAOS, FAAP; Lee S. Segal, MD, FAAOS, FAAP; and Section on Orthopaedics

ABSTRACT. Developmental dysplasia of the hip (DDH) encompasses a wide spectrum of clinical severity, from mild developmental abnormalities to frank dislocation. Clinical hip instability occurs in 1% to 2% of full-term infants, and up to 15% have hip instability or hip immaturity detectable by imaging studies. Hip dysplasia is the most common cause of hip arthritis in women younger than 40 years and accounts for 5% to 10% of all total hip replacements in the United States. Newborn and periodic screening have been practiced for decades, because DDH is clinically silent during the first year of life, can be treated more effectively if detected early, and can have severe consequences if left untreated. However, screening programs and techniques are not uniform, and there is little evidence-based literature to support current practice, leading to controversy. Recent literature shows that many mild forms of DDH resolve without treatment, and there is a lack of agreement on ultrasonographic diagnostic criteria for DDH as a disease versus developmental variations. The American Academy of Pediatrics has not published any policy statements on DDH since its 2000 clinical practice guideline and accompanying technical report. Developments since then include a controversial US Preventive Services Task Force "inconclusive" determination regarding usefulness of DDH screening, several prospective studies supporting observation over treatment of minor ultrasonographic hip variations, and a recent evidence-based clinical practice guideline from the American Academy of Orthopaedic Surgeons on the detection and management of DDH in infants 0 to 6 months of age. The purpose of this clinical report was to provide literature-based updated direction for the clinician in screening and referral for DDH, with the primary goal of preventing and/or detecting a dislocated hip by 6 to 12 months of age in an otherwise healthy child, understanding that no screening program has eliminated late development or presentation of a dislocated hip and that the diagnosis and treatment of milder forms of hip dysplasia remain controversial. (11/16)

http://pediatrics.aappublications.org/content/138/6/e20163107

EVALUATION AND REFERRAL OF CHILDREN WITH SIGNS OF EARLY PUBERTY (CLINICAL REPORT)

Paul Kaplowitz, MD, PhD, FAAP; Clifford Bloch, MD, FAAP; and Section on Endocrinology

ABSTRACT. Concerns about possible early pubertal development are a common cause for referral to pediatric medical subspecialists. Several recent studies have suggested that onset of breast and/or pubic hair development may be occurring earlier than in the past. Although there is a chance of finding pathology in girls with signs of puberty before 8 years of age and in boys before 9 years of age, the vast majority of these children with signs of apparent puberty have variations of normal growth and physical development and do not require laboratory testing, bone age radiographs, or intervention. The most common of these signs of early puberty are premature adrenarche (early onset of pubic hair and/or body odor), premature thelarche (nonprogressive breast development, usually occurring before 2 years of age), and lipomastia, in which girls have apparent breast development which, on careful palpation, is determined to be adipose tissue. Indicators that the signs of sexual maturation may represent true, central precocious puberty include progressive breast development over a 4- to 6-month period of observation or progressive penis and testicular enlargement, especially if accompanied by rapid linear growth. Children exhibiting these true indicators of early puberty need prompt evaluation by the appropriate pediatric medical subspecialist. Therapy with a

gonadotropin-releasing hormone agonist may be indicated, as discussed in this report. (12/15)
http://pediatrics.aappublications.org/content/137/1/e20153732

EVALUATION FOR BLEEDING DISORDERS IN SUSPECTED CHILD ABUSE (CLINICAL REPORT)

James D. Anderst, MD, MS; Shannon L. Carpenter, MD, MS; Thomas C. Abshire, MD; Section on Hematology/Oncology; and Committee on Child Abuse and Neglect

ABSTRACT. Bruising or bleeding in a child can raise the concern for child abuse. Assessing whether the findings are the result of trauma and/or whether the child has a bleeding disorder is critical. Many bleeding disorders are rare, and not every child with bruising/bleeding concerning for abuse requires an evaluation for bleeding disorders. In some instances, however, bleeding disorders can present in a manner similar to child abuse. The history and clinical evaluation can be used to determine the necessity of an evaluation for a possible bleeding disorder, and prevalence and known clinical presentations of individual bleeding disorders can be used to guide the extent of the laboratory testing. This clinical report provides guidance to pediatricians and other clinicians regarding the evaluation for bleeding disorders when child abuse is suspected. (3/13, reaffirmed 7/16)
http://pediatrics.aappublications.org/content/131/4/e1314

THE EVALUATION OF CHILDREN IN THE PRIMARY CARE SETTING WHEN SEXUAL ABUSE IS SUSPECTED (CLINICAL REPORT)

Carole Jenny, MD, MBA, FAAP; James E. Crawford-Jakubiak, MD, FAAP; and Committee on Child Abuse and Neglect

ABSTRACT. This clinical report updates a 2005 report from the American Academy of Pediatrics on the evaluation of sexual abuse in children. The medical assessment of suspected child sexual abuse should include obtaining a history, performing a physical examination, and obtaining appropriate laboratory tests. The role of the physician includes determining the need to report suspected sexual abuse; assessing the physical, emotional, and behavioral consequences of sexual abuse; providing information to parents about how to support their child; and coordinating with other professionals to provide comprehensive treatment and follow-up of children exposed to child sexual abuse. (7/13, reaffirmed 8/18)
http://pediatrics.aappublications.org/content/132/2/e558

THE EVALUATION OF SEXUAL BEHAVIORS IN CHILDREN (CLINICAL REPORT)

Nancy D. Kellogg, MD, and Committee on Child Abuse and Neglect

ABSTRACT. Most children will engage in sexual behaviors at some time during childhood. These behaviors may be normal but can be confusing and concerning to parents or disruptive or intrusive to others. Knowledge of age-appropriate sexual behaviors that vary with situational and environmental factors can assist the clinician in differentiating normal sexual behaviors from sexual behavior problems. Most situations that involve sexual behaviors in young children do not require child protective services intervention; for behaviors that are age-appropriate and transient, the pediatrician may provide guidance in supervision and monitoring of the behavior. If the behavior is intrusive, hurtful, and/or age-inappropriate, a more comprehensive assessment is warranted. Some children with sexual behavior problems may reside or have resided in homes characterized by inconsistent parenting, violence, abuse, or neglect and may require more immediate intervention and referrals. (8/09, reaffirmed 3/13, 10/18)
http://pediatrics.aappublications.org/content/124/3/992

THE EVALUATION OF SUSPECTED CHILD PHYSICAL ABUSE (CLINICAL REPORT)

Cindy W. Christian, MD, FAAP, and Committee on Child Abuse and Neglect

ABSTRACT. Child physical abuse is an important cause of pediatric morbidity and mortality and is associated with major physical and mental health problems that can extend into adulthood. Pediatricians are in a unique position to identify and prevent child abuse, and this clinical report provides guidance to the practitioner regarding indicators and evaluation of suspected physical abuse of children. The role of the physician may include identifying abused children with suspicious injuries who present for care, reporting suspected abuse to the child protection agency for investigation, supporting families who are affected by child abuse, coordinating with other professionals and community agencies to provide immediate and long-term treatment to victimized children, providing court testimony when necessary, providing preventive care and anticipatory guidance in the office, and advocating for policies and programs that support families and protect vulnerable children. (4/15)
http://pediatrics.aappublications.org/content/135/5/e1337

EVIDENCE FOR THE DIAGNOSIS AND TREATMENT OF ACUTE UNCOMPLICATED SINUSITIS IN CHILDREN: A SYSTEMATIC REVIEW (TECHNICAL REPORT)

Michael J. Smith, MD, MSCE

ABSTRACT. In 2001, the American Academy of Pediatrics published clinical practice guidelines for the management of acute bacterial sinusitis (ABS) in children. The technical report accompanying those guidelines included 21 studies that assessed the diagnosis and management of ABS in children. This update to that report incorporates studies of pediatric ABS that have been performed since 2001. Overall, 17 randomized controlled trials of the treatment of sinusitis in children were identified and analyzed. Four randomized, double-blind, placebo-controlled trials of antimicrobial therapy have been published. The results of these studies varied, likely due to differences in inclusion and exclusion criteria. Because of this heterogeneity, formal meta-analyses were not performed. However, qualitative analysis of these studies suggests that children with greater severity of illness at presentation are more likely to benefit from antimicrobial therapy. An additional 5 trials compared different antimicrobial therapies but did not include placebo groups. Six trials assessed a variety of ancillary treatments for ABS in children, and 3 focused on subacute sinusitis. Although the number of pediatric trials has increased since 2001, there are still limited data to guide the diagnosis and management of ABS in children. Diagnostic and treatment guidelines focusing on severity of illness at the time of presentation have the potential to identify those children most likely to benefit from antimicrobial therapy and at the same time minimize unnecessary use of antibiotics. (6/13)
http://pediatrics.aappublications.org/content/132/1/e284

EXECUTIVE SUMMARY: CRITERIA FOR CRITICAL CARE OF INFANTS AND CHILDREN: PICU ADMISSION, DISCHARGE, AND TRIAGE PRACTICE STATEMENT AND LEVELS OF CARE GUIDANCE

Benson S. Hsu, MD, MBA, FAAP; Vanessa Hill, MD, FAAP; Lorry R. Frankel, MD, FCCM; Timothy S. Yeh, MD, MCCM; Shari Simone, CRNP, DNP, FCCM, FAANP, FAAN; Marjorie J. Arca, MD, FACS, FAAP; Jorge A. Coss-Bu, MD; Mary E. Fallat, MD, FACS, FAAP; Jason Foland, MD; Samir Gadepalli, MD, MBA; Michael O. Gayle, BS, MD, FCCM; Lori A. Harmon, RRT, MBA, CPHQ; Christa A. Joseph, RN, MSN; Aaron D. Kessel, BS, MD; Niranjan Kissoon, MD, MCCM; Michele Moss, MD, FCCM; Mohan R. Mysore, MD, FAAP, FCCM; Michele C. Papo, MD, MPH, FCCM; Kari L. Rajzer-Wakeham, CCRN, MSN, PCCNP, RN; Tom B. Rice, MD; David L. Rosenberg, MD, FAAP, FCCM;

Martin K. Wakeham, MD; Edward E. Conway, Jr, MD, FCCM, MS; Michael S.D. Agus, MD, FAAP, FCCM

ABSTRACT. This is an executive summary of the 2019 update of the 2004 guidelines and levels of care for PICU. Since previous guidelines, there has been a tremendous transformation of Pediatric Critical Care Medicine with advancements in pediatric cardiovascular medicine, transplant, neurology, trauma, and oncology as well as improvements of care in general PICUs. This has led to the evolution of resources and training in the provision of care through the PICU. Outcome and quality research related to admission, transfer, and discharge criteria as well as literature regarding PICU levels of care to include volume, staffing, and structure were reviewed and included in this statement as appropriate. Consequently, the purposes of this significant update are to address the transformation of the field and codify a revised set of guidelines that will enable hospitals, institutions, and individuals in developing the appropriate PICU for their community needs. The target audiences of the practice statement and guidance are broad and include critical care professionals; pediatricians; pediatric subspecialists; pediatric surgeons; pediatric surgical subspecialists; pediatric imaging physicians; and other members of the patient care team such as nurses, therapists, dieticians, pharmacists, social workers, care coordinators, and hospital administrators who make daily administrative and clinical decisions in all PICU levels of care. (9/19)

https://pediatrics.aappublications.org/content/144/4/e20192433

EXECUTIVE SUMMARY: IDENTIFICATION, EVALUATION, AND MANAGEMENT OF CHILDREN WITH AUTISM SPECTRUM DISORDER (CLINICAL REPORT)

Susan L. Hyman, MD, FAAP; Susan E. Levy, MD, MPH, FAAP; Scott M. Myers, MD, FAAP; Council on Children With Disabilities; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. Autism spectrum disorder (ASD) is a common neurodevelopmental disorder with reported prevalence in the United States of 1 in 59 children (approximately 1.7%). ASD significantly influences the lives of affected children and families because they may need extensive behavioral, educational, health, and other services. Primary care providers play a critical role in identifying, diagnosing, and managing ASD in children and providing support for their families. This document provides a summary of the clinical report "Identification, Evaluation, and Management of Children with Autism Spectrum Disorder," published concurrently in the online version of *Pediatrics*. In the years since 2007, when the American Academy of Pediatrics published the clinical reports "Identification and Diagnosis of Children with Autism Spectrum Disorders" and "Management of Children with Autism Spectrum Disorders," reported prevalence rates of children with ASD have increased, understanding of potential risk factors has expanded, awareness of co-occurring medical and behavioral conditions and genetic contribution to etiology has improved, and the body of research supporting evidence-based interventions has grown substantially. The updated document discusses evaluation and treatment as a continuum in 1 publication with a table of contents to help the reader identify topic areas within the report. ASD is more commonly diagnosed than in the past, and the significant health, educational, and social needs of individuals with ASD and their families constitute an area of critical need for resources, research, and professional education. (12/19)

See full text on page 773.

https://pediatrics.aappublications.org/content/145/1/e20193448

EXPERT WITNESS PARTICIPATION IN CIVIL AND CRIMINAL PROCEEDINGS

Stephan R. Paul, MD, JD, FAAP; Sandeep K. Narang, MD, JD, FAAP; and Committee on Medical Liability and Risk Management

ABSTRACT. The interests of the public and both the medical and legal professions are best served when scientifically sound and unbiased expert witness testimony is readily available in civil and criminal proceedings. As members of the medical community, patient advocates, and private citizens, pediatricians have ethical and professional obligations to assist in the civil and criminal judicial processes. This policy statement offers recommendations on advocacy, education, research, qualifications, standards, and ethical business practices all aimed at improving expert testimony. (2/17)

http://pediatrics.aappublications.org/content/139/3/e20163862

EXPERT WITNESS PARTICIPATION IN CIVIL AND CRIMINAL PROCEEDINGS (TECHNICAL REPORT)

Sandeep K. Narang, MD, JD, FAAP; Stephan R. Paul, MD, JD, FAAP; and Committee on Medical Liability and Risk Management

ABSTRACT. The interests of the public and both the medical and legal professions are best served when scientifically sound and unbiased expert witness testimony is readily available in civil and criminal proceedings. As members of the medical community, patient advocates, and private citizens, pediatricians have ethical and professional obligations to assist in the civil and criminal judicial processes. This technical report explains how the role of the expert witness differs in civil and criminal proceedings, legal and ethical standards for expert witnesses, and strategies that have been employed to deter unscientific and irresponsible testimony. A companion policy statement offers recommendations on advocacy, education, research, qualifications, standards, and ethical business practices all aimed at improving expert testimony. (2/17)

http://pediatrics.aappublications.org/content/139/3/e20164122

EXPOSURE TO NONTRADITIONAL PETS AT HOME AND TO ANIMALS IN PUBLIC SETTINGS: RISKS TO CHILDREN (CLINICAL REPORT)

Larry K. Pickering, MD; Nina Marano, DVM, MPH; Joseph A. Bocchini, MD; Frederick J. Angulo, DVM, PhD; and Committee on Infectious Diseases

ABSTRACT. Exposure to animals can provide many benefits during the growth and development of children. However, there are potential risks associated with animal exposures, including exposure to nontraditional pets in the home and animals in public settings. Educational materials, regulations, and guidelines have been developed to minimize these risks. Pediatricians, veterinarians, and other health care professionals can provide advice on selection of appropriate pets as well as prevention of disease transmission from nontraditional pets and when children contact animals in public settings. (10/08, reaffirmed 12/11, 1/15, 6/15, 5/19)

http://pediatrics.aappublications.org/content/122/4/876

THE EYE EXAMINATION IN THE EVALUATION OF CHILD ABUSE (CLINICAL REPORT)

Cindy W. Christian, MD, FAAP; Alex V. Levin, MD, MHSc, FAAO, FRCSC, FAAP; Council on Child Abuse and Neglect; and Section on Ophthalmology (joint with American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology and Strabismus, and American Academy of Ophthalmology)

ABSTRACT. Child abuse can cause injury to any part of the eye. The most common manifestations are retinal hemorrhages (RHs) in infants and young children with abusive head trauma (AHT). Although RHs are an important indicator of possible AHT, they

are also found in other conditions. Distinguishing the number, type, location, and pattern of RHs is important in evaluating a differential diagnosis. Eye trauma can be seen in cases of physical abuse or AHT and may prompt referral for ophthalmologic assessment. Physicians have a responsibility to consider abuse in the differential diagnosis of pediatric eye trauma. Identification and documentation of inflicted ocular trauma requires a thorough examination by an ophthalmologist, including indirect ophthalmoscopy, most optimally through a dilated pupil, especially for the evaluation of possible RHs. An eye examination is helpful in detecting abnormalities that can help identify a medical or traumatic etiology for previously well young children who experience unexpected and unexplained mental status changes with no obvious cause, children with head trauma that results in significant intracranial hemorrhage and brain injury, and children with unexplained death. (7/18)
http://pediatrics.aappublications.org/content/142/2/e20181411

FACILITIES AND EQUIPMENT FOR THE CARE OF PEDIATRIC PATIENTS IN A COMMUNITY HOSPITAL (CLINICAL REPORT)

Committee on Hospital Care

ABSTRACT. Many children who require hospitalization are admitted to community hospitals that are more accessible for families and their primary care physicians but vary substantially in their pediatric resources. The intent of this clinical report is to provide basic guidelines for furnishing and equipping a pediatric area in a community hospital. (5/03, reaffirmed 5/07, 8/13, 1/17)
http://pediatrics.aappublications.org/content/111/5/1120

FALLS FROM HEIGHTS: WINDOWS, ROOFS, AND BALCONIES

Committee on Injury and Poison Prevention

ABSTRACT. Falls of all kinds represent an important cause of child injury and death. In the United States, approximately 140 deaths from falls occur annually in children younger than 15 years. Three million children require emergency department care for fall-related injuries. This policy statement examines the epidemiology of falls from heights and recommends preventive strategies for pediatricians and other child health care professionals. Such strategies involve parent counseling, community programs, building code changes, legislation, and environmental modification, such as the installation of window guards and balcony railings. (5/01, reaffirmed 10/04, 5/07, 6/10)
http://pediatrics.aappublications.org/content/107/5/1188

FAMILIES AFFECTED BY PARENTAL SUBSTANCE USE (CLINICAL REPORT)

Vincent C. Smith, MD, MPH, FAAP; Celeste R. Wilson, MD, FAAP; and Committee on Substance Use and Prevention

ABSTRACT. Children whose parents or caregivers use drugs or alcohol are at increased risk of short- and long-term sequelae ranging from medical problems to psychosocial and behavioral challenges. In the course of providing health care services to children, pediatricians are likely to encounter families affected by parental substance use and are in a unique position to intervene. Therefore, pediatricians need to know how to assess a child's risk in the context of a parent's substance use. The purposes of this clinical report are to review some of the short-term effects of maternal substance use during pregnancy and long-term implications of fetal exposure; describe typical medical, psychiatric, and behavioral symptoms of children and adolescents in families affected by substance use; and suggest proficiencies for pediatricians involved in the care of children and adolescents of families affected by substance use, including screening families, mandated reporting requirements, and directing families to community, regional, and state resources that can address needs and problems. (7/16)
http://pediatrics.aappublications.org/content/138/2/e20161575

FATHERS' ROLES IN THE CARE AND DEVELOPMENT OF THEIR CHILDREN: THE ROLE OF PEDIATRICIANS (CLINICAL REPORT)

Michael Yogman, MD, FAAP; Craig F. Garfield, MD, FAAP; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Fathers' involvement in and influence on the health and development of their children have increased in a myriad of ways in the past 10 years and have been widely studied. The role of pediatricians in working with fathers has correspondingly increased in importance. This report reviews new studies of the epidemiology of father involvement, including nonresidential as well as residential fathers. The effects of father involvement on child outcomes are discussed within each phase of a child's development. Particular emphasis is placed on (1) fathers' involvement across childhood ages and (2) the influence of fathers' physical and mental health on their children. Implications and advice for all child health providers to encourage and support father involvement are outlined. (6/16)
http://pediatrics.aappublications.org/content/138/1/e20161128

THE FEMALE ATHLETE TRIAD (CLINICAL REPORT)

Amanda K. Weiss Kelly, MD, FAAP; Suzanne Hecht, MD, FACSM; and Council on Sports Medicine and Fitness

ABSTRACT. The number of girls participating in sports has increased significantly since the introduction of Title XI in 1972. As a result, more girls have been able to experience the social, educational, and health-related benefits of sports participation. However, there are risks associated with sports participation, including the female athlete triad. The triad was originally recognized as the interrelationship of amenorrhea, osteoporosis, and disordered eating, but our understanding has evolved to recognize that each of the components of the triad exists on a spectrum from optimal health to disease. The triad occurs when energy intake does not adequately compensate for exercise-related energy expenditure, leading to adverse effects on reproductive, bone, and cardiovascular health. Athletes can present with a single component or any combination of the components. The triad can have a more significant effect on the health of adolescent athletes than on adults because adolescence is a critical time for bone mass accumulation. This report outlines the current state of knowledge on the epidemiology, diagnosis, and treatment of the triad conditions. (7/16)
http://pediatrics.aappublications.org/content/138/2/e20160922

FERTILITY PRESERVATION FOR PEDIATRIC AND ADOLESCENT PATIENTS WITH CANCER: MEDICAL AND ETHICAL CONSIDERATIONS (CLINICAL REPORT)

Sigal Klipstein, MD, FACOG; Mary E. Fallat, MD, FAAP; Stephanie Savelli, MD, FAAP; Committee on Bioethics; Section on Hematology/Oncology; and Section on Surgery

ABSTRACT. Many cancers presenting in children and adolescents are curable with surgery, chemotherapy, and/or radiotherapy. Potential adverse consequences of treatment include sterility, infertility, or subfertility as a result of gonad removal, damage to germ cells as a result of adjuvant therapy, or damage to the pituitary and hypothalamus or uterus as a result of irradiation. In recent years, treatment of solid tumors and hematologic malignancies has been modified in an attempt to reduce damage to the gonadal axis. Simultaneously, advances in assisted reproductive technology have led to new possibilities for the prevention and treatment of infertility. This clinical report reviews the medical aspects and ethical considerations that arise when

considering fertility preservation in pediatric and adolescent patients with cancer. (2/20)

See full text on page 781.

https://pediatrics.aappublications.org/content/145/3/e20193994

FETAL ALCOHOL SPECTRUM DISORDERS (CLINICAL REPORT)

Janet F. Williams, MD, FAAP; Vincent C. Smith, MD, MPH, FAAP; and Committee on Substance Abuse

ABSTRACT. Prenatal exposure to alcohol can damage the developing fetus and is the leading preventable cause of birth defects and intellectual and neurodevelopmental disabilities. In 1973, fetal alcohol syndrome was first described as a specific cluster of birth defects resulting from alcohol exposure in utero. Subsequently, research unequivocally revealed that prenatal alcohol exposure causes a broad range of adverse developmental effects. Fetal alcohol spectrum disorder (FASD) is the general term that encompasses the range of adverse effects associated with prenatal alcohol exposure. The diagnostic criteria for fetal alcohol syndrome are specific, and comprehensive efforts are ongoing to establish definitive criteria for diagnosing the other FASDs. A large and growing body of research has led to evidence-based FASD education of professionals and the public, broader prevention initiatives, and recommended treatment approaches based on the following premises:

- Alcohol-related birth defects and developmental disabilities are completely preventable when pregnant women abstain from alcohol use.
- Neurocognitive and behavioral problems resulting from prenatal alcohol exposure are lifelong.
- Early recognition, diagnosis, and therapy for any condition along the FASD continuum can result in improved outcomes.
- During pregnancy:
  - — no amount of alcohol intake should be considered safe;
  - — there is no safe trimester to drink alcohol;
  - — all forms of alcohol, such as beer, wine, and liquor, pose similar risk; and
  - — binge drinking poses dose-related risk to the developing fetus. (10/15)

http://pediatrics.aappublications.org/content/136/5/e1395

FEVER AND ANTIPYRETIC USE IN CHILDREN (CLINICAL REPORT)

Janice E. Sullivan, MD; Henry C. Farrar, MD; Section on Clinical Pharmacology and Therapeutics; and Committee on Drugs

ABSTRACT. Fever in a child is one of the most common clinical symptoms managed by pediatricians and other health care providers and a frequent cause of parental concern. Many parents administer antipyretics even when there is minimal or no fever, because they are concerned that the child must maintain a "normal" temperature. Fever, however, is not the primary illness but is a physiologic mechanism that has beneficial effects in fighting infection. There is no evidence that fever itself worsens the course of an illness or that it causes long-term neurologic complications. Thus, the primary goal of treating the febrile child should be to improve the child's overall comfort rather than focus on the normalization of body temperature. When counseling the parents or caregivers of a febrile child, the general well-being of the child, the importance of monitoring activity, observing for signs of serious illness, encouraging appropriate fluid intake, and the safe storage of antipyretics should be emphasized. Current evidence suggests that there is no substantial difference in the safety and effectiveness of acetaminophen and ibuprofen in the care of a generally healthy child with fever. There is evidence that combining these 2 products is more effective than the use of a single agent alone; however, there are concerns that combined treatment may be more complicated and contribute to the unsafe use of these drugs. Pediatricians should also promote patient safety by advocating for simplified formulations, dosing instructions, and dosing devices. (2/11, reaffirmed 7/16)

http://pediatrics.aappublications.org/content/127/3/580

FINANCING GRADUATE MEDICAL EDUCATION TO MEET THE NEEDS OF CHILDREN AND THE FUTURE PEDIATRICIAN WORKFORCE

Committee on Pediatric Workforce

ABSTRACT. The American Academy of Pediatrics (AAP) believes that an appropriately financed graduate medical education (GME) system is critical to ensuring that sufficient numbers of trained pediatricians are available to provide optimal health care to all children. A shortage of pediatric medical subspecialists and pediatric surgical specialists currently exists in the United States, and this shortage is likely to intensify because of the growing numbers of children with chronic health problems and special health care needs. It is equally important to maintain the supply of primary care pediatricians. The AAP, therefore, recommends that children's hospital GME positions funded by the Health Resources and Services Administration be increased to address this escalating demand for pediatric health services. The AAP also recommends that GME funding for pediatric physician training provide full financial support for all years of training necessary to meet program requirements. In addition, all other entities that gain from GME training should participate in its funding in a manner that does not influence curriculum, requirements, or outcomes. Furthermore, the AAP supports funding for training innovations that improve the health of children. Finally, the AAP recommends that all institutional recipients of GME funding allocate these funds directly to the settings where training occurs in a transparent manner. (3/16)

http://pediatrics.aappublications.org/content/137/4/e20160211

FINANCING OF PEDIATRIC HOME HEALTH CARE

Edwin Simpser, MD, FAAP; Mark L. Hudak, MD, FAAP; Section on Home Care; and Committee on Child Health Financing

ABSTRACT. Pediatric home health care is an effective and holistic venue of treatment of children with medical complexity or developmental disabilities who otherwise may experience frequent and/or prolonged hospitalizations or who may enter chronic institutional care. Demand for pediatric home health care is increasing while the provider base is eroding, primarily because of inadequate payment or restrictions on benefits. As a result, home care responsibilities assumed by family caregivers have increased and imposed financial, physical, and psychological burdens on the family. The Patient Protection and Affordable Care Act set forth 10 mandated essential health benefits. Home care should be considered as an integral component of the habilitative and rehabilitative services and devices benefit, even though it is not explicitly recognized as a specific category of service. Pediatric-specific home health care services should be defined clearly as components of pediatric services, the 10th essential benefit, and recognized by all payers. Payments for home health care services should be sufficient to maintain an adequate provider work force with the pediatric-specific expertise and skills to care for children with medical complexity or developmental disability. Furthermore, coordination of care among various providers and the necessary direct patient care from which these care coordination plans are developed should be required and enabled by adequate payment. The American Academy of Pediatrics advocates for high-quality care by calling for development of pediatric-specific home health regulations and the licensure and certification of pediatric home health providers. (2/17)

http://pediatrics.aappublications.org/content/139/3/e20164202

FIREARM-RELATED INJURIES AFFECTING THE PEDIATRIC POPULATION

Council on Injury, Violence, and Poison Prevention Executive Committee

ABSTRACT. The absence of guns from children's homes and communities is the most reliable and effective measure to prevent firearm-related injuries in children and adolescents. Adolescent suicide risk is strongly associated with firearm availability. Safe gun storage (guns unloaded and locked, ammunition locked separately) reduces children's risk of injury. Physician counseling of parents about firearm safety appears to be effective, but firearm safety education programs directed at children are ineffective. The American Academy of Pediatrics continues to support a number of specific measures to reduce the destructive effects of guns in the lives of children and adolescents, including the regulation of the manufacture, sale, purchase, ownership, and use of firearms; a ban on semiautomatic assault weapons; and the strongest possible regulations of handguns for civilian use. (10/12, reaffirmed 12/16)

http://pediatrics.aappublications.org/content/130/5/e1416

FIREWORKS-RELATED INJURIES TO CHILDREN

Committee on Injury and Poison Prevention

ABSTRACT. An estimated 8500 individuals, approximately 45% of them children younger than 15 years, were treated in US hospital emergency departments during 1999 for fireworks-related injuries. The hands (40%), eyes (20%), and head and face (20%) are the body areas most often involved. Approximately one third of eye injuries from fireworks result in permanent blindness. During 1999, 16 people died as a result of injuries associated with fireworks. Every type of legally available consumer (so-called "safe and sane") firework has been associated with serious injury or death. In 1997, 20,100 fires were caused by fireworks, resulting in $22.7 million in direct property damage. Fireworks typically cause more fires in the United States on the Fourth of July than all other causes of fire combined on that day. Pediatricians should educate parents, children, community leaders, and others about the dangers of fireworks. Fireworks for individual private use should be banned. Children and their families should be encouraged to enjoy fireworks at public fireworks displays conducted by professionals rather than purchase fireworks for home or private use. (7/01, reaffirmed 1/05, 2/08, 10/11, 11/14)

http://pediatrics.aappublications.org/content/108/1/190

FISH, SHELLFISH, AND CHILDREN'S HEALTH: AN ASSESSMENT OF BENEFITS, RISKS, AND SUSTAINABILITY (TECHNICAL REPORT)

Aaron S. Bernstein, MD, MPH, FAAP; Emily Oken, MD, MPH; Sarah de Ferranti, MD, MPH, FAAP; Council on Environmental Health; and Committee on Nutrition

ABSTRACT. American children eat relatively little fish and shellfish in comparison with other sources of animal protein, despite the health benefits that eating fish and shellfish may confer. At the same time, fish and shellfish may be sources of toxicants. This report serves to inform pediatricians about available research that elucidates health risks and benefits associated with fish and shellfish consumption in childhood as well as the sustainability of fish and shellfish harvests. (5/19)

https://pediatrics.aappublications.org/content/143/6/e20190999

FLUORIDE USE IN CARIES PREVENTION IN THE PRIMARY CARE SETTING (CLINICAL REPORT)

Melinda B. Clark, MD, FAAP; Martha Ann Keels, DDS, PhD; Rebecca L. Slayton, DDS, PhD; and Section on Oral Health

ABSTRACT. Dental caries remains the most common chronic disease of childhood in the United States. Caries is a largely preventable condition, and fluoride has proven effectiveness in caries prevention. This clinical report aims to clarify the use of available fluoride modalities for caries prevention in the primary care setting and to assist pediatricians in using fluoride to achieve maximum protection against dental caries, while minimizing the likelihood of enamel fluorosis. Fluoride varnish application is now considered the standard of care in pediatric primary care. This report highlights administration, billing, and payment information regarding the fluoride varnish procedure. (11/20)

See full text on page 803.

https://pediatrics.aappublications.org/content/146/6/e2020034637

FOLIC ACID FOR THE PREVENTION OF NEURAL TUBE DEFECTS

Committee on Genetics

ABSTRACT. The American Academy of Pediatrics endorses the US Public Health Service (USPHS) recommendation that all women capable of becoming pregnant consume 400 μg of folic acid daily to prevent neural tube defects (NTDs). Studies have demonstrated that periconceptional folic acid supplementation can prevent 50% or more of NTDs such as spina bifida and anencephaly. For women who have previously had an NTD-affected pregnancy, the Centers for Disease Control and Prevention (CDC) recommends increasing the intake of folic acid to 4000 μg per day beginning at least 1 month before conception and continuing through the first trimester. Implementation of these recommendations is essential for the primary prevention of these serious and disabling birth defects. Because fewer than 1 in 3 women consume the amount of folic acid recommended by the USPHS, the Academy notes that the prevention of NTDs depends on an urgent and effective campaign to close this prevention gap. (8/99, reaffirmed 9/16)

http://pediatrics.aappublications.org/content/104/2/325

FOLLOW-UP MANAGEMENT OF CHILDREN WITH TYMPANOSTOMY TUBES

Section on Otolaryngology and Bronchoesophagology

ABSTRACT. The follow-up care of children in whom tympanostomy tubes have been placed is shared by the pediatrician and the otolaryngologist. Guidelines are provided for routine follow-up evaluation, perioperative hearing assessment, and the identification of specific conditions and complications that warrant urgent otolaryngologic consultation. These guidelines have been developed by a consensus of expert opinions. (2/02)

http://pediatrics.aappublications.org/content/109/2/328

FOOD ADDITIVES AND CHILD HEALTH

Leonardo Trasande, MD, MPP, FAAP; Rachel M. Shaffer, MPH; Sheela Sathyanarayana, MD, MPH; and Council on Environmental Health

ABSTRACT. Our purposes with this policy statement and its accompanying technical report are to review and highlight emerging child health concerns related to the use of colorings, flavorings, and chemicals deliberately added to food during processing (direct food additives) as well as substances in food contact materials, including adhesives, dyes, coatings, paper, paperboard, plastic, and other polymers, which may contaminate food as part of packaging or manufacturing equipment (indirect food additives); to make reasonable recommendations that the pediatrician might be able to adopt into the guidance provided during pediatric visits; and to propose urgently needed reforms to the current regulatory process at the US Food and Drug Administration (FDA) for food additives. Concern regarding food additives has increased in the past 2 decades, in part because of studies in which authors document endocrine disruption and other adverse health effects. In some cases, exposure to these chemicals is disproportionate among minority and

low-income populations. Regulation and oversight of many food additives is inadequate because of several key problems in the Federal Food, Drug, and Cosmetic Act. Current requirements for a "generally recognized as safe" (GRAS) designation are insufficient to ensure the safety of food additives and do not contain sufficient protections against conflict of interest. Additionally, the FDA does not have adequate authority to acquire data on chemicals on the market or reassess their safety for human health. These are critical weaknesses in the current regulatory system for food additives. Data about health effects of food additives on infants and children are limited or missing; however, in general, infants and children are more vulnerable to chemical exposures. Substantial improvements to the food additives regulatory system are urgently needed, including greatly strengthening or replacing the "generally recognized as safe" (GRAS) determination process, updating the scientific foundation of the FDA's safety assessment program, retesting all previously approved chemicals, and labeling direct additives with limited or no toxicity data. (7/18)

http://pediatrics.aappublications.org/content/142/2/e20181408

FOOD ADDITIVES AND CHILD HEALTH (TECHNICAL REPORT)

Leonardo Trasande, MD, MPP, FAAP; Rachel M. Shaffer, MPH; Sheela Sathyanarayana, MD, MPH; and Council on Environmental Health

ABSTRACT. Increasing scientific evidence suggests potential adverse effects on children's health from synthetic chemicals used as food additives, both those deliberately added to food during processing (direct) and those used in materials that may contaminate food as part of packaging or manufacturing (indirect). Concern regarding food additives has increased in the past 2 decades in part because of studies that increasingly document endocrine disruption and other adverse health effects. In some cases, exposure to these chemicals is disproportionate among minority and low-income populations. This report focuses on those food additives with the strongest scientific evidence for concern. Further research is needed to study effects of exposure over various points in the life course, and toxicity testing must be advanced to be able to better identify health concerns prior to widespread population exposure. The accompanying policy statement describes approaches policy makers and pediatricians can take to prevent the disease and disability that are increasingly being identified in relation to chemicals used as food additives, among other uses. (7/18)

http://pediatrics.aappublications.org/content/142/2/e20181410

FORGOING MEDICALLY PROVIDED NUTRITION AND HYDRATION IN CHILDREN (CLINICAL REPORT)

Douglas S. Diekema, MD, MPH; Jeffrey R. Botkin, MD, MPH; and Committee on Bioethics

ABSTRACT. There is broad consensus that withholding or withdrawing medical interventions is morally permissible when requested by competent patients or, in the case of patients without decision-making capacity, when the interventions no longer confer a benefit to the patient or when the burdens associated with the interventions outweigh the benefits received. The withdrawal or withholding of measures such as attempted resuscitation, ventilators, and critical care medications is common in the terminal care of adults and children. In the case of adults, a consensus has emerged in law and ethics that the medical administration of fluid and nutrition is not fundamentally different from other medical interventions such as use of ventilators; therefore, it can be forgone or withdrawn when a competent adult or legally authorized surrogate requests withdrawal or when the intervention no longer provides a net benefit to the patient. In pediatrics, forgoing or withdrawing medically administered fluids and nutrition has been more controversial because of the inability of children to make autonomous decisions and the emotional power of feeding as a basic element of the care of children. This statement reviews the medical, ethical, and legal issues relevant to the withholding or withdrawing of medically provided fluids and nutrition in children. The American Academy of Pediatrics concludes that the withdrawal of medically administered fluids and nutrition for pediatric patients is ethically acceptable in limited circumstances. Ethics consultation is strongly recommended when particularly difficult or controversial decisions are being considered. (7/09, reaffirmed 1/14)

http://pediatrics.aappublications.org/content/124/2/813

FRUIT JUICE IN INFANTS, CHILDREN, AND ADOLESCENTS: CURRENT RECOMMENDATIONS

Melvin B. Heyman, MD, FAAP; Steven A. Abrams, MD, FAAP; Section on Gastroenterology, Hepatology, and Nutrition; and Committee on Nutrition

ABSTRACT. Historically, fruit juice was recommended by pediatricians as a source of vitamin C and as an extra source of water for healthy infants and young children as their diets expanded to include solid foods with higher renal solute load. It was also sometimes recommended for children with constipation. Fruit juice is marketed as a healthy, natural source of vitamins and, in some instances, calcium. Because juice tastes good, children readily accept it. Although juice consumption has some benefits, it also has potential detrimental effects. High sugar content in juice contributes to increased calorie consumption and the risk of dental caries. In addition, the lack of protein and fiber in juice can predispose to inappropriate weight gain (too much or too little). Pediatricians need to be knowledgeable about juice to inform parents and patients on its appropriate uses. (5/17)

http://pediatrics.aappublications.org/content/139/6/e20170967

GASTROESOPHAGEAL REFLUX: MANAGEMENT GUIDANCE FOR THE PEDIATRICIAN (CLINICAL REPORT)

Jenifer R. Lightdale, MD, MPH; David A. Gremse, MD; and Section on Gastroenterology, Hepatology, and Nutrition

ABSTRACT. Recent comprehensive guidelines developed by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition define the common entities of gastroesophageal reflux (GER) as the physiologic passage of gastric contents into the esophagus and gastroesophageal reflux disease (GERD) as reflux associated with troublesome symptoms or complications. The ability to distinguish between GER and GERD is increasingly important to implement best practices in the management of acid reflux in patients across all pediatric age groups, as children with GERD may benefit from further evaluation and treatment, whereas conservative recommendations are the only indicated therapy in those with uncomplicated physiologic reflux. This clinical report endorses the rigorously developed, well-referenced North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition guidelines and likewise emphasizes important concepts for the general pediatrician. A key issue is distinguishing between clinical manifestations of GER and GERD in term infants, children, and adolescents to identify patients who can be managed with conservative treatment by the pediatrician and to refer patients who require consultation with the gastroenterologist. Accordingly, the evidence basis presented by the guidelines for diagnostic approaches as well as treatments is discussed. Lifestyle changes are emphasized as first-line therapy in both GER and GERD, whereas medications are explicitly indicated only for patients with GERD. Surgical therapies are reserved for children with intractable symptoms or who are at risk for life-threatening complications of GERD. Recent black box warnings from the US Food and Drug Administration are discussed, and caution is underlined when using promoters of gastric emptying and

motility. Finally, attention is paid to increasing evidence of inappropriate prescriptions for proton pump inhibitors in the pediatric population. (4/13)
http://pediatrics.aappublications.org/content/131/5/e1684

GENERIC PRESCRIBING, GENERIC SUBSTITUTION, AND THERAPEUTIC SUBSTITUTION

Committee on Drugs
(5/87, reaffirmed 6/93, 5/96, 6/99, 5/01, 5/05, 10/08, 10/12, 9/19)
http://pediatrics.aappublications.org/content/79/5/835

GLOBAL CLIMATE CHANGE AND CHILDREN'S HEALTH

Council on Environmental Health
ABSTRACT. Rising global temperatures are causing major physical, chemical, and ecological changes in the planet. There is wide consensus among scientific organizations and climatologists that these broad effects, known as "climate change," are the result of contemporary human activity. Climate change poses threats to human health, safety, and security, and children are uniquely vulnerable to these threats. The effects of climate change on child health include: physical and psychological sequelae of weather disasters; increased heat stress; decreased air quality; altered disease patterns of some climate-sensitive infections; and food, water, and nutrient insecurity in vulnerable regions. The social foundations of children's mental and physical health are threatened by the specter of far-reaching effects of unchecked climate change, including community and global instability, mass migrations, and increased conflict. Given this knowledge, failure to take prompt, substantive action would be an act of injustice to all children. A paradigm shift in production and consumption of energy is both a necessity and an opportunity for major innovation, job creation, and significant, immediate associated health benefits. Pediatricians have a uniquely valuable role to play in the societal response to this global challenge. (10/15)
http://pediatrics.aappublications.org/content/136/5/992

GLOBAL CLIMATE CHANGE AND CHILDREN'S HEALTH (TECHNICAL REPORT)

Samantha Ahdoot, MD, FAAP; Susan E. Pacheco, MD, FAAP; and Council on Environmental Health
ABSTRACT. Rising global temperature is causing major physical, chemical, and ecological changes across the planet. There is wide consensus among scientific organizations and climatologists that these broad effects, known as climate change, are the result of contemporary human activity. Climate change poses threats to human health, safety, and security. Children are uniquely vulnerable to these threats. The effects of climate change on child health include physical and psychological sequelae of weather disasters, increased heat stress, decreased air quality, altered disease patterns of some climate-sensitive infections, and food, water, and nutrient insecurity in vulnerable regions. Prompt implementation of mitigation and adaptation strategies will protect children against worsening of the problem and its associated health effects. This technical report reviews the nature of climate change and its associated child health effects and supports the recommendations in the accompanying policy statement on climate change and children's health. (10/15)
http://pediatrics.aappublications.org/content/136/5/e1468

GLOBAL HUMAN TRAFFICKING AND CHILD VICTIMIZATION

Jordan Greenbaum, MD; Nia Bodrick, MD, MPH, FAAP; Committee on Child Abuse and Neglect; and Section on International Child Health
ABSTRACT. Trafficking of children for labor and sexual exploitation violates basic human rights and constitutes a major global public health problem. Pediatricians and other health care professionals may encounter victims who present with infections, injuries, posttraumatic stress disorder, suicidality, or a variety of other physical or behavioral health conditions. Preventing child trafficking, recognizing victimization, and intervening appropriately require a public health approach that incorporates rigorous research on the risk factors, health impact, and effective treatment options for child exploitation as well as implementation and evaluation of primary prevention programs. Health care professionals need training to recognize possible signs of exploitation and to intervene appropriately. They need to adopt a multidisciplinary, outward-focused approach to service provision, working with nonmedical professionals in the community to assist victims. Pediatricians also need to advocate for legislation and policies that promote child rights and victim services as well as those that address the social determinants of health, which influence the vulnerability to human trafficking. This policy statement outlines major issues regarding public policy, medical education, research, and collaboration in the area of child labor and sex trafficking and provides recommendations for future work. (11/17)
http://pediatrics.aappublications.org/content/140/6/e20173138

GUIDANCE FOR THE ADMINISTRATION OF MEDICATION IN SCHOOL

Council on School Health
ABSTRACT. Many children who take medications require them during the school day. This policy statement is designed to guide prescribing health care professionals, school physicians, and school health councils on the administration of medications to children at school. All districts and schools need to have policies and plans in place for safe, effective, and efficient administration of medications at school. Having full-time licensed registered nurses administering all routine and emergency medications in schools is the best situation. When a licensed registered nurse is not available, a licensed practical nurse may administer medications. When a nurse cannot administer medication in school, the American Academy of Pediatrics supports appropriate delegation of nursing services in the school setting. Delegation is a tool that may be used by the licensed registered school nurse to allow unlicensed assistive personnel to provide standardized, routine health services under the supervision of the nurse and on the basis of physician guidance and school nursing assessment of the unique needs of the individual child and the suitability of delegation of specific nursing tasks. Any delegation of nursing duties must be consistent with the requirements of state nurse practice acts, state regulations, and guidelines provided by professional nursing organizations. Long-term, emergency, and short-term medications; over-the-counter medications; alternative medications; and experimental drugs that are administered as part of a clinical trial are discussed in this statement. This statement has been endorsed by the American School Health Association. (9/09, reaffirmed 2/13)
http://pediatrics.aappublications.org/content/124/4/1244

GUIDANCE ON COMPLETING A WRITTEN ALLERGY AND ANAPHYLAXIS EMERGENCY PLAN (CLINICAL REPORT)

Julie Wang, MD, FAAP; Scott H. Sicherer, MD, FAAP; and Section on Allergy and Immunology
ABSTRACT. Anaphylaxis is a potentially life-threatening, severe allergic reaction. The immediate assessment of patients having an allergic reaction and prompt administration of epinephrine, if criteria for anaphylaxis are met, promote optimal outcomes. National and international guidelines for the management of anaphylaxis, including those for management of allergic reactions at school, as well as several clinical reports from the American Academy of Pediatrics, recommend the provision of written emergency action plans to those at risk of anaphylaxis, in addition to the prescription of epinephrine autoinjectors. This clinical report provides information to help health care providers understand the role of a written, personalized allergy and

anaphylaxis emergency plan to enhance the care of children at risk of allergic reactions, including anaphylaxis. This report offers a comprehensive written plan, with advice on individualizing instructions to suit specific patient circumstances. (2/17)
http://pediatrics.aappublications.org/content/139/3/e20164005

GUIDANCE ON FORGOING LIFE-SUSTAINING MEDICAL TREATMENT

Kathryn L. Weise, MD, MA, FAAP; Alexander L. Okun, MD, FAAP; Brian S. Carter, MD, FAAP; Cindy W. Christian, MD, FAAP; Committee on Bioethics; Section on Hospice and Palliative Medicine; and Committee on Child Abuse and Neglect

ABSTRACT. Pediatric health care is practiced with the goal of promoting the best interests of the child. Treatment generally is rendered under a presumption in favor of sustaining life. However, in some circumstances, the balance of benefits and burdens to the child leads to an assessment that forgoing life-sustaining medical treatment (LSMT) is ethically supportable or advisable. Parents are given wide latitude in decision-making concerning end-of-life care for their children in most situations. Collaborative decision-making around LSMT is improved by thorough communication among all stakeholders, including medical staff, the family, and the patient, when possible, throughout the evolving course of the patient's illness. Clear communication of overall goals of care is advised to promote agreed-on plans, including resuscitation status. Perceived disagreement among the team of professionals may be stressful to families. At the same time, understanding the range of professional opinions behind treatment recommendations is critical to informing family decision-making. Input from specialists in palliative care, ethics, pastoral care, and other disciplines enhances support for families and medical staff when decisions to forgo LSMT are being considered. Understanding specific applicability of institutional, regional, state, and national regulations related to forgoing LSMT is important to practice ethically within existing legal frameworks. This guidance represents an update of the 1994 statement from the American Academy of Pediatrics on forgoing LSMT. (8/17)
http://pediatrics.aappublications.org/content/140/3/e20171905

GUIDANCE ON MANAGEMENT OF ASYMPTOMATIC NEONATES BORN TO WOMEN WITH ACTIVE GENITAL HERPES LESIONS (CLINICAL REPORT)

Committee on Infectious Diseases and Committee on Fetus and Newborn

ABSTRACT. Herpes simplex virus (HSV) infection of the neonate is uncommon, but genital herpes infections in adults are very common. Thus, although treating an infant with neonatal herpes is a relatively rare occurrence, managing infants potentially exposed to HSV at the time of delivery occurs more frequently. The risk of transmitting HSV to an infant during delivery is determined in part by the mother's previous immunity to HSV. Women with primary genital HSV infections who are shedding HSV at delivery are 10 to 30 times more likely to transmit the virus to their newborn infants than are women with recurrent HSV infection who are shedding virus at delivery. With the availability of commercial serological tests that reliably can distinguish type-specific HSV antibodies, it is now possible to determine the type of maternal infection and, thus, further refine management of infants delivered to women who have active genital HSV lesions. The management algorithm presented herein uses both serological and virological studies to determine the risk of HSV transmission to the neonate who is delivered to a mother with active herpetic genital lesions and tailors management accordingly. The algorithm does not address the approach to asymptomatic neonates delivered to women with a history of genital herpes but no active lesions at delivery. (1/13, reaffirmed 9/16)
http://pediatrics.aappublications.org/content/131/2/e635

GUIDELINES FOR DEVELOPING ADMISSION AND DISCHARGE POLICIES FOR THE PEDIATRIC INTENSIVE CARE UNIT (CLINICAL REPORT)

Committee on Hospital Care and Section on Critical Care (joint with Society of Critical Care Medicine Pediatric Section Admission Criteria Task Force)

ABSTRACT. These guidelines were developed to provide a reference for preparing policies on admission to and discharge from pediatric intensive care units. They represent a consensus opinion of physicians, nurses, and allied health care professionals. By using this document as a framework for developing multidisciplinary admission and discharge policies, use of pediatric intensive care units can be optimized and patients can receive the level of care appropriate for their condition. (4/99, reaffirmed 5/17)
http://pediatrics.aappublications.org/content/103/4/840

GUIDELINES FOR MONITORING AND MANAGEMENT OF PEDIATRIC PATIENTS BEFORE, DURING, AND AFTER SEDATION FOR DIAGNOSTIC AND THERAPEUTIC PROCEDURES

Charles J. Coté, MD, FAAP; Stephen Wilson, DMD, MA, PhD; and American Academy of Pediatrics (joint with American Academy of Pediatric Dentistry)

ABSTRACT. The safe sedation of children for procedures requires a systematic approach that includes the following: no administration of sedating medication without the safety net of medical/dental supervision, careful presedation evaluation for underlying medical or surgical conditions that would place the child at increased risk from sedating medications, appropriate fasting for elective procedures and a balance between the depth of sedation and risk for those who are unable to fast because of the urgent nature of the procedure, a focused airway examination for large (kissing) tonsils or anatomic airway abnormalities that might increase the potential for airway obstruction, a clear understanding of the medication's pharmacokinetic and pharmacodynamic effects and drug interactions, appropriate training and skills in airway management to allow rescue of the patient, age- and size-appropriate equipment for airway management and venous access, appropriate medications and reversal agents, sufficient numbers of appropriately trained staff to both carry out the procedure and monitor the patient, appropriate physiologic monitoring during and after the procedure, a properly equipped and staffed recovery area, recovery to the presedation level of consciousness before discharge from medical/dental supervision, and appropriate discharge instructions. This report was developed through a collaborative effort of the American Academy of Pediatrics and the American Academy of Pediatric Dentistry to offer pediatric providers updated information and guidance in delivering safe sedation to children. (5/19)
https://pediatrics.aappublications.org/content/143/6/e20191000

GUIDELINES FOR PEDIATRIC CANCER CENTERS

Section on Hematology/Oncology

ABSTRACT. Since the American Academy of Pediatrics published guidelines for pediatric cancer centers in 1986 and 1997, significant changes in the delivery of health care have prompted a review of the role of tertiary medical centers in the care of pediatric patients. The potential effect of these changes on the treatment and survival rates of children with cancer led to this revision. The intent of this statement is to delineate personnel and facilities that are essential to provide state-of-the-art care for children and adolescents with cancer. This statement emphasizes the importance of board-certified pediatric hematologists/oncologists, pediatric subspecialty consultants, and appropriately qualified pediatric medical subspecialists and pediatric surgical specialists overseeing the care of all pediatric and adolescent cancer patients and the need for facilities

available only at a tertiary center as essential for the initial management and much of the follow-up for pediatric and adolescent cancer patients. (6/04, reaffirmed 10/08, 10/18)
http://pediatrics.aappublications.org/content/113/6/1833

GUIDELINES FOR THE DETERMINATION OF BRAIN DEATH IN INFANTS AND CHILDREN: AN UPDATE OF THE 1987 TASK FORCE RECOMMENDATIONS (CLINICAL REPORT)

Thomas A. Nakagawa, MD; Stephen Ashwal, MD; Mudit Mathur, MD; Mohan Mysore, MD; Section on Critical Care; and Section on Neurology (joint with Society of Critical Care Medicine and Child Neurology Society)

ABSTRACT. *Objective.* To review and revise the 1987 pediatric brain death guidelines.

Methods. Relevant literature was reviewed. Recommendations were developed using the GRADE system.

Conclusions and Recommendations.

1. Determination of brain death in term newborns, infants and children is a clinical diagnosis based on the absence of neurologic function with a known irreversible cause of coma. Because of insufficient data in the literature, recommendations for preterm infants less than 37 weeks' gestational age are not included in this guideline.
2. Hypotension, hypothermia, and metabolic disturbances should be treated and corrected and medications that can interfere with the neurologic examination and apnea testing should be discontinued allowing for adequate clearance before proceeding with these evaluations.
3. Two examinations including apnea testing with each examination separated by an observation period are required. Examinations should be performed by different attending physicians. Apnea testing may be performed by the same physician. An observation period of 24 hours for term newborns (37 weeks' gestational age) to 30 days of age, and 12 hours for infants and children (> 30 days to 18 years) is recommended. The first examination determines the child has met the accepted neurologic examination criteria for brain death. The second examination confirms brain death based on an unchanged and irreversible condition. Assessment of neurologic function following cardiopulmonary resuscitation or other severe acute brain injuries should be deferred for 24 hours or longer if there are concerns or inconsistencies in the examination.
4. Apnea testing to support the diagnosis of brain death must be performed safely and requires documentation of an arterial $Paco_2$ 20 mm Hg above the baseline and ≥60 mm Hg with no respiratory effort during the testing period. If the apnea test cannot be safely completed, an ancillary study should be performed.
5. Ancillary studies (electroencephalogram and radionuclide cerebral blood flow) are not required to establish brain death and are not a substitute for the neurologic examination. Ancillary studies may be used to assist the clinician in making the diagnosis of brain death (1) when components of the examination or apnea testing cannot be completed safely due to the underlying medical condition of the patient; (2) if there is uncertainty about the results of the neurologic examination; (3) if a medication effect may be present; or (4) to reduce the inter-examination observation period. When ancillary studies are used, a second clinical examination and apnea test should be performed and components that can be completed must remain consistent with brain death. In this instance the observation interval may be shortened and the second neurologic examination and apnea test (or all components that are able to be completed safely) can be performed at any time thereafter.
6. Death is declared when the above criteria are fulfilled. (8/11, reaffirmed 1/15, 5/19)
http://pediatrics.aappublications.org/content/128/3/e720

GUIDELINES FOR THE ETHICAL CONDUCT OF STUDIES TO EVALUATE DRUGS IN PEDIATRIC POPULATIONS (CLINICAL REPORT)

Robert E. Shaddy, MD; Scott C. Denne, MD; Committee on Drugs; and Committee on Pediatric Research

ABSTRACT. The proper ethical conduct of studies to evaluate drugs in children is of paramount importance to all those involved in these types of studies. This report is an updated revision to the previously published guidelines from the American Academy of Pediatrics in 1995. Since the previous publication, there have been great strides made in the science and ethics of studying drugs in children. There have also been numerous legislative and regulatory advancements that have promoted the study of drugs in children while simultaneously allowing for the protection of this particularly vulnerable group. This report summarizes these changes and advances and provides a framework from which to guide and monitor the ethical conduct of studies to evaluate drugs in children. (3/10, reaffirmed 1/14, 2/18)
http://pediatrics.aappublications.org/content/125/4/850

GUIDING PRINCIPLES FOR MANAGED CARE ARRANGEMENTS FOR THE HEALTH CARE OF NEWBORNS, INFANTS, CHILDREN, ADOLESCENTS, AND YOUNG ADULTS

Committee on Child Health Financing

ABSTRACT. By including the precepts of primary care and the medical home in the delivery of services, managed care can be effective in increasing access to a full range of health care services and clinicians. A carefully designed and administered managed care plan can minimize patient under- and overutilization of services, as well as enhance quality of care. Therefore, the American Academy of Pediatrics urges the use of the key principles outlined in this statement in designing and implementing managed care programs for newborns, infants, children, adolescents, and young adults to maximize the positive potential of managed care for pediatrics. (10/13)
http://pediatrics.aappublications.org/content/132/5/e1452

GUIDING PRINCIPLES FOR TEAM-BASED PEDIATRIC CARE

Julie P. Katkin, MD, FAAP; Susan J. Kressly, MD, FAAP; Anne R. Edwards, MD, FAAP; James M. Perrin, MD, FAAP; Colleen A. Kraft, MD, FAAP; Julia E. Richerson, MD, FAAP; Joel S. Tieder, MD, MPH, FAAP; Liz Wall; and Task Force on Pediatric Practice Change

ABSTRACT. The American Academy of Pediatrics (AAP) recognizes that children's unique and ever-changing needs depend on a variety of support systems. Key components of effective support systems address the needs of the child and family in the context of their home and community and are dynamic so that they reflect, monitor, and respond to changes as the needs of the child and family change. The AAP believes that team-based care involving medical providers and community partners (eg, teachers and state agencies) is a crucial and necessary component of providing high-quality care to children and their families. Team-based care builds on the foundation of the medical home by reaching out to a potentially broad array of participants in the life of a child and incorporating them into the care provided. Importantly, the AAP believes that a high-functioning team includes children and their families as essential partners. The overall goal of team-based care is to enhance communication and cooperation among the varied medical, social, and educational partners in a child's life to better meet the global needs of children and their families, helping them to achieve their best potential. In support of the team-based approach, the AAP urges

stakeholders to invest in infrastructure, education, and privacy-secured technology to meet the needs of children. This statement includes limited specific examples of potential team members, including health care providers and community partners, that are meant to be illustrative and in no way represent a complete or comprehensive listing of all team members who may be of importance for a specific child and family. (7/17)
http://pediatrics.aappublications.org/content/140/2/e20171489

GYNECOLOGIC EXAMINATION FOR ADOLESCENTS IN THE PEDIATRIC OFFICE SETTING (CLINICAL REPORT)

Paula K. Braverman, MD; Lesley Breech, MD; and Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics promotes the inclusion of the gynecologic examination in the primary care setting within the medical home. Gynecologic issues are commonly seen by clinicians who provide primary care to adolescents. Some of the most common concerns include questions related to pubertal development; menstrual disorders such as dysmenorrhea, amenorrhea, oligomenorrhea, and abnormal uterine bleeding; contraception; and sexually transmitted and non–sexually transmitted infections. The gynecologic examination is a key element in assessing pubertal status and documenting physical findings. Most adolescents do not need an internal examination involving a speculum or bimanual examination. However, for cases in which more extensive examination is needed, the primary care office with the primary care clinician who has established rapport and trust with the patient is often the best setting for pelvic examination. This report reviews the gynecologic examination, including indications for the pelvic examination in adolescents and the approach to this examination in the office setting. Indications for referral to a gynecologist are included. The pelvic examination may be successfully completed when conducted without pressure and approached as a normal part of routine young women's health care. (8/10, reaffirmed 5/13)
http://pediatrics.aappublications.org/content/126/3/583

HANDOFFS: TRANSITIONS OF CARE FOR CHILDREN IN THE EMERGENCY DEPARTMENT

Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. Transitions of care (ToCs), also referred to as handoffs or sign-outs, occur when the responsibility for a patient's care transfers from 1 health care provider to another. Transitions are common in the acute care setting and have been noted to be vulnerable events with opportunities for error. Health care is taking ideas from other high-risk industries, such as aerospace and nuclear power, to create models of structured transition processes. Although little literature currently exists to establish 1 model as superior, multiorganizational consensus groups agree that standardization is warranted and that additional work is needed to establish characteristics of ToCs that are associated with clinical or practice outcomes. The rationale for structuring ToCs, specifically those related to the care of children in the emergency setting, and a description of identified strategies are presented, along with resources for educating health care providers on ToCs. Recommendations for development, education, and implementation of transition models are included. (10/16)
http://pediatrics.aappublications.org/content/138/5/e20162680

HEAD LICE (CLINICAL REPORT)

Cynthia D. Devore, MD, FAAP; Gordon E. Schutze, MD, FAAP; Council on School Health; and Committee on Infectious Diseases

ABSTRACT. Head lice infestation is associated with limited morbidity but causes a high level of anxiety among parents of school-aged children. Since the 2010 clinical report on head lice was published by the American Academy of Pediatrics, newer medications have been approved for the treatment of head lice. This revised clinical report clarifies current diagnosis and treatment protocols and provides guidance for the management of children with head lice in the school setting. (4/15, reaffirmed 6/20)
http://pediatrics.aappublications.org/content/135/5/e1355

HEALTH AND MENTAL HEALTH NEEDS OF CHILDREN IN US MILITARY FAMILIES (CLINICAL REPORT)

CDR Chadley R. Huebner, MD, MPH, FAAP; Section on Uniformed Services; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Children in US military families share common experiences and unique challenges, including parental deployment and frequent relocation. Although some of the stressors of military life have been associated with higher rates of mental health disorders and increased health care use among family members, there are various factors and interventions that have been found to promote resilience. Military children often live on or near military installations, where they may attend Department of Defense–sponsored child care programs and schools and receive medical care through military treatment facilities. However, many families live in remote communities without access to these services. Because of this wide geographic distribution, military children are cared for in both military and civilian medical practices. This clinical report provides a background to military culture and offers practical guidance to assist civilian and military pediatricians caring for military children. (12/18)
https://pediatrics.aappublications.org/content/143/1/e20183258

HEALTH CARE ISSUES FOR CHILDREN AND ADOLESCENTS IN FOSTER CARE AND KINSHIP CARE

Council on Foster Care, Adoption, and Kinship Care; Committee on Adolescence; and Council on Early Childhood

ABSTRACT. Children and adolescents who enter foster care often do so with complicated and serious medical, mental health, developmental, oral health, and psychosocial problems rooted in their history of childhood trauma. Ideally, health care for this population is provided in a pediatric medical home by physicians who are familiar with the sequelae of childhood trauma and adversity. As youth with special health care needs, children and adolescents in foster care require more frequent monitoring of their health status, and pediatricians have a critical role in ensuring the well-being of children in out-of-home care through the provision of high-quality pediatric health services, health care coordination, and advocacy on their behalves. (9/15)
http://pediatrics.aappublications.org/content/136/4/e1131

HEALTH CARE ISSUES FOR CHILDREN AND ADOLESCENTS IN FOSTER CARE AND KINSHIP CARE (TECHNICAL REPORT)

Moira A. Szilagyi, MD, PhD; David S. Rosen, MD, MPH; David Rubin, MD, MSCE; Sarah Zlotnik, MSW, MSPH; Council on Foster Care, Adoption, and Kinship Care; Committee on Adolescence; and Council on Early Childhood

ABSTRACT. Children and adolescents involved with child welfare, especially those who are removed from their family of origin and placed in out-of-home care, often present with complex and serious physical, mental health, developmental, and psychosocial problems rooted in childhood adversity and trauma. As such, they are designated as children with special health care needs. There are many barriers to providing high-quality comprehensive health care services to children and adolescents whose lives are characterized by transience and uncertainty. Pediatricians have a critical role in ensuring the well-being of children in out-of-home care through the provision

of high-quality pediatric health services in the context of a medical home, and health care coordination and advocacy on their behalf. This technical report supports the policy statement of the same title. (9/15)
http://pediatrics.aappublications.org/content/136/4/e1142

HEALTH CARE OF YOUTH AGING OUT OF FOSTER CARE

Council on Foster Care, Adoption, and Kinship Care and Committee on Early Childhood

ABSTRACT. Youth transitioning out of foster care face significant medical and mental health care needs. Unfortunately, these youth rarely receive the services they need because of lack of health insurance. Through many policies and programs, the federal government has taken steps to support older youth in foster care and those aging out. The Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub L No. 110-354) requires states to work with youth to develop a transition plan that addresses issues such as health insurance. In addition, beginning in 2014, the Patient Protection and Affordable Care Act of 2010 (Pub L No. 111-148) makes youth aging out of foster care eligible for Medicaid coverage until age 26 years, regardless of income. Pediatricians can support youth aging out of foster care by working collaboratively with the child welfare agency in their state to ensure that the ongoing health needs of transitioning youth are met. (11/12, reaffirmed 7/17)
http://pediatrics.aappublications.org/content/130/6/1170

HEALTH CARE SUPERVISION FOR CHILDREN WITH WILLIAMS SYNDROME (CLINICAL REPORT)

Colleen A. Morris, MD; Stephen R. Braddock, MD; and Council on Genetics

ABSTRACT. This set of recommendations is designed to assist the pediatrician in caring for children with Williams syndrome (WS) who were diagnosed by using clinical features and with chromosome 7 microdeletion confirmed by fluorescence in situ hybridization, chromosome microarray, or multiplex ligation-dependent probe amplification. The recommendations in this report reflect review of the current literature, including previously peer-reviewed and published management suggestions for WS, as well as the consensus of physicians and psychologists with expertise in the care of individuals with WS. These general recommendations for the syndrome do not replace individualized medical assessment and treatment. (1/20)
See full text on page 817.
https://pediatrics.aappublications.org/content/145/2/e20193761

HEALTH INFORMATION TECHNOLOGY AND THE MEDICAL HOME

Council on Clinical Information Technology

ABSTRACT. The American Academy of Pediatrics (AAP) supports development and universal implementation of a comprehensive electronic infrastructure to support pediatric information functions of the medical home. These functions include (1) timely and continuous management and tracking of health data and services over a patient's lifetime for all providers, patients, families, and guardians, (2) comprehensive organization and secure transfer of health data during patient-care transitions between providers, institutions, and practices, (3) establishment and maintenance of central coordination of a patient's health information among multiple repositories (including personal health records and information exchanges), (4) translation of evidence into actionable clinical decision support, and (5) reuse of archived clinical data for continuous quality improvement. The AAP supports universal, secure, and vendor-neutral portability of health information for all patients contained within the medical home across all care settings (ambulatory practices, inpatient settings, emergency departments, pharmacies, consultants, support service providers, and therapists) for multiple purposes including direct care, personal health records, public health, and registries. The AAP also supports financial incentives that promote the development of information tools that meet the needs of pediatric workflows and that appropriately recognize the added value of medical homes to pediatric care. (4/11, reaffirmed 7/15)
http://pediatrics.aappublications.org/content/127/5/978

HEALTH SUPERVISION FOR CHILDREN WITH DOWN SYNDROME (CLINICAL REPORT)

Marilyn J. Bull, MD, and Committee on Genetics

ABSTRACT. These guidelines are designed to assist the pediatrician in caring for the child in whom a diagnosis of Down syndrome has been confirmed by chromosome analysis. Although a pediatrician's initial contact with the child is usually during infancy, occasionally the pregnant woman who has been given a prenatal diagnosis of Down syndrome will be referred for review of the condition and the genetic counseling provided. Therefore, this report offers guidance for this situation as well. (7/11, reaffirmed 9/16, 1/18)
http://pediatrics.aappublications.org/content/128/2/393

HEALTH SUPERVISION FOR CHILDREN WITH FRAGILE X SYNDROME (CLINICAL REPORT)

Joseph H. Hersh, MD; Robert A. Saul, MD; and Committee on Genetics

ABSTRACT. Fragile X syndrome (an *FMR1*–related disorder) is the most commonly inherited form of mental retardation. Early physical recognition is difficult, so boys with developmental delay should be strongly considered for molecular testing. The characteristic adult phenotype usually does not develop until the second decade of life. Girls can also be affected with developmental delay. Because multiple family members can be affected with mental retardation and other conditions (premature ovarian failure and tremor/ataxia), family history information is of critical importance for the diagnosis and management of affected patients and their families. This report summarizes issues for fragile X syndrome regarding clinical diagnosis, laboratory diagnosis, genetic counseling, related health problems, behavior management, and age-related health supervision guidelines. The diagnosis of fragile X syndrome not only involves the affected children but also potentially has significant health consequences for multiple generations in each family. (4/11)
http://pediatrics.aappublications.org/content/127/5/994

HEALTH SUPERVISION FOR CHILDREN WITH MARFAN SYNDROME (CLINICAL REPORT)

Brad T. Tinkle, MD, PhD; Howard M. Saal, MD; and Committee on Genetics

ABSTRACT. Marfan syndrome is a systemic, heritable connective tissue disorder that affects many different organ systems and is best managed by using a multidisciplinary approach. The guidance in this report is designed to assist the pediatrician in recognizing the features of Marfan syndrome as well as caring for the individual with this disorder. (9/13, 10/19)
http://pediatrics.aappublications.org/content/132/4/e1059

HEALTH SUPERVISION FOR CHILDREN WITH NEUROFIBROMATOSIS TYPE 1 (CLINICAL REPORT)

David T. Miller, MD, PhD, FAAP; Debra Freedenberg, MD, PhD, FAAP; Elizabeth Schorry, MD; Nicole J. Ullrich, MD, PhD; David Viskochil, MD, PhD; Bruce R. Korf, MD, PhD, FAAP; and Council on Genetics (joint with American College of Medical Genetics and Genomics)

ABSTRACT. Neurofibromatosis type 1 (NF1) is a multisystem disorder that primarily involves the skin and peripheral nervous system. Its population prevalence is approximately 1 in 3000.

The condition is usually recognized in early childhood, when pigmentary manifestations emerge. Although NF1 is associated with marked clinical variability, most children affected follow patterns of growth and development within the normal range. Some features of NF1 can be present at birth, but most manifestations emerge with age, necessitating periodic monitoring to address ongoing health and developmental needs and minimize the risk of serious medical complications. In this report, we provide a review of the clinical criteria needed to establish a diagnosis, the inheritance pattern of NF1, its major clinical and developmental manifestations, and guidelines for monitoring and providing intervention to maximize the health and quality of life of a child affected. (4/19)

https://pediatrics.aappublications.org/content/143/5/e20190660

HEALTH SUPERVISION FOR CHILDREN WITH PRADER-WILLI SYNDROME (CLINICAL REPORT)

Shawn E. McCandless, MD, and Committee on Genetics

ABSTRACT. This set of guidelines was designed to assist the pediatrician in caring for children with Prader-Willi syndrome diagnosed by clinical features and confirmed by molecular testing. Prader-Willi syndrome provides an excellent example of how early diagnosis and management can improve the long-term outcome for some genetic disorders. (12/10)

http://pediatrics.aappublications.org/content/127/1/195

HEALTH SUPERVISION FOR CHILDREN WITH SICKLE CELL DISEASE

Section on Hematology/Oncology and Committee on Genetics

ABSTRACT. Sickle cell disease (SCD) is a group of complex genetic disorders with multisystem manifestations. This statement provides pediatricians in primary care and subspecialty practice with an overview of the genetics, diagnosis, clinical manifestations, and treatment of SCD. Specialized comprehensive medical care decreases morbidity and mortality during childhood. The provision of comprehensive care is a time-intensive endeavor that includes ongoing patient and family education, periodic comprehensive evaluations and other disease-specific health maintenance services, psychosocial care, and genetic counseling. Timely and appropriate treatment of acute illness is critical, because life-threatening complications develop rapidly. It is essential that every child with SCD receive comprehensive care that is coordinated through a medical home with appropriate expertise. (3/02, reaffirmed 1/06, 1/11, 2/16, 9/20)

http://pediatrics.aappublications.org/content/109/3/526

HEALTH SUPERVISION FOR PEOPLE WITH ACHONDROPLASIA (CLINICAL REPORT)

Julie Hoover-Fong, MD, PhD, FACMG; Charles I. Scott, MD, FAAP; Marilyn C. Jones, MD, FAAP; and Committee on Genetics

ABSTRACT. Achondroplasia is the most common short-stature skeletal dysplasia, additionally marked by rhizomelia, macrocephaly, midface hypoplasia, and normal cognition. Potential medical complications associated with achondroplasia include lower extremity long bone bowing, middle-ear dysfunction, obstructive sleep apnea, and, more rarely, cervicomedullary compression, hydrocephalus, thoracolumbar kyphosis, and central sleep apnea. This is the second revision to the original 1995 health supervision guidance from the American Academy of Pediatrics for caring for patients with achondroplasia. Although many of the previously published recommendations remain appropriate for contemporary medical care, this document highlights interval advancements in the clinical methods available to monitor for complications associated with achondroplasia. This document is intended to provide guidance for health care providers to help identify individual patients at high risk of developing serious sequelae and to enable intervention before complications develop. (5/20)

See full text on page 833.

https://pediatrics.aappublications.org/content/145/6/e20201010

HELPING CHILDREN AND FAMILIES DEAL WITH DIVORCE AND SEPARATION (CLINICAL REPORT)

George J. Cohen, MD, FAAP; Carol C. Weitzman, MD, FAAP; Committee on Psychosocial Aspects of Child and Family Health; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. For the past several years in the United States, there have been more than 800 000 divorces and parent separations annually, with over 1 million children affected. Children and their parents can experience emotional trauma before, during, and after a separation or divorce. Pediatricians can be aware of their patients' behavior and parental attitudes and behaviors that may indicate family dysfunction and that can indicate need for intervention. Age-appropriate explanation and counseling for the child and advice and guidance for the parents, as well as recommendation of reading material, may help reduce the potential negative effects of divorce. Often, referral to professionals with expertise in the social, emotional, and legal aspects of the separation and its aftermath may be helpful for these families. (11/16)

http://pediatrics.aappublications.org/content/138/6/e20163020

HIGH-DEDUCTIBLE HEALTH PLANS

Committee on Child Health Financing

ABSTRACT. High-deductible health plans (HDHPs) are insurance policies with higher deductibles than conventional plans. The Medicare Prescription Drug Improvement and Modernization Act of 2003 linked many HDHPs with tax-advantaged spending accounts. The 2010 Patient Protection and Affordable Care Act continues to provide for HDHPs in its lower-level plans on the health insurance marketplace and provides for them in employer-offered plans. HDHPs decrease the premium cost of insurance policies for purchasers and shift the risk of further payments to the individual subscriber. HDHPs reduce utilization and total medical costs, at least in the short term. Because HDHPs require out-of-pocket payment in the initial stages of care, primary care and other outpatient services as well as elective procedures are the services most affected, whereas higher-cost services in the health care system, incurred after the deductible is met, are unaffected. HDHPs promote adverse selection because healthier and wealthier patients tend to opt out of conventional plans in favor of HDHPs. Because the ill pay more than the healthy under HDHPs, families with children with special health care needs bear an increased cost burden in this model. HDHPs discourage use of nonpreventive primary care and thus are at odds with most recommendations for improving the organization of health care, which focus on strengthening primary care.

This policy statement provides background information on HDHPs, discusses the implications for families and pediatric care providers, and suggests courses of action. (4/14, reaffirmed 10/18)

http://pediatrics.aappublications.org/content/133/5/e1461

HIV TESTING AND PROPHYLAXIS TO PREVENT MOTHER-TO-CHILD TRANSMISSION IN THE UNITED STATES

Committee on Pediatric AIDS

ABSTRACT. Universal HIV testing of pregnant women in the United States is the key to prevention of mother-to-child transmission of HIV. Repeat testing in the third trimester and rapid HIV testing at labor and delivery are additional strategies to further reduce the rate of perinatal HIV transmission. Prevention of mother-to-child transmission of HIV is most effective when antiretroviral drugs are received by the mother during her pregnancy and continued through delivery and then administered to the infant after birth. Antiretroviral drugs are

effective in reducing the risk of mother-to-child transmission of HIV even when prophylaxis is started for the infant soon after birth. New rapid testing methods allow identification of HIV-infected women or HIV-exposed infants in 20 to 60 minutes. The American Academy of Pediatrics recommends documented, routine HIV testing for all pregnant women in the United States after notifying the patient that testing will be performed, unless the patient declines HIV testing ("opt-out" consent or "right of refusal"). For women in labor with undocumented HIV-infection status during the current pregnancy, immediate maternal HIV testing with opt-out consent, using a rapid HIV antibody test, is recommended. Positive HIV antibody screening test results should be confirmed with immunofluorescent antibody or Western blot assay. For women with a positive rapid HIV antibody test result, antiretroviral prophylaxis should be administered promptly to the mother and newborn infant on the basis of the positive result of the rapid antibody test without waiting for results of confirmatory HIV testing. If the confirmatory test result is negative, then prophylaxis should be discontinued. For a newborn infant whose mother's HIV serostatus is unknown, the health care professional should perform rapid HIV antibody testing on the mother or on the newborn infant, with results reported to the health care professional no later than 12 hours after the infant's birth. If the rapid HIV antibody test result is positive, antiretroviral prophylaxis should be instituted as soon as possible after birth but certainly by 12 hours after delivery, pending completion of confirmatory HIV testing. The mother should be counseled not to breastfeed the infant. Assistance with immediate initiation of hand and pump expression to stimulate milk production should be offered to the mother, given the possibility that the confirmatory test result may be negative. If the confirmatory test result is negative, then prophylaxis should be stopped and breastfeeding may be initiated. If the confirmatory test result is positive, infants should receive antiretroviral prophylaxis for 6 weeks after birth, and the mother should not breastfeed the infant. (11/08, reaffirmed 6/11, 11/14, 10/20)
http://pediatrics.aappublications.org/content/122/5/1127

HOME CARE OF CHILDREN AND YOUTH WITH COMPLEX HEALTH CARE NEEDS AND TECHNOLOGY DEPENDENCIES (CLINICAL REPORT)

Ellen Roy Elias, MD; Nancy A. Murphy, MD; and Council on Children With Disabilities

ABSTRACT. Children and youth with complex medical issues, especially those with technology dependencies, experience frequent and often lengthy hospitalizations. Hospital discharges for these children can be a complicated process that requires a deliberate, multistep approach. In addition to successful discharges to home, it is essential that pediatric providers develop and implement an interdisciplinary and coordinated plan of care that addresses the child's ongoing health care needs. The goal is to ensure that each child remains healthy, thrives, and obtains optimal medical home and developmental supports that promote ongoing care at home and minimize recurrent hospitalizations. This clinical report presents an approach to discharging the child with complex medical needs with technology dependencies from hospital to home and then continually addressing the needs of the child and family in the home environment. (4/12, reaffirmed 5/17)
http://pediatrics.aappublications.org/content/129/5/996

HONORING DO-NOT-ATTEMPT-RESUSCITATION REQUESTS IN SCHOOLS

Council on School Health and Committee on Bioethics

ABSTRACT. Increasingly, children and adolescents with complex chronic conditions are living in the community. Federal legislation and regulations facilitate their participation in school. Some of these children and adolescents and their families may wish to forego life-sustaining medical treatment, including cardiopulmonary resuscitation, because they would be ineffective or because the risks outweigh the benefits. Honoring these requests in the school environment is complex because of the limited availability of school nurses and the frequent lack of supporting state legislation and regulations. Understanding and collaboration on the part of all parties is essential. Pediatricians have an important role in helping school nurses incorporate a specific action plan into the student's individualized health care plan. The action plan should include both communication and comfort-care plans. Pediatricians who work directly with schools can also help implement policies, and professional organizations can advocate for regulations and legislation that enable students and their families to effectuate their preferences. (4/10, reaffirmed 7/13, 8/16)
http://pediatrics.aappublications.org/content/125/5/1073

HOSPITAL DISCHARGE OF THE HIGH-RISK NEONATE

Committee on Fetus and Newborn

ABSTRACT. This policy statement updates the guidelines on discharge of the high-risk neonate first published by the American Academy of Pediatrics in 1998. As with the earlier document, this statement is based, insofar as possible, on published, scientifically derived information. This updated statement incorporates new knowledge about risks and medical care of the high-risk neonate, the timing of discharge, and planning for care after discharge. It also refers to other American Academy of Pediatrics publications that are relevant to these issues. This statement draws on the previous classification of high-risk infants into 4 categories: (1) the preterm infant; (2) the infant with special health care needs or dependence on technology; (3) the infant at risk because of family issues; and (4) the infant with anticipated early death. The issues of deciding when discharge is appropriate, defining the specific needs for follow-up care, and the process of detailed discharge planning are addressed as they apply in general to all 4 categories; in addition, special attention is directed to the particular issues presented by the 4 individual categories. Recommendations are given to aid in deciding when discharge is appropriate and to ensure that all necessary care will be available and well coordinated after discharge. The need for individualized planning and physician judgment is emphasized. (11/08, reaffirmed 5/11, 11/18)
http://pediatrics.aappublications.org/content/122/5/1119

THE HOSPITAL RECORD OF THE INJURED CHILD AND THE NEED FOR EXTERNAL CAUSE-OF-INJURY CODES

Committee on Injury and Poison Prevention

ABSTRACT. Proper record-keeping of emergency department visits and hospitalizations of injured children is vital for appropriate patient management. Determination and documentation of the circumstances surrounding the injury event are essential. This information not only is the basis for preventive counseling, but also provides clues about how similar injuries in other youth can be avoided. The hospital records have an important secondary purpose; namely, if sufficient information about the cause and mechanism of injury is documented, it can be subsequently coded, electronically compiled, and retrieved later to provide an epidemiologic profile of the injury, the first step in prevention at the population level. To be of greatest use, hospital records should indicate the "who, what, when, where, why, and how" of the injury occurrence and whether protective equipment (eg, a seat belt) was used. The pediatrician has two important roles in this area: to document fully the injury event and to advocate the use of standardized external cause-of-injury codes, which allow such data to be compiled and analyzed. (2/99, reaffirmed 5/02, 5/05, 10/08, 10/13)
http://pediatrics.aappublications.org/content/103/2/524

HOSPITAL STAY FOR HEALTHY TERM NEWBORN INFANTS

William E. Benitz, MD, FAAP, and Committee on Fetus and Newborn

ABSTRACT. The hospital stay of the mother and her healthy term newborn infant should be long enough to allow identification of problems and to ensure that the mother is sufficiently recovered and prepared to care for herself and her newborn at home. The length of stay should be based on the unique characteristics of each mother-infant dyad, including the health of the mother, the health and stability of the newborn, the ability and confidence of the mother to care for herself and her newborn, the adequacy of support systems at home, and access to appropriate follow-up care in a medical home. Input from the mother and her obstetrical care provider should be considered before a decision to discharge a newborn is made, and all efforts should be made to keep a mother and her newborn together to ensure simultaneous discharge. (4/15)

http://pediatrics.aappublications.org/content/135/5/948

HUMAN EMBRYONIC STEM CELL (HESC) AND HUMAN EMBRYO RESEARCH

Committee on Pediatric Research and Committee on Bioethics

ABSTRACT. Human embryonic stem cell research has emerged as an important platform for the understanding and treatment of pediatric diseases. From its inception, however, it has raised ethical concerns based not on the use of stem cells themselves but on objections to the source of the cells—specifically, the destruction of preimplantation human embryos. Despite differences in public opinion on this issue, a large majority of the public supports continued research using embryonic stem cells. Given the possible substantial benefit of stem cell research on child health and development, the American Academy of Pediatrics believes that funding and oversight for human embryo and embryonic stem cell research should continue. (10/12, reaffirmed 7/17)

http://pediatrics.aappublications.org/content/130/5/972

HYPOTHERMIA AND NEONATAL ENCEPHALOPATHY (CLINICAL REPORT)

Committee on Fetus and Newborn

ABSTRACT. Data from large randomized clinical trials indicate that therapeutic hypothermia, using either selective head cooling or systemic cooling, is an effective therapy for neonatal encephalopathy. Infants selected for cooling must meet the criteria outlined in published clinical trials. The implementation of cooling needs to be performed at centers that have the capability to manage medically complex infants. Because the majority of infants who have neonatal encephalopathy are born at community hospitals, centers that perform cooling should work with their referring hospitals to implement education programs focused on increasing the awareness and identification of infants at risk for encephalopathy, and the initial clinical management of affected infants. (5/14)

http://pediatrics.aappublications.org/content/133/6/1146

IDENTIFICATION, EVALUATION, AND MANAGEMENT OF CHILDREN WITH AUTISM SPECTRUM DISORDER (CLINICAL REPORT)

Susan L. Hyman, MD, FAAP; Susan E. Levy, MD, MPH, FAAP; Scott M. Myers, MD, FAAP; Council on Children With Disabilities; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. Autism spectrum disorder (ASD) is a common neurodevelopmental disorder with reported prevalence in the United States of 1 in 59 children (approximately 1.7%). Core deficits are identified in 2 domains: social communication/interaction and restrictive, repetitive patterns of behavior. Children and youth with ASD have service needs in behavioral, educational, health, leisure, family support, and other areas. Standardized screening for ASD at 18 and 24 months of age with ongoing developmental surveillance continues to be recommended in primary care (although it may be performed in other settings), because ASD is common, can be diagnosed as young as 18 months of age, and has evidenced-based interventions that may improve function. More accurate and culturally sensitive screening approaches are needed. Primary care providers should be familiar with the diagnostic criteria for ASD, appropriate etiologic evaluation, and co-occurring medical and behavioral conditions (such as disorders of sleep and feeding, gastrointestinal tract symptoms, obesity, seizures, attention-deficit/hyperactivity disorder, anxiety, and wandering) that affect the child's function and quality of life. There is an increasing evidence base to support behavioral and other interventions to address specific skills and symptoms. Shared decision making calls for collaboration with families in evaluation and choice of interventions. This single clinical report updates the 2007 American Academy of Pediatrics clinical reports on the evaluation and treatment of ASD in one publication with an online table of contents and section view available through the American Academy of Pediatrics Gateway to help the reader identify topic areas within the report. (12/19)

See full text on page 855.

https://pediatrics.aappublications.org/content/145/1/e20193447

IDENTIFICATION AND CARE OF HIV-EXPOSED AND HIV-INFECTED INFANTS, CHILDREN, AND ADOLESCENTS IN FOSTER CARE

Committee on Pediatric AIDS

ABSTRACT. As a consequence of the expanding human immunodeficiency virus (HIV) epidemic and major advances in medical management of HIV-exposed and HIV-infected persons, revised recommendations are provided for HIV testing of infants, children, and adolescents in foster care. Updated recommendations also are provided for the care of HIV-exposed and HIV-infected persons who are in foster care. (7/00, reaffirmed 12/16)

http://pediatrics.aappublications.org/content/106/1/149

IDENTIFYING CHILD ABUSE FATALITIES DURING INFANCY (CLINICAL REPORT)

Vincent J. Palusci, MD, MS, FAAP; Amanda J. Kay, MD, MPH, FAAP; Erich Batra, MD, FAAP; Rachel Y. Moon, MD, FAAP; Council on Child Abuse and Neglect; Section on Child Death Review and Prevention; and Task Force on Sudden Infant Death Syndrome (joint with Tracey S. Corey, MD; Thomas Andrew, MD; Michael Graham, MD; and National Association of Medical Examiners)

ABSTRACT. When a healthy infant dies suddenly and unexpectedly, it is critical to correctly determine if the death was caused by child abuse or neglect. Sudden unexpected infant deaths should be comprehensively investigated, ancillary tests and forensic procedures should be used to more-accurately identify the cause of death, and parents deserve to be approached in a nonaccusatory manner during the investigation. Missing a child abuse death can place other children at risk, and inappropriately approaching a sleep-related death as maltreatment can result in inappropriate criminal and protective services investigations. Communities can learn from these deaths by using multidisciplinary child death reviews. Pediatricians can support families during investigation, advocate for and support state policies that require autopsies and scene investigation, and advocate for establishing comprehensive and fully funded child death investigation and reviews at the local and state levels. Additional funding is also needed for research to advance our ability to prevent these deaths. (8/19)

https://pediatrics.aappublications.org/content/144/3/e20192076

IDENTIFYING INFANTS AND YOUNG CHILDREN WITH DEVELOPMENTAL DISORDERS IN THE MEDICAL HOME: AN ALGORITHM FOR DEVELOPMENTAL SURVEILLANCE AND SCREENING

Council on Children With Disabilities, Section on Developmental and Behavioral Pediatrics, Bright Futures Steering Committee, and Medical Home Initiatives for Children With Special Needs Project Advisory Committee

ABSTRACT. Early identification of developmental disorders is critical to the well-being of children and their families. It is an integral function of the primary care medical home and an appropriate responsibility of all pediatric health care professionals. This statement provides an algorithm as a strategy to support health care professionals in developing a pattern and practice for addressing developmental concerns in children from birth through 3 years of age. The authors recommend that developmental surveillance be incorporated at every well-child preventive care visit. Any concerns raised during surveillance should be promptly addressed with standardized developmental screening tests. In addition, screening tests should be administered regularly at the 9-, 18-, and 30-month visits. (Because the 30-month visit is not yet a part of the preventive care system and is often not reimbursable by third-party payers at this time, developmental screening can be performed at 24 months of age. In addition, because the frequency of regular pediatric visits decreases after 24 months of age, a pediatrician who expects that his or her patients will have difficulty attending a 30-month visit should conduct screening during the 24-month visit.) The early identification of developmental problems should lead to further developmental and medical evaluation, diagnosis, and treatment, including early developmental intervention. Children diagnosed with developmental disorders should be identified as children with special health care needs, and chronic-condition management should be initiated. Identification of a developmental disorder and its underlying etiology may also drive a range of treatment planning, from medical treatment of the child to family planning for his or her parents. (7/06, reaffirmed 12/09, 8/14)

http://pediatrics.aappublications.org/content/118/1/405

IDENTIFYING THE MISSHAPEN HEAD: CRANIOSYNOSTOSIS AND RELATED DISORDERS (CLINICAL REPORT)

Mark S. Dias, MD, FAAP, FAANS; Thomas Samson, MD, FAAP; Elias B. Rizk, MD, FAAP, FAANS; Lance S. Governale, MD, FAAP, FAANS; Joan T. Richtsmeier, PhD; Section on Neurologic Surgery; and Section on Plastic and Reconstructive Surgery

ABSTRACT. Pediatric care providers, pediatricians, pediatric subspecialty physicians, and other health care providers should be able to recognize children with abnormal head shapes that occur as a result of both synostotic and deformational processes. The purpose of this clinical report is to review the characteristic head shape changes, as well as secondary craniofacial characteristics, that occur in the setting of the various primary craniosynostoses and deformations. As an introduction, the physiology and genetics of skull growth as well as the pathophysiology underlying craniosynostosis are reviewed. This is followed by a description of each type of primary craniosynostosis (metopic, unicoronal, bicoronal, sagittal, lambdoid, and frontosphenoidal) and their resultant head shape changes, with an emphasis on differentiating conditions that require surgical correction from those (bathrocephaly, deformational plagiocephaly/brachycephaly, and neonatal intensive care unit-associated skill deformation, known as NICUcephaly) that do not. The report ends with a brief discussion of microcephaly as it relates to craniosynostosis as well as fontanelle closure. The intent is to improve pediatric care providers' recognition and timely referral for craniosynostosis and their differentiation of synostotic from deformational and other nonoperative head shape changes. (8/20)

See full text on page 927.

https://pediatrics.aappublications.org/content/146/3/e2020015511

IMMERSION IN WATER DURING LABOR AND DELIVERY (CLINICAL REPORT)

Committee on Fetus and Newborn (joint with American College of Obstetricians and Gynecologists Committee on Obstetric Practice)

ABSTRACT. Immersion in water has been suggested as a beneficial alternative for labor, delivery, or both and over the past decades has gained popularity in many parts of the world. Immersion in water during the first stage of labor may be associated with decreased pain or use of anesthesia and decreased duration of labor. However, there is no evidence that immersion in water during the first stage of labor otherwise improves perinatal outcomes, and it should not prevent or inhibit other elements of care. The safety and efficacy of immersion in water during the second stage of labor have not been established, and immersion in water during the second stage of labor has not been associated with maternal or fetal benefit. Given these facts and case reports of rare but serious adverse effects in the newborn, the practice of immersion in the second stage of labor (underwater delivery) should be considered an experimental procedure that only should be performed within the context of an appropriately designed clinical trial with informed consent. Facilities that plan to offer immersion in the first stage of labor need to establish rigorous protocols for candidate selection, maintenance and cleaning of tubs and immersion pools, infection control procedures, monitoring of mothers and fetuses at appropriate intervals while immersed, and immediately and safely moving women out of the tubs if maternal or fetal concerns develop. (3/14)

http://pediatrics.aappublications.org/content/133/4/758

IMMUNIZATION INFORMATION SYSTEMS

Committee on Practice and Ambulatory Medicine

ABSTRACT. The American Academy of Pediatrics continues to support the development and implementation of immunization information systems, previously referred to as immunization registries, and other systems for the benefit of children, pediatricians, and their communities. Pediatricians and others must be aware of the value that immunization information systems have for society, the potential fiscal influences on their practice, the costs and benefits, and areas for future improvement. (9/06, reaffirmed 10/11)

http://pediatrics.aappublications.org/content/118/3/1293

IMMUNIZING PARENTS AND OTHER CLOSE FAMILY CONTACTS IN THE PEDIATRIC OFFICE SETTING (TECHNICAL REPORT)

Herschel R. Lessin, MD; Kathryn M. Edwards, MD; Committee on Practice and Ambulatory Medicine; and Committee on Infectious Diseases

ABSTRACT. Additional strategies are needed to protect children from vaccine-preventable diseases. In particular, very young infants, as well as children who are immunocompromised, are at especially high risk for developing the serious consequences of vaccine-preventable diseases and cannot be immunized completely. There is some evidence that children who become infected with these diseases are exposed to pathogens through household contacts, particularly from parents or other close family contacts. Such infections likely are attributable to adults who are not fully protected from these diseases, either because their immunity to vaccine-preventable diseases has waned over time or because they have not received a vaccine. There are many challenges that have added to low adult immunization rates in the United States. One option to increase immunization coverage for parents and close family contacts of infants and vulnerable children is to provide alternative locations for these adults to be immunized, such as the pediatric office setting. Ideally, adults

should receive immunizations in their medical homes; however, to provide greater protection to these adults and reduce the exposure of children to pathogens, immunizing parents or other adult family contacts in the pediatric office setting could increase immunization coverage for this population to protect themselves as well as children to whom they provide care. (12/11, reaffirmed 8/16)
http://pediatrics.aappublications.org/content/129/1/e247

THE IMPACT OF MARIJUANA POLICIES ON YOUTH: CLINICAL, RESEARCH, AND LEGAL UPDATE

Committee on Substance Abuse and Committee on Adolescence

ABSTRACT. This policy statement is an update of the American Academy of Pediatrics policy statement "Legalization of Marijuana: Potential Impact on Youth," published in 2004. Pediatricians have special expertise in the care of children and adolescents and may be called on to advise legislators about the potential impact of changes in the legal status of marijuana on adolescents. Parents also may look to pediatricians for advice as they consider whether to support state-level initiatives that propose to legalize the use of marijuana for medical and nonmedical purposes or to decriminalize the possession of small amounts of marijuana. This policy statement provides the position of the American Academy of Pediatrics on the issue of marijuana legalization. The accompanying technical report reviews what is currently known about the relationships of marijuana use with health and the developing brain and the legal status of marijuana and adolescents' use of marijuana to better understand how change in legal status might influence the degree of marijuana use by adolescents in the future. (2/15)
http://pediatrics.aappublications.org/content/135/3/584

THE IMPACT OF MARIJUANA POLICIES ON YOUTH: CLINICAL, RESEARCH, AND LEGAL UPDATE (TECHNICAL REPORT)

Seth Ammerman, MD, FAAP; Sheryl Ryan, MD, FAAP; William P. Adelman, MD, FAAP; Committee on Substance Abuse; and Committee on Adolescence

ABSTRACT. This technical report updates the 2004 American Academy of Pediatrics technical report on the legalization of marijuana. Current epidemiology of marijuana use is presented, as are definitions and biology of marijuana compounds, side effects of marijuana use, and effects of use on adolescent brain development. Issues concerning medical marijuana specifically are also addressed. Concerning legalization of marijuana, 4 different approaches in the United States are discussed: legalization of marijuana solely for medical purposes, decriminalization of recreational use of marijuana, legalization of recreational use of marijuana, and criminal prosecution of recreational (and medical) use of marijuana. These approaches are compared, and the latest available data are presented to aid in forming public policy. The effects on youth of criminal penalties for marijuana use and possession are also addressed, as are the effects or potential effects of the other 3 policy approaches on adolescent marijuana use. Recommendations are included in the accompanying policy statement. (2/15)
http://pediatrics.aappublications.org/content/135/3/e769

THE IMPACT OF RACISM ON CHILD AND ADOLESCENT HEALTH

Maria Trent, MD, MPH, FAAP, FSAHM; Danielle G. Dooley, MD, MPhil, FAAP; Jacqueline Dougé, MD, MPH, FAAP; Section on Adolescent Health; Council on Community Pediatrics; and Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics is committed to addressing the factors that affect child and adolescent health with a focus on issues that may leave some children more vulnerable than others. Racism is a social determinant of health that has a profound impact on the health status of children, adolescents, emerging adults, and their families. Although progress has been made toward racial equality and equity, the evidence to support the continued negative impact of racism on health and well-being through implicit and explicit biases, institutional structures, and interpersonal relationships is clear. The objective of this policy statement is to provide an evidence-based document focused on the role of racism in child and adolescent development and health outcomes. By acknowledging the role of racism in child and adolescent health, pediatricians and other pediatric health professionals will be able to proactively engage in strategies to optimize clinical care, workforce development, professional education, systems engagement, and research in a manner designed to reduce the health effects of structural, personally mediated, and internalized racism and improve the health and well-being of all children, adolescents, emerging adults, and their families. (7/19)
https://pediatrics.aappublications.org/content/144/2/e20191765

THE IMPACT OF SOCIAL MEDIA ON CHILDREN, ADOLESCENTS, AND FAMILIES (CLINICAL REPORT)

Gwenn Schurgin O'Keeffe, MD; Kathleen Clarke-Pearson, MD; and Council on Communications and Media

ABSTRACT. Using social media Web sites is among the most common activity of today's children and adolescents. Any Web site that allows social interaction is considered a social media site, including social networking sites such as Facebook, MySpace, and Twitter; gaming sites and virtual worlds such as Club Penguin, Second Life, and the Sims; video sites such as YouTube; and blogs. Such sites offer today's youth a portal for entertainment and communication and have grown exponentially in recent years. For this reason, it is important that parents become aware of the nature of social media sites, given that not all of them are healthy environments for children and adolescents. Pediatricians are in a unique position to help families understand these sites and to encourage healthy use and urge parents to monitor for potential problems with cyberbullying, "Facebook depression," sexting, and exposure to inappropriate content. (3/11)
http://pediatrics.aappublications.org/content/127/4/800

IMPROVING HEALTH AND SAFETY AT CAMP

Michael J. Ambrose, MD, FAAP; Edward A. Walton, MD, FAAP; and Council on School Health

ABSTRACT. The American Academy of Pediatrics has created recommendations for health appraisal and preparation of young people before participation in day, resident, or family camps and to guide health and safety practices at camp. These recommendations are intended for parents and families, primary health care providers, and camp administration and health center staff. Although camps have diverse environments, there are general guidelines that apply to all situations and specific recommendations that are appropriate under special conditions. This policy statement has been reviewed and is supported by the American Camp Association and Association of Camp Nursing. (6/19)
https://pediatrics.aappublications.org/content/144/1/e20191355

INCIDENTAL FINDINGS ON BRAIN AND SPINE IMAGING IN CHILDREN (CLINICAL REPORT)

Cormac O. Maher, MD, FAAP; Joseph H. Piatt Jr, MD, FAAP; and Section on Neurologic Surgery

ABSTRACT. In recent years, the utilization of diagnostic imaging of the brain and spine in children has increased dramatically, leading to a corresponding increase in the detection of incidental findings of the central nervous system. Patients with unexpected findings on imaging are often referred for subspecialty evaluation. Even with rational use of diagnostic imaging and subspecialty consultation, the diagnostic process will always generate unexpected findings that must be explained

and managed. Familiarity with the most common findings that are discovered incidentally on diagnostic imaging of the brain and spine will assist the pediatrician in providing counseling to families and in making recommendations in conjunction with a neurosurgeon, when needed, regarding additional treatments and prognosis. (3/15)
http://pediatrics.aappublications.org/content/135/4/e1084

INCORPORATING RECOGNITION AND MANAGEMENT OF PERINATAL DEPRESSION INTO PEDIATRIC PRACTICE

Marian F. Earls, MD, MTS, FAAP; Michael W. Yogman, MD, FAAP; Gerri Mattson, MD, MSPH, FAAP; Jason Rafferty, MD, MPH, EdM, FAAP; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Perinatal depression (PND) is the most common obstetric complication in the United States. Even when screening results are positive, mothers often do not receive further evaluation, and even when PND is diagnosed, mothers do not receive evidence-based treatments. Studies reveal that postpartum depression (PPD), a subset of PND, leads to increased costs of medical care, inappropriate medical treatment of the infant, discontinuation of breastfeeding, family dysfunction, and an increased risk of abuse and neglect. PPD, specifically, adversely affects this critical early period of infant brain development. PND is an example of an adverse childhood experience that has potential long-term adverse health complications for the mother, her partner, the infant, and the mother-infant dyad. However, PND can be treated effectively, and the stress on the infant can be buffered. Pediatric medical homes should coordinate care more effectively with prenatal providers for women with prenatally diagnosed maternal depression; establish a system to implement PPD screening at the 1-, 2-, 4-, and 6-month well-child visits; use community resources for the treatment and referral of the mother with depression; and provide support for the maternal-child (dyad) relationship, including breastfeeding support. State chapters of the American Academy of Pediatrics, working with state departments of public health, public and private payers, and maternal and child health programs, should advocate for payment and for increased training for PND screening and treatment. American Academy of Pediatrics recommends advocacy for workforce development for mental health professionals who care for young children and mother-infant dyads, and for promotion of evidence-based interventions focused on healthy attachment and parent-child relationships. (12/18)
https://pediatrics.aappublications.org/content/143/1/e20183259

INCORPORATING RECOGNITION AND MANAGEMENT OF PERINATAL DEPRESSION INTO PEDIATRIC PRACTICE (TECHNICAL REPORT)

Jason Rafferty, MD, MPH, EdM, FAAP; Gerri Mattson, MD, MSPH, FAAP; Marian F. Earls, MD, MTS, FAAP; Michael W. Yogman, MD, FAAP; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Perinatal depression is the most common obstetric complication in the United States, with prevalence rates of 15% to 20% among new mothers. Untreated, it can adversly affect the well-being of children and families through increasing the risk for costly complications during birth and lead to deterioration of core supports, including partner relationships and social networks. Perinatal depression contributes to long-lasting, and even permanent, consequences for the physical and mental health of parents and children, including poor family functioning, increased risk of child abuse and neglect, delayed infant development, perinatal obstetric complications, challenges with breastfeeding, and costly increases in health care use. Perinatal depression can interfere with early parent-infant interaction and attachment, leading to potentially long-term disturbances in the child's physical, emotional, cognitive, and social development. Fortunately, perinatal depression is identifiable and treatable. The US Preventive Services Task Force, Centers for Medicare and Medicaid Services, and many professional organizations recommend routine universal screening for perinatal depression in women to facilitate early evidence-based treatment and referrals, if necessary. Despite significant gains in screening rates from 2004 to 2013, a minority of pediatricians routinely screen for postpartum depression, and many mothers are still not identified or treated. Pediatric primary care clinicians, with a core mission of promoting child and family health, are in an ideal position to implement routine postpartum depression screens at several well-child visits throughout infancy and to provide mental health support through referrals and/or the interdisciplinary services of a pediatric patient-centered medical home model. (12/18)
https://pediatrics.aappublications.org/content/143/1/e20183260

INCREASING ANTIRETROVIRAL DRUG ACCESS FOR CHILDREN WITH HIV INFECTION

Committee on Pediatric AIDS and Section on International Child Health

ABSTRACT. Although there have been great gains in the prevention of pediatric HIV infection and provision of antiretroviral therapy for children with HIV infection in resource-rich countries, many barriers remain to scaling up HIV prevention and treatment for children in resource-limited areas of the world. Appropriate testing technologies need to be made more widely available to identify HIV infection in infants. Training of practitioners in the skills required to care for children with HIV infection is required to increase the number of children receiving antiretroviral therapy. Lack of availability of appropriate antiretroviral drug formulations that are easily usable and inexpensive is a major impediment to optimal care for children with HIV. The time and energy spent trying to develop liquid antiretroviral formulations might be better used in the manufacture of smaller pill sizes or crushable tablets, which are easier to dispense, transport, store, and administer to children. (4/07, reaffirmed 4/10, 4/16)
http://pediatrics.aappublications.org/content/119/4/838

INCREASING IMMUNIZATION COVERAGE

Committee on Practice and Ambulatory Medicine and Council on Community Pediatrics

ABSTRACT. In 1977, the American Academy of Pediatrics issued a statement calling for universal immunization of all children for whom vaccines are not contraindicated. In 1995, the policy statement "Implementation of the Immunization Policy" was published by the American Academy of Pediatrics, followed in 2003 with publication of the first version of this statement, "Increasing Immunization Coverage." Since 2003, there have continued to be improvements in immunization coverage, with progress toward meeting the goals set forth in *Healthy People 2010.* Data from the 2007 National Immunization Survey showed that 90% of children 19 to 35 months of age have received recommended doses of each of the following vaccines: inactivated poliovirus (IPV), measles-mumps-rubella (MMR), varicella-zoster virus (VZB), hepatitis B virus (HBV), and *Haemophilus influenzae* type b (Hib). For diphtheria and tetanus and acellular pertussis (DTaP) vaccine, 84.5% have received the recommended 4 doses by 35 months of age. Nevertheless, the *Healthy People 2010* goal of at least 80% coverage for the full series (at least 4 doses of DTaP, 3 doses of IPV, 1 dose of MMR, 3 doses of Hib, 3 doses of HBV, and 1 dose of varicella-zoster virus vaccine) has not yet been met, and immunization coverage of adolescents continues to lag behind the goals set forth in *Healthy People 2010.* Despite these encouraging data, a vast number of new challenges that threaten continued success toward the goal of universal immunization coverage have emerged. These challenges include an increase in new vaccines and new vaccine combinations as well as a significant

number of vaccines currently under development; a dramatic increase in the acquisition cost of vaccines, coupled with a lack of adequate payment to practitioners to buy and administer vaccines; unanticipated manufacturing and delivery problems that have caused significant shortages of various vaccine products; and the rise of a public antivaccination movement that uses the Internet as well as standard media outlets to advance a position, wholly unsupported by any scientific evidence, linking vaccines with various childhood conditions, particularly autism. Much remains to be accomplished by physician organizations; vaccine manufacturers; third-party payers; the media; and local, state, and federal governments to ensure dependable vaccine supply and payments that are sufficient to continue to provide immunizations in public and private settings and to promote effective strategies to combat unjustified misstatements by the antivaccination movement.

Pediatricians should work individually and collectively at the local, state, and national levels to ensure that all children without a valid contraindication receive all childhood immunizations on time. Pediatricians and pediatric organizations, in conjunction with government agencies such as the Centers for Disease Control and Prevention, must communicate effectively with parents to maximize their understanding of the overall safety and efficacy of vaccines. Most parents and children have not experienced many of the vaccine-preventable diseases, and the general public is not well informed about the risks and sequelae of these conditions. A number of recommendations are included for pediatricians, individually and collectively, to support further progress toward the goal of universal immunization coverage of all children for whom vaccines are not contraindicated. (5/10)
http://pediatrics.aappublications.org/content/125/6/1295

THE INDIVIDUALS WITH DISABILITIES EDUCATION ACT (IDEA) FOR CHILDREN WITH SPECIAL EDUCATIONAL NEEDS (CLINICAL REPORT)

Paul H. Lipkin, MD, FAAP; Jeffrey Okamoto, MD, FAAP; Council on Children With Disabilities; and Council on School Health

ABSTRACT. The pediatric health care provider has a critical role in supporting the health and well-being of children and adolescents in all settings, including early intervention (EI), preschool, and school environments. It is estimated that 15% of children in the United States have a disability. The Individuals with Disabilities Education Act entitles every affected child in the United States from infancy to young adulthood to a free appropriate public education through EI and special education services. These services bolster development and learning of children with various disabilities. This clinical report provides the pediatric health care provider with a summary of key components of the most recent version of this law. Guidance is also provided to ensure that every child in need receives the EI and special education services to which he or she is entitled. (11/15, reaffirmed 10/19)
http://pediatrics.aappublications.org/content/136/6/e1650

INDOOR ENVIRONMENTAL CONTROL PRACTICES AND ASTHMA MANAGEMENT (CLINICAL REPORT)

Elizabeth C. Matsui, MD, MHS, FAAP; Stuart L. Abramson, MD, PhD, AE-C, FAAP; Megan T. Sandel, MD, MPH, FAAP; Section on Allergy and Immunology; and Council on Environmental Health

ABSTRACT. Indoor environmental exposures, particularly allergens and pollutants, are major contributors to asthma morbidity in children; environmental control practices aimed at reducing these exposures are an integral component of asthma management. Some individually tailored environmental control practices that have been shown to reduce asthma symptoms and exacerbations are similar in efficacy and cost to controller medications. As a part of developing tailored strategies regarding environmental control measures, an environmental history can be obtained to evaluate the key indoor environmental exposures that are known to trigger asthma symptoms and exacerbations, including both indoor pollutants and allergens. An environmental history includes questions regarding the presence of pets or pests or evidence of pests in the home, as well as knowledge regarding whether the climatic characteristics in the community favor dust mites. In addition, the history focuses on sources of indoor air pollution, including the presence of smokers who live in the home or care for children and the use of gas stoves and appliances in the home. Serum allergen-specific immunoglobulin E antibody tests can be performed or the patient can be referred for allergy skin testing to identify indoor allergens that are most likely to be clinically relevant. Environmental control strategies are tailored to each potentially relevant indoor exposure and are based on knowledge of the sources and underlying characteristics of the exposure. Strategies include source removal, source control, and mitigation strategies, such as high-efficiency particulate air purifiers and allergen-proof mattress and pillow encasements, as well as education, which can be delivered by primary care pediatricians, allergists, pediatric pulmonologists, other health care workers, or community health workers trained in asthma environmental control and asthma education. (10/16)
http://pediatrics.aappublications.org/content/138/5/e20162589

INFANT FEEDING AND TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS IN THE UNITED STATES

Committee on Pediatric AIDS

ABSTRACT. Physicians caring for infants born to women infected with HIV are likely to be involved in providing guidance to HIV-infected mothers on appropriate infant feeding practices. It is critical that physicians are aware of the HIV transmission risk from human milk and the current recommendations for feeding HIV-exposed infants in the United States. Because the only intervention to completely prevent HIV transmission via human milk is not to breastfeed, in the United States, where clean water and affordable replacement feeding are available, the American Academy of Pediatrics recommends that HIV-infected mothers not breastfeed their infants, regardless of maternal viral load and antiretroviral therapy. (1/13, reaffirmed 4/16)
http://pediatrics.aappublications.org/content/131/2/391

INFANT METHEMOGLOBINEMIA: THE ROLE OF DIETARY NITRATE IN FOOD AND WATER (CLINICAL REPORT)

Frank R. Greer, MD; Michael Shannon, MD; Committee on Nutrition; and Committee on Environmental Health

ABSTRACT. Infants for whom formula may be prepared with well water remain a high-risk group for nitrate poisoning. This clinical report reinforces the need for testing of well water for nitrate content. There seems to be little or no risk of nitrate poisoning from commercially prepared infant foods in the United States. However, reports of nitrate poisoning from home-prepared vegetable foods for infants continue to occur. Breastfeeding infants are not at risk of methemoglobinemia even when mothers ingest water with very high concentrations of nitrate nitrogen (100 ppm). (9/05, reaffirmed 4/09)
http://pediatrics.aappublications.org/content/116/3/784

INFECTION PREVENTION AND CONTROL IN PEDIATRIC AMBULATORY SETTINGS

Mobeen H. Rathore, MD, FAAP; Mary Anne Jackson, MD, FAAP; and Committee on Infectious Diseases

ABSTRACT. Since the American Academy of Pediatrics published its statement titled "Infection Prevention and Control in Pediatric Ambulatory Settings" in 2007, there have been significant changes that prompted this updated statement. Infection prevention and control is an integral part of pediatric practice in ambulatory medical settings as well as in hospitals.

Infection prevention and control practices should begin at the time the ambulatory visit is scheduled. All health care personnel should be educated regarding the routes of transmission and techniques used to prevent the transmission of infectious agents. Policies for infection prevention and control should be written, readily available, updated every 2 years, and enforced. Many of the recommendations for infection control and prevention from the Centers for Disease Control and Prevention for hospitalized patients are also applicable in the ambulatory setting. These recommendations include requirements for pediatricians to take precautions to identify and protect employees likely to be exposed to blood or other potentially infectious materials while on the job. In addition to emphasizing the key principles of infection prevention and control in this policy, we update those that are relevant to the ambulatory care patient. These guidelines emphasize the role of hand hygiene and the implementation of diagnosis- and syndrome-specific isolation precautions, with the exemption of the use of gloves for routine diaper changes and wiping a well child's nose or tears for most patient encounters. Additional topics include respiratory hygiene and cough etiquette strategies for patients with a respiratory tract infection, including those relevant for special populations like patients with cystic fibrosis or those in short-term residential facilities; separation of infected, contagious children from uninfected children when feasible; safe handling and disposal of needles and other sharp medical devices; appropriate use of personal protective equipment, such as gloves, gowns, masks, and eye protection; and appropriate use of sterilization, disinfection, and antisepsis. Lastly, in this policy, we emphasize the importance of public health interventions, including vaccination for patients and health care personnel, and outline the responsibilities of the health care provider related to prompt public health notification for specific reportable diseases and communication with colleagues who may be providing subsequent care of an infected patient to optimize the use of isolation precautions and limit the spread of contagions. (10/17)

http://pediatrics.aappublications.org/content/140/5/e20172857

INFECTIOUS COMPLICATIONS WITH THE USE OF BIOLOGIC RESPONSE MODIFIERS IN INFANTS AND CHILDREN (CLINICAL REPORT)

H. Dele Davies, MD, FAAP, and Committee on Infectious Diseases

ABSTRACT. Biologic response modifiers (BRMs) are substances that interact with and modify the host immune system. BRMs that dampen the immune system are used to treat conditions such as juvenile idiopathic arthritis, psoriatic arthritis, or inflammatory bowel disease and often in combination with other immunosuppressive agents, such as methotrexate and corticosteroids. Cytokines that are targeted include tumor necrosis factor α; interleukins (ILs) 6, 12, and 23; and the receptors for IL-1α (IL-1A) and IL-1β (IL-1B) as well as other molecules. Although the risk varies with the class of BRM, patients receiving immune-dampening BRMs generally are at increased risk of infection or reactivation with mycobacterial infections (*Mycobacterium tuberculosis* and nontuberculous mycobacteria), some viral (herpes simplex virus, varicella-zoster virus, Epstein-Barr virus, hepatitis B) and fungal (histoplasmosis, coccidioidomycosis) infections, as well as other opportunistic infections. The use of BRMs warrants careful determination of infectious risk on the basis of history (including exposure, residence, and travel and immunization history) and selected baseline screening test results. Routine immunizations should be given at least 2 weeks (inactivated or subunit vaccines) or 4 weeks (live vaccines) before initiation of BRMs whenever feasible, and inactivated influenza vaccine should be given annually. Inactivated and subunit vaccines should be given when needed while taking BRMs, but live vaccines should be avoided unless under special circumstances in consultation with an infectious diseases specialist. If the patient develops a febrile or serious respiratory illness during BRM therapy, consideration should be given to stopping the BRM while actively searching for and treating possible infectious causes. (7/16)

http://pediatrics.aappublications.org/content/138/2/e20161209

INFECTIOUS DISEASES ASSOCIATED WITH ORGANIZED SPORTS AND OUTBREAK CONTROL (CLINICAL REPORT)

H. Dele Davies, MD, MS, MHCM, FAAP; Mary Anne Jackson, MD, FAAP; Stephen G. Rice, MD, PhD, MPH, FAAP; Committee on Infectious Diseases; and Council on Sports Medicine and Fitness

ABSTRACT. Participation in organized sports has a variety of health benefits but also has the potential to expose the athlete to a variety of infectious diseases, some of which may produce outbreaks. Major risk factors for infection include skin-to-skin contact with athletes who have active skin infections, environmental exposures and physical trauma, and sharing of equipment and contact with contaminated fomites. Close contact that is intrinsic to team sports and psychosocial factors associated with adolescence are additional risks. Minimizing risk requires leadership by the organized sports community (including the athlete's primary care provider) and depends on outlining key hygiene behaviors, recognition, diagnosis, and treatment of common sports-related infections, and the implementation of preventive interventions. (9/17)

http://pediatrics.aappublications.org/content/140/4/e20172477

INFLUENZA IMMUNIZATION FOR ALL HEALTH CARE PERSONNEL: KEEP IT MANDATORY

Committee on Infectious Diseases

ABSTRACT. The purpose of this statement is to reaffirm the American Academy of Pediatrics' support for a mandatory influenza immunization policy for all health care personnel. With an increasing number of organizations requiring influenza vaccination, coverage among health care personnel has risen to 75% in the 2013 to 2014 influenza season but still remains below the Healthy People 2020 objective of 90%. Mandatory influenza immunization for all health care personnel is ethical, just, and necessary to improve patient safety. It is a crucial step in efforts to reduce health care–associated influenza infections. (9/15)

http://pediatrics.aappublications.org/content/136/4/809

INFORMED CONSENT IN DECISION-MAKING IN PEDIATRIC PRACTICE

Committee on Bioethics

ABSTRACT. Informed consent should be seen as an essential part of health care practice; parental permission and childhood assent is an active process that engages patients, both adults and children, in health care. Pediatric practice is unique in that developmental maturation allows, over time, for increasing inclusion of the child's and adolescent's opinion in medical decision-making in clinical practice and research. (7/16)

http://pediatrics.aappublications.org/content/138/2/e20161484

INFORMED CONSENT IN DECISION-MAKING IN PEDIATRIC PRACTICE (TECHNICAL REPORT)

Aviva L. Katz, MD, FAAP; Sally A. Webb, MD, FAAP; and Committee on Bioethics

ABSTRACT. Informed consent should be seen as an essential part of health care practice; parental permission and childhood assent is an active process that engages patients, both adults and children, in their health care. Pediatric practice is unique in that developmental maturation allows, over time, for increasing inclusion of the child's and adolescent's opinion in medical decision-making in clinical practice and research. This technical report, which accompanies the policy statement "Informed Consent in Decision-Making in Pediatric Practice," was written to provide a broader background on the nature of informed

consent, surrogate decision-making in pediatric practice, information on child and adolescent decision-making, and special issues in adolescent informed consent, assent, and refusal. It is anticipated that this information will help provide support for the recommendations included in the policy statement. (7/16)
http://pediatrics.aappublications.org/content/138/2/e20161485

INJURIES ASSOCIATED WITH INFANT WALKERS

Committee on Injury and Poison Prevention
ABSTRACT. In 1999, an estimated 8800 children younger than 15 months were treated in hospital emergency departments in the United States for injuries associated with infant walkers. Thirty-four infant walker-related deaths were reported from 1973 through 1998. The vast majority of injuries occur from falls down stairs, and head injuries are common. Walkers do not help a child learn to walk; indeed, they can delay normal motor and mental development. The use of warning labels, public education, adult supervision during walker use, and stair gates have all been demonstrated to be insufficient strategies to prevent injuries associated with infant walkers. To comply with the revised voluntary standard (ASTM F977-96), walkers manufactured after June 30, 1997, must be wider than a 36-in doorway or must have a braking mechanism designed to stop the walker if 1 or more wheels drop off the riding surface, such as at the top of a stairway. Because data indicate a considerable risk of major and minor injury and even death from the use of infant walkers, and because there is no clear benefit from their use, the American Academy of Pediatrics recommends a ban on the manufacture and sale of mobile infant walkers. If a parent insists on using a mobile infant walker, it is vital that they choose a walker that meets the performance standards of ASTM F977-96 to prevent falls down stairs. Stationary activity centers should be promoted as a safer alternative to mobile infant walkers. (9/01, reaffirmed 1/05, 2/08, 10/11, 11/14)
http://pediatrics.aappublications.org/content/108/3/790

INJURY RISK OF NONPOWDER GUNS (TECHNICAL REPORT)

Committee on Injury, Violence, and Poison Prevention
ABSTRACT. Nonpowder guns (ball-bearing [BB] guns, pellet guns, air rifles, paintball guns) continue to cause serious injuries to children and adolescents. The muzzle velocity of these guns can range from approximately 150 ft/second to 1200 ft/second (the muzzle velocities of traditional firearm pistols are 750 ft/second to 1450 ft/second). Both low- and high-velocity nonpowder guns are associated with serious injuries, and fatalities can result from high-velocity guns. A persisting problem is the lack of medical recognition of the severity of injuries that can result from these guns, including penetration of the eye, skin, internal organs, and bone. Nationally, in 2000, there were an estimated 21840 (coefficient of variation: 0.0821) injuries related to nonpowder guns, with approximately 4% resulting in hospitalization. Between 1990 and 2000, the US Consumer Product Safety Commission reported 39 nonpowder gun–related deaths, of which 32 were children younger than 15 years. The introduction of high-powered air rifles in the 1970s has been associated with approximately 4 deaths per year. The advent of war games and the use of paintball guns have resulted in a number of reports of injuries, especially to the eye. Injuries associated with nonpowder guns should receive prompt medical management similar to the management of firearm-related injuries, and nonpowder guns should never be characterized as toys. (11/04, reaffirmed 2/08, 10/11)
http://pediatrics.aappublications.org/content/114/5/1357

IN-LINE SKATING INJURIES IN CHILDREN AND ADOLESCENTS

Committee on Injury and Poison Prevention and Committee on Sports Medicine and Fitness
ABSTRACT. In-line skating has become one of the fastest-growing recreational sports in the United States. Recent studies emphasize the value of protective gear in reducing the incidence of injuries. Recommendations are provided for parents and pediatricians, with special emphasis on the novice or inexperienced skater. (4/98, reaffirmed 1/02, 1/06, 1/09, 11/11)
http://pediatrics.aappublications.org/content/101/4/720

INSTITUTIONAL ETHICS COMMITTEES

Margaret Moon, MD, MPH, FAAP, and Committee on Bioethics
ABSTRACT. In hospitals throughout the United States, institutional ethics committees (IECs) have become a standard vehicle for the education of health professionals about biomedical ethics, for the drafting and review of hospital policy, and for clinical ethics case consultation. In addition, there is increasing interest in a role for the IEC in organizational ethics. Recommendations are made about the membership and structure of an IEC, and guidance is provided for those serving on an IEC. (4/19)
https://pediatrics.aappublications.org/content/143/5/e20190659

INSUFFICIENT SLEEP IN ADOLESCENTS AND YOUNG ADULTS: AN UPDATE ON CAUSES AND CONSEQUENCES (TECHNICAL REPORT)

Judith Owens, MD, MPH, FAAP; Adolescent Sleep Working Group; and Committee on Adolescence
ABSTRACT. Chronic sleep loss and associated sleepiness and daytime impairments in adolescence are a serious threat to the academic success, health, and safety of our nation's youth and an important public health issue. Understanding the extent and potential short- and long-term repercussions of sleep restriction, as well as the unhealthy sleep practices and environmental factors that contribute to sleep loss in adolescents, is key in setting public policies to mitigate these effects and in counseling patients and families in the clinical setting. This report reviews the current literature on sleep patterns in adolescents, factors contributing to chronic sleep loss (ie, electronic media use, caffeine consumption), and health-related consequences, such as depression, increased obesity risk, and higher rates of drowsy driving accidents. The report also discusses the potential role of later school start times as a means of reducing adolescent sleepiness. (8/14)
http://pediatrics.aappublications.org/content/134/3/e921

INTENSIVE TRAINING AND SPORTS SPECIALIZATION IN YOUNG ATHLETES

Committee on Sports Medicine and Fitness
ABSTRACT. Children involved in sports should be encouraged to participate in a variety of different activities and develop a wide range of skills. Young athletes who specialize in just one sport may be denied the benefits of varied activity while facing additional physical, physiologic, and psychologic demands from intense training and competition.

This statement reviews the potential risks of high-intensity training and sports specialization in young athletes. Pediatricians who recognize these risks can have a key role in monitoring the health of these young athletes and helping reduce risks associated with high-level sports participation. (7/00, reaffirmed 11/04, 1/06, 5/09, 10/14)
http://pediatrics.aappublications.org/content/106/1/154

INTERFERON-γ RELEASE ASSAYS FOR DIAGNOSIS OF TUBERCULOSIS INFECTION AND DISEASE IN CHILDREN (TECHNICAL REPORT)

Jeffrey R. Starke, MD, FAAP, and Committee on Infectious Diseases

ABSTRACT. Tuberculosis (TB) remains an important problem among children in the United States and throughout the world. Although diagnosis and treatment of infection with *Mycobacterium tuberculosis* (also referred to as latent tuberculosis infection [LTBI] or TB infection) remain the lynchpins of TB prevention, there is no diagnostic reference standard for LTBI. The tuberculin skin test (TST) has many limitations, including difficulty in administration and interpretation, the need for a return visit by the patient, and false-positive results caused by significant cross-reaction with *Mycobacterium bovis*–bacille Calmette-Guérin (BCG) vaccines and many nontuberculous mycobacteria. Interferon-γ release assays (IGRAs) are blood tests that measure ex vivo T-lymphocyte release of interferon-γ after stimulation by antigens specific for *M tuberculosis.* Because these antigens are not found on *M bovis*–BCG or most nontuberculous mycobacteria, IGRAs are more specific tests than the TST, yielding fewer false-positive results. However, IGRAs have little advantage over the TST in sensitivity, and both methods have reduced sensitivity in immunocompromised children, including children with severe TB disease. Both methods have a higher positive predictive value when applied to children with risk factors for LTBI. Unfortunately, neither method distinguishes between TB infection and TB disease. The objective of this technical report is to review what IGRAs are most useful for: (1) increasing test specificity in children who have received a BCG vaccine and may have a false-positive TST result; (2) using with the TST to increase sensitivity for finding LTBI in patients at high risk of developing progression from LTBI to disease; and (3) helping to diagnose TB disease. (11/14, reaffirmed 7/18)

http://pediatrics.aappublications.org/content/134/6/e1763

INTERPRETATION OF DO NOT ATTEMPT RESUSCITATION ORDERS FOR CHILDREN REQUIRING ANESTHESIA AND SURGERY (CLINICAL REPORT)

Mary E. Fallat, MD, FAAP; Courtney Hardy, MD, MBA, FAAP; Section on Surgery; Section on Anesthesiology and Pain Medicine; and Committee on Bioethics

ABSTRACT. This clinical report addresses the topic of preexisting do not attempt resuscitation or limited resuscitation orders for children and adolescents undergoing anesthesia and surgery. Pertinent considerations for the clinician include the rights of children, decision-making by parents or legally approved representatives, the process of informed consent, and the roles of surgeon and anesthesiologist. A process of re-evaluation of the do not attempt resuscitation orders, called "required reconsideration," should be incorporated into the process of informed consent for surgery and anesthesia, distinguishing between goal-directed and procedure-directed approaches. The child's individual needs are best served by allowing the parent or legally approved representative and involved clinicians to consider whether full resuscitation, limitations based on procedures, or limitations based on goals is most appropriate. (4/18)

http://pediatrics.aappublications.org/content/141/5/e20180598

INTIMATE PARTNER VIOLENCE: THE ROLE OF THE PEDIATRICIAN (CLINICAL REPORT)

Jonathan D. Thackeray, MD; Roberta Hibbard, MD; M. Denise Dowd, MD, MPH; Committee on Child Abuse and Neglect; and Committee on Injury, Violence, and Poison Prevention

ABSTRACT. The American Academy of Pediatrics and its members recognize the importance of improving the physician's ability to recognize intimate partner violence (IPV) and understand its effects on child health and development and its role in the continuum of family violence. Pediatricians are in a unique position to identify abused caregivers in pediatric settings and to evaluate and treat children raised in homes in which IPV may occur. Children exposed to IPV are at increased risk of being abused and neglected and are more likely to develop adverse health, behavioral, psychological, and social disorders later in life. Identifying IPV, therefore, may be one of the most effective means of preventing child abuse and identifying caregivers and children who may be in need of treatment and/or therapy. Pediatricians should be aware of the profound effects of exposure to IPV on children. (4/10, reaffirmed 1/14, 3/19)

http://pediatrics.aappublications.org/content/125/5/1094

IODINE DEFICIENCY, POLLUTANT CHEMICALS, AND THE THYROID: NEW INFORMATION ON AN OLD PROBLEM

Council on Environmental Health

ABSTRACT. Many women of reproductive age in the United States are marginally iodine deficient, perhaps because the salt in processed foods is not iodized. Iodine deficiency, per se, can interfere with normal brain development in their offspring; in addition, it increases vulnerability to the effects of certain environmental pollutants, such as nitrate, thiocyanate, and perchlorate. Although pregnant and lactating women should take a supplement containing adequate iodide, only about 15% do so. Such supplements, however, may not contain enough iodide and may not be labeled accurately. The American Thyroid Association recommends that pregnant and lactating women take a supplement with adequate iodide. The American Academy of Pediatrics recommends that pregnant and lactating women also avoid exposure to excess nitrate, which would usually occur from contaminated well water, and thiocyanate, which is in cigarette smoke. Perchlorate is currently a candidate for regulation as a water pollutant. The Environmental Protection Agency should proceed with appropriate regulation, and the Food and Drug Administration should address the mislabeling of the iodine content of prenatal/lactation supplements. (5/14)

http://pediatrics.aappublications.org/content/133/6/1163

LACTOSE INTOLERANCE IN INFANTS, CHILDREN, AND ADOLESCENTS (CLINICAL REPORT)

Melvin B. Heyman, MD, MPH, and Committee on Nutrition

ABSTRACT. The American Academy of Pediatrics Committee on Nutrition presents an updated review of lactose intolerance in infants, children, and adolescents. Differences between primary, secondary, congenital, and developmental lactase deficiency that may result in lactose intolerance are discussed. Children with suspected lactose intolerance can be assessed clinically by dietary lactose elimination or by tests including noninvasive hydrogen breath testing or invasive intestinal biopsy determination of lactase (and other disaccharidase) concentrations. Treatment consists of use of lactase-treated dairy products or oral lactase supplementation, limitation of lactose-containing foods, or dairy elimination. The American Academy of Pediatrics supports use of dairy foods as an important source of calcium for bone mineral health and of other nutrients that facilitate growth in children and adolescents. If dairy products are eliminated, other dietary sources of calcium or calcium supplements need to be provided. (9/06, reaffirmed 8/12)

http://pediatrics.aappublications.org/content/118/3/1279

"LATE-PRETERM" INFANTS: A POPULATION AT RISK (CLINICAL REPORT)

William A. Engle, MD; Kay M. Tomashek, MD; Carol Wallman, MSN; and Committee on Fetus and Newborn

ABSTRACT. Late-preterm infants, defined by birth at 34⁰⁄₇ through 36⁶⁄₇ weeks' gestation, are less physiologically and metabolically mature than term infants. Thus, they are at higher risk of morbidity and mortality than term infants. The purpose of this report is to define "late preterm," recommend a change

in terminology from "near term" to "late preterm," present the characteristics of late-preterm infants that predispose them to a higher risk of morbidity and mortality than term infants, and propose guidelines for the evaluation and management of these infants after birth. (12/07, reaffirmed 5/10, 6/18)
http://pediatrics.aappublications.org/content/120/6/1390

LAWN MOWER-RELATED INJURIES TO CHILDREN

Committee on Injury and Poison Prevention

ABSTRACT. Lawn mower-related injuries to children are relatively common and can result in severe injury or death. Many amputations during childhood are caused by power mowers. Pediatricians have an important role as advocates and educators to promote the prevention of these injuries. (6/01, reaffirmed 10/04, 5/07, 6/10)
http://pediatrics.aappublications.org/content/107/6/1480

LAWN MOWER-RELATED INJURIES TO CHILDREN (TECHNICAL REPORT)

Committee on Injury and Poison Prevention

ABSTRACT. In the United States, approximately 9400 children younger than 18 years receive emergency treatment annually for lawn mower-related injuries. More than 7% of these children require hospitalization, and power mowers cause a large proportion of the amputations during childhood. Prevention of lawn mower-related injuries can be achieved by design changes of lawn mowers, guidelines for mower operation, and education of parents, child caregivers, and children. Pediatricians have an important role as advocates and educators to promote the prevention of these injuries. (6/01, reaffirmed 10/04, 5/07, 6/10)
http://pediatrics.aappublications.org/content/107/6/e106

LEARNING DISABILITIES, DYSLEXIA, AND VISION

Section on Ophthalmology and Council on Children With Disabilities (joint with American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists)

ABSTRACT. Learning disabilities, including reading disabilities, are commonly diagnosed in children. Their etiologies are multifactorial, reflecting genetic influences and dysfunction of brain systems. Learning disabilities are complex problems that require complex solutions. Early recognition and referral to qualified educational professionals for evidence-based evaluations and treatments seem necessary to achieve the best possible outcome. Most experts believe that dyslexia is a language-based disorder. Vision problems can interfere with the process of learning; however, vision problems are not the cause of primary dyslexia or learning disabilities. Scientific evidence does not support the efficacy of eye exercises, behavioral vision therapy, or special tinted filters or lenses for improving the long-term educational performance in these complex pediatric neurocognitive conditions. Diagnostic and treatment approaches that lack scientific evidence of efficacy, including eye exercises, behavioral vision therapy, or special tinted filters or lenses, are not endorsed and should not be recommended. (7/09, reaffirmed 7/14)
http://pediatrics.aappublications.org/content/124/2/837

LEARNING DISABILITIES, DYSLEXIA, AND VISION (TECHNICAL REPORT)

Sheryl M. Handler, MD; Walter M. Fierson, MD; Section on Ophthalmology; and Council on Children With Disabilities (joint with American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists)

ABSTRACT. Learning disabilities constitute a diverse group of disorders in which children who generally possess at least average intelligence have problems processing information or generating output. Their etiologies are multifactorial and reflect genetic influences and dysfunction of brain systems. Reading disability, or dyslexia, is the most common learning disability. It is a receptive language-based learning disability that is characterized by difficulties with decoding, fluent word recognition, rapid automatic naming, and/or reading-comprehension skills. These difficulties typically result from a deficit in the phonologic component of language that makes it difficult to use the alphabetic code to decode the written word. Early recognition and referral to qualified professionals for evidence-based evaluations and treatments are necessary to achieve the best possible outcome. Because dyslexia is a language-based disorder, treatment should be directed at this etiology. Remedial programs should include specific instruction in decoding, fluency training, vocabulary, and comprehension. Most programs include daily intensive individualized instruction that explicitly teaches phonemic awareness and the application of phonics. Vision problems can interfere with the process of reading, but children with dyslexia or related learning disabilities have the same visual function and ocular health as children without such conditions. Currently, there is inadequate scientific evidence to support the view that subtle eye or visual problems cause or increase the severity of learning disabilities. Because they are difficult for the public to understand and for educators to treat, learning disabilities have spawned a wide variety of scientifically unsupported vision-based diagnostic and treatment procedures. Scientific evidence does not support the claims that visual training, muscle exercises, ocular pursuit-and-tracking exercises, behavioral/perceptual vision therapy, "training" glasses, prisms, and colored lenses and filters are effective direct or indirect treatments for learning disabilities. There is no valid evidence that children who participate in vision therapy are more responsive to educational instruction than children who do not participate. (3/11)
http://pediatrics.aappublications.org/content/127/3/e818

LEVELS OF NEONATAL CARE

Committee on Fetus and Newborn

ABSTRACT. Provision of risk-appropriate care for newborn infants and mothers was first proposed in 1976. This updated policy statement provides a review of data supporting evidence for a tiered provision of care and reaffirms the need for uniform, nationally applicable definitions and consistent standards of service for public health to improve neonatal outcomes. Facilities that provide hospital care for newborn infants should be classified on the basis of functional capabilities, and these facilities should be organized within a regionalized system of perinatal care. (8/12, reaffirmed 9/15)
http://pediatrics.aappublications.org/content/130/3/587

THE LIFELONG EFFECTS OF EARLY CHILDHOOD ADVERSITY AND TOXIC STRESS (TECHNICAL REPORT)

Jack P. Shonkoff, MD; Andrew S. Garner, MD, PhD; Committee on Psychosocial Aspects of Child and Family Health; Committee on Early Childhood, Adoption, and Dependent Care; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. Advances in fields of inquiry as diverse as neuroscience, molecular biology, genomics, developmental psychology, epidemiology, sociology, and economics are catalyzing an important paradigm shift in our understanding of health and disease across the lifespan. This converging, multidisciplinary science of human development has profound implications for our ability to enhance the life prospects of children and to strengthen the social and economic fabric of society. Drawing on these multiple streams of investigation, this report presents an ecobiodevelopmental framework that illustrates how early experiences and environmental influences can leave a lasting signature on the genetic predispositions that affect emerging brain architecture and long-term health. The report also examines extensive evidence of the disruptive impacts of toxic stress, offering intriguing

insights into causal mechanisms that link early adversity to later impairments in learning, behavior, and both physical and mental well-being. The implications of this framework for the practice of medicine, in general, and pediatrics, specifically, are potentially transformational. They suggest that many adult diseases should be viewed as developmental disorders that begin early in life and that persistent health disparities associated with poverty, discrimination, or maltreatment could be reduced by the alleviation of toxic stress in childhood. An ecobiodevelopmental framework also underscores the need for new thinking about the focus and boundaries of pediatric practice. It calls for pediatricians to serve as both front-line guardians of healthy child development and strategically positioned, community leaders to inform new science-based strategies that build strong foundations for educational achievement, economic productivity, responsible citizenship, and lifelong health. (12/11, reaffirmed 7/16)
http://pediatrics.aappublications.org/content/129/1/e232

THE LINK BETWEEN SCHOOL ATTENDANCE AND GOOD HEALTH

Mandy A. Allison, MD, MSPH, FAAP; Elliott Attisha, DO, FAAP; and Council on School Health

ABSTRACT. More than 6.5 million children in the United States, approximately 13% of all students, miss 15 or more days of school each year. The rates of chronic absenteeism vary between states, communities, and schools, with significant disparities based on income, race, and ethnicity. Chronic school absenteeism, starting as early as preschool and kindergarten, puts students at risk for poor school performance and school dropout, which in turn, put them at risk for unhealthy behaviors as adolescents and young adults as well as poor long-term health outcomes. Pediatricians and their colleagues caring for children in the medical setting have opportunities at the individual patient and/or family, practice, and population levels to promote school attendance and reduce chronic absenteeism and resulting health disparities. Although this policy statement is primarily focused on absenteeism related to students' physical and mental health, pediatricians may play a role in addressing absenteeism attributable to a wide range of factors through individual interactions with patients and their parents and through community-, state-, and federal-level advocacy. (1/19)
https://pediatrics.aappublications.org/content/143/2/e20183648

LITERACY PROMOTION: AN ESSENTIAL COMPONENT OF PRIMARY CARE PEDIATRIC PRACTICE

Council on Early Childhood

ABSTRACT. Reading regularly with young children stimulates optimal patterns of brain development and strengthens parent-child relationships at a critical time in child development, which, in turn, builds language, literacy, and social-emotional skills that last a lifetime. Pediatric providers have a unique opportunity to encourage parents to engage in this important and enjoyable activity with their children beginning in infancy. Research has revealed that parents listen and children learn as a result of literacy promotion by pediatricians, which provides a practical and evidence-based opportunity to support early brain development in primary care practice. The American Academy of Pediatrics (AAP) recommends that pediatric providers promote early literacy development for children beginning in infancy and continuing at least until the age of kindergarten entry by (1) advising all parents that reading aloud with young children can enhance parent-child relationships and prepare young minds to learn language and early literacy skills; (2) counseling all parents about developmentally appropriate shared-reading activities that are enjoyable for children and their parents and offer language-rich exposure to books, pictures, and the written word; (3) providing developmentally appropriate books given at health supervision visits for all high-risk, low-income young children; (4) using a robust spectrum of options to support and promote these efforts; and (5) partnering with other child advocates to influence national messaging and policies that support and promote these key early shared-reading experiences. The AAP supports federal and state funding for children's books to be provided at pediatric health supervision visits to children at high risk living at or near the poverty threshold and the integration of literacy promotion, an essential component of pediatric primary care, into pediatric resident education. This policy statement is supported by the AAP technical report "School Readiness" and supports the AAP policy statement "Early Childhood Adversity, Toxic Stress, and the Role of the Pediatrician: Translating Developmental Science Into Lifelong Health." (7/14)
http://pediatrics.aappublications.org/content/134/2/404

LONG-ACTING REVERSIBLE CONTRACEPTION: SPECIFIC ISSUES FOR ADOLESCENTS (CLINICAL REPORT)

Seema Menon, MD, and Committee on Adolescence

ABSTRACT. Long-acting reversible contraceptives are the most effective methods to prevent pregnancy and also offer noncontraceptive benefits such as reducing menstrual blood flow and dysmenorrhea. The safety and efficacy of long-acting reversible contraception are well established for adolescents, but the rate of use remains low for this population. The pediatrician can play a key role in increasing access to long-acting reversible contraception for adolescents by providing accurate patient-centered contraception counseling and by understanding and addressing the barriers to use. (7/20)
See full text on page 949.
https://pediatrics.aappublications.org/content/146/2/e2020007252

LONG-TERM FOLLOW-UP CARE FOR PEDIATRIC CANCER SURVIVORS (CLINICAL REPORT)

Section on Hematology/Oncology (joint with Children's Oncology Group)

ABSTRACT. Progress in therapy has made survival into adulthood a reality for most children, adolescents, and young adults diagnosed with cancer today. Notably, this growing population remains vulnerable to a variety of long-term therapy-related sequelae. Systematic ongoing follow-up of these patients, therefore, is important for providing for early detection of and intervention for potentially serious late-onset complications. In addition, health counseling and promotion of healthy lifestyles are important aspects of long-term follow-up care to promote risk reduction for health problems that commonly present during adulthood. Both general and subspecialty pediatric health care providers are playing an increasingly important role in the ongoing care of childhood cancer survivors, beyond the routine preventive care, health supervision, and anticipatory guidance provided to all patients. This report is based on the guidelines that have been developed by the Children's Oncology Group to facilitate comprehensive long-term follow-up of childhood cancer survivors (www.survivorshipguidelines.org). (3/09, reaffirmed 4/13, 8/17)
http://pediatrics.aappublications.org/content/123/3/906

MAINTAINING AND IMPROVING THE ORAL HEALTH OF YOUNG CHILDREN

Section on Oral Health

ABSTRACT. Oral health is an integral part of the overall health of children. Dental caries is a common and chronic disease process with significant short- and long-term consequences. The prevalence of dental caries for the youngest of children has not decreased over the past decade, despite improvements for older children. As health care professionals responsible for the overall health of children, pediatricians frequently confront morbidity associated with dental caries. Because the youngest children visit the pediatrician more often than they visit the dentist, it is

important that pediatricians be knowledgeable about the disease process of dental caries, prevention of the disease, and interventions available to the pediatrician and the family to maintain and restore health. (11/14, reaffirmed 1/19)
http://pediatrics.aappublications.org/content/134/6/1224

MALE ADOLESCENT SEXUAL AND REPRODUCTIVE HEALTH CARE (CLINICAL REPORT)

Arik V. Marcell, MD, MPH; Charles Wibbelsman, MD; Warren M. Seigel, MD; and Committee on Adolescence

ABSTRACT. Male adolescents' sexual and reproductive health needs often go unmet in the primary care setting. This report discusses specific issues related to male adolescents' sexual and reproductive health care in the context of primary care, including pubertal and sexual development, sexual behavior, consequences of sexual behavior, and methods of preventing sexually transmitted infections (including HIV) and pregnancy. Pediatricians are encouraged to address male adolescent sexual and reproductive health on a regular basis, including taking a sexual history, performing an appropriate examination, providing patient-centered and age-appropriate anticipatory guidance, and delivering appropriate vaccinations. Pediatricians should provide these services to male adolescent patients in a confidential and culturally appropriate manner, promote healthy sexual relationships and responsibility, and involve parents in age-appropriate discussions about sexual health with their sons. (11/11, reaffirmed 5/15)
http://pediatrics.aappublications.org/content/128/6/e1658

MALE CIRCUMCISION (TECHNICAL REPORT)

Task Force on Circumcision

ABSTRACT. Male circumcision consists of the surgical removal of some, or all, of the foreskin (or prepuce) from the penis. It is one of the most common procedures in the world. In the United States, the procedure is commonly performed during the newborn period. In 2007, the American Academy of Pediatrics (AAP) convened a multidisciplinary workgroup of AAP members and other stakeholders to evaluate the evidence regarding male circumcision and update the AAP's 1999 recommendations in this area. The Task Force included AAP representatives from specialty areas as well as members of the AAP Board of Directors and liaisons representing the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the Centers for Disease Control and Prevention. The Task Force members identified selected topics relevant to male circumcision and conducted a critical review of peer-reviewed literature by using the American Heart Association's template for evidence evaluation.

Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks; furthermore, the benefits of newborn male circumcision justify access to this procedure for families who choose it. Specific benefits from male circumcision were identified for the prevention of urinary tract infections, acquisition of HIV, transmission of some sexually transmitted infections, and penile cancer. Male circumcision does not appear to adversely affect penile sexual function/sensitivity or sexual satisfaction. It is imperative that those providing circumcision are adequately trained and that both sterile techniques and effective pain management are used. Significant acute complications are rare. In general, untrained providers who perform circumcisions have more complications than well-trained providers who perform the procedure, regardless of whether the former are physicians, nurses, or traditional religious providers.

Parents are entitled to factually correct, nonbiased information about circumcision and should receive this information from clinicians before conception or early in pregnancy, which is when parents typically make circumcision decisions. Parents should determine what is in the best interest of their child. Physicians who counsel families about this decision should provide assistance by explaining the potential benefits and risks and ensuring that parents understand that circumcision is an elective procedure. The Task Force strongly recommends the creation, revision, and enhancement of educational materials to assist parents of male infants with the care of circumcised and uncircumcised penises. The Task Force also strongly recommends the development of educational materials for providers to enhance practitioners' competency in discussing circumcision's benefits and risks with parents.

The Task Force made the following recommendations:

- Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks, and the benefits of newborn male circumcision justify access to this procedure for those families who choose it.
- Parents are entitled to factually correct, nonbiased information about circumcision that should be provided before conception and early in pregnancy, when parents are most likely to be weighing the option of circumcision of a male child.
- Physicians counseling families about elective male circumcision should assist parents by explaining, in a nonbiased manner, the potential benefits and risks and by ensuring that they understand the elective nature of the procedure.
- Parents should weigh the health benefits and risks in light of their own religious, cultural, and personal preferences, as the medical benefits alone may not outweigh these other considerations for individual families.
- Parents of newborn boys should be instructed in the care of the penis, regardless of whether the newborn has been circumcised or not.
- Elective circumcision should be performed only if the infant's condition is stable and healthy.
- Male circumcision should be performed by trained and competent practitioners, by using sterile techniques and effective pain management.
- Analgesia is safe and effective in reducing the procedural pain associated with newborn circumcision; thus, adequate analgesia should be provided whenever newborn circumcision is performed.
  - — Nonpharmacologic techniques (eg, positioning, sucrose pacifiers) alone are insufficient to prevent procedural and postprocedural pain and are not recommended as the sole method of analgesia. They should be used only as analgesic adjuncts to improve infant comfort during circumcision.
  - — If used, topical creams may cause a higher incidence of skin irritation in low birth weight infants, compared with infants of normal weight; penile nerve block techniques should therefore be chosen for this group of newborns.
- Key professional organizations (AAP, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Society of Anesthesiologists, the American College of Nurse Midwives, and other midlevel clinicians such as nurse practitioners) should work collaboratively to:
  - — Develop standards of trainee proficiency in the performance of anesthetic and procedure techniques, including suturing;
  - — Teach the procedure and analgesic techniques during postgraduate training programs;

— Develop educational materials for clinicians to enhance their own competency in discussing the benefits and risks of circumcision with parents;

— Offer educational materials to assist parents of male infants with the care of both circumcised and uncircumcised penises.

- The preventive and public health benefits associated with newborn male circumcision warrant third-party reimbursement of the procedure.

The American College of Obstetricians and Gynecologists has endorsed this technical report. (8/12)

http://pediatrics.aappublications.org/content/130/3/e756

MALTREATMENT OF CHILDREN WITH DISABILITIES (CLINICAL REPORT)

Roberta A. Hibbard, MD; Larry W. Desch, MD; Committee on Child Abuse and Neglect; and Council on Children With Disabilities

ABSTRACT. Widespread efforts are being made to increase awareness and provide education to pediatricians regarding risk factors of child abuse and neglect. The purpose of this clinical report is to ensure that children with disabilities are recognized as a population that is also at risk of maltreatment. Some conditions related to a disability can be confused with maltreatment. The need for early recognition and intervention of child abuse and neglect in this population, as well as the ways that a medical home can facilitate the prevention and early detection of child maltreatment, are the subject of this report. (5/07, reaffirmed 1/11, 4/16)

http://pediatrics.aappublications.org/content/119/5/1018

MANAGEMENT OF DENTAL TRAUMA IN A PRIMARY CARE SETTING (CLINICAL REPORT)

Martha Ann Keels, DDS, PhD, and Section on Oral Health

ABSTRACT. The American Academy of Pediatrics and its Section on Oral Health have developed this clinical report for pediatricians and primary care physicians regarding the diagnosis, evaluation, and management of dental trauma in children aged 1 to 21 years. This report was developed through a comprehensive search and analysis of the medical and dental literature and expert consensus. Guidelines published and updated by the International Association of Dental Traumatology (www.dentaltraumaguide.com) are an excellent resource for both dental and nondental health care providers. (1/14)

http://pediatrics.aappublications.org/content/133/2/e466

MANAGEMENT OF FOOD ALLERGY IN THE SCHOOL SETTING (CLINICAL REPORT)

Scott H. Sicherer, MD; Todd Mahr, MD; and Section on Allergy and Immunology

ABSTRACT. Food allergy is estimated to affect approximately 1 in 25 school-aged children and is the most common trigger of anaphylaxis in this age group. School food-allergy management requires strategies to reduce the risk of ingestion of the allergen as well as procedures to recognize and treat allergic reactions and anaphylaxis. The role of the pediatrician or pediatric health care provider may include diagnosing and documenting a potentially life-threatening food allergy, prescribing selfinjectable epinephrine, helping the child learn how to store and use the medication in a responsible manner, educating the parents of their responsibility to implement prevention strategies within and outside the home environment, and working with families, schools, and students in developing written plans to reduce the risk of anaphylaxis and to implement emergency treatment in the event of a reaction. This clinical report highlights the role of the pediatrician and pediatric health care provider in managing students with food allergies. (11/10, reaffirmed 10/20)

http://pediatrics.aappublications.org/content/126/6/1232

MANAGEMENT OF INFANTS AT RISK FOR GROUP B STREPTOCOCCAL DISEASE (CLINICAL REPORT)

Karen M. Puopolo, MD, PhD, FAAP; Ruth Lynfield, MD, FAAP; James J. Cummings, MD, MS, FAAP; Committee on Fetus and Newborn; and Committee on Infectious Diseases

ABSTRACT. Group B streptococcal (GBS) infection remains the most common cause of neonatal early-onset sepsis and a significant cause of late-onset sepsis among young infants. Administration of intrapartum antibiotic prophylaxis is the only currently available effective strategy for the prevention of perinatal GBS early-onset disease, and there is no effective approach for the prevention of late-onset disease. The American Academy of Pediatrics joins with the American College of Obstetricians and Gynecologists to reaffirm the use of universal antenatal microbiologic-based testing for the detection of maternal GBS colonization to facilitate appropriate administration of intrapartum antibiotic prophylaxis. The purpose of this clinical report is to provide neonatal clinicians with updated information regarding the epidemiology of GBS disease as well current recommendations for the evaluation of newborn infants at risk for GBS disease and for treatment of those with confirmed GBS infection. This clinical report is endorsed by the American College of Obstetricians and Gynecologists (ACOG), July 2019, and should be construed as ACOG clinical guidance. (7/19)

https://pediatrics.aappublications.org/content/144/2/e20191881

MANAGEMENT OF NEONATES BORN AT ≥35 0/7 WEEKS' GESTATION WITH SUSPECTED OR PROVEN EARLY-ONSET BACTERIAL SEPSIS (CLINICAL REPORT)

Karen M. Puopolo, MD, PhD, FAAP; William E. Benitz, MD, FAAP; Theoklis E. Zaoutis, MD, MSCE, FAAP; Committee on Fetus and Newborn; and Committee on Infectious Diseases

ABSTRACT. The incidence of neonatal early-onset sepsis (EOS) has declined substantially over the last 2 decades, primarily because of the implementation of evidence-based intrapartum antimicrobial therapy. However, EOS remains a serious and potentially fatal illness. Laboratory tests alone are neither sensitive nor specific enough to guide EOS management decisions. Maternal and infant clinical characteristics can help identify newborn infants who are at risk and guide the administration of empirical antibiotic therapy. The incidence of EOS, the prevalence and implications of established risk factors, the predictive value of commonly used laboratory tests, and the uncertainties in the risk/benefit balance of antibiotic exposures all vary significantly with gestational age at birth. Our purpose in this clinical report is to provide a summary of the current epidemiology of neonatal sepsis among infants born at ≥35 0/7 weeks' gestation and a framework for the development of evidence-based approaches to sepsis risk assessment among these infants. (11/18)

http://pediatrics.aappublications.org/content/142/6/e20182894

MANAGEMENT OF NEONATES BORN AT ≤34 6/7 WEEKS' GESTATION WITH SUSPECTED OR PROVEN EARLY-ONSET BACTERIAL SEPSIS (CLINICAL REPORT)

Karen M. Puopolo, MD, PhD, FAAP; William E. Benitz, MD, FAAP; Theoklis E. Zaoutis, MD, MSCE, FAAP; Committee on Fetus and Newborn; and Committee on Infectious Diseases

ABSTRACT. Early-onset sepsis (EOS) remains a serious and often fatal illness among infants born preterm, particularly among newborn infants of the lowest gestational age. Currently, most preterm infants with very low birth weight are treated empirically with antibiotics for risk of EOS, often for prolonged periods, in the absence of a culture-confirmed infection. Retrospective studies have revealed that antibiotic exposures after birth are associated with multiple subsequent poor outcomes among preterm infants, making the risk/benefit balance of these antibiotic treatments uncertain. Gestational age is the strongest single predictor of EOS, and the majority of preterm

births occur in the setting of other factors associated with risk of EOS, making it difficult to apply risk stratification strategies to preterm infants. Laboratory tests alone have a poor predictive value in preterm EOS. Delivery characteristics of extremely preterm infants present an opportunity to identify those with a lower risk of EOS and may inform decisions to initiate or extend antibiotic therapies. Our purpose for this clinical report is to provide a summary of the current epidemiology of preterm neonatal sepsis and provide guidance for the development of evidence-based approaches to sepsis risk assessment among preterm newborn infants. (11/18)

http://pediatrics.aappublications.org/content/142/6/e20182896

MANAGEMENT OF PEDIATRIC TRAUMA

Committee on Pediatric Emergency Medicine; Council on Injury, Violence, and Poison Prevention; Section on Critical Care; Section on Orthopaedics; Section on Surgery; and Section on Transport Medicine (joint with Pediatric Trauma Society and Society of Trauma Nurses Pediatric Committee)

ABSTRACT. Injury is still the number 1 killer of children ages 1 to 18 years in the United States (http://www.cdc.gov/nchs/fastats/children.htm). Children who sustain injuries with resulting disabilities incur significant costs not only for their health care but also for productivity lost to the economy. The families of children who survive childhood injury with disability face years of emotional and financial hardship, along with a significant societal burden. The entire process of managing childhood injury is enormously complex and varies by region. Only the comprehensive cooperation of a broadly diverse trauma team will have a significant effect on improving the care of injured children. (7/16)

http://pediatrics.aappublications.org/content/138/2/e20161569

MANAGEMENT OF TYPE 2 DIABETES MELLITUS IN CHILDREN AND ADOLESCENTS (TECHNICAL REPORT)

Shelley C. Springer, MD, MBA, MSc, JD, FAAP; Janet Silverstein, MD, FAAP; Kenneth Copeland, MD, FAAP; Kelly R. Moore, MD, FAAP; Greg E. Prazar, MD, FAAP; Terry Raymer, MD, CDE; Richard N. Shiffman, MD, FAAP; Vidhu V. Thaker, MD, FAAP; Meaghan Anderson, MS, RD, LD, CDE; Stephen J. Spann, MD, MBA, FAAFP; and Susan K. Flinn, MA

ABSTRACT. *Objective.* Over the last 3 decades, the prevalence of childhood obesity has increased dramatically in North America, ushering in a variety of health problems, including type 2 diabetes mellitus (T2DM), which previously was not typically seen until much later in life. This technical report describes, in detail, the procedures undertaken to develop the recommendations given in the accompanying clinical practice guideline, "Management of Type 2 Diabetes Mellitus in Children and Adolescents," and provides in-depth information about the rationale for the recommendations and the studies used to make the clinical practice guideline's recommendations.

Methods. A primary literature search was conducted relating to the treatment of T2DM in children and adolescents, and a secondary literature search was conducted relating to the screening and treatment of T2DM's comorbidities in children and adolescents. Inclusion criteria were prospectively and unanimously agreed on by members of the committee. An article was eligible for inclusion if it addressed treatment (primary search) or 1 of 4 comorbidities (secondary search) of T2DM, was published in 1990 or later, was written in English, and included an abstract. Only primary research inquiries were considered; review articles were considered if they included primary data or opinion. The research population had to constitute children and/or adolescents with an existing diagnosis of T2DM; studies of adult patients were considered if at least 10% of the study population was younger than 35 years. All retrieved titles, abstracts, and articles were reviewed by the consulting epidemiologist.

Results. Thousands of articles were retrieved and considered in both searches on the basis of the aforementioned criteria. From those, in the primary search, 199 abstracts were identified for possible inclusion, 58 of which were retained for systematic review. Five of these studies were classified as grade A studies, 1 as grade B, 20 as grade C, and 32 as grade D. Articles regarding treatment of T2DM selected for inclusion were divided into 4 major subcategories on the basis of type of treatment being discussed: (1) medical treatments (32 studies); (2) nonmedical treatments (9 studies); (3) provider behaviors (8 studies); and (4) social issues (9 studies). From the secondary search, an additional 336 abstracts relating to comorbidities were identified for possible inclusion, of which 26 were retained for systematic review. These articles included the following: 1 systematic review of literature regarding comorbidities of T2DM in adolescents; 5 expert opinions presenting global recommendations not based on evidence; 5 cohort studies reporting natural history of disease and comorbidities; 3 with specific attention to comorbidity patterns in specific ethnic groups (case-control, cohort, and clinical report using adult literature); 3 reporting an association between microalbuminuria and retinopathy (2 case-control, 1 cohort); 3 reporting the prevalence of nephropathy (cohort); 1 reporting peripheral vascular disease (case series); 2 discussing retinopathy (1 case-control, 1 position statement); and 3 addressing hyperlipidemia (American Heart Association position statement on cardiovascular risks; American Diabetes Association consensus statement; case series). A breakdown of grade of recommendation shows no grade A studies, 10 grade B studies, 6 grade C studies, and 10 grade D studies. With regard to screening and treatment recommendations for comorbidities, data in children are scarce, and the available literature is conflicting. Therapeutic recommendations for hypertension, dyslipidemia, retinopathy, microalbuminuria, and depression were summarized from expert guideline documents and are presented in detail in the guideline. The references are provided, but the committee did not independently assess the supporting evidence. Screening tools are provided in the Supplemental Information. (1/13)

http://pediatrics.aappublications.org/content/131/2/e648

MARIJUANA USE DURING PREGNANCY AND BREASTFEEDING: IMPLICATIONS FOR NEONATAL AND CHILDHOOD OUTCOMES (CLINICAL REPORT)

Sheryl A. Ryan, MD, FAAP; Seth D. Ammerman, MD, FAAP, FSAHM, DABAM; Mary E. O'Connor, MD, MPH, FAAP; Committee on Substance Use and Prevention; and Section on Breastfeeding

ABSTRACT. Marijuana is one of the most widely used substances during pregnancy in the United States. Emerging data on the ability of cannabinoids to cross the placenta and affect the development of the fetus raise concerns about both pregnancy outcomes and long-term consequences for the infant or child. Social media is used to tout the use of marijuana for severe nausea associated with pregnancy. Concerns have also been raised about marijuana use by breastfeeding mothers. With this clinical report, we provide data on the current rates of marijuana use among pregnant and lactating women, discuss what is known about the effects of marijuana on fetal development and later neurodevelopmental and behavioral outcomes, and address implications for education and policy. (8/18)

http://pediatrics.aappublications.org/content/142/3/e20181889

MATERNAL-FETAL INTERVENTION AND FETAL CARE CENTERS (CLINICAL REPORT)

Committee on Bioethics (joint with American College of Obstetricians and Gynecologists Committee on Ethics)

ABSTRACT. The past 2 decades have yielded profound advances in the fields of prenatal diagnosis and fetal intervention. Although fetal interventions are driven by a beneficence-based motivation to improve fetal and neonatal outcomes, advancement in fetal therapies raises ethical issues surrounding maternal autonomy and decision-making, concepts of innovation versus research, and organizational aspects within institutions in the development of fetal care centers. To safeguard the interests of both the pregnant woman and the fetus, the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics make recommendations regarding informed consent, the role of research subject advocates and other independent advocates, the availability of support services, the multidisciplinary nature of fetal intervention teams, the oversight of centers, and the need to accumulate maternal and fetal outcome data. (7/11, reaffirmed 2/18)

http://pediatrics.aappublications.org/content/128/2/e473

MEDIA AND YOUNG MINDS

Council on Communications and Media

ABSTRACT. Infants, toddlers, and preschoolers are now growing up in environments saturated with a variety of traditional and new technologies, which they are adopting at increasing rates. Although there has been much hope for the educational potential of interactive media for young children, accompanied by fears about their overuse during this crucial period of rapid brain development, research in this area still remains limited. This policy statement reviews the existing literature on television, videos, and mobile/interactive technologies; their potential for educational benefit; and related health concerns for young children (0 to 5 years of age). The statement also highlights areas in which pediatric providers can offer specific guidance to families in managing their young children's media use, not only in terms of content or time limits, but also emphasizing the importance of parent-child shared media use and allowing the child time to take part in other developmentally healthy activities. (10/16)

http://pediatrics.aappublications.org/content/138/5/e20162591

MEDIA EDUCATION

Committee on Communications and Media

ABSTRACT. The American Academy of Pediatrics recognizes that exposure to mass media (eg, television, movies, video and computer games, the Internet, music lyrics and videos, newspapers, magazines, books, advertising) presents health risks for children and adolescents but can provide benefits as well. Media education has the potential to reduce the harmful effects of media and accentuate the positive effects. By understanding and supporting media education, pediatricians can play an important role in reducing harmful effects of media on children and adolescents. (9/10)

http://pediatrics.aappublications.org/content/126/5/1012

MEDIA USE IN SCHOOL-AGED CHILDREN AND ADOLESCENTS

Council on Communications and Media

ABSTRACT. This policy statement focuses on children and adolescents 5 through 18 years of age. Research suggests both benefits and risks of media use for the health of children and teenagers. Benefits include exposure to new ideas and knowledge acquisition, increased opportunities for social contact and support, and new opportunities to access health-promotion messages and information. Risks include negative health effects on weight and sleep; exposure to inaccurate, inappropriate, or unsafe content and contacts; and compromised privacy and confidentiality. Parents face challenges in monitoring their children's and their own media use and in serving as positive role models. In this new era, evidence regarding healthy media use does not support a one-size-fits-all approach. Parents and pediatricians can work together to develop a Family Media Use Plan (www.healthychildren.org/MediaUsePlan) that considers their children's developmental stages to individualize an appropriate balance for media time and consistent rules about media use, to mentor their children, to set boundaries for accessing content and displaying personal information, and to implement open family communication about media. (10/16)

http://pediatrics.aappublications.org/content/138/5/e20162592

MEDIATORS AND ADVERSE EFFECTS OF CHILD POVERTY IN THE UNITED STATES (TECHNICAL REPORT)

John M. Pascoe, MD, MPH, FAAP; David L. Wood, MD, MPH, FAAP; James H. Duffee, MD, MPH, FAAP; Alice Kuo, MD, PhD, MEd, FAAP; Committee on Psychosocial Aspects of Child and Family Health; and Council on Community Pediatrics

ABSTRACT. The link between poverty and children's health is well recognized. Even temporary poverty may have an adverse effect on children's health, and data consistently support the observation that poverty in childhood continues to have a negative effect on health into adulthood. In addition to childhood morbidity being related to child poverty, epidemiologic studies have documented a mortality gradient for children aged 1 to 15 years (and adults), with poor children experiencing a higher mortality rate than children from higher-income families. The global great recession is only now very slowly abating for millions of America's children and their families. At this difficult time in the history of our nation's families and immediately after the 50th anniversary year of President Lyndon Johnson's War on Poverty, it is particularly germane for the American Academy of Pediatrics, which is "dedicated to the health of all children," to publish a research-supported technical report that examines the mediators associated with the long-recognized adverse effects of child poverty on children and their families. This technical report draws on research from a number of disciplines, including physiology, sociology, psychology, economics, and epidemiology, to describe the present state of knowledge regarding poverty's negative impact on children's health and development. Children inherit not only their parents' genes but also the family ecology and its social milieu. Thus, parenting skills, housing, neighborhood, schools, and other factors (eg, medical care) all have complex relations to each other and influence how each child's genetic canvas is expressed. Accompanying this technical report is a policy statement that describes specific actions that pediatricians and other child advocates can take to attenuate the negative effects of the mediators identified in this technical report and improve the well-being of our nation's children and their families. (3/16)

http://pediatrics.aappublications.org/content/137/4/e20160340

MEDICAID POLICY STATEMENT

Committee on Child Health Financing

ABSTRACT. Medicaid insures 39% of the children in the United States. This revision of the 2005 Medicaid Policy Statement of the American Academy of Pediatrics reflects opportunities for changes in state Medicaid programs resulting from the 2010 Patient Protection and Affordable Care Act as upheld in 2012 by the Supreme Court. Policy recommendations focus on the areas of benefit coverage, financing and payment, eligibility, outreach and enrollment, managed care, and quality improvement. (4/13, reaffirmed 3/19)

http://pediatrics.aappublications.org/content/131/5/e1697

MEDICAL COUNTERMEASURES FOR CHILDREN IN PUBLIC HEALTH EMERGENCIES, DISASTERS, OR TERRORISM

Disaster Preparedness Advisory Council

ABSTRACT. Significant strides have been made over the past 10 to 15 years to develop medical countermeasures (MCMs) to address potential disaster hazards, including chemical, biological, radiologic, and nuclear threats. Significant and effective collaboration between the pediatric health community, including the American Academy of Pediatrics, and federal partners, such as the Office of the Assistant Secretary for Preparedness and Response, Centers for Disease Control and Prevention, Federal Emergency Management Agency, National Institutes of Health, Food and Drug Administration, and other federal agencies, over the past 5 years has resulted in substantial gains in addressing the needs of children related to disaster preparedness in general and MCMs in particular. Yet, major gaps still remain related to MCMs for children, a population highly vulnerable to the effects of exposure to such threats, because many vaccines and pharmaceuticals approved for use by adults as MCMs do not yet have pediatric formulations, dosing information, or safety information. As a result, the nation's stockpiles and other caches (designated supply of MCMs) where pharmacotherapeutic and other MCMs are stored are less prepared to address the needs of children compared with those of adults in the event of a disaster. This policy statement provides recommendations to close the remaining gaps for the development and use of MCMs in children during public health emergencies or disasters. The progress made by federal agencies to date to address the needs of children and the shared commitment of collaboration that characterizes the current relationship between the pediatric health community and the federal agencies responsible for MCMs should encourage all child advocates to invest the necessary energy and resources now to complete the process of remedying the remaining significant gaps in preparedness. (1/16)

http://pediatrics.aappublications.org/content/137/2/e20154273

MEDICAL EMERGENCIES OCCURRING AT SCHOOL

Council on School Health

ABSTRACT. Children and adults might experience medical emergency situations because of injuries, complications of chronic health conditions, or unexpected major illnesses that occur in schools. In February 2001, the American Academy of Pediatrics issued a policy statement titled "Guidelines for Emergency Medical Care in Schools" (available at: http://aappolicy.aappublications.org/cgi/content/full/pediatrics;107/2/435). Since the release of that statement, the spectrum of potential individual student emergencies has changed significantly. The increase in the number of children with special health care needs and chronic medical conditions attending schools and the challenges associated with ensuring that schools have access to on-site licensed health care professionals on an ongoing basis have added to increasing the risks of medical emergencies in schools. The goal of this statement is to increase pediatricians' awareness of schools' roles in preparing for individual student emergencies and to provide recommendations for primary care and school physicians on how to assist and support school personnel. (10/08, reaffirmed 9/11, 4/17)

http://pediatrics.aappublications.org/content/122/4/887

MEDICAL STAFF APPOINTMENT AND DELINEATION OF PEDIATRIC PRIVILEGES IN HOSPITALS (CLINICAL REPORT)

Daniel A. Rauch, MD; Committee on Hospital Care; and Section on Hospital Medicine

ABSTRACT. The review and verification of credentials and the granting of clinical privileges are required of every hospital to ensure that members of the medical staff are competent and qualified to provide specified levels of patient care. The credentialing process involves the following: (1) assessment of the professional and personal background of each practitioner seeking privileges; (2) assignment of privileges appropriate for the clinician's training and experience; (3) ongoing monitoring of the professional activities of each staff member; and (4) periodic reappointment to the medical staff on the basis of objectively measured performance. We examine the essential elements of a credentials review for initial and renewed medical staff appointments along with suggested criteria for the delineation of clinical privileges. Sample forms for the delineation of privileges can be found on the American Academy of Pediatrics Committee on Hospital Care Web site (http://www.aap.org/visit/cmte19.htm). Because of differences among individual hospitals, no 1 method for credentialing is universally applicable. The medical staff of each hospital must, therefore, establish its own process based on the general principles reviewed in this report. The issues of medical staff membership and credentialing have become very complex, and institutions and medical staffs are vulnerable to legal action. Consequently, it is advisable for hospitals and medical staffs to obtain expert legal advice when medical staff bylaws are constructed or revised. (3/12, reaffirmed 2/16)

http://pediatrics.aappublications.org/content/129/4/797

MEDICAL VERSUS NONMEDICAL IMMUNIZATION EXEMPTIONS FOR CHILD CARE AND SCHOOL ATTENDANCE

Committee on Practice and Ambulatory Medicine, Committee on Infectious Diseases, Committee on State Government Affairs, Council on School Health, and Section on Administration and Practice Management

ABSTRACT. Routine childhood immunizations against infectious diseases are an integral part of our public health infrastructure. They provide direct protection to the immunized individual and indirect protection to children and adults unable to be immunized via the effect of community immunity. All 50 states, the District of Columbia, and Puerto Rico have regulations requiring proof of immunization for child care and school attendance as a public health strategy to protect children in these settings and to secondarily serve as a mechanism to promote timely immunization of children by their caregivers. Although all states and the District of Columbia have mechanisms to exempt school attendees from specific immunization requirements for medical reasons, the majority also have a heterogeneous collection of regulations and laws that allow nonmedical exemptions from childhood immunizations otherwise required for child care and school attendance. The American Academy of Pediatrics (AAP) supports regulations and laws requiring certification of immunization to attend child care and school as a sound means of providing a safe environment for attendees and employees of these settings. The AAP also supports medically indicated exemptions to specific immunizations as determined for each individual child. The AAP views nonmedical exemptions to school-required immunizations as inappropriate for individual, public health, and ethical reasons and advocates for their elimination. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20162145

MEDICATION-ASSISTED TREATMENT OF ADOLESCENTS WITH OPIOID USE DISORDERS

Committee on Substance Use and Prevention

ABSTRACT. Opioid use disorder is a leading cause of morbidity and mortality among US youth. Effective treatments, both medications and substance use disorder counseling, are available but underused, and access to developmentally appropriate treatment is severely restricted for adolescents and young adults. Resources to disseminate available therapies and to develop new treatments specifically for this age group are needed to save and improve lives of youth with opioid addiction. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20161893

MENSTRUAL MANAGEMENT FOR ADOLESCENTS WITH DISABILITIES (CLINICAL REPORT)

Elisabeth H. Quint, MD; Rebecca F. O'Brien, MD; and Committee on Adolescence (joint with North American Society for Pediatric and Adolescent Gynecology)

ABSTRACT. The onset of menses for adolescents with physical or intellectual disabilities can affect their independence and add additional concerns for families at home, in schools, and in other settings. The pediatrician is the primary health care provider to explore and assist with the pubertal transition and menstrual management. Menstrual management of both normal and abnormal cycles may be requested to minimize hygiene issues, premenstrual symptoms, dysmenorrhea, heavy or irregular bleeding, contraception, and conditions exacerbated by the menstrual cycle. Several options are available for menstrual management, depending on the outcome that is desired, ranging from cycle regulation to complete amenorrhea. The use of medications or the request for surgeries to help with the menstrual cycles in teenagers with disabilities has medical, social, legal, and ethical implications. This clinical report is designed to help guide pediatricians in assisting adolescent females with intellectual and/or physical disabilities and their families in making decisions related to successfully navigating menarche and subsequent menstrual cycles. (6/16)

http://pediatrics.aappublications.org/content/138/1/e20160295

MENTAL HEALTH COMPETENCIES FOR PEDIATRIC PRACTICE

Jane Meschan Foy, MD, FAAP; Cori M. Green, MD, MS, FAAP; Marian F. Earls, MD, MTS, FAAP; Committee on Psychosocial Aspects of Child and Family Health; and Mental Health Leadership Work Group

ABSTRACT. Pediatricians have unique opportunities and an increasing sense of responsibility to promote healthy social-emotional development of children and to prevent and address their mental health and substance use conditions. In this report, the American Academy of Pediatrics updates its 2009 policy statement, which proposed competencies for providing mental health care to children in primary care settings and recommended steps toward achieving them. This 2019 policy statement affirms the 2009 statement and expands competencies in response to science and policy that have emerged since: the impact of adverse childhood experiences and social determinants on mental health, trauma-informed practice, and team-based care. Importantly, it also recognizes ways in which the competencies are pertinent to pediatric subspecialty practice. Proposed mental health competencies include foundational communication skills, capacity to incorporate mental health content and tools into health promotion and primary and secondary preventive care, skills in the psychosocial assessment and care of children with mental health conditions, knowledge and skills of evidence-based psychosocial therapy and psychopharmacologic therapy, skills to function as a team member and comanager with mental health specialists, and commitment to embrace mental health practice as integral to pediatric care. Achievement of these competencies will necessarily be incremental, requiring partnership with fellow advocates, system changes, new payment mechanisms, practice enhancements, and decision support for pediatricians in their expanded scope of practice. (10/19)

https://pediatrics.aappublications.org/content/144/5/e20192757

METABOLIC AND BARIATRIC SURGERY FOR PEDIATRIC PATIENTS WITH SEVERE OBESITY (TECHNICAL REPORT)

Christopher F. Bolling, MD, FAAP; Sarah C. Armstrong, MD, FAAP; Kirk W. Reichard, MD, MBA, FAAP; Marc P. Michalsky, MD, FACS, FAAP, FASMBS; Section on Obesity; and Section on Surgery

ABSTRACT. Severe obesity affects the health and well-being of millions of children and adolescents in the United States and is widely considered to be an "epidemic within an epidemic" that poses a major public health crisis. Currently, few effective treatments for severe obesity exist. Metabolic and bariatric surgery are existing but underuse treatment options for pediatric patients with severe obesity. Roux-en-Y gastric bypass and vertical sleeve gastrectomy are the most commonly performed metabolic and bariatric procedures in the United States and have been shown to result in sustained short-, mid-, and long-term weight loss, with associated resolution of multiple obesity-related comorbid diseases. Substantial evidence supports the safety and effectiveness of surgical weight loss for children and adolescents, and robust best practice guidelines for these procedures exist. (11/19)

https://pediatrics.aappublications.org/content/144/6/e20193224

THE METABOLIC SYNDROME IN CHILDREN AND ADOLESCENTS: SHIFTING THE FOCUS TO CARDIOMETABOLIC RISK FACTOR CLUSTERING (CLINICAL REPORT)

Sheela N. Magge, MD, MSCE, FAAP; Elizabeth Goodman, MD, MBA, FAAP; Sarah C. Armstrong, MD, FAAP; Committee on Nutrition; Section on Endocrinology; and Section on Obesity

ABSTRACT. Metabolic syndrome (MetS) was developed by the National Cholesterol Education Program Adult Treatment Panel III, identifying adults with at least 3 of 5 cardiometabolic risk factors (hyperglycemia, increased central adiposity, elevated triglycerides, decreased high-density lipoprotein cholesterol, and elevated blood pressure) who are at increased risk of diabetes and cardiovascular disease. The constellation of MetS component risk factors has a shared pathophysiology and many common treatment approaches grounded in lifestyle modification. Several attempts have been made to define MetS in the pediatric population. However, in children, the construct is difficult to define and has unclear implications for clinical care. In this Clinical Report, we focus on the importance of screening for and treating the individual risk factor components of MetS. Focusing attention on children with cardiometabolic risk factor clustering is emphasized over the need to define a pediatric MetS. (7/17)

http://pediatrics.aappublications.org/content/140/2/e20171603

METRIC UNITS AND THE PREFERRED DOSING OF ORALLY ADMINISTERED LIQUID MEDICATIONS

Committee on Drugs

ABSTRACT. Medication overdoses are a common, but preventable, problem among children. Volumetric dosing errors and the use of incorrect dosing delivery devices are 2 common sources of these preventable errors for orally administered liquid medications. To reduce errors and increase precision of drug administration, milliliter-based dosing should be used exclusively when prescribing and administering liquid medications. Teaspoon- and tablespoon-based dosing should not be used. Devices that allow for precise dose administration (preferably syringes with metric markings) should be used instead of household spoons and should be distributed with the medication. (3/15)

http://pediatrics.aappublications.org/content/135/4/784

MIND-BODY THERAPIES IN CHILDREN AND YOUTH (CLINICAL REPORT)

Section on Integrative Medicine

ABSTRACT. Mind-body therapies are popular and are ranked among the top 10 complementary and integrative medicine practices reportedly used by adults and children in the 2007–2012 National Health Interview Survey. A growing body of evidence supports the effectiveness and safety of mind-body therapies in pediatrics. This clinical report outlines popular mind-body therapies for children and youth and examines the best-available evidence for a variety of mind-body therapies and practices, including biofeedback, clinical hypnosis, guided imagery, meditation, and yoga. The report is intended to help

health care professionals guide their patients to nonpharmacologic approaches to improve concentration, help decrease pain, control discomfort, or ease anxiety. (8/16)
http://pediatrics.aappublications.org/content/138/3/e20161896

MINORS AS LIVING SOLID-ORGAN DONORS (CLINICAL REPORT)

Lainie Friedman Ross, MD, PhD; J. Richard Thistlethwaite Jr, MD, PhD; and Committee on Bioethics

ABSTRACT. In the past half-century, solid-organ transplantation has become standard treatment for a variety of diseases in children and adults. The major limitation for all transplantation is the availability of donors, and the gap between demand and supply continues to grow despite the increase in living donors. Although rare, children do serve as living donors, and these donations raise serious ethical issues. This clinical report includes a discussion of the ethical considerations regarding minors serving as living donors, using the traditional benefit/burden calculus from the perspectives of both the donor and the recipient. The report also includes an examination of the circumstances under which a minor may morally participate as a living donor, how to minimize risks, and what the informed-consent process should entail. The American Academy of Pediatrics holds that minors can morally serve as living organ donors but only in exceptional circumstances when specific criteria are fulfilled. (8/08, reaffirmed 5/11)
http://pediatrics.aappublications.org/content/122/2/454

MODEL CONTRACTUAL LANGUAGE FOR MEDICAL NECESSITY FOR CHILDREN

Committee on Child Health Financing

ABSTRACT. The term "medical necessity" is used by Medicare and Medicaid and in insurance contracts to refer to medical services that are generally recognized as appropriate for the diagnosis, prevention, or treatment of disease and injury. There is no consensus on how to define and apply the term and the accompanying rules and regulations, and as a result there has been substantial variation in medical-necessity definitions and interpretations. With this policy statement, the American Academy of Pediatrics hopes to encourage insurers to adopt more consistent medical-necessity definitions that take into account the needs of children. (7/05, reaffirmed 10/11)
http://pediatrics.aappublications.org/content/116/1/261

MOTOR DELAYS: EARLY IDENTIFICATION AND EVALUATION (CLINICAL REPORT)

Garey H. Noritz, MD; Nancy A. Murphy, MD; and Neuromotor Screening Expert Panel

ABSTRACT. Pediatricians often encounter children with delays of motor development in their clinical practices. Earlier identification of motor delays allows for timely referral for developmental interventions as well as diagnostic evaluations and treatment planning. A multidisciplinary expert panel developed an algorithm for the surveillance and screening of children for motor delays within the medical home, offering guidance for the initial workup and referral of the child with possible delays in motor development. Highlights of this clinical report include suggestions for formal developmental screening at the 9-, 18-, 30-, and 48-month well-child visits; approaches to the neurologic examination, with emphasis on the assessment of muscle tone; and initial diagnostic approaches for medical home providers. Use of diagnostic tests to evaluate children with motor delays are described, including brain MRI for children with high muscle tone, and measuring serum creatine kinase concentration of those with decreased muscle tone. The importance of pursuing diagnostic tests while concurrently referring patients to early intervention programs is emphasized. (5/13, reaffirmed 5/17)
http://pediatrics.aappublications.org/content/131/6/e2016

THE NEED TO OPTIMIZE ADOLESCENT IMMUNIZATION (CLINICAL REPORT)

Henry H. Bernstein, DO, MHCM, FAAP; Joseph A. Bocchini Jr, MD, FAAP; and Committee on Infectious Diseases

ABSTRACT. The adolescent period heralds the pediatric patient's transition into adulthood. It is a time of dynamic development during which effective preventive care measures can promote safe behaviors and the development of lifelong health habits. One of the foundations of preventive adolescent health care is timely vaccination, and every visit can be viewed as an opportunity to update and complete an adolescent's immunizations.

In the past decade, the adolescent immunization schedule has expanded to include 2 doses of quadrivalent meningococcal conjugate vaccine; 1 dose of tetanus, diphtheria, acellular pertussis, absorbed vaccine; 2 or 3 doses of human papillomavirus vaccine, depending on the child's age; and an annual influenza vaccine. In addition, during adolescent visits, health care providers can determine whether catch-up vaccination is needed to meet early childhood recommendations for hepatitis B; hepatitis A; measles, mumps, rubella; poliovirus; and varicella vaccines. New serogroup B meningococcal vaccines are now available for those at increased risk for meningococcal disease; in addition, these serogroup B meningococcal vaccines received a Category B recommendation for healthy adolescents, where individual counseling and risk–benefit evaluation based on health care provider judgements and patient preferences are indicated. This clinical report focuses on the epidemiology of adolescent vaccine-preventable diseases by reviewing the rationale for the annual universally recommended adolescent immunization schedule of the American Academy of Pediatrics, the American Academy of Family Physicians, the Centers for Disease Control and Prevention, and the American Congress of Obstetricians and Gynecologists. In addition, the barriers that negatively influence adherence to this current adolescent immunization schedule will be highlighted. (2/17)
http://pediatrics.aappublications.org/content/139/3/e20164186

NEEDS OF KINSHIP CARE FAMILIES AND PEDIATRIC PRACTICE

David Rubin, MD, FAAP; Sarah H. Springer, MD, FAAP; Sarah Zlotnik, MSW, MSPH; Christina D. Kang-Yi, PhD; and Council on Foster Care, Adoption, and Kinship Care

ABSTRACT. As many as 3% of children in the United States live in kinship care arrangements with caregivers who are relatives but not the biological parents of the child. A growing body of evidence suggests that children who cannot live with their biological parents fare better, overall, when living with extended family than with nonrelated foster parents. Acknowledging this, federal laws and public policies increasingly favor kinship care over nonrelative foster care when children are unable to live with their biological parents. Despite overall better outcomes, families providing kinship care experience many hardships, and the children experience many of the same adversities of children in traditional foster care. This policy statement reviews both the strengths and vulnerabilities of kinship families and suggests strategies for pediatricians to use to address the needs of individual patients and families. Strategies are also outlined for community, state, and federal advocacy on behalf of these children and their families. (3/17)
http://pediatrics.aappublications.org/content/139/4/e20170099

NEONATAL DRUG WITHDRAWAL (CLINICAL REPORT)

Mark L. Hudak, MD; Rosemarie C. Tan, MD, PhD; Committee on Drugs; and Committee on Fetus and Newborn

ABSTRACT. Maternal use of certain drugs during pregnancy can result in transient neonatal signs consistent with withdrawal or acute toxicity or cause sustained signs consistent with a lasting drug effect. In addition, hospitalized infants who are treated

with opioids or benzodiazepines to provide analgesia or sedation may be at risk for manifesting signs of withdrawal. This statement updates information about the clinical presentation of infants exposed to intrauterine drugs and the therapeutic options for treatment of withdrawal and is expanded to include evidence-based approaches to the management of the hospitalized infant who requires weaning from analgesics or sedatives. (1/12, reaffirmed 2/16)
http://pediatrics.aappublications.org/content/129/2/e540

NEONATAL OPIOID WITHDRAWAL SYNDROME (CLINICAL REPORT)

Stephen W. Patrick, MD, MPH, MS, FAAP; Wanda D. Barfield, MD, MPH, FAAP; Brenda B. Poindexter, MD, MS, FAAP; Committee on Fetus and Newborn; and Committee on Substance Use and Prevention

ABSTRACT. The opioid crisis has grown to affect pregnant women and infants across the United States, as evidenced by rising rates of opioid use disorder among pregnant women and neonatal opioid withdrawal syndrome among infants. Across the country, pregnant women lack access to evidence-based therapies, including medications for opioid use disorder, and infants with opioid exposure frequently receive variable care. In addition, public systems, such as child welfare and early intervention, are increasingly stretched by increasing numbers of children affected by the crisis. Systematic, enduring, coordinated, and holistic approaches are needed to improve care for the mother-infant dyad. In this statement, we provide an overview of the effect of the opioid crisis on the mother-infant dyad and provide recommendations for management of the infant with opioid exposure, including clinical presentation, assessment, treatment, and discharge. (10/20)

See full text on page 963.

https://pediatrics.aappublications.org/content/146/5/e2020029074

NEONATAL PROVIDER WORKFORCE (TECHNICAL REPORT)

Erin L. Keels, DNP, APRN-CNP, NNP-BC; Jay P. Goldsmith, MD, FAAP; and Committee on Fetus and Newborn

ABSTRACT. This technical report reviews education, training, competency requirements, and scopes of practice of the different neonatal care providers who work to meet the special needs of neonatal patients and their families in the NICU. Additionally, this report examines the current workforce issues of NICU providers, offers suggestions for establishing and monitoring quality and safety of care, and suggests potential solutions to the NICU provider workforce shortages now and in the future. (11/19)

https://pediatrics.aappublications.org/content/144/6/e20193147

A NEW ERA IN QUALITY MEASUREMENT: THE DEVELOPMENT AND APPLICATION OF QUALITY MEASURES

Terry Adirim, MD, MPH, FAAP; Kelley Meade, MD, FAAP; Kamila Mistry, PhD, MPH; Council on Quality Improvement and Patient Safety; and Committee on Practice and Ambulatory Medicine

ABSTRACT. Quality measures are used for a variety of purposes in health care, including clinical care improvement, regulation, accreditation, public reporting, surveillance, and maintenance of certification. Most quality measures are 1 of 3 types: structure, process, or outcome. Health care quality measures should address the domains of quality across the continuum of care and reflect patient and family experience. Measure development for pediatric health care has a number of important challenges, including gaps in the evidence base; the fact that measures for most conditions must be age-specific; the long, resourceintensive development process; and the national focus on measure development for adult conditions. Numerous national organizations focus on the development and application of quality measures, including the Pediatric Quality Measures Program, which is focused solely on the development and implementation of pediatric-specific measures. Once a quality measure is developed for use in national measurement programs, the organization that develops and/or "stewards" the measure may submit the measure or set of measures for endorsement, which is recognition of the scientific soundness, usability, and relevance of the measure. Quality measures must then be disseminated and applied to improve care. Although pediatric health care providers and child health care institutions alike must continually balance time and resources needed to address multiple reporting requirements, quality measurement is an important tool for advancing high-quality and safe health care for children. This policy statement provides an overview of quality measurement and describes the opportunities for pediatric health care providers to apply quality measures to improve clinical quality and performance in the delivery of pediatric health care services. (12/16)

http://pediatrics.aappublications.org/content/139/1/e20163442

NEWBORN SCREENING EXPANDS: RECOMMENDATIONS FOR PEDIATRICIANS AND MEDICAL HOMES—IMPLICATIONS FOR THE SYSTEM (CLINICAL REPORT)

Newborn Screening Authoring Committee

ABSTRACT. Advances in newborn screening technology, coupled with recent advances in the diagnosis and treatment of rare but serious congenital conditions that affect newborn infants, provide increased opportunities for positively affecting the lives of children and their families. These advantages also pose new challenges to primary care pediatricians, both educationally and in response to the management of affected infants. Primary care pediatricians require immediate access to clinical and diagnostic information and guidance and have a proactive role to play in supporting the performance of the newborn screening system. Primary care pediatricians must develop office policies and procedures to ensure that newborn screening is conducted and that results are transmitted to them in a timely fashion; they must also develop strategies to use should these systems fail. In addition, collaboration with local, state, and national partners is essential for promoting actions and policies that will optimize the function of the newborn screening systems and ensure that families receive the full benefit of them. (1/08, reaffirmed 9/16)

http://pediatrics.aappublications.org/content/121/1/192

NEWBORN SCREENING FOR BILIARY ATRESIA (TECHNICAL REPORT)

Kasper S. Wang, MD, FAAP, FACS; Section on Surgery; and Committee on Fetus and Newborn (joint with Childhood Liver Disease Research Network)

ABSTRACT. Biliary atresia is the most common cause of pediatric end-stage liver disease and the leading indication for pediatric liver transplantation. Affected infants exhibit evidence of biliary obstruction within the first few weeks after birth. Early diagnosis and successful surgical drainage of bile are associated with greater survival with the child's native liver. Unfortunately, because noncholestatic jaundice is extremely common in early infancy, it is difficult to identify the rare infant with cholestatic jaundice who has biliary atresia. Hence, the need for timely diagnosis of this disease warrants a discussion of the feasibility of screening for biliary atresia to improve outcomes. Herein, newborn screening for biliary atresia in the United States is assessed by using criteria established by the Discretionary Advisory Committee on Heritable Disorders in Newborns and Children. Published analyses indicate that newborn screening for biliary atresia by using serum bilirubin concentrations or stool color cards is potentially life-saving and cost-effective. Further studies are necessary to evaluate the feasibility, effectiveness,

and costs of potential screening strategies for early identification of biliary atresia in the United States. (11/15)
http://pediatrics.aappublications.org/content/136/6/e1663

NICKEL ALLERGIC CONTACT DERMATITIS: IDENTIFICATION, TREATMENT, AND PREVENTION

Nanette B. Silverberg, MD, FAAP, FAAD; Janice L. Pelletier, MD, FAAP; Sharon E. Jacob, MD, FAAP, FAAD; Lynda C. Schneider, MD, FAAP; Section on Dermatology; and Section on Allergy and Immunology

ABSTRACT. Nickel is a ubiquitous metal added to jewelry and metallic substances for its hardening properties and because it is inexpensive. Estimates suggest that at least 1.1 million children in the United States are sensitized to nickel. Nickel allergic contact dermatitis (Ni-ACD) is the most common cutaneous delayed-type hypersensitivity reaction worldwide. The incidence among children tested has almost quadrupled over the past 3 decades. The associated morbidities include itch, discomfort, school absence, and reduced quality of life. In adulthood, individuals with Ni-ACD may have severe disabling hand eczema. The increasing rate of Ni-ACD in children has been postulated to result from early and frequent exposure to metals with high amounts of nickel release (eg, as occurs with ear piercing or with products used daily in childhood such as toys, belt buckles, and electronics).

To reduce exposure to metal sources with high nickel release by prolonged and direct contact with human skin, Denmark and the European Union legislated a directive several decades ago with the goal of reducing high nickel release and the incidence of Ni-ACD. Since then, there has been a global reduction in incidence of Ni-ACD in population-based studies of adults and studies of children and young adults being tested for allergic contact dermatitis. These data point to nickel exposure as a trigger for elicitation of Ni-ACD and, further, provide evidence that legislation can have a favorable effect on the economic and medical health of a population.

This policy statement reviews the epidemiology, history, and appearances of Ni-ACD. Examples of sources of high nickel release are discussed to highlight how difficult it is to avoid this metal in modern daily lives. Treatments are outlined, and avoidance strategies are presented. Long-term epidemiological interventions are addressed. Advocacy for smarter nickel use is reviewed. The American Academy of Pediatrics supports US legislation that advances safety standards (as modeled by the European Union) that protect children from early and prolonged skin exposure to high–nickel-releasing items. Our final aim for this article is to aid the pediatric community in developing nickel-avoidance strategies on both individual and global levels. (4/20)

See full text on page 983.

https://pediatrics.aappublications.org/content/145/5/e20200628

NICOTINE AND TOBACCO AS SUBSTANCES OF ABUSE IN CHILDREN AND ADOLESCENTS (TECHNICAL REPORT)

Lorena M. Siqueira, MD, MSPH, FAAP, FSAHM, and Committee on Substance Use and Prevention

ABSTRACT. Nicotine is the primary pharmacologic component of tobacco, and users of tobacco products seek out its effects. The highly addictive nature of nicotine is responsible for its widespread use and difficulty with quitting. This technical report focuses on nicotine and discusses the stages of use in progression to dependence on nicotine-containing products; the physiologic characteristics, neurobiology, metabolism, pharmacogenetics, and health effects of nicotine; and acute nicotine toxicity. Finally, some newer approaches to cessation are noted. (12/16)
http://pediatrics.aappublications.org/content/139/1/e20163436

NONDISCRIMINATION IN PEDIATRIC HEALTH CARE

Committee on Pediatric Workforce

ABSTRACT. This policy statement is a revision of a 2001 statement and articulates the positions of the American Academy of Pediatrics on nondiscrimination in pediatric health care. It addresses both pediatricians who provide health care and the infants, children, adolescents, and young adults whom they serve. (10/07, reaffirmed 6/11, 1/15)
http://pediatrics.aappublications.org/content/120/4/922

NONEMERGENCY ACUTE CARE: WHEN IT'S NOT THE MEDICAL HOME

Gregory P. Conners, MD, MPH, MBA, FAAP; Susan J. Kressly, MD, FAAP; James M. Perrin, MD, FAAP; Julia E. Richerson, MD, FAAP; Usha M. Sankrithi, MBBS, MPH, FAAP; Committee on Practice and Ambulatory Medicine; Committee on Pediatric Emergency Medicine; Section on Telehealth Care; Section on Emergency Medicine; Subcommittee on Urgent Care; and Task Force on Pediatric Practice Change

ABSTRACT. The American Academy of Pediatrics (AAP) affirms that the optimal location for children to receive care for acute, nonemergency health concerns is the medical home. The medical home is characterized by the AAP as a care model that "must be accessible, family centered, continuous, comprehensive, coordinated, compassionate, and culturally effective." However, some children and families use acute care services outside the medical home because there is a perceived or real benefit related to accessibility, convenience, or cost of care. Examples of such acute care entities include urgent care facilities, retail-based clinics, and commercial telemedicine services. Children deserve high-quality, appropriate, and safe acute care services wherever they access the health care system, with timely and complete communication with the medical home, to ensure coordinated and continuous care. Treatment of children under established, new, and evolving practice arrangements in acute care entities should adhere to the core principles of continuity of care and communication, best practices within a defined scope of services, pediatric-trained staff, safe transitions of care, and continuous improvement. In support of the medical home, the AAP urges stakeholders, including payers, to avoid any incentives (eg, reduced copays) that encourage visits to external entities for acute issues as a preference over the medical home. (4/17)
http://pediatrics.aappublications.org/content/139/5/e20170629

NONINITIATION OR WITHDRAWAL OF INTENSIVE CARE FOR HIGH-RISK NEWBORNS

Committee on Fetus and Newborn

ABSTRACT. Advances in medical technology have led to dilemmas in initiation and withdrawal of intensive care of newborn infants with a very poor prognosis. Physicians and parents together must make difficult decisions guided by their understanding of the child's best interest. The foundation for these decisions consists of several key elements: (1) direct and open communication between the health care team and the parents of the child with regard to the medical status, prognosis, and treatment options; (2) inclusion of the parents as active participants in the decision process; (3) continuation of comfort care even when intensive care is not being provided; and (4) treatment decisions that are guided primarily by the best interest of the child. (2/07, reaffirmed 5/10, 6/15)
http://pediatrics.aappublications.org/content/119/2/401

NONINVASIVE RESPIRATORY SUPPORT (CLINICAL REPORT)

James J. Cummings, MD, FAAP; Richard A. Polin, MD, FAAP; and Committee on Fetus and Newborn

ABSTRACT. Mechanical ventilation is associated with increased survival of preterm infants but is also associated with an increased incidence of chronic lung disease (bronchopulmonary

dysplasia) in survivors. Nasal continuous positive airway pressure (nCPAP) is a form of noninvasive ventilation that reduces the need for mechanical ventilation and decreases the combined outcome of death or bronchopulmonary dysplasia. Other modes of noninvasive ventilation, including nasal intermittent positive pressure ventilation, biphasic positive airway pressure, and high-flow nasal cannula, have recently been introduced into the NICU setting as potential alternatives to mechanical ventilation or nCPAP. Randomized controlled trials suggest that these newer modalities may be effective alternatives to nCPAP and may offer some advantages over nCPAP, but efficacy and safety data are limited. (12/15)
http://pediatrics.aappublications.org/content/137/1/e20153758

NONORAL FEEDING FOR CHILDREN AND YOUTH WITH DEVELOPMENTAL OR ACQUIRED DISABILITIES (CLINICAL REPORT)

Richard C. Adams, MD, FAAP; Ellen Roy Elias, MD, FAAP; and Council on Children With Disabilities

ABSTRACT. The decision to initiate enteral feedings is multifaceted, involving medical, financial, cultural, and emotional considerations. Children who have developmental or acquired disabilities are at risk for having primary and secondary conditions that affect growth and nutritional well-being. This clinical report provides (1) an overview of clinical issues in children who have developmental or acquired disabilities that may prompt a need to consider nonoral feedings, (2) a systematic way to support the child and family in clinical decisions related to initiating nonoral feeding, (3) information on surgical options that the family may need to consider in that decision-making process, and (4) pediatric guidance for ongoing care after initiation of nonoral feeding intervention, including care of the gastrostomy tube and skin site. Ongoing medical and psychosocial support is needed after initiation of nonoral feedings and is best provided through the collaborative efforts of the family and a team of professionals that may include the pediatrician, dietitian, social worker, and/or therapists. (11/14, reaffirmed 6/19)
http://pediatrics.aappublications.org/content/134/6/e1745

NONTHERAPEUTIC USE OF ANTIMICROBIAL AGENTS IN ANIMAL AGRICULTURE: IMPLICATIONS FOR PEDIATRICS (TECHNICAL REPORT)

Jerome A. Paulson, MD, FAAP; Theoklis E. Zaoutis, MD, MSCE, FAAP; Council on Environmental Health; and Committee on Infectious Diseases

ABSTRACT. Antimicrobial resistance is one of the most serious threats to public health globally and threatens our ability to treat infectious diseases. Antimicrobial-resistant infections are associated with increased morbidity, mortality, and health care costs. Infants and children are affected by transmission of susceptible and resistant food zoonotic pathogens through the food supply, direct contact with animals, and environmental pathways. The overuse and misuse of antimicrobial agents in veterinary and human medicine is, in large part, responsible for the emergence of antibiotic resistance. Approximately 80% of the overall tonnage of antimicrobial agents sold in the United States in 2012 was for animal use, and approximately 60% of those agents are considered important for human medicine. Most of the use involves the addition of low doses of antimicrobial agents to the feed of healthy animals over prolonged periods to promote growth and increase feed efficiency or at a range of doses to prevent disease. These nontherapeutic uses contribute to resistance and create new health dangers for humans. This report describes how antimicrobial agents are used in animal agriculture, reviews the mechanisms of how such use contributes to development of resistance, and discusses US and global initiatives to curb the use of antimicrobial agents in agriculture. (11/15)
http://pediatrics.aappublications.org/content/136/6/e1670

OFFICE-BASED CARE FOR LESBIAN, GAY, BISEXUAL, TRANSGENDER, AND QUESTIONING YOUTH

Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics issued its last statement on homosexuality and adolescents in 2004. Although most lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth are quite resilient and emerge from adolescence as healthy adults, the effects of homophobia and heterosexism can contribute to health disparities in mental health with higher rates of depression and suicidal ideation, higher rates of substance abuse, and more sexually transmitted and HIV infections. Pediatricians should have offices that are teen-friendly and welcoming to sexual minority youth. Obtaining a comprehensive, confidential, developmentally appropriate adolescent psychosocial history allows for the discovery of strengths and assets as well as risks. Referrals for mental health or substance abuse may be warranted. Sexually active LGBTQ youth should have sexually transmitted infection/HIV testing according to recommendations of the Sexually Transmitted Diseases Treatment Guidelines of the Centers for Disease Control and Prevention based on sexual behaviors. With appropriate assistance and care, sexual minority youth should live healthy, productive lives while transitioning through adolescence and young adulthood. (6/13)
http://pediatrics.aappublications.org/content/132/1/198

OFFICE-BASED CARE FOR LESBIAN, GAY, BISEXUAL, TRANSGENDER, AND QUESTIONING YOUTH (TECHNICAL REPORT)

David A. Levine, MD, and Committee on Adolescence

ABSTRACT. The American Academy of Pediatrics issued its last statement on homosexuality and adolescents in 2004. This technical report reflects the rapidly expanding medical and psychosocial literature about sexual minority youth. Pediatricians should be aware that some youth in their care may have concerns or questions about their sexual orientation or that of siblings, friends, parents, relatives, or others and should provide factual, current, nonjudgmental information in a confidential manner. Although most lesbian, gay, bisexual, transgender, and questioning (LGBTQ) youth are quite resilient and emerge from adolescence as healthy adults, the effects of homophobia and heterosexism can contribute to increased mental health issues for sexual minority youth. LGBTQ and MSM/WSW (men having sex with men and women having sex with women) adolescents, in comparison with heterosexual adolescents, have higher rates of depression and suicidal ideation, higher rates of substance abuse, and more risky sexual behaviors. Obtaining a comprehensive, confidential, developmentally appropriate adolescent psychosocial history allows for the discovery of strengths and assets as well as risks. Pediatricians should have offices that are teen-friendly and welcoming to sexual minority youth. This includes having supportive, engaging office staff members who ensure that there are no barriers to care. For transgender youth, pediatricians should provide the opportunity to acknowledge and affirm their feelings of gender dysphoria and desires to transition to the opposite gender. Referral of transgender youth to a qualified mental health professional is critical to assist with the dysphoria, to educate them, and to assess their readiness for transition. With appropriate assistance and care, sexual minority youth should live healthy, productive lives while transitioning through adolescence and young adulthood. (6/13)
http://pediatrics.aappublications.org/content/132/1/e297

OFFICE-BASED COUNSELING FOR UNINTENTIONAL INJURY PREVENTION (CLINICAL REPORT)

H. Garry Gardner, MD, and Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Unintentional injuries are the leading cause of death for children older than 1 year. Pediatricians should

include unintentional injury prevention as a major component of anticipatory guidance for infants, children, and adolescents. The content of injury-prevention counseling varies for infants, preschool-aged children, school-aged children, and adolescents. This report provides guidance on the content of unintentional injury-prevention counseling for each of those age groups. (1/07)
http://pediatrics.aappublications.org/content/119/1/202

OFF-LABEL USE OF DRUGS IN CHILDREN

Committee on Drugs

ABSTRACT. The passage of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act has collectively resulted in an improvement in rational prescribing for children, including more than 500 labeling changes. However, off-label drug use remains an important public health issue for infants, children, and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics. The purpose of off-label use is to benefit the individual patient. Practitioners use their professional judgment to determine these uses. As such, the term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient. (2/14, reaffirmed 11/20)
http://pediatrics.aappublications.org/content/133/3/563

OFF-LABEL USE OF MEDICAL DEVICES IN CHILDREN

Section on Cardiology and Cardiac Surgery and Section on Orthopaedics

ABSTRACT. Despite widespread therapeutic needs, the majority of medical and surgical devices used in children do not have approval or clearance from the Food and Drug Administration (FDA) for use in pediatric populations. The clinical need for devices to diagnose and treat diseases or conditions occurring in children has led to the widespread and necessary practice in pediatric medicine and surgery of using approved devices for "off-label" or "physician-directed" applications that are not included in FDA-approved labeling. This practice is common and often appropriate, even with the highest-risk (class III) devices. The legal and regulatory framework used by the FDA for devices is complex, and economic or market barriers to medical and surgical device development for children are significant. Given the need for pediatric medical and surgical devices and the challenges to pediatric device development, off-label use is a necessary and appropriate part of care. In addition, because of the relatively uncommon nature of pediatric conditions, FDA clearance or approval often requires other regulatory pathways (eg, Humanitarian Device Exemption), which can cause confusion among pediatricians and payers about whether a specific use, even of an approved device, is considered experimental. This policy statement describes the appropriateness of off-label use of devices in children; the use of devices approved or cleared through the FDA regulatory processes, including through the Humanitarian Device Exemption; and the important need to increase pediatric device labeling information for all devices and especially those that pose the highest risk to children. (12/16)
http://pediatrics.aappublications.org/content/139/1/e20163439

ONGOING PEDIATRIC HEALTH CARE FOR THE CHILD WHO HAS BEEN MALTREATED (CLINICAL REPORT)

Emalee Flaherty, MD, FAAP; Lori Legano, MD, FAAP; Sheila Idzerda, MD, FAAP; and Council on Child Abuse and Neglect

ABSTRACT. Pediatricians provide continuous medical care and anticipatory guidance for children who have been reported to state child protection agencies, including tribal child protection agencies, because of suspected child maltreatment. Because families may continue their relationships with their pediatricians after these reports, these primary care providers are in a unique position to recognize and manage the physical, developmental, academic, and emotional consequences of maltreatment and exposure to childhood adversity. Substantial information is available to optimize follow-up medical care of maltreated children. This new clinical report will provide guidance to pediatricians about how they can best oversee and foster the optimal physical health, growth, and development of children who have been maltreated and remain in the care of their biological family or are returned to their care by Child Protective Services agencies. The report describes the pediatrician's role in helping to strengthen families' and caregivers' capabilities and competencies and in promoting and maximizing high-quality services for their families in their community. Pediatricians should refer to other reports and policies from the American Academy of Pediatrics for more information about the emotional and behavioral consequences of child maltreatment and the treatment of these consequences. (3/19)
https://pediatrics.aappublications.org/content/143/4/e20190284

OPHTHALMOLOGIC EXAMINATIONS IN CHILDREN WITH JUVENILE RHEUMATOID ARTHRITIS (CLINICAL REPORT)

James Cassidy, MD; Jane Kivlin, MD; Carol Lindsley, MD; James Nocton, MD; Section on Rheumatology; and Section on Ophthalmology

ABSTRACT. Unlike the joints, ocular involvement with juvenile rheumatoid arthritis is most often asymptomatic; yet, the inflammation can cause serious morbidity with loss of vision. Scheduled slit-lamp examinations by an ophthalmologist at specific intervals can detect ocular disease early, and prompt treatment can prevent vision loss. (5/06, reaffirmed 10/12, 7/18)
http://pediatrics.aappublications.org/content/117/5/1843

OPTIMIZING BONE HEALTH IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Neville H. Golden, MD; Steven A. Abrams, MD; and Committee on Nutrition

ABSTRACT. The pediatrician plays a major role in helping optimize bone health in children and adolescents. This clinical report reviews normal bone acquisition in infants, children, and adolescents and discusses factors affecting bone health in this age group. Previous recommended daily allowances for calcium and vitamin D are updated, and clinical guidance is provided regarding weight-bearing activities and recommendations for calcium and vitamin D intake and supplementation. Routine calcium supplementation is not recommended for healthy children and adolescents, but increased dietary intake to meet daily requirements is encouraged. The American Academy of Pediatrics endorses the higher recommended dietary allowances for vitamin D advised by the Institute of Medicine and supports testing for vitamin D deficiency in children and adolescents with conditions associated with increased bone fragility. Universal screening for vitamin D deficiency is not routinely recommended in healthy children or in children with dark skin or obesity because there is insufficient evidence of the cost–benefit of such a practice in reducing fracture risk. The preferred test to assess bone health is dual-energy x-ray absorptiometry, but caution is advised when interpreting results in children and adolescents who may not yet have achieved peak bone mass. For analyses, *z* scores should be used instead of T scores, and corrections should be made for size. Office-based strategies for the pediatrician to optimize bone health are provided. This clinical report has been endorsed by American Bone Health. (9/14)
http://pediatrics.aappublications.org/content/134/4/e1229

OPTIMIZING RESOURCES IN CHILDREN'S SURGICAL CARE: AN UPDATE ON THE AMERICAN COLLEGE OF SURGEONS' VERIFICATION PROGRAM (TECHNICAL REPORT)

Kasper S. Wang, MD, FAAP; James Cummings, MD, FAAP; Ann Stark, MD, FAAP; Constance Houck, MD, MPH, FAAP; Keith Oldham, MD, FAAP; Catherine Grant, BSN, RN; Mary Fallat, MD, FAAP; Section on Surgery; Committee on Fetus and Newborn; and Section on Anesthesiology and Pain Medicine

ABSTRACT. Surgical procedures are performed in the United States in a wide variety of clinical settings and with variation in clinical outcomes. In May 2012, the Task Force for Children's Surgical Care, an ad hoc multidisciplinary group comprising physicians representing specialties relevant to pediatric perioperative care, was convened to generate recommendations to optimize the delivery of children's surgical care. This group generated a white paper detailing the consensus opinions of the involved experts. Following these initial recommendations, the American College of Surgeons (ACS), Children's Hospital Association, and Task Force for Children's Surgical Care, with input from all related perioperative specialties, developed and published specific and detailed resource and quality standards designed to improve children's surgical care (https://www.facs.org/quality-programs/childrens-surgery/childrens-surgery-verification). In 2015, with the endorsement of the American Academy of Pediatrics (https://pediatrics.aappublications.org/content/135/6/e1538), the ACS established a pilot verification program. In January 2017, after completion of the pilot program, the ACS Children's Surgery Verification Quality Improvement Program was officially launched. Verified sites are listed on the program Web site at https://www.facs.org/quality-programs/childrens-surgery/childrens-surgery-verification/centers, and more than 150 are interested in verification. This report provides an update on the ACS Children's Surgery Verification Quality Improvement Program as it continues to evolve. (4/20)

See full text on page 999.

https://pediatrics.aappublications.org/content/145/5/e20200708

OPTIONS COUNSELING FOR THE PREGNANT ADOLESCENT PATIENT

Laurie L. Hornberger, MD, MPH, FAAP, and Committee on Adolescence

ABSTRACT. Each year, more than 500 000 girls and young women younger than 20 years become pregnant. It is important for pediatricians to have the ability and the resources in their offices to make a timely pregnancy diagnosis in their adolescent patients and provide them with nonjudgmental pregnancy options counseling. Counseling includes an unbiased discussion of the adolescent's legal options to either continue or terminate her pregnancy, supporting the adolescent in the decision-making process, and referring the adolescent to appropriate resources and services. Pediatricians who choose not to provide such discussions should promptly refer pregnant adolescent patients to a health care professional who will offer developmentally appropriate pregnancy options counseling. This approach to pregnancy options counseling has not changed since the original 1989 American Academy of Pediatrics statement on this issue. (8/17)

http://pediatrics.aappublications.org/content/140/3/e20172274

ORAL AND DENTAL ASPECTS OF CHILD ABUSE AND NEGLECT (CLINICAL REPORT)

Susan A. Fisher-Owens, MD, MPH, FAAP; James L. Lukefahr, MD, FAAP; Anupama Rao Tate, DMD, MPH; Section on Oral Health; and Committee on Child Abuse and Neglect (joint with American Academy of Pediatric Dentistry Council on Clinical Affairs, Council on Scientific Affairs, and Ad Hoc Work Group on Child Abuse and Neglect)

ABSTRACT. In all 50 states, health care providers (including dentists) are mandated to report suspected cases of abuse and neglect to social service or law enforcement agencies. The purpose of this report is to review the oral and dental aspects of physical and sexual abuse and dental neglect in children and the role of pediatric care providers and dental providers in evaluating such conditions. This report addresses the evaluation of bite marks as well as perioral and intraoral injuries, infections, and diseases that may raise suspicion for child abuse or neglect. Oral health issues can also be associated with bullying and are commonly seen in human trafficking victims. Some medical providers may receive less education pertaining to oral health and dental injury and disease and may not detect the mouth and gum findings that are related to abuse or neglect as readily as they detect those involving other areas of the body. Therefore, pediatric care providers and dental providers are encouraged to collaborate to increase the prevention, detection, and treatment of these conditions in children. (7/17)

http://pediatrics.aappublications.org/content/140/2/e20171487

ORAL HEALTH CARE FOR CHILDREN WITH DEVELOPMENTAL DISABILITIES (CLINICAL REPORT)

Kenneth W. Norwood Jr, MD; Rebecca L. Slayton, DDS, PhD; Council on Children With Disabilities; and Section on Oral Health

ABSTRACT. Children with developmental disabilities often have unmet complex health care needs as well as significant physical and cognitive limitations. Children with more severe conditions and from low-income families are particularly at risk with high dental needs and poor access to care. In addition, children with developmental disabilities are living longer, requiring continued oral health care. This clinical report describes the effect that poor oral health has on children with developmental disabilities as well as the importance of partnerships between the pediatric medical and dental homes. Basic knowledge of the oral health risk factors affecting children with developmental disabilities is provided. Pediatricians may use the report to guide their incorporation of oral health assessments and education into their well-child examinations for children with developmental disabilities. This report has medical, legal, educational, and operational implications for practicing pediatricians. (2/13, reaffirmed 6/18)

http://pediatrics.aappublications.org/content/131/3/614

ORGANIC FOODS: HEALTH AND ENVIRONMENTAL ADVANTAGES AND DISADVANTAGES (CLINICAL REPORT)

Joel Forman, MD; Janet Silverstein, MD; Committee on Nutrition; and Council on Environmental Health

ABSTRACT. The US market for organic foods has grown from $3.5 billion in 1996 to $28.6 billion in 2010, according to the Organic Trade Association. Organic products are now sold in specialty stores and conventional supermarkets. Organic products contain numerous marketing claims and terms, only some of which are standardized and regulated.

In terms of health advantages, organic diets have been convincingly demonstrated to expose consumers to fewer pesticides associated with human disease. Organic farming has been demonstrated to have less environmental impact than conventional approaches. However, current evidence does not support any meaningful nutritional benefits or deficits from eating organic compared with conventionally grown foods, and there are no well-powered human studies that directly demonstrate health benefits or disease protection as a result of consuming an organic diet. Studies also have not demonstrated any detrimental or disease-promoting effects from an organic diet. Although organic foods regularly command a significant price premium, well-designed farming studies demonstrate that costs can be competitive and yields comparable to those of conventional farming techniques. Pediatricians should incorporate this evidence when discussing the health and environmental

impact of organic foods and organic farming while continuing to encourage all patients and their families to attain optimal nutrition and dietary variety consistent with the US Department of Agriculture's MyPlate recommendations.

This clinical report reviews the health and environmental issues related to organic food production and consumption. It defines the term "organic," reviews organic food-labeling standards, describes organic and conventional farming practices, and explores the cost and environmental implications of organic production techniques. It examines the evidence available on nutritional quality and production contaminants in conventionally produced and organic foods. Finally, this report provides guidance for pediatricians to assist them in advising their patients regarding organic and conventionally produced food choices. (10/12)

http://pediatrics.aappublications.org/content/130/5/e1406

ORGANIZED SPORTS FOR CHILDREN, PREADOLESCENTS, AND ADOLESCENTS (CLINICAL REPORT)

Kelsey Logan, MD, MPH, FAAP; Steven Cuff, MD, FAAP; and Council on Sports Medicine and Fitness

ABSTRACT. Interest and participation in organized sports for children, preadolescents, and adolescents continue to grow. Because of increased participation, and younger entry age, in organized sports, appropriate practice, game schedules, and content become more important, taking into account athlete developmental stage and skills. Parental support for organized sports in general, with focus on development and fun instead of winning, has emerged as a key factor in the athlete's enjoyment of sports. Schools and community sports organizations who support multiple levels of sport (eg, recreational, competitive, elite) can include more youth who want to play sports and combat sport dropout. This report reviews the benefits and risks of organized sports as well as the roles of schools, community organizations, parents, and coaches in organized sports. It is designed to complement the American Academy of Pediatrics clinical reports "Physical Activity Assessment and Counseling in Pediatric Clinical Settings" and "Sports Specialization and Intensive Training in Young Athletes" by reviewing relevant literature on healthy organized sports for youth and providing guidance on organized sport readiness and entry. The report also provides guidance for pediatricians on counseling parents and advocating for healthy organized sports participation. (5/19)

https://pediatrics.aappublications.org/content/143/6/e20190997

OUT-OF-HOME PLACEMENT FOR CHILDREN AND ADOLESCENTS WITH DISABILITIES (CLINICAL REPORT)

Sandra L. Friedman, MD, MPH, FAAP; Miriam A. Kalichman, MD, FAAP; and Council on Children With Disabilities

ABSTRACT. The vast majority of children and youth with chronic and complex health conditions who also have intellectual and developmental disabilities are cared for in their homes. Social, legal, policy, and medical changes through the years have allowed for an increase in needed support within the community. However, there continues to be a relatively small group of children who live in various types of congregate care settings. This clinical report describes these settings and the care and services that are provided in them. The report also discusses reasons families choose out-of-home placement for their children, barriers to placement, and potential effects of this decision on family members. We examine the pediatrician's role in caring for children with severe intellectual and developmental disabilities and complex medical problems in the context of responding to parental inquiries about out-of-home placement and understanding factors affecting these types of decisions. Common medical problems and care issues for children residing outside the family home are reviewed. Variations in state and federal regulations, challenges in understanding local systems, and access to services are also discussed. (9/14, reaffirmed 2/19)

http://pediatrics.aappublications.org/content/134/4/836

OUT-OF-HOME PLACEMENT FOR CHILDREN AND ADOLESCENTS WITH DISABILITIES—ADDENDUM: CARE OPTIONS FOR CHILDREN AND ADOLESCENTS WITH DISABILITIES AND MEDICAL COMPLEXITY (CLINICAL REPORT)

Sandra L. Friedman, MD, MPH, FAAP; Kenneth W. Norwood Jr, MD, FAAP; and Council on Children With Disabilities

ABSTRACT. Children and adolescents with significant intellectual and developmental disabilities and complex medical problems require safe and comprehensive care to meet their medical and psychosocial needs. Ideally, such children and youth should be cared for by their families in their home environments. When this type of arrangement is not possible, there should be exploration of appropriate, alternative noncongregate community-based settings, especially alternative family homes. Government funding sources exist to support care in the community, although there is variability among states with regard to the availability of community programs and resources. It is important that families are supported in learning about options of care. Pediatricians can serve as advocates for their patients and their families to access community-based services and to increase the availability of resources to ensure that the option to live in a family home is available to all children with complex medical needs. (11/16, reaffirmed 2/19)

http://pediatrics.aappublications.org/content/138/6/e20163216

OUT-OF-SCHOOL SUSPENSION AND EXPULSION

Council on School Health

ABSTRACT. The primary mission of any school system is to educate students. To achieve this goal, the school district must maintain a culture and environment where all students feel safe, nurtured, and valued and where order and civility are expected standards of behavior. Schools cannot allow unacceptable behavior to interfere with the school district's primary mission. To this end, school districts adopt codes of conduct for expected behaviors and policies to address unacceptable behavior. In developing these policies, school boards must weigh the severity of the offense and the consequences of the punishment and the balance between individual and institutional rights and responsibilities. Out-of-school suspension and expulsion are the most severe consequences that a school district can impose for unacceptable behavior. Traditionally, these consequences have been reserved for offenses deemed especially severe or dangerous and/or for recalcitrant offenders. However, the implications and consequences of out-of-school suspension and expulsion and "zero-tolerance" are of such severity that their application and appropriateness for a developing child require periodic review. The indications and effectiveness of exclusionary discipline policies that demand automatic or rigorous application are increasingly questionable. The impact of these policies on offenders, other children, school districts, and communities is broad. Periodic scrutiny of policies should be placed not only on the need for a better understanding of the educational, emotional, and social impact of out-of-school suspension and expulsion on the individual student but also on the greater societal costs of such rigid policies. Pediatricians should be prepared to assist students and families affected by out-of-school suspension and expulsion and should be willing to guide school districts in their communities to find more effective and appropriate alternatives to exclusionary discipline policies for the developing child. A discussion of preventive strategies and alternatives to out-of-school suspension and expulsion, as well as recommendations for the role of the physician in matters of out-of-school

suspension and expulsion are included. School-wide positive behavior support/positive behavior intervention and support is discussed as an effective alternative. (2/13)
http://pediatrics.aappublications.org/content/131/3/e1000

OVERCROWDING CRISIS IN OUR NATION'S EMERGENCY DEPARTMENTS: IS OUR SAFETY NET UNRAVELING?

Committee on Pediatric Emergency Medicine

ABSTRACT. Emergency departments (EDs) are a vital component in our health care safety net, available 24 hours a day, 7 days a week, for all who require care. There has been a steady increase in the volume and acuity of patient visits to EDs, now with well over 100 million Americans (30 million children) receiving emergency care annually. This rise in ED utilization has effectively saturated the capacity of EDs and emergency medical services in many communities. The resulting phenomenon, commonly referred to as ED overcrowding, now threatens access to emergency services for those who need them the most. As managers of the pediatric medical home and advocates for children and optimal pediatric health care, there is a very important role for pediatricians and the American Academy of Pediatrics in guiding health policy decision-makers toward effective solutions that promote the medical home and timely access to emergency care. (9/04, reaffirmed 5/07, 6/11, 7/16)
http://pediatrics.aappublications.org/content/114/3/878

OVERUSE INJURIES, OVERTRAINING, AND BURNOUT IN CHILD AND ADOLESCENT ATHLETES (CLINICAL REPORT)

Joel S. Brenner, MD, MPH, and Council on Sports Medicine and Fitness

ABSTRACT. Overuse is one of the most common etiologic factors that lead to injuries in the pediatric and adolescent athlete. As more children are becoming involved in organized and recreational athletics, the incidence of overuse injuries is increasing. Many children are participating in sports year-round and sometimes on multiple teams simultaneously. This overtraining can lead to burnout, which may have a detrimental effect on the child participating in sports as a lifelong healthy activity. One contributing factor to overtraining may be parental pressure to compete and succeed. The purpose of this clinical report is to assist pediatricians in identifying and counseling at-risk children and their families. This report supports the American Academy of Pediatrics policy statement on intensive training and sport specialization. (6/07, reaffirmed 3/11, 6/14)
http://pediatrics.aappublications.org/content/119/6/1242

OXYGEN TARGETING IN EXTREMELY LOW BIRTH WEIGHT INFANTS (CLINICAL REPORT)

James J. Cummings, MD, FAAP; Richard A. Polin, MD, FAAP; and Committee on Fetus and Newborn

ABSTRACT. The use of supplemental oxygen plays a vital role in the care of the critically ill preterm infant, but the unrestricted use of oxygen can lead to unintended harms, such as chronic lung disease and retinopathy of prematurity. An overly restricted use of supplemental oxygen may have adverse effects as well. Ideally, continuous monitoring of tissue and cellular oxygen delivery would allow clinicians to better titrate the use of supplemental oxygen, but such monitoring is not currently feasible in the clinical setting. The introduction of pulse oximetry has greatly aided the clinician by providing a relatively easy and continuous estimate of arterial oxygen saturation, but pulse oximetry has several practical, technical, and physiologic limitations. Recent randomized clinical trials comparing different pulse oximetry targets have been conducted to better inform the practice of supplemental oxygen use. This clinical report discusses the benefits and limitations of pulse oximetry for assessing oxygenation, summarizes randomized clinical trials of oxygen saturation targeting, and addresses implications for practice. (7/16)
http://pediatrics.aappublications.org/content/138/2/e20161576

PAIN ASSESSMENT AND TREATMENT IN CHILDREN WITH SIGNIFICANT IMPAIRMENT OF THE CENTRAL NERVOUS SYSTEM (CLINICAL REPORT)

Julie Hauer, MD, FAAP; Amy J. Houtrow, MD, PhD, MPH, FAAP; Section on Hospice and Palliative Medicine; and Council on Children With Disabilities

ABSTRACT. Pain is a frequent and significant problem for children with impairment of the central nervous system, with the highest frequency and severity occurring in children with the greatest impairment. Despite the significance of the problem, this population remains vulnerable to underrecognition and undertreatment of pain. Barriers to treatment may include uncertainty in identifying pain along with limited experience and fear with the use of medications for pain treatment. Behavioral pain-assessment tools are reviewed in this clinical report, along with other strategies for monitoring pain after an intervention. Sources of pain in this population include acute-onset pain attributable to tissue injury or inflammation resulting in nociceptive pain, with pain then expected to resolve after treatment directed at the source. Other sources can result in chronic intermittent pain that, for many, occurs on a weekly to daily basis, commonly attributed to gastroesophageal reflux, spasticity, and hip subluxation. Most challenging are pain sources attributable to the impaired central nervous system, requiring empirical medication trials directed at causes that cannot be identified by diagnostic tests, such as central neuropathic pain. Interventions reviewed include integrative therapies and medications, such as gabapentinoids, tricyclic antidepressants, α-agonists, and opioids. This clinical report aims to address, with evidence-based guidance, the inherent challenges with the goal to improve comfort throughout life in this vulnerable group of children. (5/17)
http://pediatrics.aappublications.org/content/139/6/e20171002

PARENTAL LEAVE FOR RESIDENTS AND PEDIATRIC TRAINING PROGRAMS

Section on Medical Students, Residents, and Fellowship Trainees and Committee on Early Childhood

ABSTRACT. The American Academy of Pediatrics (AAP) is committed to the development of rational, equitable, and effective parental leave policies that are sensitive to the needs of pediatric residents, families, and developing infants and that enable parents to spend adequate and good-quality time with their young children. It is important for each residency program to have a policy for parental leave that is written, that is accessible to residents, and that clearly delineates program practices regarding parental leave. At a minimum, a parental leave policy for residents and fellows should conform legally with the Family Medical Leave Act as well as with respective state laws and should meet institutional requirements of the Accreditation Council for Graduate Medical Education for accredited programs. Policies should be well formulated and communicated in a culturally sensitive manner. The AAP advocates for extension of benefits consistent with the Family Medical Leave Act to all residents and interns beginning at the time that pediatric residency training begins. The AAP recommends that regardless of gender, residents who become parents should be guaranteed 6 to 8 weeks, at a minimum, of parental leave with pay after the infant's birth. In addition, in conformance with federal law, the resident should be allowed to extend the leave time when necessary by using paid vacation time or leave without pay. Coparenting, adopting, or fostering of a child should entitle the resident, regardless of gender, to the same amount of paid leave (6–8 weeks) as a person who takes maternity/paternity leave.

Flexibility, creativity, and advanced planning are necessary to arrange schedules that optimize resident education and experience, cultivate equity in sharing workloads, and protect pregnant residents from overly strenuous work experiences at critical times of their pregnancies. (1/13, reaffirmed 4/19)
http://pediatrics.aappublications.org/content/131/2/387

PARENTAL PRESENCE DURING TREATMENT OF EBOLA OR OTHER HIGHLY CONSEQUENTIAL INFECTION (CLINICAL REPORT)

H. Dele Davies, MD, MS, MHCM, FAAP; Carrie L. Byington, MD, FAAP; and Committee on Infectious Diseases

ABSTRACT. This clinical report offers guidance to health care providers and hospitals on options to consider regarding parental presence at the bedside while caring for a child with suspected or proven Ebola virus disease (Ebola) or other highly consequential infection. Options are presented to help meet the needs of the patient and the family while also posing the least risk to providers and health care organizations. The optimal way to minimize risk is to limit contact between the person under investigation or treatment and family members/caregivers whenever possible while working to meet the emotional support needs of both patient and family. At times, caregiver presence may be deemed to be in the best interest of the patient, and in such situations, a strong effort should be made to limit potential risks of exposure to the caregiver, health care providers, and the community. The decision to allow parental/caregiver presence should be made in consultation with a team including an infectious diseases expert and state and/or local public health authorities and should involve consideration of many factors, depending on the stage of investigation and management, including (1) a careful history, physical examination, and investigations to elucidate the likelihood of the diagnosis of Ebola or other highly consequential infection; (2) ability of the facility to offer appropriate isolation for the person under investigation and family members and to manage Ebola; (3) ability to recognize and exclude people at increased risk of worse outcomes (eg, pregnant women); and (4) ability of parent/caregiver to follow instructions, including appropriate donning and doffing of personal protective equipment. (8/16)
http://pediatrics.aappublications.org/content/138/3/e20161891

PARENT-PROVIDER-COMMUNITY PARTNERSHIPS: OPTIMIZING OUTCOMES FOR CHILDREN WITH DISABILITIES (CLINICAL REPORT)

Nancy A. Murphy, MD; Paul S. Carbone, MD; and Council on Children With Disabilities

ABSTRACT. Children with disabilities and their families have multifaceted medical, developmental, educational, and habilitative needs that are best addressed through strong partnerships among parents, providers, and communities. However, traditional health care systems are designed to address acute rather than chronic conditions. Children with disabilities require high-quality medical homes that provide care coordination and transitional care, and their families require social and financial supports. Integrated community systems of care that promote participation of all children are needed. The purpose of this clinical report is to explore the challenges of developing effective community-based systems of care and to offer suggestions to pediatricians and policy-makers regarding the development of partnerships among children with disabilities, their families, and health care and other providers to maximize health and well-being of these children and their families. (9/11, reaffirmed 5/17)
http://pediatrics.aappublications.org/content/128/4/795

PARTICIPATION OF CHILDREN AND ADOLESCENTS IN LIVE CRISIS DRILLS AND EXERCISES

David J. Schonfeld, MD, FAAP; Marlene Melzer-Lange, MD, FAAP; Andrew N. Hashikawa, MD, MS, FAAP; Peter A. Gorski, MD, MPA, FAAP; Council on Children and Disasters; Council on Injury, Violence, and Poison Prevention; and Council on School Health

ABSTRACT. Children and adolescents should be included in exercises and drills to the extent that their involvement advances readiness to meet their unique needs in the event of a crisis and/or furthers their own preparedness or resiliency. However, there is also a need to be cautious about the potential psychological risks and other unintended consequences of directly involving children in live exercises and drills. These risks and consequences are especially a concern when children are deceived and led to believe there is an actual attack and not a drill and/or for high-intensity active shooter drills. High-intensity active shooter drills may involve the use of real weapons, gunfire or blanks, theatrical makeup to give a realistic image of blood or gunshot wounds, predatory and aggressive acting by the individual posing to be the shooter, or other means to simulate an actual attack, even when participants are aware that it is a drill. This policy statement outlines some of the considerations regarding the prevalent practice of live active shooter drills in schools, including the recommendations to eliminate children's involvement in high-intensity drills and exercises (with the possible exception of adolescent volunteers), prohibit deception in drills and exercises, and ensure appropriate accommodations during drills and exercises based on children's unique vulnerabilities. (8/20)
See full text on page 1009.
https://pediatrics.aappublications.org/content/146/3/e2020015503

PATENT DUCTUS ARTERIOSUS IN PRETERM INFANTS (CLINICAL REPORT)

William E. Benitz, MD, FAAP, and Committee on Fetus and Newborn

ABSTRACT. Despite a large body of basic science and clinical research and clinical experience with thousands of infants over nearly 6 decades, there is still uncertainty and controversy about the significance, evaluation, and management of patent ductus arteriosus in preterm infants, resulting in substantial heterogeneity in clinical practice. The purpose of this clinical report is to summarize the evidence available to guide evaluation and treatment of preterm infants with prolonged ductal patency in the first few weeks after birth. (12/15)
http://pediatrics.aappublications.org/content/137/1/e20153730

PATIENT- AND FAMILY-CENTERED CARE AND THE PEDIATRICIAN'S ROLE

Committee on Hospital Care and Institute for Patient- and Family-Centered Care

ABSTRACT. Drawing on several decades of work with families, pediatricians, other health care professionals, and policy makers, the American Academy of Pediatrics provides a definition of patient- and family-centered care. In pediatrics, patient- and family-centered care is based on the understanding that the family is the child's primary source of strength and support. Further, this approach to care recognizes that the perspectives and information provided by families, children, and young adults are essential components of high-quality clinical decision-making, and that patients and family are integral partners with the health care team. This policy statement outlines the core principles of patient- and family-centered care, summarizes some of the recent literature linking patient- and family-centered care to improved health outcomes, and lists various other benefits to be expected when engaging in patient- and family-centered pediatric practice. The statement concludes with specific recommendations

for how pediatricians can integrate patient- and family-centered care in hospitals, clinics, and community settings, and in broader systems of care, as well. (1/12, reaffirmed 2/18)
http://pediatrics.aappublications.org/content/129/2/394

PATIENT- AND FAMILY-CENTERED CARE AND THE ROLE OF THE EMERGENCY PHYSICIAN PROVIDING CARE TO A CHILD IN THE EMERGENCY DEPARTMENT

Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians)

ABSTRACT. Patient- and family-centered care is an approach to health care that recognizes the role of the family in providing medical care; encourages collaboration between the patient, family, and health care professionals; and honors individual and family strengths, cultures, traditions, and expertise. Although there are many opportunities for providing patient- and family-centered care in the emergency department, there are also challenges to doing so. The American Academy of Pediatrics and the American College of Emergency Physicians support promoting patient dignity, comfort, and autonomy; recognizing the patient and family as key decision-makers in the patient's medical care; recognizing the patient's experience and perspective in a culturally sensitive manner; acknowledging the interdependence of child and parent as well as the pediatric patient's evolving independence; encouraging family-member presence; providing information to the family during interventions; encouraging collaboration with other health care professionals; acknowledging the importance of the patient's medical home; and encouraging institutional policies for patient- and family-centered care. (11/06, reaffirmed 6/09, 10/11, 9/15, 10/19)
http://pediatrics.aappublications.org/content/118/5/2242

PATIENT- AND FAMILY-CENTERED CARE COORDINATION: A FRAMEWORK FOR INTEGRATING CARE FOR CHILDREN AND YOUTH ACROSS MULTIPLE SYSTEMS

Council on Children With Disabilities and Medical Home Implementation Project Advisory Committee

ABSTRACT. Understanding a care coordination framework, its functions, and its effects on children and families is critical for patients and families themselves, as well as for pediatricians, pediatric medical subspecialists/surgical specialists, and anyone providing services to children and families. Care coordination is an essential element of a transformed American health care delivery system that emphasizes optimal quality and cost outcomes, addresses family-centered care, and calls for partnership across various settings and communities. High-quality, cost-effective health care requires that the delivery system include elements for the provision of services supporting the coordination of care across settings and professionals. This requirement of supporting coordination of care is generally true for health systems providing care for all children and youth but especially for those with special health care needs. At the foundation of an efficient and effective system of care delivery is the patient-/family-centered medical home. From its inception, the medical home has had care coordination as a core element. In general, optimal outcomes for children and youth, especially those with special health care needs, require interfacing among multiple care systems and individuals, including the following: medical, social, and behavioral professionals; the educational system; payers; medical equipment providers; home care agencies; advocacy groups; needed supportive therapies/services; and families. Coordination of care across settings permits an integration of services that is centered on the comprehensive needs of the patient and family, leading to decreased health care costs, reduction in fragmented care, and improvement in the patient/family experience of care. (4/14, reaffirmed 4/18)
http://pediatrics.aappublications.org/content/133/5/e1451

PATIENT- AND FAMILY-CENTERED CARE OF CHILDREN IN THE EMERGENCY DEPARTMENT (TECHNICAL REPORT)

Nanette Dudley, MD, FAAP; Alice Ackerman, MD, MBA, FAAP; Kathleen M. Brown, MD, FACEP; Sally K. Snow, BSN, RN, CPEN, FAEN; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. Patient- and family-centered care is an approach to the planning, delivery, and evaluation of health care that is grounded in a mutually beneficial partnership among patients, families, and health care professionals. Providing patient- and family-centered care to children in the emergency department setting presents many opportunities and challenges. This revised technical report draws on previously published policy statements and reports, reviews the current literature, and describes the present state of practice and research regarding patient- and family-centered care for children in the emergency department setting as well as some of the complexities of providing such care. (12/14, reaffirmed 10/19)
http://pediatrics.aappublications.org/content/135/1/e255

PATIENT SAFETY IN THE PEDIATRIC EMERGENCY CARE SETTING

Committee on Pediatric Emergency Medicine

ABSTRACT. Patient safety is a priority for all health care professionals, including those who work in emergency care. Unique aspects of pediatric care may increase the risk of medical error and harm to patients, especially in the emergency care setting. Although errors can happen despite the best human efforts, given the right set of circumstances, health care professionals must work proactively to improve safety in the pediatric emergency care system. Specific recommendations to improve pediatric patient safety in the emergency department are provided in this policy statement. (12/07, reaffirmed 6/11, 7/14, 8/18)
http://pediatrics.aappublications.org/content/120/6/1367

PEDESTRIAN SAFETY

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Each year, approximately 900 pediatric pedestrians younger than 19 years are killed. In addition, 51000 children are injured as pedestrians, and 5300 of them are hospitalized because of their injuries. Parents should be warned that young children often do not have the cognitive, perceptual, and behavioral abilities to negotiate traffic independently. Parents should also be informed about the danger of vehicle back-over injuries to toddlers playing in driveways. Because posttraumatic stress syndrome commonly follows even minor pedestrian injury, pediatricians should screen and refer for this condition as necessary. The American Academy of Pediatrics supports community- and school-based strategies that minimize a child's exposure to traffic, especially to high-speed, high-volume traffic. Furthermore, the American Academy of Pediatrics supports governmental and industry action that would lead to improvements in vehicle design, driver manuals, driver education, and data collection for the purpose of reducing pediatric pedestrian injury. (7/09, reaffirmed 8/13, 5/19)
http://pediatrics.aappublications.org/content/124/2/802

PEDIATRIC AND ADOLESCENT MENTAL HEALTH EMERGENCIES IN THE EMERGENCY MEDICAL SERVICES SYSTEM (TECHNICAL REPORT)

Margaret A. Dolan, MD; Joel A. Fein, MD, MPH; and Committee on Pediatric Emergency Medicine

ABSTRACT. Emergency department (ED) health care professionals often care for patients with previously diagnosed psychiatric illnesses who are ill, injured, or having a behavioral crisis. In addition, ED personnel encounter children with psychiatric

illnesses who may not present to the ED with overt mental health symptoms. Staff education and training regarding identification and management of pediatric mental health illness can help EDs overcome the perceived limitations of the setting that influence timely and comprehensive evaluation. In addition, ED physicians can inform and advocate for policy changes at local, state, and national levels that are needed to ensure comprehensive care of children with mental health illnesses. This report addresses the roles that the ED and ED health care professionals play in emergency mental health care of children and adolescents in the United States, which includes the stabilization and management of patients in mental health crisis, the discovery of mental illnesses and suicidal ideation in ED patients, and approaches to advocating for improved recognition and treatment of mental illnesses in children. The report also addresses special issues related to mental illness in the ED, such as minority populations, children with special health care needs, and children's mental health during and after disasters and trauma. (4/11, reaffirmed 7/14, 4/20)
http://pediatrics.aappublications.org/content/127/5/e1356

PEDIATRIC ANTHRAX CLINICAL MANAGEMENT (CLINICAL REPORT)

John S. Bradley, MD, FAAP, FIDSA, FPIDS; Georgina Peacock, MD, MPH, FAAP; Steven E. Krug, MD, FAAP; William A. Bower, MD, FIDSA; Amanda C. Cohn, MD; Dana Meaney-Delman, MD, MPH, FACOG; Andrew T. Pavia, MD, FAAP, FIDSA; Committee on Infectious Diseases; and Disaster Preparedness Advisory Council

ABSTRACT. Anthrax is a zoonotic disease caused by *Bacillus anthracis,* which has multiple routes of infection in humans, manifesting in different initial presentations of disease. Because *B anthracis* has the potential to be used as a biological weapon and can rapidly progress to systemic anthrax with high mortality in those who are exposed and untreated, clinical guidance that can be quickly implemented must be in place before any intentional release of the agent. This document provides clinical guidance for the prophylaxis and treatment of neonates, infants, children, adolescents, and young adults up to the age of 21 (referred to as "children") in the event of a deliberate *B anthracis* release and offers guidance in areas where the unique characteristics of children dictate a different clinical recommendation from adults. (4/14)
http://pediatrics.aappublications.org/content/133/5/e1411

PEDIATRIC ANTHRAX CLINICAL MANAGEMENT: EXECUTIVE SUMMARY

John S. Bradley, MD, FAAP, FIDSA, FPIDS; Georgina Peacock, MD, MPH, FAAP; Steven E. Krug, MD, FAAP; William A. Bower, MD, FIDSA; Amanda C. Cohn, MD; Dana Meaney-Delman, MD, MPH, FACOG; Andrew T. Pavia, MD, FAAP, FIDSA; Committee on Infectious Diseases; and Disaster Preparedness Advisory Council

The use of *Bacillus anthracis* as a biological weapon is considered a potential national security threat by the US government. *B anthracis* has the ability to be used as a biological weapon and to cause anthrax, which can rapidly progress to systemic disease with high mortality in those who are untreated. Therefore, clear plans for managing children after a *B anthracis* bioterror exposure event must be in place before any intentional release of the agent. This document provides a summary of the guidance contained in the clinical report (appendices cited in this executive summary refer to those in the clinical report) for diagnosis and management of anthrax, including antimicrobial treatment and postexposure prophylaxis (PEP), use of antitoxin, and recommendations for use of anthrax vaccine in neonates, infants, children, adolescents, and young adults up to the age of 21 years (referred to as "children"). (4/14)
http://pediatrics.aappublications.org/content/133/5/940

PEDIATRIC APPLICATION OF CODING AND VALUATION SYSTEMS

David M. Kanter, MD, MBA, FAAP; Richard Lander, MD, FAAP, CIC; Richard A. Molteni, MD, FAAP; Committee on Coding and Nomenclature; and Private Payer Advocacy Advisory Committee

ABSTRACT. The American Academy of Pediatrics provides this revised policy statement to address health care changes that impact procedural and visit coding and valuation as well as the incorporation of coding principles into innovative, newer payment models. This policy statement focuses solely on recommendations, and an accompanying technical report provides supplemental coding and valuation background. (9/19)
https://pediatrics.aappublications.org/content/144/4/e20192496

PEDIATRIC APPLICATION OF CODING AND VALUATION SYSTEMS (TECHNICAL REPORT)

David M. Kanter, MD, MBA, FAAP; Richard A. Molteni, MD, FAAP; and Committee on Coding and Nomenclature

ABSTRACT. The American Academy of Pediatrics provides this technical report as supplemental background to the accompanying coding and valuation system policy statement. The rapid evolution in health care payment modeling requires that clinicians have a current appreciation of the mechanics of service representation and valuation. The accompanying policy statement provides recommendations relevant to this area, and this technical report provides a format to outline important concepts that allow for effective translation of bedside clinical events into physician payment. (9/19)
https://pediatrics.aappublications.org/content/144/4/e20192498

PEDIATRIC ASPECTS OF INPATIENT HEALTH INFORMATION TECHNOLOGY SYSTEMS (TECHNICAL REPORT)

Christoph U. Lehmann, MD, FAAP, FACMI, and Council on Clinical Information Technology

ABSTRACT. In the past 3 years, the Health Information Technology for Economic and Clinical Health Act accelerated the adoption of electronic health records (EHRs) with providers and hospitals, who can claim incentive monies related to meaningful use. Despite the increase in adoption of commercial EHRs in pediatric settings, there has been little support for EHR tools and functionalities that promote pediatric quality improvement and patient safety, and children remain at higher risk than adults for medical errors in inpatient environments. Health information technology (HIT) tailored to the needs of pediatric health care providers can improve care by reducing the likelihood of errors through information assurance and minimizing the harm that results from errors. This technical report outlines pediatric-specific concepts, child health needs and their data elements, and required functionalities in inpatient clinical information systems that may be missing in adult-oriented HIT systems with negative consequences for pediatric inpatient care. It is imperative that inpatient (and outpatient) HIT systems be adapted to improve their ability to properly support safe health care delivery for children. (2/15)
http://pediatrics.aappublications.org/content/135/3/e756

PEDIATRIC CONSIDERATIONS BEFORE, DURING, AND AFTER RADIOLOGICAL OR NUCLEAR EMERGENCIES

Jerome A. Paulson, MD, FAAP, and Council on Environmental Health

ABSTRACT. Infants, children, and adolescents can be exposed unexpectedly to ionizing radiation from nuclear power plant events, improvised nuclear or radiologic dispersal device explosions, or inappropriate disposal of radiotherapy equipment. Children are likely to experience higher external and internal radiation exposure levels than adults because of their smaller body and organ size and other physiologic characteristics, by picking up contaminated items, and through consumption

of contaminated milk or foodstuffs. This policy statement and accompanying technical report update the 2003 American Academy of Pediatrics policy statement on pediatric radiation emergencies by summarizing newer scientific knowledge from studies of the Chernobyl and Fukushima Daiichi nuclear power plant events, use of improvised radiologic dispersal devices, exposures from inappropriate disposal of radiotherapy equipment, and potential health effects from residential proximity to nuclear plants. Policy recommendations are made for providers and governments to improve future responses to these types of events. (11/18)

http://pediatrics.aappublications.org/content/142/6/e20183000

PEDIATRIC CONSIDERATIONS BEFORE, DURING, AND AFTER RADIOLOGICAL OR NUCLEAR EMERGENCIES (TECHNICAL REPORT)

Martha S. Linet, MD, MPH; Ziad Kazzi, MD; Jerome A. Paulson, MD, FAAP; and Council on Environmental Health

ABSTRACT. Infants, children, and adolescents can be exposed unexpectedly to ionizing radiation from nuclear power plant events, improvised nuclear or radiologic dispersal device explosions, or inappropriate disposal of radiotherapy equipment. Children are likely to experience higher external and internal radiation exposure levels than adults because of their smaller body and organ size and other physiologic characteristics as well as their tendency to pick up contaminated items and consume contaminated milk or foodstuffs. This technical report accompanies the revision of the 2003 American Academy of Pediatrics policy statement on pediatric radiation emergencies by summarizing newer scientific data from studies of the Chernobyl and the Fukushima Daiichi nuclear power plant events, use of improvised radiologic dispersal devices, exposures from inappropriate disposal of radiotherapy equipment, and potential health effects from residential proximity to nuclear plants. Also included are recommendations from epidemiological studies and biokinetic models to address mitigation efforts. The report includes major emphases on acute radiation syndrome, acute and long-term psychological effects, cancer risks, and other late tissue reactions after low-to-high levels of radiation exposure. Results, along with public health and clinical implications, are described from studies of the Japanese atomic bomb survivors, nuclear plant accidents (eg, Three Mile Island, Chernobyl, and Fukushima), improper disposal of radiotherapy equipment in Goiania, Brazil, and residence in proximity to nuclear plants. Measures to reduce radiation exposure in the immediate aftermath of a radiologic or nuclear disaster are described, including the diagnosis and management of external and internal contamination, use of potassium iodide, and actions in relation to breastfeeding. (11/18)

http://pediatrics.aappublications.org/content/142/6/e20183001

PEDIATRIC INTEGRATIVE MEDICINE (CLINICAL REPORT)

Hilary McClafferty, MD, FAAP; Sunita Vohra, MD, FAAP; Michelle Bailey, MD, FAAP; Melanie Brown, MD, MSE, FAAP; Anna Esparham, MD, FAAP; Dana Gerstbacher, MD, FAAP; Brenda Golianu, MD, FAAP; Anna-Kaisa Niemi, MD, PhD, FAAP, FACMG; Erica Sibinga, MD, FAAP; Joy Weydert, MD, FAAP; Ann Ming Yeh, MD; and Section on Integrative Medicine

ABSTRACT. The American Academy of Pediatrics is dedicated to optimizing the well-being of children and advancing family-centered health care. Related to this mission, the American Academy of Pediatrics recognizes the increasing use of complementary and integrative therapies for children and the subsequent need to provide reliable information and high-quality clinical resources to support pediatricians. This Clinical Report serves as an update to the original 2008 statement on complementary medicine. The range of complementary therapies is both extensive and diverse. Therefore, in-depth discussion of each therapy or product is beyond the scope of this report. Instead, our intentions are to define terms; describe epidemiology of use; outline common types of complementary therapies; review medicolegal, ethical, and research implications; review education and training for select providers of complementary therapies; provide educational resources; and suggest communication strategies for discussing complementary therapies with patients and families. (8/17)

http://pediatrics.aappublications.org/content/140/3/e20171961

PEDIATRIC MEDICATION SAFETY IN THE EMERGENCY DEPARTMENT

Lee Benjamin, MD, FAAP, FACEP; Karen Frush, MD, FAAP; Kathy Shaw, MD, MSCE, FAAP; Joan E. Shook, MD, MBA, FAAP; Sally K. Snow, BSN, RN, CPEN, FAEN; and Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Emergency Medicine Committee)

ABSTRACT. Pediatric patients cared for in emergency departments (EDs) are at high risk of medication errors for a variety of reasons. A multidisciplinary panel was convened by the Emergency Medical Services for Children program and the American Academy of Pediatrics Committee on Pediatric Emergency Medicine to initiate a discussion on medication safety in the ED. Top opportunities identified to improve medication safety include using kilogram-only weight-based dosing, optimizing computerized physician order entry by using clinical decision support, developing a standard formulary for pediatric patients while limiting variability of medication concentrations, using pharmacist support within EDs, enhancing training of medical professionals, systematizing the dispensing and administration of medications within the ED, and addressing challenges for home medication administration before discharge. (2/18)

http://pediatrics.aappublications.org/content/141/3/e20174066

PEDIATRIC MENTAL HEALTH EMERGENCIES IN THE EMERGENCY MEDICAL SERVICES SYSTEM

Committee on Pediatric Emergency Medicine (joint with American College of Emergency Physicians)

ABSTRACT. Emergency departments are vital in the management of pediatric patients with mental health emergencies. Pediatric mental health emergencies are an increasing part of emergency medical practice because emergency departments have become the safety net for a fragmented mental health infrastructure that is experiencing critical shortages in services in all sectors. Emergency departments must safely, humanely, and in a culturally and developmentally appropriate manner manage pediatric patients with undiagnosed and known mental illnesses, including those with mental retardation, autistic spectrum disorders, and attention-deficit/hyperactivity disorder and those experiencing a behavioral crisis. Emergency departments also manage patients with suicidal ideation, depression, escalating aggression, substance abuse, posttraumatic stress disorder, and maltreatment and those exposed to violence and unexpected deaths. Emergency departments must address not only the physical but also the mental health needs of patients during and after mass-casualty incidents and disasters. The American Academy of Pediatrics and the American College of Emergency Physicians support advocacy for increased mental health resources, including improved pediatric mental health tools for the emergency department, increased mental health insurance coverage, and adequate reimbursement at all levels; acknowledgment of the importance of the child's medical home; and promotion of education and research for mental health emergencies. (10/06, reaffirmed 6/09, 4/13, 4/20)

http://pediatrics.aappublications.org/content/118/4/1764

PEDIATRIC METABOLIC AND BARIATRIC SURGERY: EVIDENCE, BARRIERS, AND BEST PRACTICES

Sarah C. Armstrong, MD, FAAP; Christopher F. Bolling, MD, FAAP; Marc P. Michalsky, MD, FACS, FAAP, FASMBS; Kirk W. Reichard, MD, MBA, FAAP, FACS; Section on Obesity; and Section on Surgery

ABSTRACT. Severe obesity among youth is an "epidemic within an epidemic" and portends a shortened life expectancy for today's children compared with those of their parents' generation. Severe obesity has outpaced less severe forms of childhood obesity in prevalence, and it disproportionately affects adolescents. Emerging evidence has linked severe obesity to the development and progression of multiple comorbid states, including increased cardiometabolic risk resulting in end-organ damage in adulthood. Lifestyle modification treatment has achieved moderate short-term success among young children and those with less severe forms of obesity, but no studies to date demonstrate significant and durable weight loss among youth with severe obesity. Metabolic and bariatric surgery has emerged as an important treatment for adults with severe obesity and, more recently, has been shown to be a safe and effective strategy for groups of youth with severe obesity. However, current data suggest that youth with severe obesity may not have adequate access to metabolic and bariatric surgery, especially among underserved populations. This report outlines the current evidence regarding adolescent bariatric surgery, provides recommendations for practitioners and policy makers, and serves as a companion to an accompanying technical report, "Metabolic and Bariatric Surgery for Pediatric Patients With Severe Obesity," which provides details and supporting evidence. (11/19)

https://pediatrics.aappublications.org/content/144/6/e20193223

PEDIATRIC OBSERVATION UNITS (CLINICAL REPORT)

Gregory P. Conners, MD, MPH, MBA; Sanford M. Melzer, MD, MBA; Committee on Hospital Care; and Committee on Pediatric Emergency Medicine

ABSTRACT. Pediatric observation units (OUs) are hospital areas used to provide medical evaluation and/or management for health-related conditions in children, typically for a well-defined, brief period. Pediatric OUs represent an emerging alternative site of care for selected groups of children who historically may have received their treatment in an ambulatory setting, emergency department, or hospital-based inpatient unit. This clinical report provides an overview of pediatric OUs, including the definitions and operating characteristics of different types of OUs, quality considerations and coding for observation services, and the effect of OUs on inpatient hospital utilization. (6/12, reaffirmed 9/15)

http://pediatrics.aappublications.org/content/130/1/172

PEDIATRIC ORGAN DONATION AND TRANSPLANTATION

Committee on Hospital Care, Section on Surgery, and Section on Critical Care

ABSTRACT. Pediatric organ donation and organ transplantation can have a significant life-extending benefit to the young recipients of these organs and a high emotional impact on donor and recipient families. Pediatricians, pediatric medical specialists, and pediatric transplant surgeons need to be better acquainted with evolving national strategies that involve organ procurement and organ transplantation to help acquaint families with the benefits and risks of organ donation and transplantation. Efforts of pediatric professionals are needed to shape public policies to provide a system in which procurement, distribution, and cost are fair and equitable to children and adults. Major issues of concern are availability of and access to donor organs; oversight and control of the process; pediatric medical and surgical consultation and continued care throughout the organ-donation and transplantation process; ethical, social, financial, and follow-up issues; insurance-coverage issues; and public awareness of the need for organ donors of all ages. (3/10, reaffirmed 3/14, 4/19)

http://pediatrics.aappublications.org/content/125/4/822

PEDIATRIC PALLIATIVE CARE AND HOSPICE CARE COMMITMENTS, GUIDELINES, AND RECOMMENDATIONS

Section on Hospice and Palliative Medicine and Committee on Hospital Care

ABSTRACT. Pediatric palliative care and pediatric hospice care (PPC-PHC) are often essential aspects of medical care for patients who have life-threatening conditions or need end-of-life care. PPC-PHC aims to relieve suffering, improve quality of life, facilitate informed decision-making, and assist in care coordination between clinicians and across sites of care. Core commitments of PPC-PHC include being patient centered and family engaged; respecting and partnering with patients and families; pursuing care that is high quality, readily accessible, and equitable; providing care across the age spectrum and life span, integrated into the continuum of care; ensuring that all clinicians can provide basic palliative care and consult PPC-PHC specialists in a timely manner; and improving care through research and quality improvement efforts. PPC-PHC guidelines and recommendations include ensuring that all large health care organizations serving children with life-threatening conditions have dedicated interdisciplinary PPC-PHC teams, which should develop collaborative relationships between hospital- and community-based teams; that PPC-PHC be provided as integrated multimodal care and practiced as a cornerstone of patient safety and quality for patients with life-threatening conditions; that PPC-PHC teams should facilitate clear, compassionate, and forthright discussions about medical issues and the goals of care and support families, siblings, and health care staff; that PPC-PHC be part of all pediatric education and training curricula, be an active area of research and quality improvement, and exemplify the highest ethical standards; and that PPC-PHC services be supported by financial and regulatory arrangements to ensure access to high-quality PPC-PHC by all patients with life-threatening and life-shortening diseases. (10/13, reaffirmed 4/19)

http://pediatrics.aappublications.org/content/132/5/966

PEDIATRIC PRIMARY HEALTH CARE

Committee on Pediatric Workforce

ABSTRACT. Primary health care is described as accessible and affordable, first contact, continuous and comprehensive, and coordinated to meet the health needs of the individual and the family being served.

Pediatric primary health care encompasses health supervision and anticipatory guidance; monitoring physical and psychosocial growth and development; age-appropriate screening; diagnosis and treatment of acute and chronic disorders; management of serious and life-threatening illness and, when appropriate, referral of more complex conditions; and provision of first contact care as well as coordinated management of health problems requiring multiple professional services.

Pediatric primary health care for children and adolescents is family centered and incorporates community resources and strengths, needs and risk factors, and sociocultural sensitivities into strategies for care delivery and clinical practice. Pediatric primary health care is best delivered within the context of a "medical home," where comprehensive, continuously accessible and affordable care is available and delivered or supervised by qualified child health specialists.

The pediatrician, because of training (which includes 4 years of medical school education, plus an additional 3 or more years of intensive training devoted solely to all aspects of medical care for children and adolescents), coupled with the demonstrated interest in and total professional commitment to the health care of infants, children, adolescents, and young adults, is the most

appropriate provider of pediatric primary health care. (1/11, reaffirmed 10/13, 5/17, 4/20)
http://pediatrics.aappublications.org/content/127/2/397

PEDIATRIC READINESS IN EMERGENCY MEDICAL SERVICES SYSTEMS

Brian Moore, MD, FAAP; Manish I. Shah, MD, MS, FAAP; Sylvia Owusu-Ansah, MD, MPH, FAAP; Toni Gross, MD, MPH, FAAP; Kathleen Brown, MD, FAAP; Marianne Gausche-Hill, MD, FACEP, FAAP, FAEMS; Katherine Remick, MD, FACEP, FAAP, FAEMS; Kathleen Adelgais, MD, MPH, FAAP; John Lyng, MD, FAEMS, FACEP, NRP; Lara Rappaport, MD, MPH, FAAP; Sally Snow, RN, BSN, CPEN, FAEN; Cynthia Wright-Johnson, MSN, RNC; Julie C. Leonard, MD, MPH, FAAP; Committee on Pediatric Emergency Medicine; Section on Emergency Medicine; and EMS Subcommittee (joint with American College of Emergency Physicians Emergency Medical Services Committee; Emergency Nurses Association Pediatric Committee; National Association of Emergency Medical Services Physicians Standards and Clinical Practice Committee; and National Association of Emergency Medical Technicians Medical Technicians Emergency Pediatric Care Committee)

ABSTRACT. Prehospital emergency care typically involves emergency medical technicians, paramedics, and other licensed medical providers who work in emergency medical services (EMS) systems in ground ambulances and fixed- or rotor-wing aircraft that are dispatched to an emergency when either a bystander calls 9-1-1 or when a patient requires interfacility transport for a medical illness or traumatic injury. Because prehospital emergency care of children plays a critical role in the continuum of health care, which also involves primary prevention, hospital-based acute care, rehabilitation, and return to the medical home, the unique needs of children must be addressed by EMS systems. Pediatric readiness encompasses the presence of equipment and medications, usage of guidelines and policies, availability of education and training, incorporation of performance-improvement practices, and integration of EMS physician medical oversight to equip EMS systems to deliver optimal care to children. It has been shown that emergency departments are more prepared to care for children when a pediatric emergency care coordinator is responsible for championing and making recommendations for policies, training, and resources pertinent to the emergency care of children. The specialty of EMS medicine has the potential to derive similar benefits when members of the EMS community are personally invested in pediatric patient care. Although a critical aspect of pediatric readiness in EMS involves strong EMS physician oversight of these investments, a discussion of physician oversight of pediatric care in EMS is outside the scope of this article. This topic is, however, well addressed in the National Association of Emergency Medical Services Physicians position statement "Physician Oversight of Pediatric Care in Emergency Medical Services." This policy statement is accompanied by a technical report published simultaneously in this issue of *Pediatrics*. (12/19)

See full text on page 1019.

https://pediatrics.aappublications.org/content/145/1/e20193307

PEDIATRIC READINESS IN EMERGENCY MEDICAL SERVICES SYSTEMS (TECHNICAL REPORT)

Sylvia Owusu-Ansah, MD, MPH, FAAP; Brian Moore, MD, FAAP; Manish I. Shah, MD, MS, FAAP; Toni Gross, MD, MPH, FAAP; Kathleen Brown, MD, FAAP; Marianne Gausche-Hill, MD, FACEP, FAAP, FAEMS; Katherine Remick, MD, FACEP, FAAP, FAEMS; Kathleen Adelgais, MD, MPH, FAAP; Lara Rappaport, MD, MPH, FAAP; Sally Snow, RN, BSN, CPEN, FAEN; Cynthia Wright-Johnson, MSN, RNC; Julie C. Leonard, MD, MPH, FAAP; John Lyng, MD, FAEMS, FACEP, NRP; Mary Fallat, MD, FACS, FAAP; Committee on Pediatric Emergency Medicine; Section on Emergency Medicine; EMS Subcommittee; and Section on Surgery

ABSTRACT. Ill and injured children have unique needs that can be magnified when the child's ailment is serious or life-threatening. This is especially true in the out-of-hospital environment. Providing high-quality out-of-hospital care to children requires an emergency medical services (EMS) system infrastructure designed to support the care of pediatric patients. As in the emergency department setting, it is important that all EMS agencies have the appropriate resources, including physician oversight, trained and competent staff, education, policies, medications, equipment, and supplies, to provide effective emergency care for children. Resource availability across EMS agencies is variable, making it essential that EMS medical directors, administrators, and personnel collaborate with outpatient and hospital-based pediatric experts, especially those in emergency departments, to optimize prehospital emergency care for children. The principles in the policy statement "Pediatric Readiness in Emergency Medical Services Systems" and this accompanying technical report establish a foundation on which to build optimal pediatric care within EMS systems and serve as a resource for clinical and administrative EMS leaders. (12/19)

See full text on page 1027.

https://pediatrics.aappublications.org/content/145/1/e20193308

PEDIATRIC READINESS IN THE EMERGENCY DEPARTMENT

Katherine Remick, MD, FAAP, FACEP, FAEMS; Marianne Gausche-Hill, MD, FAAP, FACEP, FAEMS; Madeline M. Joseph, MD, FAAP, FACEP; Kathleen Brown, MD, FAAP, FACEP; Sally K. Snow, BSN, RN, CPEN, FAEN; Joseph L. Wright, MD, MPH, FAAP; Committee on Pediatric Emergency Medicine; and Section on Surgery (joint with American College of Emergency Physicians Pediatric Emergency Medicine Committee and Emergency Nurses Association Pediatric Committee)

ABSTRACT. This is a revision of the previous joint Policy Statement titled "Guidelines for Care of Children in the Emergency Department." Children have unique physical and psychosocial needs that are heightened in the setting of serious or life-threatening emergencies. The majority of children who are ill and injured are brought to community hospital emergency departments (EDs) by virtue of proximity. It is therefore imperative that all EDs have the appropriate resources (medications, equipment, policies, and education) and capable staff to provide effective emergency care for children. In this Policy Statement, we outline the resources necessary for EDs to stand ready to care for children of all ages. These recommendations are consistent with the recommendations of the Institute of Medicine (now called the National Academy of Medicine) in its report "The Future of Emergency Care in the US Health System." Although resources within emergency and trauma care systems vary locally, regionally, and nationally, it is essential that ED staff, administrators, and medical directors seek to meet or exceed these recommendations to ensure that high-quality emergency care is available for all children. These updated recommendations are intended to serve as a resource for clinical and administrative leadership in EDs as they strive to improve their readiness for children of all ages. (10/18)

http://pediatrics.aappublications.org/content/142/5/e20182459

PEDIATRIC SUDDEN CARDIAC ARREST

Section on Cardiology and Cardiac Surgery

ABSTRACT. Pediatric sudden cardiac arrest (SCA), which can cause sudden cardiac death if not treated within minutes, has a profound effect on everyone: children, parents, family members, communities, and health care providers. Preventing the tragedy of pediatric SCA, defined as the abrupt and unexpected loss of heart function, remains a concern to all. The goal of this

statement is to increase the knowledge of pediatricians (including primary care providers and specialists) of the incidence of pediatric SCA, the spectrum of causes of pediatric SCA, disease-specific presentations, the role of patient and family screening, the rapidly evolving role of genetic testing, and finally, important aspects of secondary SCA prevention. This statement is not intended to address sudden infant death syndrome or sudden unexplained death syndrome, nor will specific treatment of individual cardiac conditions be discussed. This statement has been endorsed by the American College of Cardiology, the American Heart Association, and the Heart Rhythm Society. (3/12)
http://pediatrics.aappublications.org/content/129/4/e1094

PEDIATRICIAN GUIDANCE IN SUPPORTING FAMILIES OF CHILDREN WHO ARE ADOPTED, FOSTERED, OR IN KINSHIP CARE (CLINICAL REPORT)

Veronnie F. Jones, MD, MSPH, FAAP; Elaine E. Schulte, MD, MPH, FAAP; Douglas Waite, MD, FAAP; and Council on Foster Care, Adoption, and Kinship Care

ABSTRACT. The child welfare system strives to provide children and adolescents in foster care with a safe, nurturing environment through kinship and nonkinship foster care placement with the goal of either reunification with birth parents or adoption. Pediatricians can support families who care for children and adolescents who are fostered and adopted while attending to children's medical needs and helping each child attain their developmental potential. Although this report primarily focuses on children in the US child welfare system, private and internationally adopted children often have similar needs. (11/20)
See full text on page 1045.
https://pediatrics.aappublications.org/content/146/6/e2020034629

PEDIATRICIAN WORKFORCE POLICY STATEMENT

Committee on Pediatric Workforce

ABSTRACT. This policy statement reviews important trends and other factors that affect the pediatrician workforce and the provision of pediatric health care, including changes in the pediatric patient population, pediatrician workforce, and nature of pediatric practice. The effect of these changes on pediatricians and the demand for pediatric care are discussed. The American Academy of Pediatrics (AAP) concludes that there is currently a shortage of pediatric medical subspecialists in many fields, as well as a shortage of pediatric surgical specialists. In addition, the AAP believes that the current distribution of primary care pediatricians is inadequate to meet the needs of children living in rural and other underserved areas, and more primary care pediatricians will be needed in the future because of the increasing number of children who have significant chronic health problems, changes in physician work hours, and implementation of current health reform efforts that seek to improve access to comprehensive patient- and family-centered care for all children in a medical home. The AAP is committed to being an active participant in physician workforce policy development with both professional organizations and governmental bodies to ensure a pediatric perspective on health care workforce issues. The overall purpose of this statement is to summarize policy recommendations and serve as a resource for the AAP and other stakeholders as they address pediatrician workforce issues that ultimately influence the quality of pediatric health care provided to children in the United States. (7/13)
http://pediatrics.aappublications.org/content/132/2/390

PEDIATRICIAN-FAMILY-PATIENT RELATIONSHIPS: MANAGING THE BOUNDARIES

Committee on Bioethics

ABSTRACT. All professionals are concerned about maintaining the appropriate limits in their relationships with those they serve. Pediatricians should be aware that, under normal circumstances, caring for one's own children presents significant ethical issues. Pediatricians also must strive to maintain appropriate professional boundaries in their relationships with the family members of their patients. Pediatricians should avoid behavior that patients and parents might misunderstand as having sexual or inappropriate social meaning. Romantic and sexual involvement between physicians and patients is unacceptable. The acceptance of gifts or nonmonetary compensation for medical services has the potential to affect the professional relationship adversely. (11/09, reaffirmed 1/14, 10/20)
http://pediatrics.aappublications.org/content/124/6/1685

THE PEDIATRICIAN'S ROLE IN CHILD MALTREATMENT PREVENTION (CLINICAL REPORT)

Emalee G. Flaherty, MD; John Stirling Jr, MD; and Committee on Child Abuse and Neglect

ABSTRACT. It is the pediatrician's role to promote the child's well-being and to help parents raise healthy, well-adjusted children. Pediatricians, therefore, can play an important role in the prevention of child maltreatment. Previous clinical reports and policy statements from the American Academy of Pediatrics have focused on improving the identification and management of child maltreatment. This clinical report outlines how the pediatrician can help to strengthen families and promote safe, stable, nurturing relationships with the aim of preventing maltreatment. After describing some of the triggers and factors that place children at risk for maltreatment, the report describes how pediatricians can identify family strengths, recognize risk factors, provide helpful guidance, and refer families to programs and other resources with the goal of strengthening families, preventing child maltreatment, and enhancing child development. (9/10, reaffirmed 1/14, 7/20)
http://pediatrics.aappublications.org/content/126/4/833

THE PEDIATRICIAN'S ROLE IN FAMILY SUPPORT AND FAMILY SUPPORT PROGRAMS

Committee on Early Childhood, Adoption, and Dependent Care

ABSTRACT. Children's social, emotional, and physical health; their developmental trajectory; and the neurocircuits that are being created and reinforced in their developing brains are all directly influenced by their relationships during early childhood. The stresses associated with contemporary American life can challenge families' abilities to promote successful developmental outcomes and emotional health for their children. Pediatricians are positioned to serve as partners with families and other community providers in supporting the well-being of children and their families. The structure and support of families involve forces that are often outside the agenda of the usual pediatric health supervision visits. Pediatricians must ensure that their medical home efforts promote a holistically healthy family environment for all children. This statement recommends opportunities for pediatricians to develop their expertise in assessing the strengths and stresses in families, in counseling families about strategies and resources, and in collaborating with others in their communities to support family relationships. (11/11, reaffirmed 12/16)
http://pediatrics.aappublications.org/content/128/6/e1680

THE PEDIATRICIAN'S ROLE IN OPTIMIZING SCHOOL READINESS

Council on Early Childhood and Council on School Health

ABSTRACT. School readiness includes not only the early academic skills of children but also their physical health, language skills, social and emotional development, motivation to learn, creativity, and general knowledge. Families and communities play a critical role in ensuring children's growth in all of these areas and thus their readiness for school. Schools must be prepared to teach all children when they reach the age of school

entry, regardless of their degree of readiness. Research on early brain development emphasizes the effects of early experiences, relationships, and emotions on creating and reinforcing the neural connections that are the basis for learning. Pediatricians, by the nature of their relationships with families and children, may significantly influence school readiness. Pediatricians have a primary role in ensuring children's physical health through the provision of preventive care, treatment of illness, screening for sensory deficits, and monitoring nutrition and growth. They can promote and monitor the social-emotional development of children by providing anticipatory guidance on development and behavior, by encouraging positive parenting practices, by modeling reciprocal and respectful communication with adults and children, by identifying and addressing psychosocial risk factors, and by providing community-based resources and referrals when warranted. Cognitive and language skills are fostered through timely identification of developmental problems and appropriate referrals for services, including early intervention and special education services; guidance regarding safe and stimulating early education and child care programs; and promotion of early literacy by encouraging language-rich activities such as reading together, telling stories, and playing games. Pediatricians are also well positioned to advocate not only for children's access to health care but also for high-quality early childhood education and evidence-based family supports such as home visits, which help provide a foundation for optimal learning. (8/16)
http://pediatrics.aappublications.org/content/138/3/e20162293

THE PEDIATRICIAN'S ROLE IN SUPPORTING ADOPTIVE FAMILIES (CLINICAL REPORT)

Veronnie F. Jones, MD, PhD, MSPH; Elaine E. Schulte, MD, MPH; Committee on Early Childhood; and Council on Foster Care, Adoption, and Kinship Care

ABSTRACT. Each year, more children join families through adoption. Pediatricians have an important role in assisting adoptive families in the various challenges they may face with respect to adoption. The acceptance of the differences between families formed through birth and those formed through adoption is essential in promoting positive emotional growth within the family. It is important for pediatricians to be aware of the adoptive parents' need to be supported in their communication with their adopted children. (9/12, reaffirmed 12/16)
http://pediatrics.aappublications.org/content/130/4/e1040

THE PEDIATRICIAN'S ROLE IN THE EVALUATION AND PREPARATION OF PEDIATRIC PATIENTS UNDERGOING ANESTHESIA

Section on Anesthesiology and Pain Medicine

ABSTRACT. Pediatricians play a key role in helping prepare patients and families for anesthesia and surgery. The questions to be answered by the pediatrician fall into 2 categories. The first involves preparation: is the patient in optimal medical condition for surgery, and are the patient and family emotionally and cognitively ready for surgery? The second category concerns logistics: what communication and organizational needs are necessary to enable safe passage through the perioperative process? This revised statement updates the recommendations for the pediatrician's role in the preoperative preparation of patients. (8/14)
http://pediatrics.aappublications.org/content/134/3/634

THE PEDIATRICIAN'S ROLE IN THE PREVENTION OF MISSING CHILDREN (CLINICAL REPORT)

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. In 2002, the *Second National Incidence Studies of Missing, Abducted, Runaway, and Thrownaway Children* report was released by the US Department of Justice, providing new data on a problem that our nation continues to face. This clinical report describes the categories of missing children, the prevalence of each, and prevention strategies that primary care pediatricians can share with parents to increase awareness and education about the safety of their children. (10/04, reaffirmed 1/15)
http://pediatrics.aappublications.org/content/114/4/1100

PEDIATRICIANS AND PUBLIC HEALTH: OPTIMIZING THE HEALTH AND WELL-BEING OF THE NATION'S CHILDREN

Alice A. Kuo, MD, PhD, FAAP; Pauline A. Thomas, MD, FAAP; Lance A. Chilton, MD, FAAP; Laurene Mascola, MD, MPH; Council on Community Pediatrics; and Section on Epidemiology, Public Health, and Evidence

ABSTRACT. Ensuring optimal health for children requires a population-based approach and collaboration between pediatrics and public health. The prevention of major threats to children's health (such as behavioral health issues) and the control and management of chronic diseases, obesity, injury, communicable diseases, and other problems cannot be managed solely in the pediatric office. The integration of clinical practice with public health actions is necessary for multiple levels of disease prevention that involve the child, family, and community. Although pediatricians and public health professionals interact frequently to the benefit of children and their families, increased integration of the 2 disciplines is critical to improving child health at the individual and population levels. Effective collaboration is necessary to ensure that population health activities include children and that the child health priorities of the American Academy of Pediatrics (AAP), such as poverty and child health, early brain and child development, obesity, and mental health, can engage federal, state, and local public health initiatives. In this policy statement, we build on the 2013 AAP Policy Statement on community pediatrics by identifying specific opportunities for collaboration between pediatricians and public health professionals that are likely to improve the health of children in communities. In the statement, we provide recommendations for pediatricians, public health professionals, and the AAP and its chapters. (1/18)
http://pediatrics.aappublications.org/content/141/2/e20173848

PERSONAL WATERCRAFT USE BY CHILDREN AND ADOLESCENTS

Committee on Injury and Poison Prevention

ABSTRACT. The use of personal watercraft (PWC) has increased dramatically during the past decade as have the speed and mobility of the watercraft. A similar dramatic increase in PWC-related injury and death has occurred simultaneously. No one younger than 16 years should operate a PWC. The operator and all passengers must wear US Coast Guard-approved personal flotation devices. Other safety recommendations are suggested for parents and pediatricians. (2/00, reaffirmed 5/04, 1/07, 6/10)
http://pediatrics.aappublications.org/content/105/2/452

PESTICIDE EXPOSURE IN CHILDREN

Council on Environmental Health

ABSTRACT. This statement presents the position of the American Academy of Pediatrics on pesticides. Pesticides are a collective term for chemicals intended to kill unwanted insects, plants, molds, and rodents. Children encounter pesticides daily and have unique susceptibilities to their potential toxicity. Acute poisoning risks are clear, and understanding of chronic health implications from both acute and chronic exposure are emerging. Epidemiologic evidence demonstrates associations between early life exposure to pesticides and pediatric cancers, decreased cognitive function, and behavioral problems. Related animal toxicology studies provide supportive biological plausibility for these findings. Recognizing and reducing problematic exposures will require attention to current inadequacies in medical

training, public health tracking, and regulatory action on pesticides. Ongoing research describing toxicologic vulnerabilities and exposure factors across the life span are needed to inform regulatory needs and appropriate interventions. Policies that promote integrated pest management, comprehensive pesticide labeling, and marketing practices that incorporate child health considerations will enhance safe use. (11/12)

http://pediatrics.aappublications.org/content/130/6/e1757

PESTICIDE EXPOSURE IN CHILDREN (TECHNICAL REPORT)

James R. Roberts, MD, MPH; Catherine J. Karr, MD, PhD; and Council on Environmental Health

ABSTRACT. Pesticides are a collective term for a wide array of chemicals intended to kill unwanted insects, plants, molds, and rodents. Food, water, and treatment in the home, yard, and school are all potential sources of children's exposure. Exposures to pesticides may be overt or subacute, and effects range from acute to chronic toxicity. In 2008, pesticides were the ninth most common substance reported to poison control centers, and approximately 45% of all reports of pesticide poisoning were for children. Organophosphate and carbamate poisoning are perhaps the most widely known acute poisoning syndromes, can be diagnosed by depressed red blood cell cholinesterase levels, and have available antidotal therapy. However, numerous other pesticides that may cause acute toxicity, such as pyrethroid and neonicotinoid insecticides, herbicides, fungicides, and rodenticides, also have specific toxic effects; recognition of these effects may help identify acute exposures. Evidence is increasingly emerging about chronic health implications from both acute and chronic exposure. A growing body of epidemiological evidence demonstrates associations between parental use of pesticides, particularly insecticides, with acute lymphocytic leukemia and brain tumors. Prenatal, household, and occupational exposures (maternal and paternal) appear to be the largest risks. Prospective cohort studies link early-life exposure to organophosphates and organochlorine pesticides (primarily DDT) with adverse effects on neurodevelopment and behavior. Among the findings associated with increased pesticide levels are poorer mental development by using the Bayley index and increased scores on measures assessing pervasive developmental disorder, inattention, and attention-deficit/hyperactivity disorder. Related animal toxicology studies provide supportive biological plausibility for these findings. Additional data suggest that there may also be an association between parental pesticide use and adverse birth outcomes including physical birth defects, low birth weight, and fetal death, although the data are less robust than for cancer and neurodevelopmental effects. Children's exposures to pesticides should be limited as much as possible. (11/12)

http://pediatrics.aappublications.org/content/130/6/e1765

PHOTOTHERAPY TO PREVENT SEVERE NEONATAL HYPERBILIRUBINEMIA IN THE NEWBORN INFANT 35 OR MORE WEEKS OF GESTATION (TECHNICAL REPORT)

Vinod K. Bhutani, MD, and Committee on Fetus and Newborn

ABSTRACT. *Objective.* To standardize the use of phototherapy consistent with the American Academy of Pediatrics clinical practice guideline for the management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation.

Methods. Relevant literature was reviewed. Phototherapy devices currently marketed in the United States that incorporate fluorescent, halogen, fiber-optic, or blue light-emitting diode light sources were assessed in the laboratory.

Results. The efficacy of phototherapy units varies widely because of differences in light source and configuration. The following characteristics of a device contribute to its effectiveness: (1) emission of light in the blue-to-green range that overlaps the in vivo plasma bilirubin absorption spectrum (~460–490 nm); (2) irradiance of at least 30 μW·cm–2·nm–1 (confirmed with an appropriate irradiance meter calibrated over the appropriate wavelength range); (3) illumination of maximal body surface; and (4) demonstration of a decrease in total bilirubin concentrations during the first 4 to 6 hours of exposure.

Recommendations. The intensity and spectral output of phototherapy devices is useful in predicting potential effectiveness in treating hyperbilirubinemia (group B recommendation). Clinical effectiveness should be evaluated before and monitored during use (group B recommendation). Blocking the light source or reducing exposed body surface should be avoided (group B recommendation). Standardization of irradiance meters, improvements in device design, and lower-upper limits of light intensity for phototherapy units merit further study. Comparing the in vivo performance of devices is not practical, in general, and alternative procedures need to be explored. (9/11, reaffirmed 7/14)

http://pediatrics.aappublications.org/content/128/4/e1046

PHYSICAL ACTIVITY ASSESSMENT AND COUNSELING IN PEDIATRIC CLINICAL SETTINGS (CLINICAL REPORT)

Felipe Lobelo, MD, PhD; Natalie D. Muth, MD, MPH, FAAP, FACSM; Sara Hanson, PhD; Blaise A. Nemeth, MD, FAAP; Council on Sports Medicine and Fitness; and Section on Obesity

ABSTRACT. Physical activity plays an important role in children's cardiovascular health, musculoskeletal health, mental and behavioral health, and physical, social, and cognitive development. Despite the importance in children's lives, pediatricians are unfamiliar with assessment and guidance regarding physical activity in children. With the release of the 2018 Physical Activity Guidelines by the US Department of Health and Human Services, pediatricians play a critical role in encouraging physical activity in children through assessing physical activity and physical literacy; providing guidance toward meeting recommendations by children and their families; advocating for opportunities for physical activity for all children in schools, communities, and hospitals; setting an example and remaining physically active personally; advocating for the use of assessment tools and insurance coverage of physical activity and physical literacy screening; and incorporating physical activity assessment and prescription in medical school curricula. (2/20)

See full text on page 1069.

https://pediatrics.aappublications.org/content/145/3/e20193992

PHYSICIAN HEALTH AND WELLNESS (CLINICAL REPORT)

Hilary McClafferty, MD, FAAP; Oscar W. Brown, MD, FAAP; Section on Integrative Medicine; and Committee on Practice and Ambulatory Medicine

ABSTRACT. Physician health and wellness is a critical issue gaining national attention because of the high prevalence of physician burnout. Pediatricians and pediatric trainees experience burnout at levels equivalent to other medical specialties, highlighting a need for more effective efforts to promote health and well-being in the pediatric community. This report will provide an overview of physician burnout, an update on work in the field of preventive physician health and wellness, and a discussion of emerging initiatives that have potential to promote health at all levels of pediatric training.

Pediatricians are uniquely positioned to lead this movement nationally, in part because of the emphasis placed on wellness in the Pediatric Milestone Project, a joint collaboration between the Accreditation Council for Graduate Medical Education and the American Board of Pediatrics. Updated core competencies calling for a balanced approach to health, including focus on nutrition, exercise, mindfulness, and effective stress management, signal a paradigm shift and send the message that it is time for pediatricians to cultivate a culture of wellness better aligned

with their responsibilities as role models and congruent with advances in pediatric training.

Rather than reviewing programs in place to address substance abuse and other serious conditions in distressed physicians, this article focuses on forward progress in the field, with an emphasis on the need for prevention and anticipation of predictable stressors related to burnout in medical training and practice. Examples of positive progress and several programs designed to promote physician health and wellness are reviewed. Areas where more research is needed are highlighted. (9/14)
http://pediatrics.aappublications.org/content/134/4/830

PHYSICIAN REFUSAL TO PROVIDE INFORMATION OR TREATMENT ON THE BASIS OF CLAIMS OF CONSCIENCE

Committee on Bioethics

ABSTRACT. Health care professionals may have moral objections to particular medical interventions. They may refuse to provide or cooperate in the provision of these interventions. Such objections are referred to as conscientious objections. Although it may be difficult to characterize or validate claims of conscience, respecting the individual physician's moral integrity is important. Conflicts arise when claims of conscience impede a patient's access to medical information or care. A physician's conscientious objection to certain interventions or treatments may be constrained in some situations. Physicians have a duty to disclose to prospective patients treatments they refuse to perform. As part of informed consent, physicians also have a duty to inform their patients of all relevant and legally available treatment options, including options to which they object. They have a moral obligation to refer patients to other health care professionals who are willing to provide those services when failing to do so would cause harm to the patient, and they have a duty to treat patients in emergencies when referral would significantly increase the probability of mortality or serious morbidity. Conversely, the health care system should make reasonable accommodations for physicians with conscientious objections. (11/09, reaffirmed 1/14, 6/18)
http://pediatrics.aappublications.org/content/124/6/1689

PHYSICIAN'S ROLE IN COORDINATING CARE OF HOSPITALIZED CHILDREN (CLINICAL REPORT)

Daniel A. Rauch, MD, FAAP; Committee on Hospital Care; and Section on Hospital Medicine

ABSTRACT. The hospitalization of a child is a stressful event for the child and family. The physician responsible for the admission has an important role in directing the care of the child, communicating with the child's providers (medical and primary caregivers), and advocating for the safety of the child during the hospitalization and transition out of the hospital. These challenges remain constant across the varied facilities in which children are hospitalized. The purpose of this revised clinical report is to update pediatricians about principles to improve the coordination of care and review expectations and practice. (7/18)
http://pediatrics.aappublications.org/content/142/2/e20181503

PLANNED HOME BIRTH

Committee on Fetus and Newborn

ABSTRACT. The American Academy of Pediatrics concurs with the recent statement of the American College of Obstetricians and Gynecologists affirming that hospitals and birthing centers are the safest settings for birth in the United States while respecting the right of women to make a medically informed decision about delivery. This statement is intended to help pediatricians provide supportive, informed counsel to women considering home birth while retaining their role as child advocates and to summarize the standards of care for newborn infants born at home, which are consistent with standards for infants born in a medical care facility. Regardless of the circumstances of his or her birth, including location, every newborn infant deserves health care that adheres to the standards highlighted in this statement, more completely described in other publications from the American Academy of Pediatrics, including *Guidelines for Perinatal Care.* The goal of providing high-quality care to all newborn infants can best be achieved through continuing efforts by all participating health care providers and institutions to develop and sustain communications and understanding on the basis of professional interaction and mutual respect throughout the health care system. (4/13, reaffirmed 12/16)
http://pediatrics.aappublications.org/content/131/5/1016

POINT-OF-CARE ULTRASONOGRAPHY BY PEDIATRIC EMERGENCY MEDICINE PHYSICIANS

Committee on Pediatric Emergency Medicine (joint with Society for Academic Emergency Medicine Academy of Emergency Ultrasound, American College of Emergency Physicians Pediatric Emergency Medicine Committee, and World Interactive Network Focused on Critical Ultrasound)

ABSTRACT. Point-of-care ultrasonography is increasingly being used to facilitate accurate and timely diagnoses and to guide procedures. It is important for pediatric emergency medicine (PEM) physicians caring for patients in the emergency department to receive adequate and continued point-of-care ultrasonography training for those indications used in their practice setting. Emergency departments should have credentialing and quality assurance programs. PEM fellowships should provide appropriate training to physician trainees. Hospitals should provide privileges to physicians who demonstrate competency in point-of-care ultrasonography. Ongoing research will provide the necessary measures to define the optimal training and competency assessment standards. Requirements for credentialing and hospital privileges will vary and will be specific to individual departments and hospitals. As more physicians are trained and more research is completed, there should be one national standard for credentialing and privileging in point-of-care ultrasonography for PEM physicians. (3/15, reaffirmed 9/19)
http://pediatrics.aappublications.org/content/135/4/e1097

POINT-OF-CARE ULTRASONOGRAPHY BY PEDIATRIC EMERGENCY MEDICINE PHYSICIANS (TECHNICAL REPORT)

Jennifer R. Marin, MD, MSc; Resa E. Lewiss, MD; and Committee on Pediatric Emergency Medicine (joint with Society for Academic Emergency Medicine Academy of Emergency Ultrasound, American College of Emergency Physicians Pediatric Emergency Medicine Committee, and World Interactive Network Focused on Critical Ultrasound)

ABSTRACT. Emergency physicians have used point-of-care ultrasonography since the 1990s. Pediatric emergency medicine physicians have more recently adopted this technology. Point-of-care ultrasonography is used for various scenarios, particularly the evaluation of soft tissue infections or blunt abdominal trauma and procedural guidance. To date, there are no published statements from national organizations specifically for pediatric emergency physicians describing the incorporation of point-of-care ultrasonography into their practice. This document outlines how pediatric emergency departments may establish a formal point-of-care ultrasonography program. This task includes appointing leaders with expertise in point-of-care ultrasonography, effectively training and credentialing physicians in the department, and providing ongoing quality assurance reviews.

Point-of-care ultrasonography (US) is a bedside technology that enables clinicians to integrate clinical examination findings with real-time sonographic imaging. General emergency physicians and other specialists have used point-of-care US for many years, and more recently, pediatric emergency medicine (PEM) physicians have adopted point-of-care US as a diagnostic and

procedural adjunct. This technical report and accompanying policy statement provide a framework for point-of-care US training and point-of-care US integration into pediatric care by PEM physicians. (3/15, reaffirmed 9/19)
http://pediatrics.aappublications.org/content/135/4/e1113

POSTDISCHARGE FOLLOW-UP OF INFANTS WITH CONGENITAL DIAPHRAGMATIC HERNIA (CLINICAL REPORT)

Section on Surgery and Committee on Fetus and Newborn

ABSTRACT. Infants with congenital diaphragmatic hernia often require intensive treatment after birth, have prolonged hospitalizations, and have other congenital anomalies. After discharge from the hospital, they may have long-term sequelae such as respiratory insufficiency, gastroesophageal reflux, poor growth, neurodevelopmental delay, behavior problems, hearing loss, hernia recurrence, and orthopedic deformities. Structured follow-up for these patients facilitates early recognition and treatment of these complications. In this report, follow-up of infants with congenital diaphragmatic hernia is outlined. (3/08, reaffirmed 5/11)
http://pediatrics.aappublications.org/content/121/3/627

POSTNATAL CORTICOSTEROIDS TO PREVENT OR TREAT BRONCHOPULMONARY DYSPLASIA

Kristi L. Watterberg, MD, and Committee on Fetus and Newborn

ABSTRACT. The purpose of this revised statement is to review current information on the use of postnatal glucocorticoids to prevent or treat bronchopulmonary dysplasia in the preterm infant and to make updated recommendations regarding their use. High-dose dexamethasone (0.5 mg/kg per day) does not seem to confer additional therapeutic benefit over lower doses and is not recommended. Evidence is insufficient to make a recommendation regarding other glucocorticoid doses and preparations. The clinician must use clinical judgment when attempting to balance the potential adverse effects of glucocorticoid treatment with those of bronchopulmonary dysplasia. (9/10, reaffirmed 1/14, 9/20)
http://pediatrics.aappublications.org/content/126/4/800

POSTNATAL GLUCOSE HOMEOSTASIS IN LATE-PRETERM AND TERM INFANTS (CLINICAL REPORT)

David H. Adamkin, MD, and Committee on Fetus and Newborn

ABSTRACT. This report provides a practical guide and algorithm for the screening and subsequent management of neonatal hypoglycemia. Current evidence does not support a specific concentration of glucose that can discriminate normal from abnormal or can potentially result in acute or chronic irreversible neurologic damage. Early identification of the at-risk infant and institution of prophylactic measures to prevent neonatal hypoglycemia are recommended as a pragmatic approach despite the absence of a consistent definition of hypoglycemia in the literature. (3/11, reaffirmed 6/15)
http://pediatrics.aappublications.org/content/127/3/575

POVERTY AND CHILD HEALTH IN THE UNITED STATES

Council on Community Pediatrics

ABSTRACT. Almost half of young children in the United States live in poverty or near poverty. The American Academy of Pediatrics is committed to reducing and ultimately eliminating child poverty in the United States. Poverty and related social determinants of health can lead to adverse health outcomes in childhood and across the life course, negatively affecting physical health, socioemotional development, and educational achievement. The American Academy of Pediatrics advocates for programs and policies that have been shown to improve the quality of life and health outcomes for children and families living in poverty. With an awareness and understanding of the effects of poverty on children, pediatricians and other pediatric health practitioners in a family-centered medical home can assess the financial stability of families, link families to resources, and coordinate care with community partners. Further research, advocacy, and continuing education will improve the ability of pediatricians to address the social determinants of health when caring for children who live in poverty. Accompanying this policy statement is a technical report that describes current knowledge on child poverty and the mechanisms by which poverty influences the health and well-being of children. (3/16)
http://pediatrics.aappublications.org/content/137/4/e20160339

THE POWER OF PLAY: A PEDIATRIC ROLE IN ENHANCING DEVELOPMENT IN YOUNG CHILDREN (CLINICAL REPORT)

Michael Yogman, MD, FAAP; Andrew Garner, MD, PhD, FAAP; Jeffrey Hutchinson, MD, FAAP; Kathy Hirsh-Pasek, PhD; Roberta Michnick Golinkoff, PhD; Committee on Psychosocial Aspects of Child and Family Health; and Council on Communications and Media

ABSTRACT. Children need to develop a variety of skill sets to optimize their development and manage toxic stress. Research demonstrates that developmentally appropriate play with parents and peers is a singular opportunity to promote the social-emotional, cognitive, language, and self-regulation skills that build executive function and a prosocial brain. Furthermore, play supports the formation of the safe, stable, and nurturing relationships with all caregivers that children need to thrive.

Play is not frivolous: it enhances brain structure and function and promotes executive function (ie, the process of learning, rather than the content), which allow us to pursue goals and ignore distractions.

When play and safe, stable, nurturing relationships are missing in a child's life, toxic stress can disrupt the development of executive function and the learning of prosocial behavior; in the presence of childhood adversity, play becomes even more important. The mutual joy and shared communication and attunement (harmonious serve and return interactions) that parents and children can experience during play regulate the body's stress response. This clinical report provides pediatric providers with the information they need to promote the benefits of play and to write a prescription for play at well visits to complement reach out and read. At a time when early childhood programs are pressured to add more didactic components and less playful learning, pediatricians can play an important role in emphasizing the role of a balanced curriculum that includes the importance of playful learning for the promotion of healthy child development. (8/18)
http://pediatrics.aappublications.org/content/142/3/e20182058

PRACTICAL APPROACHES TO OPTIMIZE ADOLESCENT IMMUNIZATION (CLINICAL REPORT)

Henry H. Bernstein, DO, MHCM, FAAP; Joseph A. Bocchini Jr, MD, FAAP; and Committee on Infectious Diseases

ABSTRACT. With the expansion of the adolescent immunization schedule during the past decade, immunization rates notably vary by vaccine and by state. Addressing barriers to improving adolescent vaccination rates is a priority. Every visit can be viewed as an opportunity to update and complete an adolescent's immunizations. It is essential to continue to focus and refine the appropriate techniques in approaching the adolescent patient and parent in the office setting. Health care providers must continuously strive to educate their patients and develop skills that can help parents and adolescents overcome vaccine hesitancy. Research on strategies to achieve higher vaccination rates is ongoing, and it is important to increase the knowledge and implementation of these strategies. This clinical report focuses on increasing adherence to the universally recommended vaccines in the annual adolescent immunization schedule of the American Academy of Pediatrics, the American

Academy of Family Physicians, the Centers for Disease Control and Prevention, and the American Congress of Obstetricians and Gynecologists. This will be accomplished by (1) examining strategies that heighten confidence in immunizations and address patient and parental concerns to promote adolescent immunization and (2) exploring how best to approach the adolescent and family to improve immunization rates. (2/17)
http://pediatrics.aappublications.org/content/139/3/e20164187

PREMEDICATION FOR NONEMERGENCY ENDOTRACHEAL INTUBATION IN THE NEONATE (CLINICAL REPORT)

Praveen Kumar, MD; Susan E. Denson, MD; Thomas J. Mancuso, MD; Committee on Fetus and Newborn; and Section on Anesthesiology and Pain Medicine

ABSTRACT. Endotracheal intubation is a common procedure in newborn care. The purpose of this clinical report is to review currently available evidence on use of premedication for intubation, identify gaps in knowledge, and provide guidance for making decisions about the use of premedication. (2/10, reaffirmed 8/13, 5/18)
http://pediatrics.aappublications.org/content/125/3/608

THE PRENATAL VISIT (CLINICAL REPORT)

Michael Yogman, MD, FAAP; Arthur Lavin, MD, FAAP; George Cohen, MD, FAAP; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. A pediatric prenatal visit during the third trimester is recommended for all expectant families as an important first step in establishing a child's medical home, as recommended by *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, Fourth Edition*. As advocates for children and their families, pediatricians can support and guide expectant parents in the prenatal period. Prenatal visits allow general pediatricians to establish a supportive and trusting relationship with both parents, gather basic information from expectant parents, offer information and advice regarding the infant, and may identify psychosocial risks early and high-risk conditions that may require special care. There are several possible formats for this first visit. The one used depends on the experience and preference of the parents, the style of the pediatrician's practice, and pragmatic issues of payment. (6/18)
http://pediatrics.aappublications.org/content/142/1/e20181218

PREPARATION FOR EMERGENCIES IN THE OFFICES OF PEDIATRICIANS AND PEDIATRIC PRIMARY CARE PROVIDERS

Committee on Pediatric Emergency Medicine

ABSTRACT. High-quality pediatric emergency care can be provided only through the collaborative efforts of many health care professionals and child advocates working together throughout a continuum of care that extends from prevention and the medical home to prehospital care, to emergency department stabilization, to critical care and rehabilitation, and finally to a return to care in the medical home. At times, the office of the pediatric primary care provider will serve as the entry site into the emergency care system, which comprises out-of-hospital emergency medical services personnel, emergency department nurses and physicians, and other emergency and critical care providers. Recognizing the important role of pediatric primary care providers in the emergency care system for children and understanding the capabilities and limitations of that system are essential if pediatric primary care providers are to offer the best chance at intact survival for every child who is brought to the office with an emergency. Optimizing pediatric primary care provider office readiness for emergencies requires consideration of the unique aspects of each office practice, the types of patients and emergencies that might be seen, the resources on site, and the resources of the larger emergency care system of which the pediatric primary care provider's office is a part. Parent education regarding prevention, recognition, and response to emergencies, patient triage, early recognition and stabilization of pediatric emergencies in the office, and timely transfer to an appropriate facility for definitive care are important responsibilities of every pediatric primary care provider. In addition, pediatric primary care providers can collaborate with out-of-hospital and hospital-based providers and advocate for the best-quality emergency care for their patients. (7/07, reaffirmed 6/11, 11/18)
http://pediatrics.aappublications.org/content/120/1/200

PRESCRIBING ASSISTIVE-TECHNOLOGY SYSTEMS: FOCUS ON CHILDREN WITH IMPAIRED COMMUNICATION (CLINICAL REPORT)

Larry W. Desch, MD; Deborah Gaebler-Spira, MD; and Council on Children With Disabilities

ABSTRACT. This clinical report defines common terms of use and provides information on current practice, research, and limitations of assistive technology that can be used in systems for communication. The assessment process to determine the best devices for use with a particular child (ie, the best fit of a device) is also reviewed. The primary care pediatrician, as part of the medical home, plays an important role in the interdisciplinary effort to provide appropriate assistive technology and may be asked to make a referral for assessment or prescribe a particular device. This report provides resources to assist pediatricians in this role and reviews the interdisciplinary team functional evaluation using standardized assessments; the multiple funding opportunities available for obtaining devices and ways in which pediatricians can assist families with obtaining them; the training necessary to use these systems once the devices are procured; the follow-up evaluation to ensure that the systems are meeting their goals; and the leadership skills needed to advocate for this technology. The American Academy of Pediatrics acknowledges the need for key resources to be identified in the community and recognizes that these resources are a shared medical, educational, therapeutic, and family responsibility. Although this report primarily deals with assistive technology specific for communication impairments, many of the details in this report also can aid in the acquisition and use of other types of assistive technology. (6/08, reaffirmed 1/12, 6/18)
http://pediatrics.aappublications.org/content/121/6/1271

PRESCRIBING PHYSICAL, OCCUPATIONAL, AND SPEECH THERAPY SERVICES FOR CHILDREN WITH DISABILITIES (CLINICAL REPORT)

Amy Houtrow, MD, PhD, MPH, FAAP, FAAPMR; Nancy Murphy, MD, FAAP, FAAPMR; and Council on Children With Disabilities

ABSTRACT. Pediatric health care providers are frequently responsible for prescribing physical, occupational, and speech therapies and monitoring therapeutic progress for children with temporary or permanent disabilities in their practices. This clinical report will provide pediatricians and other pediatric health care providers with information about how best to manage the therapeutic needs of their patients in the medical home by reviewing the International Classification of Functioning, Disability and Health; describing the general goals of habilitative and rehabilitative therapies; delineating the types, locations, and benefits of therapy services; and detailing how to write a therapy prescription and include therapists in the medical home neighborhood. (3/19)
https://pediatrics.aappublications.org/content/143/4/e20190285

PREVENTING OBESITY AND EATING DISORDERS IN ADOLESCENTS (CLINICAL REPORT)

Neville H. Golden, MD, FAAP; Marcie Schneider, MD, FAAP; Christine Wood, MD, FAAP; Committee on Nutrition; Committee on Adolescence; and Section on Obesity

ABSTRACT. Obesity and eating disorders (EDs) are both prevalent in adolescents. There are concerns that obesity prevention efforts may lead to the development of an ED. Most adolescents who develop an ED did not have obesity previously, but some teenagers, in an attempt to lose weight, may develop an ED. This clinical report addresses the interaction between obesity prevention and EDs in teenagers, provides the pediatrician with evidence-informed tools to identify behaviors that predispose to both obesity and EDs, and provides guidance about obesity and ED prevention messages. The focus should be on a healthy lifestyle rather than on weight. Evidence suggests that obesity prevention and treatment, if conducted correctly, do not predispose to EDs. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20161649

PREVENTION AND MANAGEMENT OF PROCEDURAL PAIN IN THE NEONATE: AN UPDATE

Committee on Fetus and Newborn and Section on Anesthesiology and Pain Medicine

ABSTRACT. The prevention of pain in neonates should be the goal of all pediatricians and health care professionals who work with neonates, not only because it is ethical but also because repeated painful exposures have the potential for deleterious consequences. Neonates at greatest risk of neurodevelopmental impairment as a result of preterm birth (ie, the smallest and sickest) are also those most likely to be exposed to the greatest number of painful stimuli in the NICU. Although there are major gaps in knowledge regarding the most effective way to prevent and relieve pain in neonates, proven and safe therapies are currently underused for routine minor, yet painful procedures. Therefore, every health care facility caring for neonates should implement (1) a pain-prevention program that includes strategies for minimizing the number of painful procedures performed and (2) a pain assessment and management plan that includes routine assessment of pain, pharmacologic and nonpharmacologic therapies for the prevention of pain associated with routine minor procedures, and measures for minimizing pain associated with surgery and other major procedures. (1/16, reaffirmed 7/20)

http://pediatrics.aappublications.org/content/137/2/e20154271

PREVENTION OF AGRICULTURAL INJURIES AMONG CHILDREN AND ADOLESCENTS

Committee on Injury and Poison Prevention and Committee on Community Health Services

ABSTRACT. Although the annual number of farm deaths to children and adolescents has decreased since publication of the 1988 American Academy of Pediatrics statement, "Rural Injuries," the rate of nonfatal farm injuries has increased. Approximately 100 unintentional injury deaths occur annually to children and adolescents on US farms, and an additional 22 000 injuries to children younger than 20 years occur on farms. Relatively few adolescents are employed on farms compared with other types of industry, yet the proportion of fatalities in agriculture is higher than that for any other type of adolescent employment. The high mortality and severe morbidity associated with farm injuries require continuing and improved injury-control strategies. This statement provides recommendations for pediatricians regarding patient and community education as well as public advocacy related to agricultural injury prevention in childhood and adolescence. (10/01, reaffirmed 1/07, 11/11)

http://pediatrics.aappublications.org/content/108/4/1016

PREVENTION OF CHILDHOOD LEAD TOXICITY

Council on Environmental Health

ABSTRACT. Blood lead concentrations have decreased dramatically in US children over the past 4 decades, but too many children still live in housing with deteriorated lead-based paint and are at risk for lead exposure with resulting lead-associated cognitive impairment and behavioral problems. Evidence continues to accrue that commonly encountered blood lead concentrations, even those below 5 μg/dL (50 ppb), impair cognition; there is no identified threshold or safe level of lead in blood. From 2007 to 2010, approximately 2.6% of preschool children in the United States had a blood lead concentration ≥5 μg/dL (≥50 ppb), which represents about 535 000 US children 1 to 5 years of age. Evidence-based guidance is available for managing increased lead exposure in children, and reducing sources of lead in the environment, including lead in housing, soil, water, and consumer products, has been shown to be cost-beneficial. Primary prevention should be the focus of policy on childhood lead toxicity. (6/16)

http://pediatrics.aappublications.org/content/138/1/e20161493

PREVENTION OF CHOKING AMONG CHILDREN

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Choking is a leading cause of morbidity and mortality among children, especially those aged 3 years or younger. Food, coins, and toys are the primary causes of choking-related injury and death. Certain characteristics, including shape, size, and consistency, of certain toys and foods increase their potential to cause choking among children. Childhood choking hazards should be addressed through comprehensive and coordinated prevention activities. The US Consumer Product Safety Commission (CPSC) should increase efforts to ensure that toys that are sold in retail store bins, vending machines, or on the Internet have appropriate choking-hazard warnings; work with manufacturers to improve the effectiveness of recalls of products that pose a choking risk to children; and increase efforts to prevent the resale of these recalled products via online auction sites. Current gaps in choking-prevention standards for children's toys should be reevaluated and addressed, as appropriate, via revisions to the standards established under the Child Safety Protection Act, the Consumer Product Safety Improvement Act, or regulation by the CPSC. Prevention of food-related choking among children in the United States has been inadequately addressed at the federal level. The US Food and Drug Administration should establish a systematic, institutionalized process for examining and addressing the hazards of food-related choking. This process should include the establishment of the necessary surveillance, hazard evaluation, enforcement, and public education activities to prevent food-related choking among children. While maintaining its highly cooperative arrangements with the CPSC and the US Department of Agriculture, the Food and Drug Administration should have the authority to address choking-related risks of all food products, including meat products that fall under the jurisdiction of the US Department of Agriculture. The existing National Electronic Injury Surveillance System–All Injury Program of the CPSC should be modified to conduct more-detailed surveillance of choking on food among children. Food manufacturers should design new foods and redesign existing foods to avoid shapes, sizes, textures, and other characteristics that increase choking risk to children, to the extent possible. Pediatricians, dentists, and other infant and child health care providers should provide choking-prevention counseling to parents as an integral part of anticipatory guidance activities. (2/10, reaffirmed 10/19)

http://pediatrics.aappublications.org/content/125/3/601

PREVENTION OF DROWNING

Sarah A. Denny, MD, FAAP; Linda Quan, MD, FAAP; Julie Gilchrist, MD, FAAP; Tracy McCallin, MD, FAAP; Rohit Shenoi, MD, FAAP; Shabana Yusuf, MD, Med, FAAP; Benjamin Hoffman, MD, FAAP; Jeffrey Weiss, MD, FAAP; and Council on Injury, Violence, and Poison Prevention

ABSTRACT. Drowning is a leading cause of injury-related death in children. In 2017, drowning claimed the lives of almost 1000 US children younger than 20 years. A number of strategies are available to prevent these tragedies. As educators and advocates, pediatricians can play an important role in the prevention of drowning. (4/19)

https://pediatrics.aappublications.org/content/143/5/e20190850

PREVENTION OF SEXUAL HARASSMENT IN THE WORKPLACE AND EDUCATIONAL SETTINGS

Committee on Pediatric Workforce

ABSTRACT. The American Academy of Pediatrics is committed to working to ensure that workplaces and educational settings in which pediatricians spend time are free of sexual harassment. The purpose of this statement is to heighten awareness and sensitivity to this important issue, recognizing that institutions, clinics, and office-based practices may have existing policies. (10/06, reaffirmed 5/09, 1/12, 10/14, 10/19)

http://pediatrics.aappublications.org/content/118/4/1752

THE PREVENTION OF UNINTENTIONAL INJURY AMONG AMERICAN INDIAN AND ALASKA NATIVE CHILDREN: A SUBJECT REVIEW (CLINICAL REPORT)

Committee on Native American Child Health and Committee on Injury and Poison Prevention

ABSTRACT. Among ethnic groups in the United States, American Indian and Alaska Native (AI/AN) children experience the highest rates of injury mortality and morbidity. Injury mortality rates for AI/AN children have decreased during the past quarter century, but remain almost double the rate for all children in the United States. The Indian Health Service (IHS), the federal agency with the primary responsibility for the health care of AI/AN people, has sponsored an internationally recognized injury prevention program designed to reduce the risk of injury death by addressing community-specific risk factors. Model programs developed by the IHS and tribal governments have led to successful outcomes in motor vehicle occupant safety, drowning prevention, and fire safety. Injury prevention programs in tribal communities require special attention to the sovereignty of tribal governments and the unique cultural aspects of health care and communication. Pediatricians working with AI/AN children on reservations or in urban environments are strongly urged to collaborate with tribes and the IHS to create community-based coalitions and develop programs to address highly preventable injury-related mortality and morbidity. Strong advocacy also is needed to promote childhood injury prevention as an important priority for federal agencies and tribes. (12/99, reaffirmed 12/02 COIVPP, 5/03 CONACH, 1/06, 9/08)

http://pediatrics.aappublications.org/content/104/6/1397

THE PRIMARY CARE PEDIATRICIAN AND THE CARE OF CHILDREN WITH CLEFT LIP AND/OR CLEFT PALATE (CLINICAL REPORT)

Charlotte W. Lewis, MD, MPH, FAAP; Lisa S. Jacob, DDS, MS; Christoph U. Lehmann, MD, FAAP, FACMI; and Section on Oral Health

ABSTRACT. Orofacial clefts, specifically cleft lip and/or cleft palate (CL/P), are among the most common congenital anomalies. CL/P vary in their location and severity and comprise 3 overarching groups: cleft lip (CL), cleft lip with cleft palate (CLP), and cleft palate alone (CP). CL/P may be associated with one of many syndromes that could further complicate a child's needs. Care of patients with CL/P spans prenatal diagnosis into adulthood. The appropriate timing and order of specific cleft-related care are important factors for optimizing outcomes; however, care should be individualized to meet the specific needs of each patient and family. Children with CL/P should receive their specialty cleft-related care from a multidisciplinary cleft or craniofacial team with sufficient patient and surgical volume to promote successful outcomes. The primary care pediatrician at the child's medical home has an essential role in making a timely diagnosis and referral; providing ongoing health care maintenance, anticipatory guidance, and acute care; and functioning as an advocate for the patient and a liaison between the family and the craniofacial/cleft team. This document provides background on CL/P and multidisciplinary team care, information about typical timing and order of cleft-related care, and recommendations for cleft/craniofacial teams and primary care pediatricians in the care of children with CL/P. (4/17)

http://pediatrics.aappublications.org/content/139/5/e20170628

PRINCIPLES OF CHILD HEALTH CARE FINANCING

Mark L. Hudak, MD, FAAP; Mark E. Helm, MD, MBA, FAAP; Patience H. White, MD, MA, FAAP, FACP; and Committee on Child Health Financing

ABSTRACT. After passage of the Patient Protection and Affordable Care Act, more children and young adults have become insured and have benefited from health care coverage than at any time since the creation of the Medicaid program in 1965. From 2009 to 2015, the uninsurance rate for children younger than 19 years fell from 9.7% to 5.3%, whereas the uninsurance rate for young adults 19 to 25 years of age declined from 31.7% to 14.5%. Nonetheless, much work remains to be done. The American Academy of Pediatrics (AAP) believes that the United States can and should ensure that all children, adolescents, and young adults from birth through the age of 26 years who reside within its borders have affordable access to high-quality and comprehensive health care, regardless of their or their families' incomes. Public and private health insurance should safeguard existing benefits for children and take further steps to cover the full array of essential health care services recommended by the AAP. Each family should be able to afford the premiums, deductibles, and other cost-sharing provisions of the plan. Health plans providing these benefits should ensure, insofar as possible, that families have a choice of professionals and facilities with expertise in the care of children within a reasonable distance of their residence. Traditional and innovative payment methodologies by public and private payers should be structured to guarantee the economic viability of the pediatric medical home and of other pediatric specialty and subspecialty practices to address developing shortages in the pediatric specialty and subspecialty workforce, to promote the use of health information technology, to improve population health and the experience of care, and to encourage the delivery of evidence-based and quality health care in the medical home, as well as in other outpatient, inpatient, and home settings. All current and future health care insurance plans should incorporate the principles for child health financing outlined in this statement. Espousing the core principle to do no harm, the AAP believes that the United States must not sacrifice any of the hard-won gains for our children. Medicaid, as the largest single payer of health care for children and young adults, should remain true to its origins as an entitlement program; in other words, future fiscal or regulatory reforms of Medicaid should not reduce the eligibility and scope of benefits for children and young adults below current levels nor jeopardize children's access to care. Proposed Medicaid funding "reforms" (eg, institution of block grant, capped allotment, or per-capita capitation payments to states) will achieve their goal of securing cost savings but will

inevitably compel states to reduce enrollee eligibility, trim existing benefits (such as Early and Periodic Screening, Diagnostic, and Treatment), and/or compromise children's access to necessary and timely care through cuts in payments to providers and delivery systems. In fact, the AAP advocates for increased Medicaid funding to improve access to essential care for existing enrollees, fund care for eligible but uninsured children once they enroll, and accommodate enrollment growth that will occur in states that choose to expand Medicaid eligibility. The AAP also calls for Congress to extend funding for the Children's Health Insurance Program, a plan vital to the 8.9 million children it covered in fiscal year 2016, for a minimum of 5 years. (8/17)
http://pediatrics.aappublications.org/content/140/3/e20172098

PRINCIPLES OF FINANCING THE MEDICAL HOME FOR CHILDREN

Jonathan Price, MD, FAAP; Mary L. Brandt, MD, FACS, FAAP; Mark L. Hudak, MD, FAAP; and Committee on Child Health Financing

ABSTRACT. A well-implemented and adequately funded medical home not only is the best approach to optimize the health of the individual patient but also can function as an effective instrument for improving population health. Key financing elements to providing quality, effective, comprehensive care in the pediatric medical home include the following: (1) first dollar coverage without deductibles, copays, or other cost-sharing for necessary preventive care services as recommended by *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents;* (2) adoption of a uniform definition of medical necessity across payers that embraces services that promote optimal growth and development and prevent, diagnose, and treat the full range of pediatric physical, mental, behavioral, and developmental conditions, in accord with evidence-based science or evidence-informed expert opinion; (3) payment models that promote appropriate use of pediatric primary care and pediatric specialty services and discourage inappropriate, inefficient, or excessive use of medical services; and (4) payment models that strengthen the patient- and family-physician relationship and do not impose additional administrative burdens that will only erode the effectiveness of the medical home. These goals can be met by designing payment models that provide adequate funding of the cost of medical encounters, care coordination, population health services, and quality improvement activities; provide incentives for quality and effectiveness of care; and ease administrative burdens. (12/19)

See full text on page 1093.

https://pediatrics.aappublications.org/content/145/1/e20193451

PRINCIPLES OF PEDIATRIC PATIENT SAFETY: REDUCING HARM DUE TO MEDICAL CARE

Brigitta U. Mueller, MD, MHCM, CPPS, CPHQ, FAAP; Daniel Robert Neuspiel, MD, MPH, FAAP; Erin R. Stucky Fisher, MD, FAAP; Council on Quality Improvement and Patient Safety; and Committee on Hospital Care

ABSTRACT. Pediatricians render care in an increasingly complex environment, which results in multiple opportunities to cause unintended harm. National awareness of patient safety risks has grown since the National Academy of Medicine (formerly the Institute of Medicine) published its report "To Err Is Human: Building a Safer Health System" in 1999. Patients and society as a whole continue to challenge health care providers to examine their practices and implement safety solutions. The depth and breadth of harm incurred by the practice of medicine is still being defined as reports continue to reveal a variety of avoidable errors, from those that involve specific high-risk medications to those that are more generalizable, such as patient misidentification and diagnostic error. Pediatric health care providers in all practice environments benefit from having a working knowledge of patient safety language. Pediatric providers should serve as advocates for best practices and policies with the goal of attending to risks that are unique to children, identifying and supporting a culture of safety, and leading efforts to eliminate avoidable harm in any setting in which medical care is rendered to children. In this Policy Statement, we provide an update to the 2011 Policy Statement "Principles of Pediatric Patient Safety: Reducing Harm Due to Medical Care." (1/19)
https://pediatrics.aappublications.org/content/143/2/e20183649

PROBIOTICS AND PREBIOTICS IN PEDIATRICS (CLINICAL REPORT)

Dan W. Thomas, MD; Frank R. Greer, MD; Committee on Nutrition; and Section on Gastroenterology, Hepatology, and Nutrition

ABSTRACT. This clinical report reviews the currently known health benefits of probiotic and prebiotic products, including those added to commercially available infant formula and other food products for use in children. Probiotics are supplements or foods that contain viable microorganisms that cause alterations of the microflora of the host. Use of probiotics has been shown to be modestly effective in randomized clinical trials (RCTs) in (1) treating acute viral gastroenteritis in healthy children; and (2) preventing antibiotic-associated diarrhea in healthy children. There is some evidence that probiotics prevent necrotizing enterocolitis in very low birth weight infants (birth weight between 1000 and 1500 g), but more studies are needed. The results of RCTs in which probiotics were used to treat childhood *Helicobacter pylori* gastritis, irritable bowel syndrome, chronic ulcerative colitis, and infantile colic, as well as in preventing childhood atopy, although encouraging, are preliminary and require further confirmation. Probiotics have not been proven to be beneficial in treating or preventing human cancers or in treating children with Crohn disease. There are also safety concerns with the use of probiotics in infants and children who are immunocompromised, chronically debilitated, or seriously ill with indwelling medical devices.

Prebiotics are supplements or foods that contain a nondigestible food ingredient that selectively stimulates the favorable growth and/or activity of indigenous probiotic bacteria. Human milk contains substantial quantities of prebiotics. There is a paucity of RCTs examining prebiotics in children, although there may be some long-term benefit of prebiotics for the prevention of atopic eczema and common infections in healthy infants. Confirmatory well-designed clinical research studies are necessary. (11/10)
http://pediatrics.aappublications.org/content/126/6/1217

PROCEDURES FOR THE EVALUATION OF THE VISUAL SYSTEM BY PEDIATRICIANS (CLINICAL REPORT)

Sean P. Donahue, MD, PhD, FAAP; Cynthia N. Baker, MD, FAAP; Committee on Practice and Ambulatory Medicine; and Section on Ophthalmology (joint with American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology and Strabismus, and American Academy of Ophthalmology)

ABSTRACT. Vision screening is crucial for the detection of visual and systemic disorders. It should begin in the newborn nursery and continue throughout childhood. This clinical report provides details regarding methods for pediatricians to use for screening. (12/15)
http://pediatrics.aappublications.org/content/137/1/e20153597

PROFESSIONALISM IN PEDIATRICS (TECHNICAL REPORT)

Mary E. Fallat, MD; Jacqueline Glover, PhD; and Committee on Bioethics

ABSTRACT. The purpose of this report is to provide a concrete overview of the ideal standards of behavior and professional practice to which pediatricians should aspire and by which students and residents can be evaluated. Recognizing that the

ideal is not always achievable in the practical sense, this document details the key components of professionalism in pediatric practice with an emphasis on core professional values for which pediatricians should strive and that will serve as a moral compass needed to provide quality care for children and their families. (10/07, reaffirmed 5/11)
http://pediatrics.aappublications.org/content/120/4/e1123

PROFESSIONALISM IN PEDIATRICS: STATEMENT OF PRINCIPLES

Committee on Bioethics

ABSTRACT. The purpose of this statement is to delineate the concept of professionalism within the context of pediatrics and to provide a brief statement of principles to guide the behavior and professional practice of pediatricians. (10/07, reaffirmed 5/11)
http://pediatrics.aappublications.org/content/120/4/895

PROMOTING EDUCATION, MENTORSHIP, AND SUPPORT FOR PEDIATRIC RESEARCH

Committee on Pediatric Research

ABSTRACT. Pediatricians play a key role in advancing child health research to best attain and improve the physical, mental, and social health and well-being of all infants, children, adolescents, and young adults. Child health presents unique issues that require investigators who specialize in pediatric research. In addition, the scope of the pediatric research enterprise is transdisciplinary and includes the full spectrum of basic science, translational, community-based, health services, and child health policy research. Although most pediatricians do not directly engage in research, knowledge of research methodologies and approaches promotes critical evaluation of scientific literature, the practice of evidence-based medicine, and advocacy for evidence-based child health policy. This statement includes specific recommendations to promote further research education and support at all levels of pediatric training, from premedical to continuing medical education, as well as recommendations to increase support and mentorship for research activities. Pediatric research is crucial to the American Academy of Pediatrics' goal of improving the health of all children. The American Academy of Pediatrics continues to promote and encourage efforts to facilitate the creation of new knowledge and ways to reduce barriers experienced by trainees, practitioners, and academic faculty pursuing research. (4/14, reaffirmed 2/18)
http://pediatrics.aappublications.org/content/133/5/943

PROMOTING FOOD SECURITY FOR ALL CHILDREN

Council on Community Pediatrics and Committee on Nutrition

ABSTRACT. Sixteen million US children (21%) live in households without consistent access to adequate food. After multiple risk factors are considered, children who live in households that are food insecure, even at the lowest levels, are likely to be sick more often, recover from illness more slowly, and be hospitalized more frequently. Lack of adequate healthy food can impair a child's ability to concentrate and perform well in school and is linked to higher levels of behavioral and emotional problems from preschool through adolescence. Food insecurity can affect children in any community, not only traditionally underserved ones. Pediatricians can play a central role in screening and identifying children at risk for food insecurity and in connecting families with needed community resources. Pediatricians should also advocate for federal and local policies that support access to adequate healthy food for an active and healthy life for all children and their families. (10/15)
http://pediatrics.aappublications.org/content/136/5/e1431

PROMOTING OPTIMAL DEVELOPMENT: IDENTIFYING INFANTS AND YOUNG CHILDREN WITH DEVELOPMENTAL DISORDERS THROUGH DEVELOPMENTAL SURVEILLANCE AND SCREENING (CLINICAL REPORT)

Paul H. Lipkin, MD, FAAP; Michelle M. Macias, MD, FAAP; Council on Children With Disabilities; and Section on Developmental and Behavioral Pediatrics

ABSTRACT. Early identification and intervention for developmental disorders are critical to the well-being of children and are the responsibility of pediatric professionals as an integral function of the medical home. This report models a universal system of developmental surveillance and screening for the early identification of conditions that affect children's early and long-term development and achievement, followed by ongoing care. These conditions include autism, deafness/hard-of-hearing, intellectual and motor disabilities, behavioral conditions, and those seen in other medical conditions. Developmental surveillance is supported at every health supervision visit, as is as the administration of standardized screening tests at the 9-, 18-, and 30-month visits. Developmental concerns elicited on surveillance at any visit should be followed by standardized developmental screening testing or direct referral to intervention and specialty medical care. Special attention to surveillance is recommended at the 4- to 5-year well-child visit, prior to entry into elementary education, with screening completed if there are any concerns. Developmental surveillance includes bidirectional communication with early childhood professionals in child care, preschools, Head Start, and other programs, including home visitation and parenting, particularly around developmental screening. The identification of problems should lead to developmental and medical evaluations, diagnosis, counseling, and treatment, in addition to early developmental intervention. Children with diagnosed developmental disorders are identified as having special health care needs, with initiation of chronic condition management in the pediatric medical home. (12/19)
See full text on page 1103.
https://pediatrics.aappublications.org/content/145/1/e20193449

PROMOTING OPTIMAL DEVELOPMENT: SCREENING FOR BEHAVIORAL AND EMOTIONAL PROBLEMS (CLINICAL REPORT)

Carol Weitzman, MD, FAAP; Lynn Wegner, MD, FAAP; Section on Developmental and Behavioral Pediatrics; Committee on Psychosocial Aspects of Child and Family Health; and Council on Early Childhood (joint with Society for Developmental and Behavioral Pediatrics)

ABSTRACT. By current estimates, at any given time, approximately 11% to 20% of children in the United States have a behavioral or emotional disorder, as defined in the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.* Between 37% and 39% of children will have a behavioral or emotional disorder diagnosed by 16 years of age, regardless of geographic location in the United States. Behavioral and emotional problems and concerns in children and adolescents are not being reliably identified or treated in the US health system. This clinical report focuses on the need to increase behavioral screening and offers potential changes in practice and the health system, as well as the research needed to accomplish this. This report also (1) reviews the prevalence of behavioral and emotional disorders, (2) describes factors affecting the emergence of behavioral and emotional problems, (3) articulates the current state of detection of these problems in pediatric primary care, (4) describes barriers to screening and means to overcome those barriers, and (5) discusses potential changes at a practice and systems level that are needed to facilitate successful behavioral and emotional screening. Highlighted and discussed are the many factors at the level

of the pediatric practice, health system, and society contributing to these behavioral and emotional problems. (1/15)
http://pediatrics.aappublications.org/content/135/2/384

PROMOTING THE PARTICIPATION OF CHILDREN WITH DISABILITIES IN SPORTS, RECREATION, AND PHYSICAL ACTIVITIES (CLINICAL REPORT)

Nancy A. Murphy, MD; Paul S. Carbone, MD; and Council on Children With Disabilities

ABSTRACT. The benefits of physical activity are universal for all children, including those with disabilities. The participation of children with disabilities in sports and recreational activities promotes inclusion, minimizes deconditioning, optimizes physical functioning, and enhances overall well-being. Despite these benefits, children with disabilities are more restricted in their participation, have lower levels of fitness, and have higher levels of obesity than their peers without disabilities. Pediatricians and parents may overestimate the risks or overlook the benefits of physical activity in children with disabilities. Well-informed decisions regarding each child's participation must consider overall health status, individual activity preferences, safety precautions, and availability of appropriate programs and equipment. Health supervision visits afford pediatricians, children with disabilities, and parents opportunities to collaboratively generate goal-directed activity "prescriptions." Child, family, financial, and societal barriers to participation need to be directly identified and addressed in the context of local, state, and federal laws. The goal is inclusion for all children with disabilities in appropriate activities. This clinical report discusses the importance of physical activity, recreation, and sports participation for children with disabilities and offers practical suggestions to pediatric health care professionals for the promotion of participation. (5/08, reaffirmed 1/12, 6/18)
http://pediatrics.aappublications.org/content/121/5/1057

PROMOTING THE WELL-BEING OF CHILDREN WHOSE PARENTS ARE GAY OR LESBIAN

Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. To promote optimal health and well-being of all children, the American Academy of Pediatrics (AAP) supports access for all children to (1) civil marriage rights for their parents and (2) willing and capable foster and adoptive parents, regardless of the parents' sexual orientation. The AAP has always been an advocate for, and has developed policies to support, the optimal physical, mental, and social health and well-being of all infants, children, adolescents, and young adults. In so doing, the AAP has supported families in all their diversity, because the family has always been the basic social unit in which children develop the supporting and nurturing relationships with adults that they need to thrive. Children may be born to, adopted by, or cared for temporarily by married couples, nonmarried couples, single parents, grandparents, or legal guardians, and any of these may be heterosexual, gay or lesbian, or of another orientation. Children need secure and enduring relationships with committed and nurturing adults to enhance their life experiences for optimal social-emotional and cognitive development. Scientific evidence affirms that children have similar developmental and emotional needs and receive similar parenting whether they are raised by parents of the same or different genders. If a child has 2 living and capable parents who choose to create a permanent bond by way of civil marriage, it is in the best interests of their child(ren) that legal and social institutions allow and support them to do so, irrespective of their sexual orientation. If 2 parents are not available to the child, adoption or foster parenting remain acceptable options to provide a loving home for a child and should be available without regard to the sexual orientation of the parent(s). (3/13)
http://pediatrics.aappublications.org/content/131/4/827

PROMOTING THE WELL-BEING OF CHILDREN WHOSE PARENTS ARE GAY OR LESBIAN (TECHNICAL REPORT)

Ellen C. Perrin, MD, MA; Benjamin S. Siegel, MD; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Extensive data available from more than 30 years of research reveal that children raised by gay and lesbian parents have demonstrated resilience with regard to social, psychological, and sexual health despite economic and legal disparities and social stigma. Many studies have demonstrated that children's well-being is affected much more by their relationships with their parents, their parents' sense of competence and security, and the presence of social and economic support for the family than by the gender or the sexual orientation of their parents. Lack of opportunity for same-gender couples to marry adds to families' stress, which affects the health and welfare of all household members. Because marriage strengthens families and, in so doing, benefits children's development, children should not be deprived of the opportunity for their parents to be married. Paths to parenthood that include assisted reproductive techniques, adoption, and foster parenting should focus on competency of the parents rather than their sexual orientation. (3/13)
http://pediatrics.aappublications.org/content/131/4/e1374

PROMOTION OF HEALTHY WEIGHT-CONTROL PRACTICES IN YOUNG ATHLETES (CLINICAL REPORT)

Rebecca L. Carl, MD, MS, FAAP; Miriam D. Johnson, MD, FAAP; Thomas J. Martin, MD, FAAP; and Council on Sports Medicine and Fitness

ABSTRACT. Children and adolescents may participate in sports that favor a particular body type. Some sports, such as gymnastics, dance, and distance running, emphasize a slim or lean physique for aesthetic or performance reasons. Participants in weight-class sports, such as wrestling and martial arts, may attempt weight loss so they can compete at a lower weight class. Other sports, such as football and bodybuilding, highlight a muscular physique; young athletes engaged in these sports may desire to gain weight and muscle mass. This clinical report describes unhealthy methods of weight loss and gain as well as policies and approaches used to curb these practices. The report also reviews healthy strategies for weight loss and weight gain and provides recommendations for pediatricians on how to promote healthy weight control in young athletes. (8/17)
http://pediatrics.aappublications.org/content/140/3/e20171871

PROTECTING CHILDREN FROM SEXUAL ABUSE BY HEALTH CARE PROVIDERS

Committee on Child Abuse and Neglect

ABSTRACT. Sexual abuse or exploitation of children is never acceptable. Such behavior by health care providers is particularly concerning because of the trust that children and their families place on adults in the health care profession. The American Academy of Pediatrics strongly endorses the social and moral prohibition against sexual abuse or exploitation of children by health care providers. The academy opposes any such sexual abuse or exploitation by providers, particularly by the academy's members. Health care providers should be trained to recognize and abide by appropriate provider-patient boundaries. Medical institutions should screen staff members for a history of child abuse issues, train them to respect and maintain appropriate boundaries, and establish policies and procedures to receive and investigate concerns about patient abuse. Each person has a responsibility to ensure the safety of children in health care settings and to scrupulously follow appropriate legal and ethical reporting and investigation procedures. (6/11, reaffirmed 10/14, 1/20)
http://pediatrics.aappublications.org/content/128/2/407

PROTECTING CHILDREN FROM TOBACCO, NICOTINE, AND TOBACCO SMOKE (TECHNICAL REPORT)

Harold J. Farber, MD, MSPH, FAAP; Judith Groner, MD, FAAP; Susan Walley, MD, FAAP; Kevin Nelson, MD, PhD, FAAP; and Section on Tobacco Control

ABSTRACT. This technical report serves to provide the evidence base for the American Academy of Pediatrics' policy statements "Clinical Practice Policy to Protect Children From Tobacco, Nicotine, and Tobacco Smoke" and "Public Policy to Protect Children From Tobacco, Nicotine, and Tobacco Smoke." Tobacco use and involuntary exposure are major preventable causes of morbidity and premature mortality in adults and children. Tobacco dependence almost always starts in childhood or adolescence. Electronic nicotine delivery systems are rapidly gaining popularity among youth, and their significant harms are being documented. In utero tobacco smoke exposure, in addition to increasing the risk of preterm birth, low birth weight, stillbirth, placental abruption, and sudden infant death, has been found to increase the risk of obesity and neurodevelopmental disorders. Actions by pediatricians can help to reduce children's risk of developing tobacco dependence and reduce children's involuntary tobacco smoke exposure. Public policy actions to protect children from tobacco are essential to reduce the toll that the tobacco epidemic takes on our children. (10/15, reaffirmed 6/20)

http://pediatrics.aappublications.org/content/136/5/e1439

PROVIDING A PRIMARY CARE MEDICAL HOME FOR CHILDREN AND YOUTH WITH CEREBRAL PALSY (CLINICAL REPORT)

Gregory S. Liptak, MD, MPH; Nancy A. Murphy, MD; and Council on Children With Disabilities

ABSTRACT. All primary care providers will care for children with cerebral palsy in their practice. In addition to well-child and acute illness care, the role of the medical home in the management of these children includes diagnosis, planning for interventions, authorizing treatments, and follow-up. Optimizing health and well-being for children with cerebral palsy and their families entails family-centered care provided in the medical home; comanagement is the most common model. This report reviews the aspects of care specific to cerebral palsy that a medical home should provide beyond the routine health care needed by all children. (10/11, reaffirmed 11/14, 8/18)

http://pediatrics.aappublications.org/content/128/5/e1321

PROVIDING A PRIMARY CARE MEDICAL HOME FOR CHILDREN AND YOUTH WITH SPINA BIFIDA (CLINICAL REPORT)

Robert Burke, MD, MPH; Gregory S. Liptak, MD, MPH; and Council on Children With Disabilities

ABSTRACT. The pediatric primary care provider in the medical home has a central and unique role in the care of children with spina bifida. The primary care provider addresses not only the typical issues of preventive and acute health care but also the needs specific to these children. Optimal care requires communication and comanagement with pediatric medical and developmental subspecialists, surgical specialists, therapists, and community providers. The medical home provider is essential in supporting the family and advocating for the child from the time of entry into the practice through adolescence, which includes transition and transfer to adult health care. This report reviews aspects of care specific to the infant with spina bifida (particularly myelomeningocele) that will facilitate optimal medical, functional, and developmental outcomes. (11/11, reaffirmed 2/15, 7/18)

http://pediatrics.aappublications.org/content/128/6/e1645

PROVIDING CARE FOR CHILDREN AND ADOLESCENTS FACING HOMELESSNESS AND HOUSING INSECURITY

Council on Community Pediatrics

ABSTRACT. Child health and housing security are closely intertwined, and children without homes are more likely to suffer from chronic disease, hunger, and malnutrition than are children with homes. Homeless children and youth often have significant psychosocial development issues, and their education is frequently interrupted. Given the overall effects that homelessness can have on a child's health and potential, it is important for pediatricians to recognize the factors that lead to homelessness, understand the ways that homelessness and its causes can lead to poor health outcomes, and when possible, help children and families mitigate some of the effects of homelessness. Through practice change, partnership with community resources, awareness, and advocacy, pediatricians can help optimize the health and well-being of children affected by homelessness. (5/13, reaffirmed 10/16)

http://pediatrics.aappublications.org/content/131/6/1206

PROVIDING CARE FOR CHILDREN IN IMMIGRANT FAMILIES

Julie M. Linton, MD, FAAP; Andrea Green, MDCM, FAAP; and Council on Community Pediatrics

ABSTRACT. Children in immigrant families (CIF), who represent 1 in 4 children in the United States, represent a growing and ever more diverse US demographic that pediatric medical providers nationwide will increasingly encounter in clinical care. Immigrant children are those born outside the United States to non–US citizen parents, and CIF are defined as those who are either foreign born or have at least 1 parent who is foreign born. Some families immigrate for economic or educational reasons, and others come fleeing persecution and seeking safe haven. Some US-born children with a foreign-born parent may share vulnerabilities with children who themselves are foreign born, particularly regarding access to care and other social determinants of health. Therefore, the larger umbrella term of CIF is used in this statement. CIF, like all children, have diverse experiences that interact with their biopsychosocial development. CIF may face inequities that can threaten their health and well-being, and CIF also offer strengths and embody resilience that can surpass challenges experienced before and during integration. This policy statement describes the evolving population of CIF in the United States, briefly introduces core competencies to enhance care within a framework of cultural humility and safety, and discusses barriers and opportunities at the practice and systems levels. Practice-level recommendations describe how pediatricians can promote health equity for CIF through careful attention to core competencies in clinical care, thoughtful community engagement, and system-level support. Advocacy and policy recommendations offer ways pediatricians can advocate for policies that promote health equity for CIF. (8/19)

https://pediatrics.aappublications.org/content/144/3/e20192077

PROVIDING CARE FOR INFANTS BORN AT HOME

Kristi Watterberg, MD, FAAP, and Committee on Fetus and Newborn

ABSTRACT. The American Academy of Pediatrics (AAP) believes that current data show that hospitals and accredited birth centers are the safest settings for birth in the United States. The AAP does not recommend planned home birth, which has been reported to be associated with a twofold to threefold increase in infant mortality in the United States. The AAP recognizes that women may choose to plan a home birth. This statement is intended to help pediatricians provide constructive, informed counsel to women considering home birth while retaining their role as child advocates and to summarize appropriate care for newborn infants born at home that is consistent with care

provided for infants born in a medical care facility. Regardless of the circumstances of his or her birth, including location, every newborn infant deserves health care consistent with that highlighted in this statement, which is more completely described in other publications from the AAP, including *Guidelines for Perinatal Care* and the *Textbook of Neonatal Resuscitation*. All health care clinicians and institutions should promote communications and understanding on the basis of professional interaction and mutual respect. (4/20)

See full text on page 1125.

https://pediatrics.aappublications.org/content/145/5/e20200626

PROVIDING PSYCHOSOCIAL SUPPORT TO CHILDREN AND FAMILIES IN THE AFTERMATH OF DISASTERS AND CRISES (CLINICAL REPORT)

David J. Schonfeld, MD, FAAP; Thomas Demaria, PhD; Disaster Preparedness Advisory Council; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. Disasters have the potential to cause short- and long-term effects on the psychological functioning, emotional adjustment, health, and developmental trajectory of children. This clinical report provides practical suggestions on how to identify common adjustment difficulties in children in the aftermath of a disaster and to promote effective coping strategies to mitigate the impact of the disaster as well as any associated bereavement and secondary stressors. This information can serve as a guide to pediatricians as they offer anticipatory guidance to families or consultation to schools, child care centers, and other child congregate care sites. Knowledge of risk factors for adjustment difficulties can serve as the basis for mental health triage. The importance of basic supportive services, psychological first aid, and professional self-care are discussed. Stress is intrinsic to many major life events that children and families face, including the experience of significant illness and its treatment. The information provided in this clinical report may, therefore, be relevant for a broad range of patient encounters, even outside the context of a disaster. Most pediatricians enter the profession because of a heartfelt desire to help children and families most in need. If adequately prepared and supported, pediatricians who are able to draw on their skills to assist children, families, and communities to recover after a disaster will find the work to be particularly rewarding. (9/15)

http://pediatrics.aappublications.org/content/136/4/e1120

PSYCHOLOGICAL MALTREATMENT (CLINICAL REPORT)

Roberta Hibbard, MD; Jane Barlow, DPhil; Harriet MacMillan, MD; Committee on Child Abuse and Neglect (joint with American Academy of Child and Adolescent Psychiatry Child Maltreatment and Violence Committee)

ABSTRACT. Psychological or emotional maltreatment of children may be the most challenging and prevalent form of child abuse and neglect. Caregiver behaviors include acts of omission (ignoring need for social interactions) or commission (spurning, terrorizing); may be verbal or nonverbal, active or passive, and with or without intent to harm; and negatively affect the child's cognitive, social, emotional, and/or physical development. Psychological maltreatment has been linked with disorders of attachment, developmental and educational problems, socialization problems, disruptive behavior, and later psychopathology. Although no evidence-based interventions that can prevent psychological maltreatment have been identified to date, it is possible that interventions shown to be effective in reducing overall types of child maltreatment, such as the Nurse Family Partnership, may have a role to play. Furthermore, prevention before occurrence will require both the use of universal interventions aimed at promoting the type of parenting that is now recognized to be necessary for optimal child development, alongside the use of targeted interventions directed at improving parental sensitivity to a child's cues during infancy and later parent-child interactions. Intervention should, first and foremost, focus on a thorough assessment and ensuring the child's safety. Potentially effective treatments include cognitive behavioral parenting programs and other psychotherapeutic interventions. The high prevalence of psychological abuse in advanced Western societies, along with the serious consequences, point to the importance of effective management. Pediatricians should be alert to the occurrence of psychological maltreatment and identify ways to support families who have risk indicators for, or evidence of, this problem. (7/12, reaffirmed 4/16)

http://pediatrics.aappublications.org/content/130/2/372

PSYCHOSOCIAL FACTORS IN CHILDREN AND YOUTH WITH SPECIAL HEALTH CARE NEEDS AND THEIR FAMILIES (CLINICAL REPORT)

Gerri Mattson, MD, MSPH, FAAP; Dennis Z. Kuo, MD, MHS, FAAP; Committee on Psychosocial Aspects of Child and Family Health; and Council on Children With Disabilities

ABSTRACT. Children and youth with special health care needs (CYSHCN) and their families may experience a variety of internal (ie, emotional and behavioral) and external (ie, interpersonal, financial, housing, and educational) psychosocial factors that can influence their health and wellness. Many CYSHCN and their families are resilient and thrive. Medical home teams can partner with CYSHCN and their families to screen for, evaluate, and promote psychosocial health to increase protective factors and ameliorate risk factors. Medical home teams can promote protective psychosocial factors as part of coordinated, comprehensive chronic care for CYSHCN and their families. A team-based care approach may entail collaboration across the care spectrum, including youth, families, behavioral health providers, specialists, child care providers, schools, social services, and other community agencies. The purpose of this clinical report is to raise awareness of the impact of psychosocial factors on the health and wellness of CYSHCN and their families. This clinical report provides guidance for pediatric providers to facilitate and coordinate care that can have a positive influence on the overall health, wellness, and quality of life of CYSHCN and their families. (12/18)

https://pediatrics.aappublications.org/content/143/1/e20183171

PSYCHOSOCIAL SUPPORT FOR YOUTH LIVING WITH HIV (CLINICAL REPORT)

Jaime Martinez, MD, FAAP; Rana Chakraborty, MD, FAAP; and Committee on Pediatric AIDS

ABSTRACT. This clinical report provides guidance for the pediatrician in addressing the psychosocial needs of adolescents and young adults living with HIV, which can improve linkage to care and adherence to life-saving antiretroviral (ARV) therapy. Recent national case surveillance data for youth (defined here as adolescents and young adults 13 to 24 years of age) revealed that the burden of HIV/AIDS fell most heavily and disproportionately on African American youth, particularly males having sex with males. To effectively increase linkage to care and sustain adherence to therapy, interventions should address the immediate drivers of ARV compliance and also address factors that provide broader social and structural support for HIV-infected adolescents and young adults. Interventions should address psychosocial development, including lack of future orientation, inadequate educational attainment and limited health literacy, failure to focus on the long-term consequences of near-term risk behaviors, and coping ability. Associated challenges are closely linked to the structural environment. Individual case management is essential to linkage to and retention in care, ARV adherence, and management of associated comorbidities. Integrating these skills into pediatric and adolescent HIV practice in a

medical home setting is critical, given the alarming increase in new HIV infections in youth in the United States. (2/14)
http://pediatrics.aappublications.org/content/133/3/558

A PUBLIC HEALTH RESPONSE TO OPIOID USE IN PREGNANCY

Stephen W. Patrick, MD, MPH, MS, FAAP; Davida M. Schiff, MD, FAAP; and Committee on Substance Use and Prevention

ABSTRACT. The use of opioids during pregnancy has grown rapidly in the past decade. As opioid use during pregnancy increased, so did complications from their use, including neonatal abstinence syndrome. Several state governments responded to this increase by prosecuting and incarcerating pregnant women with substance use disorders; however, this approach has no proven benefits for maternal or infant health and may lead to avoidance of prenatal care and a decreased willingness to engage in substance use disorder treatment programs. A public health response, rather than a punitive approach to the opioid epidemic and substance use during pregnancy, is critical, including the following: a focus on preventing unintended pregnancies and improving access to contraception; universal screening for alcohol and other drug use in women of childbearing age; knowledge and informed consent of maternal drug testing and reporting practices; improved access to comprehensive obstetric care, including opioid-replacement therapy; gender-specific substance use treatment programs; and improved funding for social services and child welfare systems. The American College of Obstetricians and Gynecologists supports the value of this clinical document as an educational tool (December 2016). (2/17)
http://pediatrics.aappublications.org/content/139/3/e20164070

PUBLIC POLICIES TO REDUCE SUGARY DRINK CONSUMPTION IN CHILDREN AND ADOLESCENTS

Natalie D. Muth, MD, MPH, RDN, FAAP; William H. Dietz, MD, PhD, FAAP; Sheela N. Magge, MD, MSCE, FAAP; Rachel K. Johnson, PhD, MPH, RD, FAHA; Section on Obesity; and Committee on Nutrition (joint with American Heart Association)

ABSTRACT. Excess consumption of added sugars, especially from sugary drinks, poses a grave health threat to children and adolescents, disproportionately affecting children of minority and low-income communities. Public policies, such as those detailed in this statement, are needed to decrease child and adolescent consumption of added sugars and improve health. (3/19)
https://pediatrics.aappublications.org/content/143/4/e20190282

PUBLIC POLICY TO PROTECT CHILDREN FROM TOBACCO, NICOTINE, AND TOBACCO SMOKE

Section on Tobacco Control

ABSTRACT. Tobacco use and tobacco smoke exposure are among the most important health threats to children, adolescents, and adults. There is no safe level of tobacco smoke exposure. The developing brains of children and adolescents are particularly vulnerable to the development of tobacco and nicotine dependence. Tobacco is unique among consumer products in that it causes disease and death when used exactly as intended. Tobacco continues to be heavily promoted to children and young adults. Flavored and alternative tobacco products, including little cigars, chewing tobacco, and electronic nicotine delivery systems, are gaining popularity among youth. This statement describes important evidence-based public policy actions that, when implemented, will reduce tobacco product use and tobacco smoke exposure among youth and, by doing so, improve the health of children and young adults. (10/15, reaffirmed 6/20)
http://pediatrics.aappublications.org/content/136/5/998

QUALITY EARLY EDUCATION AND CHILD CARE FROM BIRTH TO KINDERGARTEN

Elaine A. Donoghue, MD, FAAP, and Council on Early Childhood

ABSTRACT. High-quality early education and child care for young children improves physical and cognitive outcomes for the children and can result in enhanced school readiness. Preschool education can be viewed as an investment (especially for at-risk children), and studies show a positive return on that investment. Barriers to high-quality early childhood education include inadequate funding and staff education as well as variable regulation and enforcement. Steps that have been taken to improve the quality of early education and child care include creating multidisciplinary, evidence-based child care practice standards; establishing state quality rating and improvement systems; improving federal and state regulations; providing child care health consultation; and initiating other innovative partnerships. Pediatricians have a role in promoting quality early education and child care for all children not only in the medical home but also at the community, state, and national levels. (7/17)
http://pediatrics.aappublications.org/content/140/2/e20171488

RACE, ETHNICITY, AND SOCIOECONOMIC STATUS IN RESEARCH ON CHILD HEALTH

Tina L. Cheng, MD, MPH, FAAP; Elizabeth Goodman, MD, FAAP; and Committee on Pediatric Research

ABSTRACT. An extensive literature documents the existence of pervasive and persistent child health, development, and health care disparities by race, ethnicity, and socioeconomic status (SES). Disparities experienced during childhood can result in a wide variety of health and health care outcomes, including adult morbidity and mortality, indicating that it is crucial to examine the influence of disparities across the life course. Studies often collect data on the race, ethnicity, and SES of research participants to be used as covariates or explanatory factors. In the past, these variables have often been assumed to exert their effects through individual or genetically determined biologic mechanisms. However, it is now widely accepted that these variables have important social dimensions that influence health. SES, a multidimensional construct, interacts with and confounds analyses of race and ethnicity. Because SES, race, and ethnicity are often difficult to measure accurately, leading to the potential for misattribution of causality, thoughtful consideration should be given to appropriate measurement, analysis, and interpretation of such factors. Scientists who study child and adolescent health and development should understand the multiple measures used to assess race, ethnicity, and SES, including their validity and shortcomings and potential confounding of race and ethnicity with SES. The American Academy of Pediatrics (AAP) recommends that research on eliminating health and health care disparities related to race, ethnicity, and SES be a priority. Data on race, ethnicity, and SES should be collected in research on child health to improve their definitions and increase understanding of how these factors and their complex interrelationships affect child health. Furthermore, the AAP believes that researchers should consider both biological and social mechanisms of action of race, ethnicity, and SES as they relate to the aims and hypothesis of the specific area of investigation. It is important to measure these variables, but it is not sufficient to use these variables alone as explanatory for differences in disease, morbidity, and outcomes without attention to the social and biologic influences they have on health throughout the life course. The AAP recommends more research, both in the United States and internationally, on measures of race, ethnicity, and SES and how these complex constructs affect health care and health outcomes throughout the life course. (12/14)
http://pediatrics.aappublications.org/content/135/1/e225

RADIATION RISK TO CHILDREN FROM COMPUTED TOMOGRAPHY (CLINICAL REPORT)

Alan S. Brody, MD; Donald P. Frush, MD; Walter Huda, PhD; Robert L. Brent, MD, PhD; and Section on Radiology

ABSTRACT. Imaging studies that use ionizing radiation are an essential tool for the evaluation of many disorders of childhood. Ionizing radiation is used in radiography, fluoroscopy, angiography, and computed tomography scanning. Computed tomography is of particular interest because of its relatively high radiation dose and wide use. Consensus statements on radiation risk suggest that it is reasonable to act on the assumption that low-level radiation may have a small risk of causing cancer. The medical community should seek ways to decrease radiation exposure by using radiation doses as low as reasonably achievable and by performing these studies only when necessary. There is wide agreement that the benefits of an indicated computed tomography scan far outweigh the risks. Pediatric health care professionals' roles in the use of computed tomography on children include deciding when a computed tomography scan is necessary and discussing the risk with patients and families. Radiologists should be a source of consultation when forming imaging strategies and should create specific protocols with scanning techniques optimized for pediatric patients. Families and patients should be encouraged to ask questions about the risks and benefits of computed tomography scanning. The information in this report is provided to aid in decision-making and discussions with the health care team, patients, and families. (9/07)

http://pediatrics.aappublications.org/content/120/3/677

RECOGNITION AND MANAGEMENT OF IATROGENICALLY INDUCED OPIOID DEPENDENCE AND WITHDRAWAL IN CHILDREN (CLINICAL REPORT)

Jeffrey Galinkin, MD, FAAP; Jeffrey Lee Koh, MD, FAAP; Committee on Drugs; and Section on Anesthesiology and Pain Medicine

ABSTRACT. Opioids are often prescribed to children for pain relief related to procedures, acute injuries, and chronic conditions. Round-the-clock dosing of opioids can produce opioid dependence within 5 days. According to a 2001 consensus paper from the American Academy of Pain Medicine, American Pain Society, and American Society of Addiction Medicine, dependence is defined as "a state of adaptation that is manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist." Although the experience of many children undergoing iatrogenically induced withdrawal may be mild or goes unreported, there is currently no guidance for recognition or management of withdrawal for this population. Guidance on this subject is available only for adults and primarily for adults with substance use disorders. The guideline will summarize existing literature and provide readers with information currently not available in any single source specific for this vulnerable pediatric population. (12/13)

http://pediatrics.aappublications.org/content/133/1/152

RECOGNITION AND MANAGEMENT OF MEDICAL COMPLEXITY (CLINICAL REPORT)

Dennis Z. Kuo, MD, MHS, FAAP; Amy J. Houtrow, MD, PhD, MPH, FAAP; and Council on Children With Disabilities

ABSTRACT. Children with medical complexity have extensive needs for health services, experience functional limitations, and are high resource utilizers. Addressing the needs of this population to achieve high-value health care requires optimizing care within the medical home and medical neighborhood. Opportunities exist for health care providers, payers, and policy makers to develop strategies to enhance care delivery and to decrease costs. Important outcomes include decreasing unplanned hospital admissions, decreasing emergency department use, ensuring access to health services, limiting out-of-pocket expenses for families, and improving patient and family experiences, quality of life, and satisfaction with care. This report describes the population of children with medical complexity and provides strategies to optimize medical and health outcomes. (11/16)

http://pediatrics.aappublications.org/content/138/6/e20163021

RECOGNIZING AND RESPONDING TO MEDICAL NEGLECT (CLINICAL REPORT)

Carole Jenny, MD, MBA, and Committee on Child Abuse and Neglect

ABSTRACT. A caregiver may fail to recognize or respond to a child's medical needs for a variety of reasons. An effective response by a health care professional to medical neglect requires a comprehensive assessment of the child's needs, the parents' resources, the parents' efforts to provide for the needs of the child, and options for ensuring optimal health for the child. Such an assessment requires clear, 2-way communication between the family and the health care professional. Physicians should consider the least intrusive options for managing cases of medical neglect that ensure the health and safety of the child. (12/07, reaffirmed 1/11, 2/16)

http://pediatrics.aappublications.org/content/120/6/1385

RECOMMENDATIONS FOR PREVENTION AND CONTROL OF INFLUENZA IN CHILDREN, 2020–2021

Committee on Infectious Diseases

ABSTRACT. This statement updates the recommendations of the American Academy of Pediatrics for the routine use of influenza vaccine and antiviral medications in the prevention and treatment of influenza in children during the 2020–2021 season.

The American Academy of Pediatrics (AAP) recommends routine influenza immunization of all children without medical contraindications, starting at 6 months of age. Influenza vaccination is an important intervention to protect vulnerable populations and reduce the burden of respiratory illnesses during the severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2) pandemic. Any licensed, recommended, age-appropriate vaccine available can be administered, without preference for one product or formulation over another.

Antiviral treatment of influenza with any licensed, recommended, age-appropriate influenza antiviral medication is recommended for children with suspected or confirmed influenza who are hospitalized, have severe or progressive disease, or have underlying conditions that increase their risk of complications of influenza. Antiviral treatment may be considered for any previously healthy, symptomatic outpatient not at high risk for influenza complications in whom an influenza diagnosis is confirmed or suspected, if treatment can be initiated within 48 hours of illness onset, and for children whose siblings or household contacts either are younger than 6 months or have a high-risk condition that predisposes them to complications of influenza. (9/20)

See full text on page 1133.

https://pediatrics.aappublications.org/content/146/4/e2020024588

RECOMMENDATIONS FOR SEROGROUP B MENINGOCOCCAL VACCINE FOR PERSONS 10 YEARS AND OLDER

Committee on Infectious Diseases

ABSTRACT. This policy statement provides recommendations for the prevention of serogroup B meningococcal disease through the use of 2 newly licensed serogroup B meningococcal vaccines: MenB-FHbp (Trumenba; Wyeth Pharmaceuticals, a subsidiary

of Pfizer, Philadelphia, PA) and MenB-4C (Bexsero; Novartis Vaccines, Siena, Italy). Both vaccines are approved for use in persons 10 through 25 years of age. MenB-FHbp is licensed as a 2- or 3-dose series, and MenB-4C is licensed as a 2-dose series for all groups. Either vaccine is recommended for routine use in persons 10 years and older who are at increased risk of serogroup B meningococcal disease (category A recommendation). Persons at increased risk of meningococcal serogroup B disease include the following: (1) persons with persistent complement component diseases, including inherited or chronic deficiencies in C3, C5–C9, properdin, factor D, or factor H, or persons receiving eculizumab (Soliris; Alexion Pharmaceuticals, Cheshire, CT), a monoclonal antibody that acts as a terminal complement inhibitor by binding C5 and inhibiting cleavage of C5 to C5A; (2) persons with anatomic or functional asplenia, including sickle cell disease; and (3) healthy persons at increased risk because of a serogroup B meningococcal disease outbreak. Both serogroup B meningococcal vaccines have been shown to be safe and immunogenic and are licensed by the US Food and Drug Administration for individuals between the ages of 10 and 25 years. On the basis of epidemiologic and antibody persistence data, the American Academy of Pediatrics agrees with the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention that either vaccine may be administered to healthy adolescents and young adults 16 through 23 years of age (preferred ages are 16 through 18 years) to provide short-term protection against most strains of serogroup B meningococcal disease (category B recommendation). (8/16)
http://pediatrics.aappublications.org/content/138/3/e20161890

RECOMMENDED CHILDHOOD AND ADOLESCENT IMMUNIZATION SCHEDULE: UNITED STATES, 2021

Committee on Infectious Diseases (2/21)
See full text on page 1165.
https://pediatrics.aappublications.org/content/early/2021/02/11/peds.2020-049775

REDUCING INJURY RISK FROM BODY CHECKING IN BOYS' YOUTH ICE HOCKEY

Council on Sports Medicine and Fitness
ABSTRACT. Ice hockey is an increasingly popular sport that allows intentional collision in the form of body checking for males but not for females. There is a two- to threefold increased risk of all injury, severe injury, and concussion related to body checking at all levels of boys' youth ice hockey. The American Academy of Pediatrics reinforces the importance of stringent enforcement of rules to protect player safety as well as educational interventions to decrease unsafe tactics. To promote ice hockey as a lifelong recreational pursuit for boys, the American Academy of Pediatrics recommends the expansion of nonchecking programs and the restriction of body checking to elite levels of boys' youth ice hockey, starting no earlier than 15 years of age. (5/14, reaffirmed 7/18)
http://pediatrics.aappublications.org/content/133/6/1151

REDUCING THE NUMBER OF DEATHS AND INJURIES FROM RESIDENTIAL FIRES

Committee on Injury and Poison Prevention
ABSTRACT. Smoke inhalation, severe burns, and death from residential fires are devastating events, most of which are preventable. In 1998, approximately 381 500 residential structure fires resulted in 3250 non-firefighter deaths, 17 175 injuries, and approximately $4.4 billion in property loss. This statement reviews important prevention messages and intervention strategies related to residential fires. It also includes recommendations for pediatricians regarding office anticipatory guidance, work in the community, and support of regulation and legislation that could result in a decrease in the number of fire-related injuries and deaths to children. (6/00)
http://pediatrics.aappublications.org/content/105/6/1355

REFERRAL TO PEDIATRIC SURGICAL SPECIALISTS

Surgical Advisory Panel
ABSTRACT. The American Academy of Pediatrics, with the collaboration of the Surgical Sections of the American Academy of Pediatrics, has created referral recommendations intended to serve as voluntary practice parameters to assist general pediatricians in determining when and to whom to refer their patients for pediatric surgical specialty care. It is recognized that these recommendations may be difficult to implement, because communities vary in terms of access to major pediatric medical centers. Limited access does not negate the value of the recommendations, however, because the child who needs specialized surgical and anesthetic care is best served by the skills of the appropriate pediatric surgical team. Major congenital anomalies, malignancies, major trauma, and chronic illnesses (including those associated with preterm birth) in infants and children should be managed by pediatric medical subspecialists and pediatric surgical specialists at pediatric referral centers that can provide expertise in many areas, including the pediatric medical subspecialties and surgical specialties of pediatric radiology, pediatric anesthesiology, pediatric pathology, and pediatric intensive care. The optimal management of the child with complex problems, chronic illness, or disabilities requires coordination, communication, and cooperation of the pediatric surgical specialist with the child's primary care pediatrician or physician. (1/14)
http://pediatrics.aappublications.org/content/133/2/350

RELIEF OF PAIN AND ANXIETY IN PEDIATRIC PATIENTS IN EMERGENCY MEDICAL SYSTEMS (CLINICAL REPORT)

Joel A. Fein, MD, MPH; William T. Zempsky, MD, MPH; Joseph P. Cravero, MD; Committee on Pediatric Emergency Medicine; and Section on Anesthesiology and Pain Medicine
ABSTRACT. Control of pain and stress for children is a vital component of emergency medical care. Timely administration of analgesia affects the entire emergency medical experience and can have a lasting effect on a child's and family's reaction to current and future medical care. A systematic approach to pain management and anxiolysis, including staff education and protocol development, can provide comfort to children in the emergency setting and improve staff and family satisfaction. (10/12, reaffirmed 9/15)
http://pediatrics.aappublications.org/content/130/5/e1391

RESCUE MEDICINE FOR EPILEPSY IN EDUCATION SETTINGS (CLINICAL REPORT)

Adam L. Hartman, MD, FAAP; Cynthia Di Laura Devore, MD; Section on Neurology; and Council on School Health
ABSTRACT. Children and adolescents with epilepsy may experience prolonged seizures in school-associated settings (eg, during transportation, in the classroom, or during sports activities). Prolonged seizures may evolve into status epilepticus. Administering a seizure rescue medication can abort the seizure and may obviate the need for emergency medical services and subsequent care in an emergency department. In turn, this may save patients from the morbidity of more invasive interventions and the cost of escalated care. There are significant variations in prescribing practices for seizure rescue medications, partly because of inconsistencies between jurisdictions in legislation and professional practice guidelines among potential first responders (including school staff). There also are potential liability issues for prescribers, school districts, and unlicensed assistive personnel who might administer the seizure rescue medications. This clinical report highlights issues that providers

may consider when prescribing seizure rescue medications and creating school medical orders and/or action plans for students with epilepsy. Collaboration among prescribing providers, families, and schools may be useful in developing plans for the use of seizure rescue medications. (12/15)
http://pediatrics.aappublications.org/content/137/1/e20153876

RESISTANCE TRAINING FOR CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Paul R. Stricker, MD, FAAP; Avery D. Faigenbaum, EdD, FACSM, FNSCA; Teri M. McCambridge, MD, FAAP; and Council on Sports Medicine and Fitness

ABSTRACT. Resistance training is becoming more important as an integral part of comprehensive sport training regimens, school physical education classes, and after-school fitness programs. The increasing number of youth who are involved in sport activities, coupled with the health problems of inactivity and being overweight, have resulted in increased interest in resistance training. Secular declines in measures of muscular fitness in modern-day youth highlight the need for participation in youth resistance training for nonathletes as well as athletes. Parents often ask pediatricians to offer advice regarding the safety, benefits, and implementation of an effective resistance-training program. This report is a revision of the 2008 American Academy of Pediatrics policy statement and reviews current information and research on the benefits and risks of resistance training for children and adolescents. (5/20)

See full text on page 1171.

https://pediatrics.aappublications.org/content/145/6/e20201011

RESOURCES RECOMMENDED FOR THE CARE OF PEDIATRIC PATIENTS IN HOSPITALS (CLINICAL REPORT)

Kimberly D. Ernst, MD, MSMI, FAAP, and Committee on Hospital Care

ABSTRACT. It is crucial that all children are provided with high-quality and safe health care. Pediatric inpatient needs are unique in regard to policies, equipment, facilities, and personnel. The intent of this clinical report is to provide recommendations for the resources necessary to provide high-quality and safe pediatric inpatient medical care. (3/20)

See full text on page 1187.

https://pediatrics.aappublications.org/content/145/4/e20200204

RESPIRATORY SUPPORT IN PRETERM INFANTS AT BIRTH

Committee on Fetus and Newborn

ABSTRACT. Current practice guidelines recommend administration of surfactant at or soon after birth in preterm infants with respiratory distress syndrome. However, recent multicenter randomized controlled trials indicate that early use of continuous positive airway pressure with subsequent selective surfactant administration in extremely preterm infants results in lower rates of bronchopulmonary dysplasia/death when compared with treatment with prophylactic or early surfactant therapy. Continuous positive airway pressure started at or soon after birth with subsequent selective surfactant administration may be considered as an alternative to routine intubation with prophylactic or early surfactant administration in preterm infants. (12/13)
http://pediatrics.aappublications.org/content/133/1/171

RESPONDING TO PARENTAL REFUSALS OF IMMUNIZATION OF CHILDREN (CLINICAL REPORT)

Douglas S. Diekema, MD, MPH, and Committee on Bioethics

ABSTRACT. The American Academy of Pediatrics strongly endorses universal immunization. However, for childhood immunization programs to be successful, parents must comply with immunization recommendations. The problem of parental refusal of immunization for children is an important one for pediatricians. The goal of this report is to assist pediatricians in understanding the reasons parents may have for refusing to immunize their children, review the limited circumstances under which parental refusals should be referred to child protective services agencies or public health authorities, and provide practical guidance to assist the pediatrician faced with a parent who is reluctant to allow immunization of his or her child. (5/05, reaffirmed 1/09, 11/12)
http://pediatrics.aappublications.org/content/115/5/1428

RESPONSIBLE INNOVATION IN CHILDREN'S SURGICAL CARE

Section on Surgery and Committee on Bioethics (joint with American Pediatric Surgical Association New Technology Committee)

ABSTRACT. Advances in medical care may occur when a change in practice incorporates a new treatment or methodology. In surgery, this may involve the translation of a completely novel concept into a new procedure or device or the adaptation of existing treatment approaches or technology to a new clinical application. Regardless of the specifics, innovation should have, as its primary goal, the enhancement of care leading to improved outcomes from the patient's perspective. This policy statement examines innovation as it pertains to surgical care, focusing on some of the definitions that help differentiate applied innovation or innovative therapy from research. The ethical challenges and the potential for conflict of interest for surgeons or institutions seeking to offer innovative surgical therapy are examined. The importance of engaging patients and families as "innovation partners" to ensure complete transparency of expectations from the patient's and provider's perspectives is also examined, with specific emphasis on cultural competence and mutually respectful approaches. A framework for identifying, evaluating, and safely implementing innovative surgical therapy in children is provided. (12/16)
http://pediatrics.aappublications.org/content/139/1/e20163437

RETURNING TO LEARNING FOLLOWING A CONCUSSION (CLINICAL REPORT)

Mark E. Halstead, MD, FAAP; Karen McAvoy, PsyD; Cynthia D. Devore, MD, FAAP; Rebecca Carl, MD, FAAP; Michael Lee, MD, FAAP; Kelsey Logan, MD, FAAP; Council on Sports Medicine and Fitness; and Council on School Health

ABSTRACT. Following a concussion, it is common for children and adolescents to experience difficulties in the school setting. Cognitive difficulties, such as learning new tasks or remembering previously learned material, may pose challenges in the classroom. The school environment may also increase symptoms with exposure to bright lights and screens or noisy cafeterias and hallways. Unfortunately, because most children and adolescents look physically normal after a concussion, school officials often fail to recognize the need for academic or environmental adjustments. Appropriate guidance and recommendations from the pediatrician may ease the transition back to the school environment and facilitate the recovery of the child or adolescent. This report serves to provide a better understanding of possible factors that may contribute to difficulties in a school environment after a concussion and serves as a framework for the medical home, the educational home, and the family home to guide the student to a successful and safe return to learning. (10/13, reaffirmed 7/18)
http://pediatrics.aappublications.org/content/132/5/948

RITUAL GENITAL CUTTING OF FEMALE MINORS

Board of Directors (6/10)
http://pediatrics.aappublications.org/content/126/1/191

THE ROLE OF INTEGRATED CARE IN A MEDICAL HOME FOR PATIENTS WITH A FETAL ALCOHOL SPECTRUM DISORDER (CLINICAL REPORT)

Renee M. Turchi, MD, MPH, FAAP; Vincent C. Smith, MD, MPH, FAAP; Committee on Substance Use and Prevention; and Council on Children With Disabilities

ABSTRACT. Fetal alcohol spectrum disorder (FASD) is an umbrella term used to describe preventable birth defects and intellectual and/or developmental disabilities resulting from prenatal alcohol exposure. The American Academy of Pediatrics has a previous clinical report in which diagnostic criteria for a child with an FASD are discussed and tools to assist pediatricians with its management can be found. This clinical report is intended to foster pediatrician awareness of approaches for screening for prenatal alcohol exposure in clinical practice, to guide management of a child with an FASD after the diagnosis is made, and to summarize available resources for FASD management. (9/18)

http://pediatrics.aappublications.org/content/142/4/e20182333

THE ROLE OF PEDIATRICIANS IN GLOBAL HEALTH

Parminder S. Suchdev, MD, MPH, FAAP; Cynthia R. Howard, MD, MPHTM, FAAP; Section on International Child Health

ABSTRACT. Ninety percent of the world's children live in low- and middle-income countries, where barriers to health contribute to significant child morbidity and mortality. The American Academy of Pediatrics is dedicated to the health and well-being of *all* children. To fulfill this promise, this policy statement defines the role of the pediatrician in global health and provides a specific set of recommendations directed to all pediatricians, emphasizing the importance of global health as an integral function of the profession of pediatrics. (11/18)

http://pediatrics.aappublications.org/content/142/6/e20182997

ROLE OF PULSE OXIMETRY IN EXAMINING NEWBORNS FOR CONGENITAL HEART DISEASE: A SCIENTIFIC STATEMENT FROM THE AHA AND AAP

William T. Mahle, MD; Jane W. Newburger, MD, MPH; G. Paul Matherne, MD; Frank C. Smith, MD; Tracey R. Hoke, MD; Robert Koppel, MD; Samuel S. Gidding, MD; Robert H. Beekman III, MD; Scott D. Grosse, PhD; on behalf of Section on Cardiology and Cardiac Surgery and Committee of Fetus and Newborn (joint with American Heart Association Congenital Heart Defects Committee of the Council on Cardiovascular Disease in the Young, Council on Cardiovascular Nursing, and Interdisciplinary Council on Quality of Care and Outcomes Research)

ABSTRACT. *Background.* The purpose of this statement is to address the state of evidence on the routine use of pulse oximetry in newborns to detect critical congenital heart disease (CCHD).

Methods and Results. A writing group appointed by the American Heart Association and the American Academy of Pediatrics reviewed the available literature addressing current detection methods for CCHD, burden of missed and/or delayed diagnosis of CCHD, rationale of oximetry screening, and clinical studies of oximetry in otherwise asymptomatic newborns. MEDLINE database searches from 1966 to 2008 were done for English-language papers using the following search terms: congenital heart disease, pulse oximetry, physical examination, murmur, echocardiography, fetal echocardiography, and newborn screening. The reference lists of identified papers were also searched. Published abstracts from major pediatric scientific meetings in 2006 to 2008 were also reviewed. The American Heart Association classification of recommendations and levels of evidence for practice guidelines were used. In an analysis of pooled studies of oximetry assessment performed after 24 hours of life, the estimated sensitivity for detecting CCHD was 69.6%, and the positive predictive value was 47.0%; however, sensitivity varied dramatically among studies from 0% to 100%. False-positive screens that required further evaluation occurred in only 0.035% of infants screened after 24 hours.

Conclusions. Currently, CCHD is not detected in some newborns until after their hospital discharge, which results in significant morbidity and occasional mortality. Furthermore, routine pulse oximetry performed on asymptomatic newborns after 24 hours of life, but before hospital discharge, may detect CCHD. Routine pulse oximetry performed after 24 hours in hospitals that have on-site pediatric cardiovascular services incurs very low cost and risk of harm. Future studies in larger populations and across a broad range of newborn delivery systems are needed to determine whether this practice should become standard of care in the routine assessment of the neonate. (8/09)

http://pediatrics.aappublications.org/content/124/2/823

THE ROLE OF THE PEDIATRICIAN IN PRIMARY PREVENTION OF OBESITY (CLINICAL REPORT)

Stephen R. Daniels, MD, PhD, FAAP; Sandra G. Hassink, MD, FAAP; and Committee on Nutrition

ABSTRACT. The adoption of healthful lifestyles by individuals and families can result in a reduction in many chronic diseases and conditions of which obesity is the most prevalent. Obesity prevention, in addition to treatment, is an important public health priority. This clinical report describes the rationale for pediatricians to be an integral part of the obesity-prevention effort. In addition, the 2012 Institute of Medicine report "Accelerating Progress in Obesity Prevention" includes health care providers as a crucial component of successful weight control. Research on obesity prevention in the pediatric care setting as well as evidence-informed practical approaches and targets for prevention are reviewed. Pediatricians should use a longitudinal, developmentally appropriate life-course approach to help identify children early on the path to obesity and base prevention efforts on family dynamics and reduction in high-risk dietary and activity behaviors. They should promote a diet free of sugar-sweetened beverages, of fewer foods with high caloric density, and of increased intake of fruits and vegetables. It is also important to promote a lifestyle with reduced sedentary behavior and with 60 minutes of daily moderate to vigorous physical activity. This report also identifies important gaps in evidence that need to be filled by future research. (6/15)

http://pediatrics.aappublications.org/content/136/1/e275

THE ROLE OF THE PEDIATRICIAN IN RURAL EMERGENCY MEDICAL SERVICES FOR CHILDREN

Committee on Pediatric Emergency Medicine

ABSTRACT. In rural America, pediatricians can play a key role in the development, implementation, and ongoing supervision of emergency medical services for children (EMSC). Pediatricians may represent the only source of pediatric expertise for a large region and are a vital resource for rural physicians (eg, general and family practice, emergency medicine) and other rural health care professionals (physician assistants, nurse practitioners, and emergency medical technicians), providing education about management and prevention of pediatric illness and injury; appropriate equipment for the acutely ill or injured child; and acute, chronic, and rehabilitative care. In addition to providing clinical expertise, the pediatrician may be involved in quality assurance, clinical protocol development, and advocacy, and may serve as a liaison between emergency medical services and other entities working with children (eg, school nurses, child care centers, athletic programs, and programs for children with special health care needs). (10/12, reaffirmed 9/15)

http://pediatrics.aappublications.org/content/130/5/978

ROLE OF THE PEDIATRICIAN IN YOUTH VIOLENCE PREVENTION

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Youth violence continues to be a serious threat to the health of children and adolescents in the United States. It is crucial that pediatricians clearly define their role and develop the appropriate skills to address this threat effectively. From a clinical perspective, pediatricians should become familiar with *Connected Kids: Safe, Strong, Secure,* the American Academy of Pediatrics' primary care violence prevention protocol. Using this material, practices can incorporate preventive education, screening for risk, and linkages to community-based counseling and treatment resources. As advocates, pediatricians may bring newly developed information regarding key risk factors such as exposure to firearms, teen dating violence, and bullying to the attention of local and national policy makers. This policy statement refines the developing role of pediatricians in youth violence prevention and emphasizes the importance of this issue in the strategic agenda of the American Academy of Pediatrics. (6/09, reaffirmed 4/19)

http://pediatrics.aappublications.org/content/124/1/393

ROLE OF THE SCHOOL NURSE IN PROVIDING SCHOOL HEALTH SERVICES

Council on School Health

ABSTRACT. The American Academy of Pediatrics recognizes the important role school nurses play in promoting the optimal biopsychosocial health and well-being of school-aged children in the school setting. Although the concept of a school nurse has existed for more than a century, uniformity among states and school districts regarding the role of a registered professional nurse in schools and the laws governing it are lacking. By understanding the benefits, roles, and responsibilities of school nurses working as a team with the school physician, as well as their contributions to school-aged children, pediatricians can collaborate with, support, and promote school nurses in their own communities, thus improving the health, wellness, and safety of children and adolescents. (5/16)

http://pediatrics.aappublications.org/content/137/6/e20160852

ROLE OF THE SCHOOL PHYSICIAN

Council on School Health

ABSTRACT. The American Academy of Pediatrics recognizes the important role physicians play in promoting the optimal biopsychosocial well-being of children in the school setting. Although the concept of a school physician has existed for more than a century, uniformity among states and school districts regarding physicians in schools and the laws governing it are lacking. By understanding the roles and contributions physicians can make to schools, pediatricians can support and promote school physicians in their communities and improve health and safety for children. (12/12, reaffirmed 1/19)

http://pediatrics.aappublications.org/content/131/1/178

ROUTINE NEUROIMAGING OF THE PRETERM BRAIN (CLINICAL REPORT)

Ivan L. Hand, MD, FAAP; Renée A. Shellhaas, MD, MS, FAAP; Sarah S. Milla, MD, FAAP; Committee on Fetus and Newborn; Section on Neurology; and Section on Radiology

ABSTRACT. Neuroimaging of the preterm infant is a common assessment performed in the NICU. Timely and focused studies can be used for diagnostic, therapeutic, and prognostic information. However, significant variability exists among neonatal units as to which modalities are used and when imaging studies are obtained. Appropriate timing and selection of neuroimaging studies can help identify neonates with brain injury who may require therapeutic intervention or who may be at risk for neurodevelopmental impairment. This clinical report reviews the different modalities of imaging broadly available to the clinician. Evidence-based indications for each modality, optimal timing of examinations, and prognostic value are discussed. (10/20)

See full text on page 1201.

https://pediatrics.aappublications.org/content/146/5/e2020029082

RUNAWAY YOUTH: CARING FOR THE NATION'S LARGEST SEGMENT OF MISSING CHILDREN (CLINICAL REPORT)

Thresia B. Gambon, MD, MPH, MBA, FAAP; Janna R. Gewirtz O'Brien, MD, FAAP; Committee on Psychosocial Aspects of Child and Family Health; and Council on Community Pediatrics

ABSTRACT. The largest segment of missing children in the United States includes runaways, children who run away from home, and thrownaways, children who are told to leave or stay away from home by a household adult. Although estimates vary, as many as 1 in 20 youth run away from home annually. These unaccompanied youth have unique health needs, including high rates of trauma, mental illness, substance use, pregnancy, and sexually transmitted infections. While away, youth who run away are at high risk for additional trauma, victimization, and violence. Runaway and thrownaway youth have high unmet health care needs and limited access to care. Several populations are at particular high risk for runaway episodes, including victims of abuse and neglect; lesbian, gay, bisexual, transgender, and questioning youth; and youth in protective custody. Pediatricians and other health care professionals have a critical role to play in supporting runaway youth, addressing their unique health needs, fostering positive relationships within their families and with other supportive adults, and connecting them with available community resources. This report provides clinical guidance for pediatricians and other health care professionals regarding (1) the identification of adolescents who are at risk for running away or being thrown away and (2) the management of the unique medical, mental health, and social needs of these youth. In partnership with national, state, and local resources, pediatricians can significantly reduce risk and improve long-term outcomes for runaway youth. (1/20)

See full text on page 1211.

https://pediatrics.aappublications.org/content/145/2/e20193752

SAFE SLEEP AND SKIN-TO-SKIN CARE IN THE NEONATAL PERIOD FOR HEALTHY TERM NEWBORNS (CLINICAL REPORT)

Lori Feldman-Winter, MD, MPH, FAAP; Jay P. Goldsmith, MD, FAAP; Committee on Fetus and Newborn; and Task Force on Sudden Infant Death Syndrome

ABSTRACT. Skin-to-skin care (SSC) and rooming-in have become common practice in the newborn period for healthy newborns with the implementation of maternity care practices that support breastfeeding as delineated in the World Health Organization's "Ten Steps to Successful Breastfeeding." SSC and rooming-in are supported by evidence that indicates that the implementation of these practices increases overall and exclusive breastfeeding, safer and healthier transitions, and improved maternal-infant bonding. In some cases, however, the practice of SSC and rooming-in may pose safety concerns, particularly with regard to sleep. There have been several recent case reports and case series of severe and sudden unexpected postnatal collapse in the neonatal period among otherwise healthy newborns and near fatal or fatal events related to sleep, suffocation, and falls from adult hospital beds. Although these are largely case reports, there are potential dangers of unobserved SSC immediately after birth and throughout the postpartum hospital period as well as with unobserved rooming-in for at-risk situations. Moreover,

behaviors that are modeled in the hospital after birth, such as sleep position, are likely to influence sleeping practices after discharge. Hospitals and birthing centers have found it difficult to develop policies that will allow SSC and rooming-in to continue in a safe manner. This clinical report is intended for birthing centers and delivery hospitals caring for healthy newborns to assist in the establishment of appropriate SSC and safe sleep policies. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20161889

SAFE TRANSPORTATION OF PRETERM AND LOW BIRTH WEIGHT INFANTS AT HOSPITAL DISCHARGE (CLINICAL REPORT)

Marilyn J. Bull, MD; William A. Engle, MD; Committee on Injury, Violence, and Poison Prevention; and Committee on Fetus and Newborn

ABSTRACT. Safe transportation of preterm and low birth weight infants requires special considerations. Both physiologic immaturity and low birth weight must be taken into account to properly position such infants. This clinical report provides guidelines for pediatricians and other caregivers who counsel parents of preterm and low birth weight infants about car safety seats. (4/09, reaffirmed 8/13, 6/18)

http://pediatrics.aappublications.org/content/123/5/1424

SCHOOL BUS TRANSPORTATION OF CHILDREN WITH SPECIAL HEALTH CARE NEEDS

Joseph O'Neil, MD, MPH, FAAP; Benjamin D. Hoffman, MD, FAAP; and Council on Injury, Violence, and Poison Prevention

ABSTRACT. School systems are responsible for ensuring that children with special needs are safely transported on all forms of federally approved transportation provided by the school system. A plan to provide the most current and proper support to children with special transportation needs should be developed by the Individualized Education Program team, including the parent, school transportation director, and school nurse, in conjunction with physician orders and recommendations. With this statement, we provide current guidance for the protection of child passengers with specific health care needs. Guidance that applies to general school transportation should be followed, inclusive of staff training, provision of nurses or aides if needed, and establishment of a written emergency evacuation plan as well as a comprehensive infection control program. Researchers provide the basis for recommendations concerning occupant securement for children in wheelchairs and children with other special needs who are transported on a school bus. Pediatricians can help their patients by being aware of guidance for restraint systems for children with special needs and by remaining informed of new resources. Pediatricians can also play an important role at the state and local level in the development of school bus specifications. (4/18)

http://pediatrics.aappublications.org/content/141/5/e20180513

SCHOOL READINESS (TECHNICAL REPORT)

P. Gail Williams, MD, FAAP; Marc Alan Lerner, MD, FAAP; Council on Early Childhood; and Council on School Health

ABSTRACT. School readiness includes the readiness of the individual child, the school's readiness for children, and the ability of the family and community to support optimal early child development. It is the responsibility of schools to meet the needs of all children at all levels of readiness. Children's readiness for kindergarten should become an outcome measure for a coordinated system of community-based programs and supports for the healthy development of young children. Our rapidly expanding insights into early brain and child development have revealed that modifiable factors in a child's early experience can greatly affect that child's health and learning trajectories. Many children in the United States enter kindergarten with limitations in their social, emotional, cognitive, and physical development that might have been significantly diminished or eliminated through early identification and attention to child and family needs. A strong correlation between social-emotional development and school and life success, combined with alarming rates of preschool expulsion, point toward the urgency of leveraging opportunities to support social-emotional development and address behavioral concerns early. Pediatric primary care providers have access to the youngest children and their families. Pediatricians can promote and use community supports, such as home visiting programs, quality early care and education programs, family support programs and resources, early intervention services, children's museums, and libraries, which are important for addressing school readiness and are too often underused by populations who can benefit most from them. When these are not available, pediatricians can support the development of such resources. The American Academy of Pediatrics affords pediatricians many opportunities to improve the physical, social-emotional, and educational health of young children, in conjunction with other advocacy groups. This technical report provides an updated version of the previous iteration from the American Academy of Pediatrics published in 2008. (7/19)

https://pediatrics.aappublications.org/content/144/2/e20191766

SCHOOL START TIMES FOR ADOLESCENTS

Adolescent Sleep Working Group, Committee on Adolescence, and Council on School Health

ABSTRACT. The American Academy of Pediatrics recognizes insufficient sleep in adolescents as an important public health issue that significantly affects the health and safety, as well as the academic success, of our nation's middle and high school students. Although a number of factors, including biological changes in sleep associated with puberty, lifestyle choices, and academic demands, negatively affect middle and high school students' ability to obtain sufficient sleep, the evidence strongly implicates earlier school start times (ie, before 8:30 AM) as a key modifiable contributor to insufficient sleep, as well as circadian rhythm disruption, in this population. Furthermore, a substantial body of research has now demonstrated that delaying school start times is an effective countermeasure to chronic sleep loss and has a wide range of potential benefits to students with regard to physical and mental health, safety, and academic achievement. The American Academy of Pediatrics strongly supports the efforts of school districts to optimize sleep in students and urges high schools and middle schools to aim for start times that allow students the opportunity to achieve optimal levels of sleep (8.5–9.5 hours) and to improve physical (eg, reduced obesity risk) and mental (eg, lower rates of depression) health, safety (eg, drowsy driving crashes), academic performance, and quality of life. (8/14)

http://pediatrics.aappublications.org/content/134/3/642

SCHOOL TRANSPORTATION SAFETY

Committee on Injury, Violence, and Poison Prevention and Council on School Health

ABSTRACT. This policy statement replaces the previous version published in 1996. It provides new information, studies, regulations, and recommendations related to the safe transportation of children to and from school and school-related activities. Pediatricians can play an important role at the patient/family, community, state, and national levels as child advocates and consultants to schools and early education programs about transportation safety. (7/07, reaffirmed 10/11)

http://pediatrics.aappublications.org/content/120/1/213

SCHOOL-AGED CHILDREN WHO ARE NOT PROGRESSING ACADEMICALLY: CONSIDERATIONS FOR PEDIATRICIANS (CLINICAL REPORT)

Celiane Rey-Casserly, PhD; Laura McGuinn, MD, FAAP; Arthur Lavin, MD, FAAP; Committee on Psychosocial Aspects of Child and Family Health; Section on Developmental and Behavioral Pediatrics

ABSTRACT. Pediatricians and other pediatric primary care providers may be consulted when families have concerns that their child is not making expected progress in school. Pediatricians care not only for an increasingly diverse population of children who may have behavioral, psychological, and learning difficulties but also for increasing numbers of children with complex and chronic medical problems that can affect the development of the central nervous system and can present with learning and academic concerns. In many instances, pediatric providers require additional information about the nature of cognitive, psychosocial, and educational difficulties that affect their school-aged patients. Our purpose for this report is to describe the current state of the science regarding educational achievement to inform pediatricians' decisions regarding further evaluation of a child's challenges. In this report, we review commonly available options for psychological evaluation and/or treatment, medical referrals, and/or recommendations for referral for eligibility determinations at school and review strategies for collaborating with families, schools, and specialists to best serve children and families. (9/19)

https://pediatrics.aappublications.org/content/144/4/e20192520

SCHOOL-BASED HEALTH CENTERS AND PEDIATRIC PRACTICE

Council on School Health

ABSTRACT. School-based health centers (SBHCs) have become an important method of health care delivery for the youth of our nation. Although they only represent 1 aspect of a coordinated school health program approach, SBHCs have provided access to health care services for youth confronted with age, financial, cultural, and geographic barriers. A fundamental principle of SBHCs is to create an environment of service coordination and collaboration that addresses the health needs and well-being of youth with health disparities or poor access to health care services. Some pediatricians have concerns that these centers are in conflict with the primary care provider's medical home. This policy provides an overview of SBHCs and some of their documented benefits, addresses the issue of potential conflict with the medical home, and provides recommendations that support the integration and coordination of SBHCs and the pediatric medical home practice. (1/12, reaffirmed 6/17)

http://pediatrics.aappublications.org/content/129/2/387

SCOPE OF HEALTH CARE BENEFITS FOR CHILDREN FROM BIRTH THROUGH AGE 26

Committee on Child Health Financing

ABSTRACT. The optimal health of all children is best achieved with access to appropriate and comprehensive health care benefits. This policy statement outlines and defines the recommended set of health insurance benefits for children through age 26. The American Academy of Pediatrics developed a set of recommendations concerning preventive care services for children, adolescents, and young adults. These recommendations are compiled in the publication *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents,* third edition. The Bright Futures recommendations were referenced as a standard for access and design of age-appropriate health insurance benefits for infants, children, adolescents, and young adults in the Patient Protection and Affordable Care Act of 2010 (Pub L No. 114–148). (12/11)

http://pediatrics.aappublications.org/content/129/1/185

SCOPE OF PRACTICE ISSUES IN THE DELIVERY OF PEDIATRIC HEALTH CARE

Committee on Pediatric Workforce

ABSTRACT. The American Academy of Pediatrics (AAP) believes that optimal pediatric health care depends on a team-based approach with supervision by a physician leader, preferably a pediatrician. The pediatrician, here defined to include not only pediatric generalists but all pediatric medical subspecialists, all surgical specialists, and internal medicine/pediatric physicians, is uniquely qualified to manage, coordinate, and supervise the entire spectrum of pediatric care, from diagnosis through all stages of treatment, in all practice settings. The AAP recognizes the valuable contributions of nonphysician clinicians, including nurse practitioners and physician assistants, in delivering optimal pediatric care. However, the expansion of the scope of practice of nonphysician pediatric clinicians raises critical public policy and child health advocacy concerns. Pediatricians should serve as advocates for optimal pediatric care in state legislatures, public policy forums, and the media and should pursue opportunities to resolve scope of practice conflicts outside state legislatures. The AAP affirms the importance of appropriate documentation and standards in pediatric education, training, skills, clinical competencies, examination, regulation, and patient care to ensure safety and quality health care for all infants, children, adolescents, and young adults. (5/13, reaffirmed 10/15)

http://pediatrics.aappublications.org/content/131/6/1211

SCREENING EXAMINATION OF PREMATURE INFANTS FOR RETINOPATHY OF PREMATURITY

Walter M. Fierson, MD, FAAP, and Section on Ophthalmology (joint with American Academy of Ophthalmology, American Association for Pediatric Ophthalmology and Strabismus, and American Association of Certified Orthoptists)

ABSTRACT. This policy statement revises a previous statement on screening of preterm infants for retinopathy of prematurity (ROP) that was published in 2013. ROP is a pathologic process that occurs in immature retinal tissue and can progress to a tractional retinal detachment, which may then result in visual loss or blindness. For more than 3 decades, treatment of severe ROP that markedly decreases the incidence of this poor visual outcome has been available. However, severe, treatment-requiring ROP must be diagnosed in a timely fashion to be treated effectively. The sequential nature of ROP requires that infants who are at-risk and preterm be examined at proper times and intervals to detect the changes of ROP before they become destructive. This statement presents the attributes of an effective program to detect and treat ROP, including the timing of initial and follow-up examinations. (11/18)

http://pediatrics.aappublications.org/content/142/6/e20183061

SCREENING FOR NONVIRAL SEXUALLY TRANSMITTED INFECTIONS IN ADOLESCENTS AND YOUNG ADULTS

Committee on Adolescence (joint with Society for Adolescent Health and Medicine)

ABSTRACT. Prevalence rates of many sexually transmitted infections (STIs) are highest among adolescents. If nonviral STIs are detected early, they can be treated, transmission to others can be eliminated, and sequelae can be averted. The US Preventive Services Task Force and the Centers for Disease Control and Prevention have published chlamydia, gonorrhea, and syphilis screening guidelines that recommend screening those at risk on the basis of epidemiologic and clinical outcomes data. This policy statement specifically focuses on these curable, nonviral STIs and reviews the evidence for nonviral STI screening in adolescents, communicates the value of screening, and outlines recommendations for routine nonviral STI screening of adolescents. (6/14)

http://pediatrics.aappublications.org/content/134/1/e302

SCREENING FOR RETINOPATHY IN THE PEDIATRIC PATIENT WITH TYPE 1 DIABETES MELLITUS (CLINICAL REPORT)

Gregg T. Lueder, MD; Janet Silverstein, MD; Section on Ophthalmology; and Section on Endocrinology (joint with American Association for Pediatric Ophthalmology and Strabismus)

ABSTRACT. Diabetic retinopathy (DR) is the leading cause of blindness in young adults in the United States. Early identification and treatment of DR can decrease the risk of vision loss in affected patients. This clinical report reviews the risk factors for the development of DR and screening guidance for pediatric patients with type 1 diabetes mellitus. (7/05, reaffirmed 1/09, 7/14, 11/19)

http://pediatrics.aappublications.org/content/116/1/270

SELECTING APPROPRIATE TOYS FOR YOUNG CHILDREN IN THE DIGITAL ERA (CLINICAL REPORT)

Aleeya Healey, MD, FAAP; Alan Mendelsohn, MD, FAAP; and Council on Early Childhood

ABSTRACT. Play is essential to optimal child development because it contributes to the cognitive, physical, social, and emotional well-being of children and youth. It also offers an ideal and significant opportunity for parents and other caregivers to engage fully with children using toys as an instrument of play and interaction. The evolution of societal perceptions of toys from children's playthings to critical facilitators of early brain and child development has challenged caregivers in deciding which toys are most appropriate for their children. This clinical report strives to provide pediatric health care providers with evidence-based information that can be used to support caregivers as they choose toys for their children. The report highlights the broad definition of a toy; consideration of potential benefits and possible harmful effects of toy choices on child development; and the promotion of positive caregiving and development when toys are used to engage caregivers in play-based interactions with their children that are rich in language, pretending, problem-solving, and creativity. The report aims to address the evolving replacement of more traditional toys with digital media–based virtual "toys" and the lack of evidence for similar benefits in child development. Furthermore, this report briefly addresses the role of toys in advertising and/or incentive programs and aims to bring awareness regarding safety and health hazards associated with toy availability and accessibility in public settings, including some health care settings. (12/18)

https://pediatrics.aappublications.org/content/143/1/e20183348

SENSORY INTEGRATION THERAPIES FOR CHILDREN WITH DEVELOPMENTAL AND BEHAVIORAL DISORDERS

Section on Complementary and Integrative Medicine and Council on Children With Disabilities

ABSTRACT. Sensory-based therapies are increasingly used by occupational therapists and sometimes by other types of therapists in treatment of children with developmental and behavioral disorders. Sensory-based therapies involve activities that are believed to organize the sensory system by providing vestibular, proprioceptive, auditory, and tactile inputs. Brushes, swings, balls, and other specially designed therapeutic or recreational equipment are used to provide these inputs. However, it is unclear whether children who present with sensory-based problems have an actual "disorder" of the sensory pathways of the brain or whether these deficits are characteristics associated with other developmental and behavioral disorders. Because there is no universally accepted framework for diagnosis, sensory processing disorder generally should not be diagnosed. Other developmental and behavioral disorders must always be considered, and a thorough evaluation should be completed. Difficulty tolerating or processing sensory information is a characteristic that may be seen in many developmental behavioral disorders, including autism spectrum disorders, attention-deficit/hyperactivity disorder, developmental coordination disorders, and childhood anxiety disorders.

Occupational therapy with the use of sensory-based therapies may be acceptable as one of the components of a comprehensive treatment plan. However, parents should be informed that the amount of research regarding the effectiveness of sensory integration therapy is limited and inconclusive. Important roles for pediatricians and other clinicians may include discussing these limitations with parents, talking with families about a trial period of sensory integration therapy, and teaching families how to evaluate the effectiveness of a therapy. (5/12)

http://pediatrics.aappublications.org/content/129/6/1186

SEXUAL AND REPRODUCTIVE HEALTH CARE SERVICES IN THE PEDIATRIC SETTING (CLINICAL REPORT)

Arik V. Marcell, MD, MPH; Gale R. Burstein, MD, MPH; and Committee on Adolescence

ABSTRACT. Pediatricians are an important source of health care for adolescents and young adults and can play a significant role in addressing their patients' sexual and reproductive health needs, including preventing unintended pregnancies and sexually transmitted infections (STIs), including HIV, and promoting healthy relationships. STIs, HIV, and unintended pregnancy are all preventable health outcomes with potentially serious permanent sequelae; the highest rates of STIs, HIV, and unintended pregnancy are reported among adolescents and young adults. Office visits present opportunities to provide comprehensive education and health care services to adolescents and young adults to prevent STIs, HIV, and unintended pregnancies. The American Academy of Pediatrics, other professional medical organizations, and the government have guidelines and recommendations regarding the provision of sexual and reproductive health information and services. However, despite these recommendations, recent studies have revealed that there is substantial room for improvement in actually delivering the recommended services. The purpose of this clinical report is to assist pediatricians to operationalize the provision of various aspects of sexual and reproductive health care into their practices and to provide guidance on overcoming barriers to providing this care routinely while maximizing opportunities for confidential health services delivery in their offices. (10/17)

http://pediatrics.aappublications.org/content/140/5/e20172858

SEXUALITY EDUCATION FOR CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Cora C. Breuner, MD, MPH, FAAP; Gerri Mattson, MD, MSPH, FAAP; Committee on Adolescence; and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. The purpose of this clinical report is to provide pediatricians updated research on evidence-based sexual and reproductive health education conducted since the original clinical report on the subject was published by the American Academy of Pediatrics in 2001. Sexuality education is defined as teaching about human sexuality, including intimate relationships, human sexual anatomy, sexual reproduction, sexually transmitted infections, sexual activity, sexual orientation, gender identity, abstinence, contraception, and reproductive rights and responsibilities. Developmentally appropriate and evidence-based education about human sexuality and sexual reproduction over time provided by pediatricians, schools, other professionals, and parents is important to help children and adolescents make informed, positive, and safe choices about healthy relationships, responsible sexual activity, and their reproductive health. Sexuality education has been shown to help to prevent and reduce the risks of adolescent pregnancy, HIV, and sexually transmitted infections for children and adolescents with and

without chronic health conditions and disabilities in the United States. (7/16)
http://pediatrics.aappublications.org/content/138/2/e20161348

SEXUALITY OF CHILDREN AND ADOLESCENTS WITH DEVELOPMENTAL DISABILITIES (CLINICAL REPORT)

Nancy A. Murphy, MD; Ellen Roy Elias, MD; for Council on Children With Disabilities

ABSTRACT. Children and adolescents with developmental disabilities, like all children, are sexual persons. However, attention to their complex medical and functional issues often consumes time that might otherwise be invested in addressing the anatomic, physiologic, emotional, and social aspects of their developing sexuality. This report discusses issues of puberty, contraception, psychosexual development, sexual abuse, and sexuality education specific to children and adolescents with disabilities and their families. Pediatricians, in the context of the medical home, are encouraged to discuss issues of sexuality on a regular basis, ensure the privacy of each child and adolescent, promote self-care and social independence among persons with disabilities, advocate for appropriate sexuality education, and provide ongoing education for children and adolescents with developmental disabilities and their families. (7/06, reaffirmed 12/09, 7/13, 11/17)
http://pediatrics.aappublications.org/content/118/1/398

SHARED DECISION-MAKING AND CHILDREN WITH DISABILITIES: PATHWAYS TO CONSENSUS (CLINICAL REPORT)

Richard C. Adams, MD, FAAP; Susan E. Levy, MD, MPH, FAAP; and Council on Children With Disabilities

ABSTRACT. Shared decision-making (SDM) promotes family and clinician collaboration, with ultimate goals of improved health and satisfaction. This clinical report provides a basis for a systematic approach to the implementation of SDM by clinicians for children with disabilities. Often in the discussion of treatment plans, there are gaps between the child's/family's values, priorities, and understanding of perceived "best choices" and those of the clinician. When conducted well, SDM affords an appropriate balance incorporating voices of all stakeholders, ultimately supporting both the child/family and clinician. With increasing knowledge of and functional use of SDM skills, the clinician will become an effective partner in the decision-making process with families, providing family-centered care. The outcome of the process will support the beneficence of the physician, the authority of the family, and the autonomy and well-being of the child. (5/17)
http://pediatrics.aappublications.org/content/139/6/e20170956

SHOPPING CART–RELATED INJURIES TO CHILDREN

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Shopping cart–related injuries to children are common and can result in severe injury or even death. Most injuries result from falls from carts or cart tip-overs, and injuries to the head and neck represent three fourths of cases. The current US standard for shopping carts should be revised to include clear and effective performance criteria to prevent falls from carts and cart tip-overs. Pediatricians have an important role as educators, researchers, and advocates to promote the prevention of these injuries. (8/06, reaffirmed 4/09, 8/13)
http://pediatrics.aappublications.org/content/118/2/825

SHOPPING CART–RELATED INJURIES TO CHILDREN (TECHNICAL REPORT)

Gary A. Smith, MD, DrPH, for Committee on Injury, Violence, and Poison Prevention

ABSTRACT. An estimated 24 200 children younger than 15 years, 20 700 (85%) of whom were younger than 5 years, were treated in US hospital emergency departments in 2005 for shopping cart–related injuries. Approximately 4% of shopping cart–related injuries to children younger than 15 years require admission to the hospital. Injuries to the head and neck represent three fourths of all injuries. Fractures account for 45% of all hospitalizations. Deaths have occurred from falls from shopping carts and cart tip-overs. Falls are the most common mechanism of injury and account for more than half of injuries associated with shopping carts. Cart tip-overs are the second most common mechanism, responsible for up to one fourth of injuries and almost 40% of shopping cart–related injuries among children younger than 2 years. Public-awareness initiatives, education programs, and parental supervision, although important, are not enough to prevent these injuries effectively. European Standard EN 1929-1:1998 and joint Australian/New Zealand Standard AS/NZS 3847.1:1999 specify requirements for the construction, performance, testing, and safety of shopping carts and have been implemented as national standards in 21 countries. A US performance standard for shopping carts (ASTM [American Society for Testing and Materials] F2372-04) was established in July 2004; however, it does not adequately address falls and cart tip-overs, which are the leading mechanisms of shopping cart–related injuries to children. The current US standard for shopping carts should be revised to include clear and effective performance criteria for shopping cart child-restraint systems and cart stability to prevent falls from carts and cart tip-overs. This is imperative to decrease the number and severity of shopping cart–related injuries to children. Recommendations from the American Academy of Pediatrics regarding prevention of shopping cart–related injuries are included in the accompanying policy statement. (8/06, reaffirmed 4/09, 8/13)
http://pediatrics.aappublications.org/content/118/2/e540

SIDS AND OTHER SLEEP-RELATED INFANT DEATHS: EVIDENCE BASE FOR 2016 UPDATED RECOMMENDATIONS FOR A SAFE INFANT SLEEPING ENVIRONMENT (TECHNICAL REPORT)

Rachel Y. Moon, MD, FAAP, and Task Force on Sudden Infant Death Syndrome

ABSTRACT. Approximately 3500 infants die annually in the United States from sleep-related infant deaths, including sudden infant death syndrome (SIDS), ill-defined deaths, and accidental suffocation and strangulation in bed. After an initial decrease in the 1990s, the overall sleep-related infant death rate has not declined in more recent years. Many of the modifiable and nonmodifiable risk factors for SIDS and other sleep-related infant deaths are strikingly similar. The American Academy of Pediatrics recommends a safe sleep environment that can reduce the risk of all sleep-related infant deaths. Recommendations for a safe sleep environment include supine positioning, use of a firm sleep surface, room-sharing without bed-sharing, and avoidance of soft bedding and overheating. Additional recommendations for SIDS risk reduction include avoidance of exposure to smoke, alcohol, and illicit drugs; breastfeeding; routine immunization; and use of a pacifier. New evidence and rationale for recommendations are presented for skin-to-skin care for newborn infants, bedside and in-bed sleepers, sleeping on couches/armchairs and in sitting devices, and use of soft bedding after 4 months of age. In addition, expanded recommendations for infant sleep location are included. The recommendations and strength of evidence for each recommendation are published in the accompanying policy statement, "SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment," which is included in this issue. (10/16)
http://pediatrics.aappublications.org/content/138/5/e20162940

SIDS AND OTHER SLEEP-RELATED INFANT DEATHS: UPDATED 2016 RECOMMENDATIONS FOR A SAFE INFANT SLEEPING ENVIRONMENT

Task Force on Sudden Infant Death Syndrome

ABSTRACT. Approximately 3500 infants die annually in the United States from sleep-related infant deaths, including sudden infant death syndrome (SIDS; International Classification of Diseases, 10th Revision [ICD-10], R95), ill-defined deaths (ICD-10 R99), and accidental suffocation and strangulation in bed (ICD-10 W75). After an initial decrease in the 1990s, the overall death rate attributable to sleep-related infant deaths has not declined in more recent years. Many of the modifiable and nonmodifiable risk factors for SIDS and other sleep-related infant deaths are strikingly similar. The American Academy of Pediatrics recommends a safe sleep environment that can reduce the risk of all sleep-related infant deaths. Recommendations for a safe sleep environment include supine positioning, the use of a firm sleep surface, room-sharing without bed-sharing, and the avoidance of soft bedding and overheating. Additional recommendations for SIDS reduction include the avoidance of exposure to smoke, alcohol, and illicit drugs; breastfeeding; routine immunization; and use of a pacifier. New evidence is presented for skin-to-skin care for newborn infants, use of bedside and in-bed sleepers, sleeping on couches/armchairs and in sitting devices, and use of soft bedding after 4 months of age. The recommendations and strength of evidence for each recommendation are included in this policy statement. The rationale for these recommendations is discussed in detail in the accompanying technical report (www.pediatrics.org/cgi/doi/10.1542/peds.2016-2940). (10/16)

http://pediatrics.aappublications.org/content/138/5/e20162938

SKATEBOARD AND SCOOTER INJURIES

Committee on Injury, Violence, and Poison Prevention

ABSTRACT. Skateboard-related injuries account for an estimated 50 000 emergency department visits and 1500 hospitalizations among children and adolescents in the United States each year. Nonpowered scooter-related injuries accounted for an estimated 9400 emergency department visits between January and August 2000, and 90% of these patients were children younger than 15 years. Many such injuries can be avoided if children and youth do not ride in traffic, if proper protective gear is worn, and if, in the absence of close adult supervision, skateboards and scooters are not used by children younger than 10 and 8 years, respectively. (3/02, reaffirmed 5/05, 10/08, 10/13)

http://pediatrics.aappublications.org/content/109/3/542

SKIN-TO-SKIN CARE FOR TERM AND PRETERM INFANTS IN THE NEONATAL ICU (CLINICAL REPORT)

Jill Baley, MD, and Committee on Fetus and Newborn

ABSTRACT. "Kangaroo mother care" was first described as an alternative method of caring for low birth weight infants in resource-limited countries, where neonatal mortality and infection rates are high because of overcrowded nurseries, inadequate staffing, and lack of equipment. Intermittent skin-to-skin care (SSC), a modified version of kangaroo mother care, is now being offered in resource-rich countries to infants needing neonatal intensive care, including those who require ventilator support or are extremely premature. SSC significantly improves milk production by the mother and is associated with a longer duration of breastfeeding. Increased parent satisfaction, better sleep organization, a longer duration of quiet sleep, and decreased pain perception during procedures have also been reported in association with SSC. Despite apparent physiologic stability during SSC, it is prudent that infants in the NICU have continuous cardiovascular monitoring and that care be taken to verify correct head positioning for airway patency as well as the stability of the endotracheal tube, arterial and venous access devices, and other life support equipment. (8/15)

http://pediatrics.aappublications.org/content/136/3/596

SNACKS, SWEETENED BEVERAGES, ADDED SUGARS, AND SCHOOLS

Council on School Health and Committee on Nutrition

ABSTRACT. Concern over childhood obesity has generated a decade-long reformation of school nutrition policies. Food is available in school in 3 venues: federally sponsored school meal programs; items sold in competition to school meals, such as a la carte, vending machines, and school stores; and foods available in myriad informal settings, including packed meals and snacks, bake sales, fundraisers, sports booster sales, in-class parties, or other school celebrations. High-energy, low-nutrient beverages, in particular, contribute substantial calories, but little nutrient content, to a student's diet. In 2004, the American Academy of Pediatrics recommended that sweetened drinks be replaced in school by water, white and flavored milks, or 100% fruit and vegetable beverages. Since then, school nutrition has undergone a significant transformation. Federal, state, and local regulations and policies, along with alternative products developed by industry, have helped decrease the availability of nutrient-poor foods and beverages in school. However, regular access to foods of high energy and low quality remains a school issue, much of it attributable to students, parents, and staff. Pediatricians, aligning with experts on child nutrition, are in a position to offer a perspective promoting nutrient-rich foods within calorie guidelines to improve those foods brought into or sold in schools. A positive emphasis on nutritional value, variety, appropriate portion, and encouragement for a steady improvement in quality will be a more effective approach for improving nutrition and health than simply advocating for the elimination of added sugars. (2/15)

http://pediatrics.aappublications.org/content/135/3/575

SNOWMOBILING HAZARDS

Committee on Injury and Poison Prevention

ABSTRACT. Snowmobiles continue to pose a significant risk to children younger than 15 years and adolescents and young adults 15 through 24 years of age. Head injuries remain the leading cause of mortality and serious morbidity, arising largely from snowmobilers colliding, falling, or overturning during operation. Children also were injured while being towed in a variety of conveyances by snowmobiles. No uniform code of state laws governs the use of snowmobiles by children and youth. Because evidence is lacking to support the effectiveness of operator safety certification and because many children and adolescents do not have the required strength and skills to operate a snowmobile safely, the recreational operation of snowmobiles by persons younger than 16 years is not recommended. Snowmobiles should not be used to tow persons on a tube, tire, sled, or saucer. Furthermore, a graduated licensing program is advised for snowmobilers 16 years and older. Both active and passive snowmobile injury prevention strategies are suggested, as well as recommendations for manufacturers to make safer equipment for snowmobilers of all ages. (11/00, reaffirmed 5/04, 1/07, 6/10)

http://pediatrics.aappublications.org/content/106/5/1142

SOCCER INJURIES IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Andrew Watson, MD, MS, FAAP; Jeffrey M. Mjaanes, MD, FAAP; Council on Sports Medicine and Fitness

ABSTRACT. Participation in youth soccer in the United States continues to increase steadily, with a greater percentage of preadolescent participants than perhaps any other youth sport. Despite the wide-ranging health benefits of participation in organized sports, injuries occur and represent a threat to the health

and performance of young athletes. Youth soccer has a greater reported injury rate than many other contact sports, and recent studies suggest that injury rates are increasing. Large increases in the incidence of concussions in youth soccer have been reported, and anterior cruciate ligament injuries remain a significant problem in this sport, particularly among female athletes. Considerable new research has identified a number of modifiable risk factors for lower-extremity injuries and concussion, and several prevention programs have been identified to reduce the risk of injury. Rule enforcement and fair play also serve an important role in reducing the risk of injury among youth soccer participants. This report provides an updated review of the relevant literature as well as recommendations to promote the safe participation of children and adolescents in soccer. (10/19)
https://pediatrics.aappublications.org/content/144/5/e20192759

SPECIAL REQUIREMENTS OF ELECTRONIC HEALTH RECORD SYSTEMS IN PEDIATRICS (CLINICAL REPORT)

S. Andrew Spooner, MD, MS, and Council on Clinical Information Technology

ABSTRACT. Some functions of an electronic health record system are much more important in providing pediatric care than in adult care. Pediatricians commonly complain about the absence of these "pediatric functions" when they are not available in electronic health record systems. To stimulate electronic health record system vendors to recognize and incorporate pediatric functionality into pediatric electronic health record systems, this clinical report reviews the major functions of importance to child health care providers. Also reviewed are important but less critical functions, any of which might be of major importance in a particular clinical context. The major areas described here are immunization management, growth tracking, medication dosing, data norms, and privacy in special pediatric populations. The American Academy of Pediatrics believes that if the functions described in this document are supported in all electronic health record systems, these systems will be more useful for patients of all ages. (3/07, reaffirmed 5/12, 5/16)
http://pediatrics.aappublications.org/content/119/3/631

SPECTRUM OF NONINFECTIOUS HEALTH EFFECTS FROM MOLDS

Committee on Environmental Health

ABSTRACT. Molds are eukaryotic (possessing a true nucleus) nonphotosynthetic organisms that flourish both indoors and outdoors. For humans, the link between mold exposure and asthma exacerbations, allergic rhinitis, infections, and toxicities from ingestion of mycotoxin-contaminated foods are well known. However, the cause-and-effect relationship between inhalational exposure to mold and other untoward health effects (eg, acute idiopathic pulmonary hemorrhage in infants and other illnesses and health complaints) requires additional investigation. Pediatricians play an important role in the education of families about mold, its adverse health effects, exposure prevention, and remediation procedures. (12/06, reaffirmed 9/16)
http://pediatrics.aappublications.org/content/118/6/2582

SPECTRUM OF NONINFECTIOUS HEALTH EFFECTS FROM MOLDS (TECHNICAL REPORT)

Lynnette J. Mazur, MD, MPH; Janice Kim, MD, PhD, MPH; and Committee on Environmental Health

ABSTRACT. Molds are multicellular fungi that are ubiquitous in outdoor and indoor environments. For humans, they are both beneficial (for the production of antimicrobial agents, chemotherapeutic agents, and vitamins) and detrimental. Exposure to mold can occur through inhalation, ingestion, and touching moldy surfaces. Adverse health effects may occur through allergic, infectious, irritant, or toxic processes. The cause-and-effect relationship between mold exposure and allergic and infectious illnesses is well known. Exposures to toxins via the gastrointestinal tract also are well described. However, the cause-and-effect relationship between inhalational exposure to mold toxins and other untoward health effects (eg, acute idiopathic pulmonary hemorrhage in infants and other illnesses and health complaints) is controversial and requires additional investigation. In this report we examine evidence of fungal-related illnesses and the unique aspects of mold exposure to children. Mold-remediation procedures are also discussed. (12/06, reaffirmed 9/16)
http://pediatrics.aappublications.org/content/118/6/e1909

SPORT-RELATED CONCUSSION IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Mark E. Halstead, MD, FAAP; Kevin D. Walter, MD, FAAP; Kody Moffatt, MD, FAAP; and Council on Sports Medicine and Fitness

ABSTRACT. Sport-related concussion is an important topic in nearly all sports and at all levels of sport for children and adolescents. Concussion knowledge and approaches to management have progressed since the American Academy of Pediatrics published its first clinical report on the subject in 2010. Concussion's definition, signs, and symptoms must be understood to diagnose it and rule out more severe intracranial injury. Pediatric health care providers should have a good understanding of diagnostic evaluation and initial management strategies. Effective management can aid recovery and potentially reduce the risk of long-term symptoms and complications. Because concussion symptoms often interfere with school, social life, family relationships, and athletics, a concussion may affect the emotional well-being of the injured athlete. Because every concussion has its own unique spectrum and severity of symptoms, individualized management is appropriate. The reduction, not necessarily elimination, of physical and cognitive activity is the mainstay of treatment. A full return to activity and/or sport is accomplished by using a stepwise program while evaluating for a return of symptoms. An understanding of prolonged symptoms and complications will help the pediatric health care provider know when to refer to a specialist. Additional research is needed in nearly all aspects of concussion in the young athlete. This report provides education on the current state of sport-related concussion knowledge, diagnosis, and management in children and adolescents. (11/18)
http://pediatrics.aappublications.org/content/142/6/e20183074

SPORTS DRINKS AND ENERGY DRINKS FOR CHILDREN AND ADOLESCENTS: ARE THEY APPROPRIATE? (CLINICAL REPORT)

Committee on Nutrition and Council on Sports Medicine and Fitness

ABSTRACT. Sports and energy drinks are being marketed to children and adolescents for a wide variety of inappropriate uses. Sports drinks and energy drinks are significantly different products, and the terms should not be used interchangeably. The primary objectives of this clinical report are to define the ingredients of sports and energy drinks, categorize the similarities and differences between the products, and discuss misuses and abuses. Secondary objectives are to encourage screening during annual physical examinations for sports and energy drink use, to understand the reasons why youth consumption is widespread, and to improve education aimed at decreasing or eliminating the inappropriate use of these beverages by children and adolescents. Rigorous review and analysis of the literature reveal that caffeine and other stimulant substances contained in energy drinks have no place in the diet of children and adolescents. Furthermore, frequent or excessive intake of caloric sports drinks can substantially increase the risk for overweight or obesity in children and adolescents. Discussion regarding the appropriate use of sports drinks in the youth athlete who participates regularly in endurance or high-intensity sports and vigorous

physical activity is beyond the scope of this report. (5/11, reaffirmed 7/17)
http://pediatrics.aappublications.org/content/127/6/1182

SPORTS SPECIALIZATION AND INTENSIVE TRAINING IN YOUNG ATHLETES (CLINICAL REPORT)

Joel S. Brenner, MD, MPH, FAAP, and Council on Sports Medicine and Fitness

ABSTRACT. Sports specialization is becoming the norm in youth sports for a variety of reasons. When sports specialization occurs too early, detrimental effects may occur, both physically and psychologically. If the timing is correct and sports specialization is performed under the correct conditions, the athlete may be successful in reaching specific goals. Young athletes who train intensively, whether specialized or not, can also be at risk of adverse effects on the mind and body. The purpose of this clinical report is to assist pediatricians in counseling their young athlete patients and their parents regarding sports specialization and intensive training. This report supports the American Academy of Pediatrics clinical report "Overuse Injuries, Overtraining, and Burnout in Child and Adolescent Athletes." (8/16)
http://pediatrics.aappublications.org/content/138/3/e20162148

STANDARD TERMINOLOGY FOR FETAL, INFANT, AND PERINATAL DEATHS (CLINICAL REPORT)

Wanda D. Barfield, MD, MPH, FAAP, and Committee on Fetus and Newborn

ABSTRACT. Accurately defining and reporting perinatal deaths (ie, fetal and infant deaths) is a critical first step in understanding the magnitude and causes of these important events. In addition to obstetric health care providers, neonatologists and pediatricians should have easy access to current and updated resources that clearly provide US definitions and reporting requirements for live births, fetal deaths, and infant deaths. Correct identification of these vital events will improve local, state, and national data so that these deaths can be better addressed and prevented. (4/16)
http://pediatrics.aappublications.org/content/137/5/e20160551

STANDARDIZATION OF INPATIENT HANDOFF COMMUNICATION (CLINICAL REPORT)

Jennifer A. Jewell, MD, FAAP, and Committee on Hospital Care

ABSTRACT. Handoff communication is identified as an integral part of hospital care. Throughout medical communities, inadequate handoff communication is being highlighted as a significant risk to patients. The complexity of hospitals and the number of providers involved in the care of hospitalized patients place inpatients at high risk of communication lapses. This miscommunication and the potential resulting harm make effective handoffs more critical than ever. Although hospitalized patients are being exposed to many handoffs each day, this report is limited to describing the best handoff practices between providers at the time of shift change. (10/16)
http://pediatrics.aappublications.org/content/138/5/e20162681

STANDARDS FOR HEALTH INFORMATION TECHNOLOGY TO ENSURE ADOLESCENT PRIVACY

Committee on Adolescence and Council on Clinical Information Technology

ABSTRACT. Privacy and security of health information is a basic expectation of patients. Despite the existence of federal and state laws safeguarding the privacy of health information, health information systems currently lack the capability to allow for protection of this information for minors. This policy statement reviews the challenges to privacy for adolescents posed by commercial health information technology systems and recommends basic principles for ideal electronic health record systems. This policy statement has been endorsed by the Society for Adolescent Health and Medicine. (10/12, reaffirmed 12/18)
http://pediatrics.aappublications.org/content/130/5/987

STANDARDS FOR PEDIATRIC CANCER CENTERS

Section on Hematology/Oncology

ABSTRACT. Since the American Academy of Pediatrics–published guidelines for pediatric cancer centers in 1986, 1997, and 2004, significant changes in the delivery of health care have prompted a review of the role of medical centers in the care of pediatric patients. The potential effect of these changes on the treatment and survival rates of children with cancer led to this revision. The intent of this statement is to delineate personnel, capabilities, and facilities that are essential to provide state-of-the-art care for children, adolescents, and young adults with cancer. This statement emphasizes the importance of board-certified pediatric hematologists/oncologists and appropriately qualified pediatric medical subspecialists and pediatric surgical specialists overseeing patient care and the need for specialized facilities as essential for the initial management and much of the follow-up for pediatric, adolescent, and young adult patients with cancer. For patients without practical access to a pediatric cancer center, care may be provided locally by a primary care physician or adult oncologist but at the direction of a pediatric oncologist. (7/14, reaffirmed 10/18)
http://pediatrics.aappublications.org/content/134/2/410

STIGMA EXPERIENCED BY CHILDREN AND ADOLESCENTS WITH OBESITY

Stephen J. Pont, MD, MPH, FAAP; Rebecca Puhl, PhD, FTOS; Stephen R. Cook, MD, MPH, FAAP, FTOS; Wendelin Slusser, MD, MS, FAAP; and Section on Obesity (joint with The Obesity Society)

ABSTRACT. The stigmatization of people with obesity is widespread and causes harm. Weight stigma is often propagated and tolerated in society because of beliefs that stigma and shame will motivate people to lose weight. However, rather than motivating positive change, this stigma contributes to behaviors such as binge eating, social isolation, avoidance of health care services, decreased physical activity, and increased weight gain, which worsen obesity and create additional barriers to healthy behavior change. Furthermore, experiences of weight stigma also dramatically impair quality of life, especially for youth. Health care professionals continue to seek effective strategies and resources to address the obesity epidemic; however, they also frequently exhibit weight bias and stigmatizing behaviors. This policy statement seeks to raise awareness regarding the prevalence and negative effects of weight stigma on pediatric patients and their families and provides 6 clinical practice and 4 advocacy recommendations regarding the role of pediatricians in addressing weight stigma. In summary, these recommendations include improving the clinical setting by modeling best practices for nonbiased behaviors and language; using empathetic and empowering counseling techniques, such as motivational interviewing, and addressing weight stigma and bullying in the clinic visit; advocating for inclusion of training and education about weight stigma in medical schools, residency programs, and continuing medical education programs; and empowering families to be advocates to address weight stigma in the home environment and school setting. (11/17)
http://pediatrics.aappublications.org/content/140/6/e20173034

STRATEGIES FOR PREVENTION OF HEALTH CARE–ASSOCIATED INFECTIONS IN THE NICU (CLINICAL REPORT)

Richard A. Polin, MD; Susan Denson, MD; Michael T. Brady, MD; Committee on Fetus and Newborn; and Committee on Infectious Diseases

ABSTRACT. Health care–associated infections in the NICU result in increased morbidity and mortality, prolonged lengths of stay, and increased medical costs. Neonates are at high risk of acquiring health care–associated infections because of impaired host-defense mechanisms, limited amounts of protective endogenous flora on skin and mucosal surfaces at time of birth, reduced barrier function of their skin, use of invasive procedures and devices, and frequent exposure to broad-spectrum antibiotic agents. This clinical report reviews management and prevention of health care–associated infections in newborn infants. (3/12, reaffirmed 2/16)

http://pediatrics.aappublications.org/content/129/4/e1085

SUBSTANCE USE SCREENING, BRIEF INTERVENTION, AND REFERRAL TO TREATMENT

Committee on Substance Use and Prevention

ABSTRACT. The enormous public health impact of adolescent substance use and its preventable morbidity and mortality show the need for the health care sector, including pediatricians and the medical home, to increase its capacity related to substance use prevention, detection, assessment, and intervention. The American Academy of Pediatrics published its policy statement "Substance Use Screening, Brief Intervention, and Referral to Treatment for Pediatricians" in 2011 to introduce the concepts and terminology of screening, brief intervention, and referral to treatment (SBIRT) and to offer clinical guidance about available substance use screening tools and intervention procedures. This policy statement is a revision of the 2011 SBIRT statement. An accompanying clinical report updates clinical guidance for adolescent SBIRT. (6/16)

http://pediatrics.aappublications.org/content/138/1/e20161210

SUBSTANCE USE SCREENING, BRIEF INTERVENTION, AND REFERRAL TO TREATMENT (CLINICAL REPORT)

Sharon J. L. Levy, MD, MPH, FAAP; Janet F. Williams, MD, FAAP; and Committee on Substance Use and Prevention

ABSTRACT. The enormous public health impact of adolescent substance use and its preventable morbidity and mortality highlight the need for the health care sector, including pediatricians and the medical home, to increase its capacity regarding adolescent substance use screening, brief intervention, and referral to treatment (SBIRT). The American Academy of Pediatrics first published a policy statement on SBIRT and adolescents in 2011 to introduce SBIRT concepts and terminology and to offer clinical guidance about available substance use screening tools and intervention procedures. This clinical report provides a simplified adolescent SBIRT clinical approach that, in combination with the accompanying updated policy statement, guides pediatricians in implementing substance use prevention, detection, assessment, and intervention practices across the varied clinical settings in which adolescents receive health care. (6/16)

http://pediatrics.aappublications.org/content/138/1/e20161211

SUICIDE AND SUICIDE ATTEMPTS IN ADOLESCENTS (CLINICAL REPORT)

Benjamin Shain, MD, PhD, and Committee on Adolescence

ABSTRACT. Suicide is the second leading cause of death for adolescents 15 to 19 years old. This report updates the previous statement of the American Academy of Pediatrics and is intended to assist pediatricians, in collaboration with other child and adolescent health care professionals, in the identification and management of the adolescent at risk for suicide. Suicide risk can only be reduced, not eliminated, and risk factors provide no more than guidance. Nonetheless, care for suicidal adolescents may be improved with the pediatrician's knowledge, skill, and comfort with the topic, as well as ready access to appropriate community resources and mental health professionals. (6/16, reaffirmed 10/20)

http://pediatrics.aappublications.org/content/138/1/e20161420

SUPPLEMENTAL SECURITY INCOME (SSI) FOR CHILDREN AND YOUTH WITH DISABILITIES

Council on Children With Disabilities

ABSTRACT. The Supplemental Security Income (SSI) program remains an important source of financial support for low-income families of children with special health care needs and disabling conditions. In most states, SSI eligibility also qualifies children for the state Medicaid program, providing access to health care services. The Social Security Administration (SSA), which administers the SSI program, considers a child disabled under SSI if there is a medically determinable physical or mental impairment or combination of impairments that results in marked and severe functional limitations. The impairment(s) must be expected to result in death or have lasted or be expected to last for a continuous period of at least 12 months. The income and assets of families of children with disabilities are also considered when determining financial eligibility. When an individual with a disability becomes an adult at 18 years of age, the SSA considers only the individual's income and assets. The SSA considers an adult to be disabled if there is a medically determinable impairment (or combination of impairments) that prevents substantial gainful activity for at least 12 continuous months. SSI benefits are important for youth with chronic conditions who are transitioning to adulthood. The purpose of this statement is to provide updated information about the SSI medical and financial eligibility criteria and the disability-determination process. This statement also discusses how pediatricians can help children and youth when they apply for SSI benefits. (11/09, reaffirmed 2/15)

http://pediatrics.aappublications.org/content/124/6/1702

SUPPORTING THE FAMILY AFTER THE DEATH OF A CHILD (CLINICAL REPORT)

Esther Wender, MD, and Committee on Psychosocial Aspects of Child and Family Health

ABSTRACT. The death of a child can have a devastating effect on the family. The pediatrician has an important role to play in supporting the parents and any siblings still in his or her practice after such a death. Pediatricians may be poorly prepared to provide this support. Also, because of the pain of confronting the grief of family members, they may be reluctant to become involved. This statement gives guidelines to help the pediatrician provide such support. It describes the grief reactions that can be expected in family members after the death of a child. Ways of supporting family members are suggested, and other helpful resources in the community are described. The goal of this guidance is to prevent outcomes that may impair the health and development of affected parents and children. (11/12, reaffirmed 12/16)

http://pediatrics.aappublications.org/content/130/6/1164

SUPPORTING THE GRIEVING CHILD AND FAMILY (CLINICAL REPORT)

David J. Schonfeld, MD, FAAP; Thomas Demaria, PhD; Committee on Psychosocial Aspects of Child and Family Health; and Disaster Preparedness Advisory Council

ABSTRACT. The death of someone close to a child often has a profound and lifelong effect on the child and results in a range of both short- and long-term reactions. Pediatricians, within a patient-centered medical home, are in an excellent position to provide anticipatory guidance to caregivers and to offer

assistance and support to children and families who are grieving. This clinical report offers practical suggestions on how to talk with grieving children to help them better understand what has happened and its implications and to address any misinformation, misinterpretations, or misconceptions. An understanding of guilt, shame, and other common reactions, as well an appreciation of the role of secondary losses and the unique challenges facing children in communities characterized by chronic trauma and cumulative loss, will help the pediatrician to address factors that may impair grieving and children's adjustment and to identify complicated mourning and situations when professional counseling is indicated. Advice on how to support children's participation in funerals and other memorial services and to anticipate and address grief triggers and anniversary reactions is provided so that pediatricians are in a better position to advise caregivers and to offer consultation to schools, early education and child care facilities, and other child congregate care sites. Pediatricians often enter their profession out of a profound desire to minimize the suffering of children and may find it personally challenging when they find themselves in situations in which they are asked to bear witness to the distress of children who are acutely grieving. The importance of professional preparation and self-care is therefore emphasized, and resources are recommended. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20162147

SUPPORTING THE HEALTH CARE TRANSITION FROM ADOLESCENCE TO ADULTHOOD IN THE MEDICAL HOME (CLINICAL REPORT)

Patience H. White, MD, MA, FAAP, FACP; W. Carl Cooley, MD, FAAP; American Academy of Pediatrics (joint with Transitions Clinical Report Authoring Group, American Academy of Family Physicians, and American College of Physicians)

ABSTRACT. Risk and vulnerability encompass many dimensions of the transition from adolescence to adulthood. Transition from pediatric, parent-supervised health care to more independent, patient-centered adult health care is no exception. The tenets and algorithm of the original 2011 clinical report, "Supporting the Health Care Transition from Adolescence to Adulthood in the Medical Home," are unchanged. This updated clinical report provides more practice-based quality improvement guidance on key elements of transition planning, transfer, and integration into adult care for all youth and young adults. It also includes new and updated sections on definition and guiding principles, the status of health care transition preparation among youth, barriers, outcome evidence, recommended health care transition processes and implementation strategies using quality improvement methods, special populations, education and training in pediatric onset conditions, and payment options. The clinical report also includes new recommendations pertaining to infrastructure, education and training, payment, and research. (10/18)

http://pediatrics.aappublications.org/content/142/5/e20182587

SURFACTANT REPLACEMENT THERAPY FOR PRETERM AND TERM NEONATES WITH RESPIRATORY DISTRESS (CLINICAL REPORT)

Richard A. Polin, MD, FAAP; Waldemar A. Carlo, MD, FAAP; and Committee on Fetus and Newborn

ABSTRACT. Respiratory failure secondary to surfactant deficiency is a major cause of morbidity and mortality in preterm infants. Surfactant therapy substantially reduces mortality and respiratory morbidity for this population. Secondary surfactant deficiency also contributes to acute respiratory morbidity in late-preterm and term neonates with meconium aspiration syndrome, pneumonia/sepsis, and perhaps pulmonary hemorrhage; surfactant replacement may be beneficial for these infants. This statement summarizes the evidence regarding indications, administration, formulations, and outcomes for surfactant-replacement therapy. The clinical strategy of intubation, surfactant administration, and extubation to continuous positive airway pressure and the effect of continuous positive airway pressure on outcomes and surfactant use in preterm infants are also reviewed. (12/13)

http://pediatrics.aappublications.org/content/133/1/156

TACKLING IN YOUTH FOOTBALL

Council on Sports Medicine and Fitness

ABSTRACT. American football remains one of the most popular sports for young athletes. The injuries sustained during football, especially those to the head and neck, have been a topic of intense interest recently in both the public media and medical literature. The recognition of these injuries and the potential for long-term sequelae have led some physicians to call for a reduction in the number of contact practices, a postponement of tackling until a certain age, and even a ban on high school football. This statement reviews the literature regarding injuries in football, particularly those of the head and neck, the relationship between tackling and football-related injuries, and the potential effects of limiting or delaying tackling on injury risk. (10/15, reaffirmed 7/20)

http://pediatrics.aappublications.org/content/136/5/e1419

TARGETED REFORMS IN HEALTH CARE FINANCING TO IMPROVE THE CARE OF ADOLESCENTS AND YOUNG ADULTS

Arik V. Marcell, MD, MPH, FAAP; Cora C. Breuner, MD, MPH, FAAP; Lawrence Hammer, MD, FAAP; Mark L. Hudak, MD, FAAP; Committee on Adolescence; and Committee on Child Health Financing

ABSTRACT. Significant changes have occurred in the commercial and government insurance marketplace after the passage of 2 federal legislation acts, the Patient Protection and Affordable Care Act of 2010 and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. Despite the potential these 2 acts held to improve the health care of adolescents and young adults (AYAs), including the financing of care, there are barriers to achieving this goal. In the first quarter of 2016, 13.7% of individuals 18 to 24 years of age still lacked health insurance. Limitations in the scope of benefits coverage and inadequate provider payment can curtail access to health care for AYAs, particularly care related to sexual and reproductive health and mental and behavioral health. Some health plans impose financial barriers to access because they require families to absorb high cost-sharing expenses (eg, deductibles, copayments, and coinsurance). Finally, challenges of confidentiality inherent in the billing and insurance claim practices of some health insurance plans can discourage access to health care in the absence of other obstacles and interfere with provision of confidential care. This policy statement summarizes the current state of impediments that AYA, including those with special health care needs, face in accessing timely and appropriate health care and that providers face in serving these patients. These impediments include limited scope of benefits, high cost sharing, inadequate provider payment, and insufficient confidentiality protections. With this statement, we aim to improve both access to health care by AYAs and providers' delivery of developmentally appropriate health care for these patients through the presentation of an overview of the issues, specific recommendations for reform of health care financing for AYAs, and practical actions that pediatricians and other providers can take to advocate for appropriate payments for providing health care to AYAs. (11/18)

http://pediatrics.aappublications.org/content/142/6/e20182998

THE TEEN DRIVER

Elizabeth M. Alderman, MD, FAAP, FSAHM; Brian D. Johnston, MD, MPH, FAAP; Committee on Adolescence; and Council on Injury, Violence, and Poison Prevention

ABSTRACT. For many teenagers, obtaining a driver's license is a rite of passage, conferring the ability to independently travel to school, work, or social events. However, immaturity, inexperience, and risky behavior put newly licensed teen drivers at risk. Motor vehicle crashes are the most common cause of mortality and injury for adolescents and young adults in developed countries. Teen drivers (15–19 years of age) have the highest rate of motor vehicle crashes among all age groups in the United States and contribute disproportionately to traffic fatalities. In addition to the deaths of teen drivers, more than half of 8- to 17-year-old children who die in car crashes are killed as passengers of drivers younger than 20 years of age. This policy statement, in which we update the previous 2006 iteration of this policy statement, is used to reflect new research on the risks faced by teen drivers and offer advice for pediatricians counseling teen drivers and their families. (9/18)

http://pediatrics.aappublications.org/content/142/4/e20182163

TELEMEDICINE FOR EVALUATION OF RETINOPATHY OF PREMATURITY (TECHNICAL REPORT)

Walter M. Fierson, MD, FAAP; Antonio Capone Jr, MD; and Section on Ophthalmology (joint with American Academy of Ophthalmology and American Association of Certified Orthoptists)

ABSTRACT. Retinopathy of prematurity (ROP) remains a significant threat to vision for extremely premature infants despite the availability of therapeutic modalities capable, in most cases, of managing this disorder. It has been shown in many controlled trials that application of therapies at the appropriate time is essential to successful outcomes in premature infants affected by ROP. Bedside binocular indirect ophthalmoscopy has been the standard technique for diagnosis and monitoring of ROP in these patients. However, implementation of routine use of this screening method for at-risk premature infants has presented challenges within our existing care systems, including relative local scarcity of qualified ophthalmologist examiners in some locations and the remote location of some NICUs. Modern technology, including the development of wide-angle ocular digital fundus photography, coupled with the ability to send digital images electronically to remote locations, has led to the development of telemedicine-based remote digital fundus imaging (RDFI-TM) evaluation techniques. These techniques have the potential to allow the diagnosis and monitoring of ROP to occur in lieu of the necessity for some repeated on-site examinations in NICUs. This report reviews the currently available literature on RDFI-TM evaluations for ROP and outlines pertinent practical and risk management considerations that should be used when including RDFI-TM in any new or existing ROP care structure. (12/14)

http://pediatrics.aappublications.org/content/135/1/e238

TELEMEDICINE: PEDIATRIC APPLICATIONS (TECHNICAL REPORT)

Bryan L. Burke Jr, MD, FAAP; R. W. Hall, MD, FAAP; and Section on Telehealth Care

ABSTRACT. Telemedicine is a technological tool that is improving the health of children around the world. This report chronicles the use of telemedicine by pediatricians and pediatric medical and surgical specialists to deliver inpatient and outpatient care, educate physicians and patients, and conduct medical research. It also describes the importance of telemedicine in responding to emergencies and disasters and providing access to pediatric care to remote and underserved populations. Barriers to telemedicine expansion are explained, such as legal issues, inadequate payment for services, technology costs and sustainability, and the lack of technology infrastructure on a national scale. Although certain challenges have constrained more widespread implementation, telemedicine's current use bears testimony to its effectiveness and potential. Telemedicine's widespread adoption will be influenced by the implementation of key provisions of the Patient Protection and Affordable Care Act, technological advances, and growing patient demand for virtual visits. (6/15)

http://pediatrics.aappublications.org/content/136/1/e293

TESTING FOR DRUGS OF ABUSE IN CHILDREN AND ADOLESCENTS (CLINICAL REPORT)

Sharon Levy, MD, MPH, FAAP; Lorena M. Siqueira, MD, MSPH, FAAP; and Committee on Substance Abuse

ABSTRACT. Drug testing is often used as part of an assessment for substance use in children and adolescents. However, the indications for drug testing and guidance on how to use this procedure effectively are not clear. The complexity and invasiveness of the procedure and limitations to the information derived from drug testing all affect its utility. The objective of this clinical report is to provide guidance to pediatricians and other clinicians on the efficacy and efficient use of drug testing on the basis of a review of the nascent scientific literature, policy guidelines, and published clinical recommendations. (5/14)

http://pediatrics.aappublications.org/content/133/6/e1798

TOWARD TRANSPARENT CLINICAL POLICIES

Steering Committee on Quality Improvement and Management

ABSTRACT. Clinical policies of professional societies such as the American Academy of Pediatrics are valued highly, not only by clinicians who provide direct health care to children but also by many others who rely on the professional expertise of these organizations, including parents, employers, insurers, and legislators. The utility of a policy depends, in large part, on the degree to which its purpose and basis are clear to policy users, an attribute known as the policy's transparency. This statement describes the critical importance and special value of transparency in clinical policies, guidelines, and recommendations; helps identify obstacles to achieving transparency; and suggests several approaches to overcome these obstacles. (3/08, reaffirmed 2/14)

http://pediatrics.aappublications.org/content/121/3/643

TRAMPOLINE SAFETY IN CHILDHOOD AND ADOLESCENCE

Council on Sports Medicine and Fitness

ABSTRACT. Despite previous recommendations from the American Academy of Pediatrics discouraging home use of trampolines, recreational use of trampolines in the home setting continues to be a popular activity among children and adolescents. This policy statement is an update to previous statements, reflecting the current literature on prevalence, patterns, and mechanisms of trampoline-related injuries. Most trampoline injuries occur with multiple simultaneous users on the mat. Cervical spine injuries often occur with falls off the trampoline or with attempts at somersaults or flips. Studies on the efficacy of trampoline safety measures are reviewed, and although there is a paucity of data, current implementation of safety measures have not appeared to mitigate risk substantially. Therefore, the home use of trampolines is strongly discouraged. The role of trampoline as a competitive sport and in structured training settings is reviewed, and recommendations for enhancing safety in these environments are made. (9/12, reaffirmed 7/15)

http://pediatrics.aappublications.org/content/130/4/774

THE TRANSFER OF DRUGS AND THERAPEUTICS INTO HUMAN BREAST MILK: AN UPDATE ON SELECTED TOPICS (CLINICAL REPORT)

Hari Cheryl Sachs, MD, FAAP, and Committee on Drugs

ABSTRACT. Many mothers are inappropriately advised to discontinue breastfeeding or avoid taking essential medications because of fears of adverse effects on their infants. This cautious approach may be unnecessary in many cases, because only a small proportion of medications are contraindicated in breastfeeding mothers or associated with adverse effects on their infants. Information to inform physicians about the extent of excretion for a particular drug into human milk is needed but may not be available. Previous statements on this topic from the American Academy of Pediatrics provided physicians with data concerning the known excretion of specific medications into breast milk. More current and comprehensive information is now available on the Internet, as well as an application for mobile devices, at LactMed (http://toxnet.nlm.nih.gov). Therefore, with the exception of radioactive compounds requiring temporary cessation of breastfeeding, the reader will be referred to LactMed to obtain the most current data on an individual medication. This report discusses several topics of interest surrounding lactation, such as the use of psychotropic therapies, drugs to treat substance abuse, narcotics, galactagogues, and herbal products, as well as immunization of breastfeeding women. A discussion regarding the global implications of maternal medications and lactation in the developing world is beyond the scope of this report. The World Health Organization offers several programs and resources that address the importance of breastfeeding (see http://www.who.int/topics/breastfeeding/en/). (8/13, reaffirmed 5/18)

http://pediatrics.aappublications.org/content/132/3/e796

TRANSPORTING CHILDREN WITH SPECIAL HEALTH CARE NEEDS

Joseph O'Neil, MD, MPH, FAAP; Benjamin Hoffman, MD, FAAP; and Council on Injury, Violence, and Poison Prevention

ABSTRACT. Children with special health care needs should have access to proper resources for safe transportation as do typical children. This policy statement reviews important considerations for transporting children with special health care needs and provides current guidance for the protection of children with specific health care needs, including those with airway obstruction, orthopedic conditions or procedures, developmental delays, muscle tone abnormalities, challenging behaviors, and gastrointestinal disorders. (4/19)

https://pediatrics.aappublications.org/content/143/5/e20190724

THE TREATMENT OF NEUROLOGICALLY IMPAIRED CHILDREN USING PATTERNING

Committee on Children With Disabilities

ABSTRACT. This statement reviews patterning as a treatment for children with neurologic impairments. This treatment is based on an outmoded and oversimplified theory of brain development. Current information does not support the claims of proponents that this treatment is efficacious, and its use continues to be unwarranted. (11/99, reaffirmed 11/02, 1/06, 8/10, 4/14, 5/18)

http://pediatrics.aappublications.org/content/104/5/1149

TRUTH, RECONCILIATION, AND TRANSFORMATION: CONTINUING ON THE PATH TO EQUITY

Board of Directors

ABSTRACT. One year ago, the American Academy of Pediatrics (AAP) published a landmark policy statement identifying racism as a core social determinant of health and a driver of health inequities. Seventy-five years ago, the AAP admitted its first Black members, Drs Alonzo deGrate Smith and Roland Boyd Scott. As the AAP continues to evolve its equity agenda, it is essential that the tortuous experiences of Drs deGrate Smith and Scott on their pathway to AAP membership be truthfully acknowledged and reckoned with. (8/20)

See full text on page 1225.

https://pediatrics.aappublications.org/content/146/3/e2020019794

ULTRAVIOLET RADIATION: A HAZARD TO CHILDREN AND ADOLESCENTS

Council on Environmental Health and Section on Dermatology

ABSTRACT. Ultraviolet radiation (UVR) causes the 3 major forms of skin cancer: basal cell carcinoma; squamous cell carcinoma; and cutaneous malignant melanoma. Public awareness of the risk is not optimal, overall compliance with sun protection is inconsistent, and melanoma rates continue to rise. The risk of skin cancer increases when people overexpose themselves to sun and intentionally expose themselves to artificial sources of UVR. Yet, people continue to sunburn, and teenagers and adults alike remain frequent visitors to tanning parlors. Pediatricians should provide advice about UVR exposure during health-supervision visits and at other relevant times. Advice includes avoiding sunburning, wearing clothing and hats, timing activities (when possible) before or after periods of peak sun exposure, wearing protective sunglasses, and applying and reapplying sunscreen. Advice should be framed in the context of promoting outdoor physical activity. Adolescents should be strongly discouraged from visiting tanning parlors. Sun exposure and vitamin D status are intertwined. Cutaneous vitamin D production requires sunlight exposure, and many factors, such as skin pigmentation, season, and time of day, complicate efficiency of cutaneous vitamin D production that results from sun exposure. Adequate vitamin D is needed for bone health. Accumulating information suggests a beneficial influence of vitamin D on many health conditions. Although vitamin D is available through the diet, supplements, and incidental sun exposure, many children have low vitamin D concentrations. Ensuring vitamin D adequacy while promoting sun-protection strategies will require renewed attention to children's use of dietary and supplemental vitamin D. (2/11, reaffirmed 9/16)

http://pediatrics.aappublications.org/content/127/3/588

ULTRAVIOLET RADIATION: A HAZARD TO CHILDREN AND ADOLESCENTS (TECHNICAL REPORT)

Sophie J. Balk, MD; Council on Environmental Health; and Section on Dermatology

ABSTRACT. Sunlight sustains life on earth. Sunlight is essential for vitamin D synthesis in the skin. The sun's ultraviolet rays can be hazardous, however, because excessive exposure causes skin cancer and other adverse health effects. Skin cancer is a major public health problem; more than 2 million new cases are diagnosed in the United States each year. Ultraviolet radiation (UVR) causes the 3 major forms of skin cancer: basal cell carcinoma; squamous cell carcinoma; and cutaneous malignant melanoma. Exposure to UVR from sunlight and artificial sources early in life elevates the risk of developing skin cancer. Approximately 25% of sun exposure occurs before 18 years of age. The risk of skin cancer is increased when people overexpose themselves to sun and intentionally expose themselves to artificial sources of UVR. Public awareness of the risk is not optimal, compliance with sun protection is inconsistent, and skin-cancer rates continue to rise in all age groups including the younger population. People continue to sunburn, and teenagers and adults are frequent visitors to tanning parlors. Sun exposure and vitamin D status are intertwined. Adequate vitamin D is needed for bone health in children and adults. In addition, there is accumulating information suggesting a beneficial influence of vitamin D on various health conditions. Cutaneous vitamin D production requires sunlight,

and many factors complicate the efficiency of vitamin D production that results from sunlight exposure. Ensuring vitamin D adequacy while promoting sun-protection strategies, therefore, requires renewed attention to evaluating the adequacy of dietary and supplemental vitamin D. Daily intake of 400 IU of vitamin D will prevent vitamin D deficiency rickets in infants. The vitamin D supplementation amounts necessary to support optimal health in older children and adolescents are less clear. This report updates information on the relationship of sun exposure to skin cancer and other adverse health effects, the relationship of exposure to artificial sources of UVR and skin cancer, sun-protection methods, vitamin D, community skin-cancer–prevention efforts, and the pediatrician's role in preventing skin cancer. In addition to pediatricians' efforts, a sustained public health effort is needed to change attitudes and behaviors regarding UVR exposure. (2/11, reaffirmed 9/16)

http://pediatrics.aappublications.org/content/127/3/e791

UMBILICAL CORD CARE IN THE NEWBORN INFANT (CLINICAL REPORT)

Dan Stewart, MD, FAAP; William Benitz, MD, FAAP; and Committee on Fetus and Newborn

ABSTRACT. Postpartum infections remain a leading cause of neonatal morbidity and mortality worldwide. A high percentage of these infections may stem from bacterial colonization of the umbilicus, because cord care practices vary in reflection of cultural traditions within communities and disparities in health care practices globally. After birth, the devitalized umbilical cord often proves to be an ideal substrate for bacterial growth and also provides direct access to the bloodstream of the neonate. Bacterial colonization of the cord not infrequently leads to omphalitis and associated thrombophlebitis, cellulitis, or necrotizing fasciitis. Various topical substances continue to be used for cord care around the world to mitigate the risk of serious infection. More recently, particularly in high-resource countries, the treatment paradigm has shifted toward dry umbilical cord care. This clinical report reviews the evidence underlying recommendations for care of the umbilical cord in different clinical settings. (8/16)

http://pediatrics.aappublications.org/content/138/3/e20162149

UNDERSTANDING LIABILITY RISKS AND PROTECTIONS FOR PEDIATRIC PROVIDERS DURING DISASTERS

Robin L. Altman, MD, FAAP; Karen A. Santucci, MD, FAAP; Michael R. Anderson, MD, MBA, FAAP; William M. McDonnell, MD, JD, FAAP; and Committee on Medical Liability and Risk Management

ABSTRACT. Although most health care providers will go through their careers without experiencing a major disaster in their local communities, if one does occur, it can be life and career altering. The American Academy of Pediatrics has been at the forefront of providing education and advocacy on the critical importance of disaster preparedness. From experiences over the past decade, new evidence and analysis have broadened our understanding that the concept of preparedness is also applicable to addressing the unique professional liability risks that can occur when caring for patients and families during a disaster. In our recommendations in this policy statement, we target pediatric health care providers, advocates, and policy makers and address how individuals, institutions, and government can work together to strengthen the system of liability protections during disasters so that appropriate and timely care can be delivered with minimal fear of legal reprisal or confusion. (2/19)

https://pediatrics.aappublications.org/content/143/3/e20183892

UNDERSTANDING LIABILITY RISKS AND PROTECTIONS FOR PEDIATRIC PROVIDERS DURING DISASTERS (TECHNICAL REPORT)

Robin L. Altman, MD, FAAP; Karen A. Santucci, MD, FAAP; Michael R. Anderson, MD, MBA, FAAP; William M. McDonnell, MD, JD, FAAP; and Committee on Medical Liability and Risk Management

ABSTRACT. Although most health care providers will go through their careers without experiencing a major disaster in their local communities, if one does occur, it can be life and career altering. The American Academy of Pediatrics has been in the forefront of providing education and advocacy on the critical importance of disaster preparedness. From experiences over the past decade, new evidence and analysis have broadened our understanding that the concept of preparedness is also applicable to addressing the unique professional liability risks that can occur when caring for patients and families during a disaster. Concepts explored in this technical report will help to inform pediatric health care providers, advocates, and policy makers about the complexities of how providers are currently protected, with a focus on areas of unappreciated liability. The timeliness of this technical report is emphasized by the fact that during the time of its development (ie, late summer and early fall of 2017), the United States went through an extraordinary period of multiple, successive, and overlapping disasters within a concentrated period of time of both natural and man-made causes. In a companion policy statement (www.pediatrics.org/cgi/doi/10.1542/peds.2018-3892), recommendations are offered on how individuals, institutions, and governments can work together to strengthen the system of liability protections during disasters so that appropriate and timely care can be delivered with minimal fear of legal reprisal or confusion. (2/19)

https://pediatrics.aappublications.org/content/143/3/e20183893

UNIQUE NEEDS OF THE ADOLESCENT

Elizabeth M. Alderman, MD, FSAHM, FAAP; Cora C. Breuner, MD, MPH, FAAP; and Committee on Adolescence

ABSTRACT. Adolescence is the transitional bridge between childhood and adulthood; it encompasses developmental milestones that are unique to this age group. Healthy cognitive, physical, sexual, and psychosocial development is both a right and a responsibility that must be guaranteed for all adolescents to successfully enter adulthood. There is consensus among national and international organizations that the unique needs of adolescents must be addressed and promoted to ensure the health of all adolescents. This policy statement outlines the special health challenges that adolescents face on their journey and transition to adulthood and provides recommendations for those who care for adolescents, their families, and the communities in which they live. (11/19)

https://pediatrics.aappublications.org/content/144/6/e20193150

UPDATE OF NEWBORN SCREENING AND THERAPY FOR CONGENITAL HYPOTHYROIDISM (CLINICAL REPORT)

Susan R. Rose, MD; Section on Endocrinology; and Committee on Genetics (joint with Rosalind S. Brown, MD; American Thyroid Association; and Lawson Wilkins Pediatric Endocrine Society)

ABSTRACT. Unrecognized congenital hypothyroidism leads to mental retardation. Newborn screening and thyroid therapy started within 2 weeks of age can normalize cognitive development. The primary thyroid-stimulating hormone screening has become standard in many parts of the world. However, newborn thyroid screening is not yet universal in some countries. Initial dosage of 10 to 15 μg/kg levothyroxine is recommended. The goals of thyroid hormone therapy should be to maintain frequent evaluations of total thyroxine or free thyroxine in the upper half of the reference range during the first 3 years of

life and to normalize the serum thyroid-stimulating hormone concentration to ensure optimal thyroid hormone dosage and compliance.

Improvements in screening and therapy have led to improved developmental outcomes in adults with congenital hypothyroidism who are now in their 20s and 30s. Thyroid hormone regimens used today are more aggressive in targeting early correction of thyroid-stimulating hormone than were those used 20 or even 10 years ago. Thus, newborn infants with congenital hypothyroidism today may have an even better intellectual and neurologic prognosis. Efforts are ongoing to establish the optimal therapy that leads to maximum potential for normal development for infants with congenital hypothyroidism.

Remaining controversy centers on infants whose abnormality in neonatal thyroid function is transient or mild and on optimal care of very low birth weight or preterm infants. Of note, thyroid-stimulating hormone is not elevated in central hypothyroidism. An algorithm is proposed for diagnosis and management.

Physicians must not relinquish their clinical judgment and experience in the face of normal newborn thyroid test results. Hypothyroidism can be acquired after the newborn screening. When clinical symptoms and signs suggest hypothyroidism, regardless of newborn screening results, serum free thyroxine and thyroid-stimulating hormone determinations should be performed. (6/06, reaffirmed 12/11)

http://pediatrics.aappublications.org/content/117/6/2290

UPDATED GUIDANCE FOR PALIVIZUMAB PROPHYLAXIS AMONG INFANTS AND YOUNG CHILDREN AT INCREASED RISK OF HOSPITALIZATION FOR RESPIRATORY SYNCYTIAL VIRUS INFECTION

Committee on Infectious Diseases and Bronchiolitis Guidelines Committee

ABSTRACT. Palivizumab was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. Since that time, the American Academy of Pediatrics has updated its guidance for the use of palivizumab 4 times as additional data became available to provide a better understanding of infants and young children at greatest risk of hospitalization attributable to RSV infection. The updated recommendations in this policy statement reflect new information regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effect of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, the effect of prophylaxis on wheezing, and palivizumab-resistant RSV isolates. (7/14, reaffirmed 2/19)

http://pediatrics.aappublications.org/content/134/2/415

UPDATED GUIDANCE FOR PALIVIZUMAB PROPHYLAXIS AMONG INFANTS AND YOUNG CHILDREN AT INCREASED RISK OF HOSPITALIZATION FOR RESPIRATORY SYNCYTIAL VIRUS INFECTION (TECHNICAL REPORT)

Committee on Infectious Diseases and Bronchiolitis Guidelines Committee

ABSTRACT. Guidance from the American Academy of Pediatrics (AAP) for the use of palivizumab prophylaxis against respiratory syncytial virus (RSV) was first published in a policy statement in 1998. Guidance initially was based on the result from a single randomized, placebo-controlled clinical trial conducted in 1996–1997 describing an overall reduction in RSV hospitalization rate from 10.6% among placebo recipients to 4.8% among children who received prophylaxis. The results of a second randomized, placebo-controlled trial of children with hemodynamically significant heart disease were published in 2003 and revealed a reduction in RSV hospitalization rate from 9.7% in control subjects to 5.3% among prophylaxis recipients. Because no additional controlled trials regarding efficacy were published, AAP guidance has been updated periodically to reflect the most recent literature regarding children at greatest risk of severe disease. Since the last update in 2012, new data have become available regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effects of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, and the effect of prophylaxis on wheezing and palivizumab-resistant RSV isolates. These data enable further refinement of AAP guidance to most clearly focus on those children at greatest risk. (7/14)

http://pediatrics.aappublications.org/content/134/2/e620

UPDATES ON AN AT-RISK POPULATION: LATE-PRETERM AND EARLY-TERM INFANTS (CLINICAL REPORT)

Dan L. Stewart, MD, FAAP; Wanda D. Barfield, MD, MPH, FAAP, RADM, USPHS; Committee on Fetus and Newborn

ABSTRACT. The American Academy of Pediatrics published a clinical report on late-preterm (LPT) infants in 2007 that was largely based on a summary of a 2005 workshop convened by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, at which a change in terminology from "near term" to "late preterm" was proposed. This paradigm-shifting recommendation had a remarkable impact: federal agencies (the Centers for Disease Control and Prevention), professional societies (the American Academy of Pediatrics and American College of Obstetricians and Gynecologists), and organizations (March of Dimes) initiated nationwide monitoring and educational plans that had a significant effect on decreasing the rates of iatrogenic LPT deliveries. However, there is now an evolving concern. After nearly a decade of steady decreases in the LPT birth rate that largely contributed to the decline in total US preterm birth rates, the birth rate in LPT infants has been inching upward since 2015. In addition, evidence revealed by strong population health research demonstrates that being born as an early-term infant poses a significant risk to an infant's survival, growth, and development. In this report, we summarize the initial progress and discuss the potential reasons for the current trends in LPT and early-term birth rates and propose research recommendations. (10/19)

https://pediatrics.aappublications.org/content/144/5/e20192760

USE OF CHAPERONES DURING THE PHYSICAL EXAMINATION OF THE PEDIATRIC PATIENT

Committee on Practice and Ambulatory Medicine

ABSTRACT. Physicians should always communicate the scope and nature of the physical examination to be performed to the pediatric patient and his or her parent. This statement addresses the use of chaperones and issues of patient comfort, confidentiality, and privacy. The use of a chaperone should be a shared decision between the patient and physician. In some states, the use of a chaperone is mandated by state regulations. (4/11, 11/17)

http://pediatrics.aappublications.org/content/127/5/991

USE OF INHALED NITRIC OXIDE IN PRETERM INFANTS (CLINICAL REPORT)

Praveen Kumar, MD, FAAP, and Committee on Fetus and Newborn

ABSTRACT. Nitric oxide, an important signaling molecule with multiple regulatory effects throughout the body, is an important tool for the treatment of full-term and late-preterm infants with persistent pulmonary hypertension of the newborn and hypoxemic respiratory failure. Several randomized controlled trials have evaluated its role in the management of preterm infants

≤34 weeks' gestational age with varying results. The purpose of this clinical report is to summarize the existing evidence for the use of inhaled nitric oxide in preterm infants and provide guidance regarding its use in this population. (12/13)
http://pediatrics.aappublications.org/content/133/1/164

THE USE OF NONNUTRITIVE SWEETENERS IN CHILDREN

Carissa M. Baker-Smith, MD, MPH, FAAP; Sarah D. de Ferranti, MD, MPH, FAAP; William J. Cochran, MD, FAAP; Committee on Nutrition; and Section on Gastroenterology, Hepatology, and Nutrition

ABSTRACT. The prevalence of nonnutritive sweeteners (NNSs) in the food supply has increased over time. Not only are more children and adolescents consuming NNSs, but they are also consuming a larger quantity of NNSs in the absence of strong scientific evidence to refute or support the safety of these agents. This policy statement from the American Academy of Pediatrics is intended to provide the pediatric provider with a review of (1) previous steps taken for approved use of NNSs, (2) existing data regarding the safety of NNS use in the general pediatric population, (3) what is known regarding the potential benefits and/or adverse effects of NNS use in children and adolescents, (4) identified gaps in existing knowledge and potential areas of future research, and (5) suggested talking points that pediatricians may use when discussing NNS use with families. (10/19)
https://pediatrics.aappublications.org/content/144/5/e20192765

USE OF PERFORMANCE-ENHANCING SUBSTANCES (CLINICAL REPORT)

Michele LaBotz, MD, FAAP; Bernard A. Griesemer, MD, FAAP; and Council on Sports Medicine and Fitness

ABSTRACT. Performance-enhancing substances (PESs) are used commonly by children and adolescents in attempts to improve athletic performance. More recent data reveal that these same substances often are used for appearance-related reasons as well. PESs include both legal over-the-counter dietary supplements and illicit pharmacologic agents. This report reviews the current epidemiology of PES use in the pediatric population, as well as information on those PESs in most common use. Concerns regarding use of legal PESs include high rates of product contamination, correlation with future use of anabolic androgenic steroids, and adverse effects on the focus and experience of youth sports participation. The physical maturation and endogenous hormone production that occur in adolescence are associated with large improvements in strength and athletic performance. For most young athletes, PES use does not produce significant gains over those seen with the onset of puberty and adherence to an appropriate nutrition and training program. (6/16)
http://pediatrics.aappublications.org/content/138/1/e20161300

THE USE OF SYSTEMIC AND TOPICAL FLUOROQUINOLONES (CLINICAL REPORT)

Mary Anne Jackson, MD, FAAP; Gordon E. Schutze, MD, FAAP; and Committee on Infectious Diseases

ABSTRACT. Appropriate prescribing practices for fluoroquinolones, as well as all antimicrobial agents, are essential as evolving resistance patterns are considered, additional treatment indications are identified, and the toxicity profile of fluoroquinolones in children has become better defined. Earlier recommendations for systemic therapy remain; expanded uses of fluoroquinolones for the treatment of certain infections are outlined in this report. Prescribing clinicians should be aware of specific adverse reactions associated with fluoroquinolones, and their use in children should continue to be limited to the treatment of infections for which no safe and effective alternative exists or in situations in which oral fluoroquinolone treatment represents a reasonable alternative to parenteral antimicrobial therapy. (10/16)
http://pediatrics.aappublications.org/content/138/5/e20162706

THE USE OF TELEMEDICINE TO ADDRESS ACCESS AND PHYSICIAN WORKFORCE SHORTAGES

Committee on Pediatric Workforce

ABSTRACT. The use of telemedicine technologies by primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists (henceforth referred to as "pediatric physicians") has the potential to transform the practice of pediatrics. The purpose of this policy statement is to describe the expected and potential impact that telemedicine will have on pediatric physicians' efforts to improve access and physician workforce shortages. The policy statement also describes how the American Academy of Pediatrics can advocate for its members and their patients to best use telemedicine technologies to improve access to care, provide more patient- and family-centered care, increase efficiencies in practice, enhance the quality of care, and address projected shortages in the clinical workforce. As the use of telemedicine increases, it is likely to impact health care access, quality, and education and costs of care. Telemedicine technologies, applied to the medical home and its collaborating providers, have the potential to improve current models of care by increasing communication among clinicians, resulting in more efficient, higher quality, and less expensive care. Such a model can serve as a platform for providing more continuous care, linking primary and specialty care to support management of the needs of complex patients. In addition, telemedicine technologies can be used to efficiently provide pediatric physicians working in remote locations with ongoing medical education, increasing their ability to care for more complex patients in their community, reducing the burdens of travel on patients and families, and supporting the medical home. On the other hand, telemedicine technologies used for episodic care by nonmedical home providers have the potential to disrupt continuity of care and to create redundancy and imprudent use of health care resources. Fragmentation should be avoided, and telemedicine, like all primary and specialty services, should be coordinated through the medical home. (6/15, reaffirmed 5/19)
http://pediatrics.aappublications.org/content/136/1/202

VIRTUAL VIOLENCE

Council on Communications and Media

ABSTRACT. In the United States, exposure to media violence is becoming an inescapable component of children's lives. With the rise in new technologies, such as tablets and new gaming platforms, children and adolescents increasingly are exposed to what is known as "virtual violence." This form of violence is not experienced physically; rather, it is experienced in realistic ways via new technology and ever more intense and realistic games. The American Academy of Pediatrics continues to be concerned about children's exposure to virtual violence and the effect it has on their overall health and well-being. This policy statement aims to summarize the current state of scientific knowledge regarding the effects of virtual violence on children's attitudes and behaviors and to make specific recommendations for pediatricians, parents, industry, and policy makers. (7/16)
http://pediatrics.aappublications.org/content/138/2/e20161298

VISUAL SYSTEM ASSESSMENT IN INFANTS, CHILDREN, AND YOUNG ADULTS BY PEDIATRICIANS

Committee on Practice and Ambulatory Medicine and Section on Ophthalmology (joint with American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology and Strabismus, and American Academy of Ophthalmology)

ABSTRACT. Appropriate visual assessments help identify children who may benefit from early interventions to correct or improve vision. Examination of the eyes and visual system should begin in the nursery and continue throughout both childhood and adolescence during routine well-child visits

in the medical home. Newborn infants should be examined using inspection and red reflex testing to detect structural ocular abnormalities, such as cataract, corneal opacity, and ptosis. Instrument-based screening, if available, should be first attempted between 12 months and 3 years of age and at annual well-child visits until acuity can be tested directly. Direct testing of visual acuity can often begin by 4 years of age, using age-appropriate symbols (optotypes). Children found to have an ocular abnormality or who fail a vision assessment should be referred to a pediatric ophthalmologist or an eye care specialist appropriately trained to treat pediatric patients. (12/15)
http://pediatrics.aappublications.org/content/137/1/e20153596

WITHHOLDING OR TERMINATION OF RESUSCITATION IN PEDIATRIC OUT-OF-HOSPITAL TRAUMATIC CARDIOPULMONARY ARREST

Committee on Pediatric Emergency Medicine (joint with American College of Surgeons Committee on Trauma and National Association of EMS Physicians)

ABSTRACT. This multiorganizational literature review was undertaken to provide an evidence base for determining whether recommendations for out-of-hospital termination of resuscitation could be made for children who are victims of traumatic cardiopulmonary arrest. Although there is increasing acceptance of out-of-hospital termination of resuscitation for adult traumatic cardiopulmonary arrest when there is no expectation of a good outcome, children are routinely excluded from state termination-of-resuscitation protocols. The decision to withhold resuscitative efforts in a child under specific circumstances (decapitation or dependent lividity, rigor mortis, etc) is reasonable. If there is any doubt as to the circumstances or timing of the traumatic cardiopulmonary arrest, under the current status of limiting termination of resuscitation in the field to persons older than 18 years in most states, resuscitation should be initiated and continued until arrival to the appropriate facility. If the patient has arrested, resuscitation has already exceeded 30 minutes, and the nearest facility is more than 30 minutes away, involvement of parents and family of these children in the decision-making process with assistance and guidance from medical professionals should be considered as part of an emphasis on family-centered care because the evidence suggests that either death or a poor outcome is inevitable. (3/14, reaffirmed 6/20)
http://pediatrics.aappublications.org/content/133/4/e1104

YOUTH PARTICIPATION AND INJURY RISK IN MARTIAL ARTS (CLINICAL REPORT)

Rebecca A. Demorest, MD, FAAP; Chris Koutures, MD, FAAP; and Council on Sports Medicine and Fitness

ABSTRACT. The martial arts can provide children and adolescents with vigorous levels of physical exercise that can improve overall physical fitness. The various types of martial arts encompass noncontact basic forms and techniques that may have a lower relative risk of injury. Contact-based sparring with competitive training and bouts have a higher risk of injury. This clinical report describes important techniques and movement patterns in several types of martial arts and reviews frequently reported injuries encountered in each discipline, with focused discussions of higher risk activities. Some of these higher risk activities include blows to the head and choking or submission movements that may cause concussions or significant head injuries. The roles of rule changes, documented benefits of protective equipment, and changes in training recommendations in attempts to reduce injury are critically assessed. This information is intended to help pediatric health care providers counsel patients and families in encouraging safe participation in martial arts. (11/16)
http://pediatrics.aappublications.org/content/138/6/e20163022

Section 5

Endorsed Policies

The American Academy of Pediatrics endorses and accepts as its policy the following documents from other organizations.

AMERICAN ACADEMY OF PEDIATRICS

Endorsed Policies

2015 SPCTPD/ACC/AAP/AHA TRAINING GUIDELINES FOR PEDIATRIC CARDIOLOGY FELLOWSHIP PROGRAMS (REVISION OF THE 2005 TRAINING GUIDELINES FOR PEDIATRIC CARDIOLOGY FELLOWSHIP PROGRAMS)

Robert D. Ross, MD, FAAP, FACC; Michael Brook, MD; Jeffrey A. Feinstein, MD; et al (8/15)

INTRODUCTION

Robert D. Ross, MD, FAAP, FACC; Michael Brook, MD; Peter Koenig, MD, FACC, FASE; et al (8/15)

TASK FORCE 1: GENERAL CARDIOLOGY

Alan B. Lewis, MD, FAAP, FACC; Gerard R. Martin, MD, FAAP, FACC, FAHA; Peter J. Bartz, MD, FASE; et al (8/15)

TASK FORCE 2: NONINVASIVE CARDIAC IMAGING

Shubhika Srivastava, MBBS, FAAP, FACC, FASE; Beth F. Printz, MD, PhD, FAAP, FASE; Tal Geva, MD, FACC; et al (8/15)

TASK FORCE 3: CARDIAC CATHETERIZATION

Laurie B. Armsby, MD, FAAP, FSCAI; Robert N. Vincent, MD, CM, FACC, FSCAI; Susan R. Foerster, MD, FSCAI; et al (8/15)

TASK FORCE 4: ELECTROPHYSIOLOGY

Anne M. Dubin, MD, FHRS; Edward P. Walsh, MD, FHRS; Wayne Franklin, MD, FAAP, FACC, FAHA; et al (8/15)

TASK FORCE 5: CRITICAL CARE CARDIOLOGY

Timothy F. Feltes, MD, FAAP, FACC, FAHA; Stephen J. Roth, MD, MPH, FAAP; Melvin C. Almodovar, MD; et al (8/15)

TASK FORCE 6: ADULT CONGENITAL HEART DISEASE

Karen Stout, MD, FACC; Anne Marie Valente, MD, FACC; Peter J. Bartz, MD, FASE; et al (8/15)

TASK FORCE 7: PULMONARY HYPERTENSION, ADVANCED HEART FAILURE, AND TRANSPLANTATION

Steven A. Webber, MB, ChB; Daphne T. Hsu, MD, FAAP, FACC, FAHA; D. Dunbar Ivy, MD, FAAP, FACC; et al (8/15)

TASK FORCE 8: RESEARCH AND SCHOLARLY ACTIVITY

William T. Mahle, MD, FAAP, FACC, FAHA; Anne M. Murphy, MD, FACC, FAHA; Jennifer S. Li, MD; et al (8/15)

ADVANCED PRACTICE REGISTERED NURSE: ROLE, PREPARATION, AND SCOPE OF PRACTICE

National Association of Neonatal Nurses

ABSTRACT. In recent years, the National Association of Neonatal Nurses (NANN) and the National Association of Neonatal Nurse Practitioners (NANNP) have developed several policy statements on neonatal advanced practice registered nurse (APRN) workforce, education, competency, fatigue, safety, and scope of practice. This position paper is a synthesis of previous efforts and discusses the role, preparation, and scope of practice of the neonatal APRN. (1/14)

ANTENATAL CORTICOSTEROID THERAPY FOR FETAL MATURATION

American College of Obstetricians and Gynecologists

ABSTRACT. Corticosteroid administration before anticipated preterm birth is one of the most important antenatal therapies available to improve newborn outcomes. A single course of corticosteroids is recommended for pregnant women between 24 0/7 weeks and 33 6/7 weeks of gestation who are at risk of preterm delivery within 7 days, including for those with ruptured membranes and multiple gestations. It also may be considered for pregnant women starting at 23 0/7 weeks of gestation who are at risk of preterm delivery within 7 days, based on a family's decision regarding resuscitation, irrespective of membrane rupture status and regardless of fetal number. Administration of betamethasone may be considered in pregnant women between 34 0/7 weeks and 36 6/7 weeks of gestation who are at risk of preterm birth within 7 days, and who have not received a previous course of antenatal corticosteroids. A single repeat course of antenatal corticosteroids should be considered in women who are less than 34 0/7 weeks of gestation who are at risk of preterm delivery within 7 days, and whose prior course of antenatal corticosteroids was administered more than 14 days previously. Rescue course corticosteroids could be provided as early as 7 days from the prior dose, if indicated by the clinical scenario. Continued surveillance of long-term outcomes after in utero corticosteroid exposure should be supported. Quality improvement strategies to optimize appropriate and timely antenatal corticosteroid administration are encouraged. (8/17)

APPROPRIATE USE CRITERIA FOR INITIAL TRANSTHORACIC ECHOCARDIOGRAPHY IN OUTPATIENT PEDIATRIC CARDIOLOGY

American College of Cardiology Appropriate Use Task Force

ABSTRACT. The American College of Cardiology (ACC) participated in a joint project with the American Society of Echocardiography, the Society of Pediatric Echocardiography, and several other subspecialty societies and organizations to establish and evaluate Appropriate Use Criteria (AUC) for the initial use of outpatient pediatric echocardiography. Assumptions for the AUC were identified, including the fact that all indications assumed a first-time transthoracic echocardiographic study in an outpatient setting for patients without previously known heart disease. The definitions for frequently used terminology in outpatient pediatric cardiology were established using published guidelines and standards and expert opinion. These AUC serve as a guide to help clinicians in the care of children with possible heart disease, specifically in terms of when a transthoracic echocardiogram is warranted as an initial diagnostic modality in the outpatient setting. They are also a useful tool for education and provide the infrastructure for future quality improvement initiatives as well as research in healthcare delivery, outcomes, and resource utilization.

To complete the AUC process, the writing group identified 113 indications based on common clinical scenarios and/or published clinical practice guidelines, and each indication was classified into 1 of 9 categories of common clinical presentations, including palpitations, syncope, chest pain, and murmur. A separate, independent rating panel evaluated each indication using a scoring scale of 1 to 9, thereby designating each indication as "Appropriate" (median score 7 to 9), "May Be Appropriate" (median score 4 to 6), or "Rarely Appropriate" (median score 1 to 3). Fifty-three indications were identified as Appropriate, 28 as May Be Appropriate, and 32 as Rarely Appropriate. (11/14)

CHILDREN'S SURGERY VERIFICATION

OPTIMAL RESOURCES FOR CHILDREN'S SURGICAL CARE

American College of Surgeons

EXECUTIVE SUMMARY. The Task Force for Children's Surgical Care, an ad hoc multidisciplinary group of invited leaders in relevant disciplines, assembled initially from April 30 to May 1, 2012, in Rosemont, IL, and subsequently in 2013, 2014, and 2015 to consider approaches to optimize the delivery of children's surgical care in today's competitive national health care environment. Specifically, a mismatch between individual patient needs and available clinical resources for some infants and children receiving surgical care is recognized as a problem in the United States and elsewhere. Although this phenomenon is apparent to most practitioners involved with children's surgical care, comprehensive data are not available, and relevant data are imperfect. The scope of this problem is unknown at present. However, the situation does periodically, and possibly systematically, result in suboptimal patient outcomes.

The composition of the task force is detailed in Appendix 4. The Children's Hospital Association and the American College of Surgeons (ACS) provided support. The group represented key disciplines and perspectives. Published literature and data were used when available, and expert opinion when not, as the basis for these recommendations. The objective was to develop consensus recommendations that would be of use to relevant policymakers and to providers.

Principles regarding resource standards, quality-improvement and safety processes, data collection, and a verification process were initially published in March 2014 [*J Am Coll Surg*. 2014;218(3):479–487]. This document details those principles in a specific manner designed to inform and direct a verification process to be conducted by the ACS and the ACS Children's Surgery Verification Committee.

Notably, there are a number of excellent children's specialty hospitals in the United States whose scope of service is more narrow than delineated in this document. A separate process will be used to develop relevant standards for those institutions to achieve the vision of prospectively matching institutional resources with individual patient needs. (12/15)

COLLABORATION IN PRACTICE: IMPLEMENTING TEAM-BASED CARE

American College of Obstetricians and Gynecologists Task Force on Collaborative Practice

INTRODUCTION. Quality, efficiency, and value are necessary characteristics of our evolving health care system. Team-based care will work toward the Triple Aim of 1) improving the experience of care of individuals and families; 2) improving the health of populations; and 3) lowering per capita costs. It also should respond to emerging demands and reduce undue burdens on health care providers. Team-based care has the ability to more effectively meet the core expectations of the health care system proposed by the Institute of Medicine. These expectations require that care be safe, effective, patient centered, timely, efficient, and equitable. This report outlines a mechanism that all specialties and practices can use to achieve these expectations.

The report was written by the interprofessional Task Force on Collaborative Practice and is intended to appeal to multiple specialties (eg, internal medicine, pediatrics, family medicine, and women's health) and professions (eg, nurse practitioners, certified nurse–midwives/certified midwives, physician assistants, physicians, clinical pharmacists, and advanced practice registered nurses). This document provides a framework for organizations or practices across all specialties to develop team-based care. In doing so, it offers a map to help practices navigate the increasingly complex and continuously evolving health care system. The guidance presented is a result of the task force's work and is based on current evidence and expert consensus. The task force challenges and welcomes all medical specialties to gather additional data on how and what types of team-based care best accomplish the Triple Aim and the Institute of Medicine's expectations of health care. (3/16)

CONFIDENTIALITY PROTECTIONS FOR ADOLESCENTS AND YOUNG ADULTS IN THE HEALTH CARE BILLING AND INSURANCE CLAIMS PROCESS

Society for Adolescent Health and Medicine

ABSTRACT. The importance of protecting confidential health care for adolescents and young adults is well documented. State and federal confidentiality protections exist for both minors and young adults, although the laws vary among states, particularly for minors. However, such confidentiality is potentially violated by billing practices and in the processing of health insurance claims. To address this problem, policies and procedures should be established so that health care billing and insurance claims processes do not impede the ability of providers to deliver essential health care services on a confidential basis to adolescents and young adults covered as dependents on a family's health insurance plan. (3/16)

CONSENSUS COMMUNICATION ON EARLY PEANUT INTRODUCTION AND THE PREVENTION OF PEANUT ALLERGY IN HIGH-RISK INFANTS

Primary contributors: David M. Fleischer, MD; Scott Sicherer, MD; Matthew Greenhawt, MD; Dianne Campbell, MB BS, FRACP, PhD; Edmond Chan, MD; Antonella Muraro, MD, PhD; Susanne Halken, MD; Yitzhak Katz, MD; Motohiro Ebisawa, MD, PhD; Lawrence Eichenfield, MD; Hugh Sampson, MD; Gideon Lack, MB, BCh; and George Du Toit, MB, BCh

INTRODUCTION AND RATIONALE. Peanut allergy is an increasingly troubling global health problem affecting between 1% and 3% of children in many westernized countries. Although multiple methods of measurement have been used and specific estimates differ, there appears to have been a sudden increase in the number of cases in the past 10- to 15-year period, suggesting that the prevalence might have tripled in some countries, such as the United States. Extrapolating the currently estimated prevalence, this translates to nearly 100 000 new cases annually (in the United States and United Kingdom), affecting some 1 in 50 primary school-aged children in the United States, Canada, the United Kingdom, and Australia. A similar increase in incidence is now being noted in developing countries, such as Ghana.

The purpose of this brief communication is to highlight emerging evidence for existing allergy prevention guidelines regarding potential benefits of supporting early rather than delayed peanut introduction during the period of complementary food introduction in infants. A recent study entitled ''Randomized trial of peanut consumption in infants at risk for peanut allergy'' demonstrated a successful 11% to 25% absolute reduction in the risk of peanut allergy in high-risk infants (and a relative risk reduction of up to 80%) if peanut was introduced between 4 and 11 months of age. In light of the significance of these findings, this document serves to better inform the decision-making process for health care providers regarding such potential benefits of early peanut introduction. More formal guidelines regarding early-life, complementary feeding practices and the risk of allergy development will follow in the next year from the National Institute of Allergy and Infectious Diseases (NIAID)–sponsored Working Group and the European Academy of Allergy and Clinical Immunology (EAACI), and thus this document should be considered interim guidance. (8/15)

CONSENSUS STATEMENT: ABUSIVE HEAD TRAUMA IN INFANTS AND YOUNG CHILDREN

Arabinda Kumar Choudhary; Sabah Servaes; Thomas L. Slovis; Vincent J. Palusci; Gary L. Hedlund; Sandeep K. Narang; Joëlle Anne Moreno; Mark S. Dias; Cindy W. Christian; Marvin D. Nelson Jr; V. Michelle Silvera; Susan Palasis; Maria Raissaki; Andrea Rossi; and Amaka C. Offiah

ABSTRACT. Abusive head trauma (AHT) is the leading cause of fatal head injuries in children younger than 2 years. A multidisciplinary team bases this diagnosis on history, physical examination, imaging and laboratory findings. Because the etiology of the injury is multifactorial (shaking, shaking and impact, impact, etc.) the current best and inclusive term is AHT. There is no controversy concerning the medical validity of the existence of AHT, with multiple components including subdural hematoma, intracranial and spinal changes, complex retinal hemorrhages, and rib and other fractures that are inconsistent with the provided mechanism of trauma. The workup must exclude medical diseases that can mimic AHT. However, the courtroom has become a forum for speculative theories that cannot be reconciled with generally accepted medical literature. There is no reliable medical evidence that the following processes are causative in the constellation of injuries of AHT: cerebral sinovenous thrombosis, hypoxic-ischemic injury, lumbar puncture or dysphagic choking/vomiting. There is no substantiation, at a time remote from birth, that an asymptomatic birth-related subdural hemorrhage can result in rebleeding and sudden collapse. Further, a diagnosis of AHT is a medical conclusion, not a legal determination of the intent of the perpetrator or a diagnosis of murder. We hope that this consensus document reduces confusion by recommending to judges and jurors the tools necessary to distinguish genuine evidence-based opinions of the relevant medical community from legal arguments or etiological speculations that are unwarranted by the clinical findings, medical evidence and evidence-based literature. (5/18)

CONSENSUS STATEMENT: DEFINITIONS FOR CONSISTENT EMERGENCY DEPARTMENT METRICS

American Academy of Emergency Medicine, American Association of Critical Care Nurses, American College of Emergency Physicians, Association of periOperative Registered Nurses, Emergency Department Practice Management Association, Emergency Nurses Association, and National Association of EMS Physicians (2/10)

DEFINING PEDIATRIC MALNUTRITION: A PARADIGM SHIFT TOWARD ETIOLOGY-RELATED DEFINITIONS

American Society for Parenteral and Enteral Nutrition

ABSTRACT. Lack of a uniform definition is responsible for underrecognition of the prevalence of malnutrition and its impact on outcomes in children. A pediatric malnutrition definitions workgroup reviewed existing pediatric age group English-language literature from 1955 to 2011, for relevant references related to 5 domains of the definition of *malnutrition* that were *a priori* identified: anthropometric parameters, growth, chronicity of malnutrition, etiology and pathogenesis, and developmental/functional outcomes. Based on available evidence and an iterative process to arrive at multidisciplinary consensus in the group, these domains were included in the overall construct of a new definition. Pediatric malnutrition (undernutrition) is defined as an imbalance between nutrient requirements and intake that results in cumulative deficits of energy, protein, or micronutrients that may negatively affect growth, development, and other relevant outcomes. A summary of the literature is presented and a new classification scheme is proposed that incorporates chronicity, etiology, mechanisms of nutrient imbalance, severity of malnutrition, and its impact on outcomes. Based on its etiology, malnutrition is either *illness related* (secondary to 1 or more diseases/injury) or *non–illness related*, (caused by environmental/behavioral factors), or both. Future research must focus on the relationship between inflammation and illness-related malnutrition. We anticipate that the definition of malnutrition will continue to evolve with improved understanding of the processes that lead to and complicate the treatment of this condition. A uniform definition should permit future research to focus on the impact of pediatric malnutrition on functional outcomes and help solidify the scientific basis for evidence-based nutrition practices. (3/13)

DELAYED UMBILICAL CORD CLAMPING AFTER BIRTH

American College of Obstetricians and Gynecologists

ABSTRACT. Delayed umbilical cord clamping appears to be beneficial for term and preterm infants. In term infants, delayed umbilical cord clamping increases hemoglobin levels at birth and improves iron stores in the first several months of life, which may have a favorable effect on developmental outcomes. There is a small increase in jaundice that requires phototherapy in this group of infants. Consequently, health care providers adopting delayed umbilical cord clamping in term infants should ensure that mechanisms are in place to monitor for and treat neonatal jaundice. In preterm infants, delayed umbilical cord clamping is associated with significant neonatal benefits, including improved transitional circulation, better establishment of red blood cell volume, decreased need for blood transfusion, and lower incidence of necrotizing enterocolitis and intraventricular hemorrhage. Delayed umbilical cord clamping was not associated with an increased risk of postpartum hemorrhage or increased blood loss at delivery, nor was it associated with a difference in postpartum hemoglobin levels or the need for blood transfusion. Given the benefits to most newborns and concordant with other professional organizations, the American College of Obstetricians and Gynecologists now recommends a delay in umbilical cord clamping in vigorous term and preterm infants for at least 30–60 seconds after birth. The ability to provide delayed umbilical cord clamping may vary among institutions and settings; decisions in those circumstances are best made by the team caring for the mother–infant dyad. (1/17)

DIABETES CARE FOR EMERGING ADULTS: RECOMMENDATIONS FOR TRANSITION FROM PEDIATRIC TO ADULT DIABETES CARE SYSTEMS

American Diabetes Association (11/11)

DIETARY REFERENCE INTAKES FOR CALCIUM AND VITAMIN D

Institute of Medicine (2011)

EMERGENCY EQUIPMENT AND SUPPLIES IN THE SCHOOL SETTING

National Association of School Nurses (1/12)

ENHANCING THE WORK OF THE HHS NATIONAL VACCINE PROGRAM IN GLOBAL IMMUNIZATIONS

National Vaccine Advisory Committee (9/13)

EPIDEMIOLOGY IN FIREARM VIOLENCE PREVENTION

Amy B. Davis; James A. Gaudino; Colin L. Soskolne; Wael K. Al-Delaimy; and International Network for Epidemiology in Policy

INTRODUCTION. Firearm violence has reached pandemic levels, with some countries experiencing high injury and death rates from privately owned guns and firearms (hereinafter collectively referred to as 'firearms'). Significant factors in the increase in deaths and injuries from privately held firearms include the ease of obtaining these arms and, most importantly, the growing lethality of these weapons.

Society cannot be satisfied with reactive responses only in treating victims' physical and psychological wounds after these occurrences; more must be done proactively to prevent firearm violence and address societal circumstances that either facilitate or impede it. Where they exist, well-intended policies fail to adequately protect people from firearm violence, often because they mainly focus on the purchase and illegal uses of guns while neglecting underlying social determinants of the violent uses of firearms.

Laws intended to curb firearm violence are often not enforced, are inadequate or do not address local societal factors of crime, mental well-being, poverty or low education in the relevant communities. These considerations point to the need for a multisectoral approach in which the public health sciences would play a pivotal role in preventing harms relating to firearm violence with a greater focus on its causes. Evidence-based multicomponent interventions, often shown by systematic reviews to be the most effective to address complex, community-level health issues, are needed but are not well-defined to address firearm violence. To both advance understanding of and to guide community-level public health services and actions needed to prevent firearm violence, decision-makers need to rely more on surveillance, research and programme evaluation by public health organizations, schools and universities.

Epidemiologists have unique interdisciplinary tools for addressing the contributors and barriers to preventing and mitigating injury, including firearm violence. These include quantitative, qualitative and social epidemiological methods. Interventions to prevent and mitigate the problem are currently under-developed, under-funded and under-utilized, particularly in the USA. The problem could be addressed by putting in place a robust evidence base to inform policy decisions. Additionally, public health can create, scale up and evaluate interventions designed to address social and behavioural factors associated with firearm violence. We call on governments, community leaders and community members to take meaningful action to support public health in addressing the problem of firearm violence. (4/18)

ETHICAL CONSIDERATION FOR INCLUDING WOMEN AS RESEARCH PARTICIPANTS

American College of Obstetricians and Gynecologists

ABSTRACT. Inclusion of women in research studies is necessary for valid inferences about health and disease in women. The generalization of results from trials conducted in men may yield erroneous conclusions that fail to account for the biologic differences between men and women. Although significant changes in research design and practice have led to an increase in the proportion of women included in research trials, knowledge gaps remain because of a continued lack of inclusion of women, especially those who are pregnant, in premarketing research trials. This document provides a historical overview of issues surrounding women as participants in research trials, followed by an ethical framework and discussion of the issues of informed consent, contraception requirements, intimate partner consent, and the appropriate inclusion of pregnant women in research studies. (11/15)

EVIDENCE-BASED MANAGEMENT OF SICKLE CELL DISEASE: EXPERT PANEL REPORT, 2014

National Heart, Lung, and Blood Institute (2014)

FACULTY COMPETENCIES FOR GLOBAL HEALTH

Academic Pediatric Association Global Health Task Force

International partnerships among medical professionals from different countries are an increasingly common form of clinical and academic collaboration. Global health partnerships can include a variety of activities and serve multiple purposes in the areas of research, medical education and training, health system improvement, and clinical care. Competency domains, introduced by the Accreditation Council for Graduate Medical Education and the American Board of Medical Specialties in 1999, are now widely accepted to provide an organized, structured set of interrelated competencies, mostly for medical trainees. Although there are now competency domains and specific competencies recommended for pediatric trainees pursuing further professional training in global child health, none of these addresses competencies for faculty in global health.

In 2010 the Academic Pediatric Association established a Global Health Task Force to provide a forum for communication and collaboration for diverse pediatric academic societies and groups to advance global child health. Given the burgeoning demand for global health training, and particularly in light of a new global perspective on health education, as outlined in a Lancet Commission Report: *Health Professionals for a New Century: Transforming Education to Strengthen Health Systems in an Interdependent World,* in 2012 the Global Health Task Force noted the lack of defined faculty competencies and decided to develop a set of global health competencies for pediatric faculty engaged in the teaching and practice of global health. Using some of the principles suggested by Milner, et al. to define a competency framework, four domains were chosen, adapted from existing collaborative practice competencies. A fifth domain was added to address some of the unique challenges of global health practice encountered when working outside of one's own culture and health system. The domains are described below and specific competencies are provided for faculty working in global health research, education, administration, and clinical practice. (6/14)

GUIDELINES FOR FIELD TRIAGE OF INJURED PATIENTS

Centers for Disease Control and Prevention (1/12)

IMPORTANCE AND IMPLEMENTATION OF TRAINING IN CARDIOPULMONARY RESUSCITATION AND AUTOMATED EXTERNAL DEFIBRILLATION IN SCHOOLS

American Heart Association Emergency Cardiovascular Care Committee; Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Cardiovascular Diseases in the Young; Council on Cardiovascular Nursing; Council on Clinical Cardiology; and Advocacy Coordinating Committee

ABSTRACT. In 2003, the International Liaison Committee on Resuscitation published a consensus document on education in resuscitation that strongly recommended that "…instruction in CPR [cardiopulmonary resuscitation] be incorporated as a standard part of the school curriculum." The next year the American Heart Association (AHA) recommended that schools "…establish a goal to train every teacher in CPR and first aid and train all students in CPR" as part of their preparation for a response to medical emergencies on campus.

Since that time, there has been an increased interest in legislation that would mandate that school curricula include training in CPR or CPR and automated external defibrillation. Laws or curriculum content standards in 36 states (as of the 2009–2010 school year) now encourage the inclusion of CPR training programs in school curricula. The language in those laws and standards varies greatly, ranging from a suggestion that students "recognize" the steps of CPR to a requirement for certification in CPR. Not surprisingly, then, implementation is not uniform among states, even those whose laws or standards encourage CPR training in schools in the strongest language. This statement recommends that training in CPR and familiarization with automated external defibrillators (AEDs) should be required elements of secondary school curricula and provides the rationale for implementation of CPR training, as well as guidance in overcoming barriers to implementation. (2/11)

INITIAL RESUSCITATION ALGORITHM FOR CHILDREN

Society of Critical Care Medicine (2020)

INTER-ASSOCIATION CONSENSUS STATEMENT ON BEST PRACTICES FOR SPORTS MEDICINE MANAGEMENT FOR SECONDARY SCHOOLS AND COLLEGES

National Athletic Trainers Association, National Interscholastic Athletic Administrators Association, College Athletic Trainers' Society, National Federation of State High School Associations, American College Health Association, American Orthopaedic Society for Sports Medicine, National Collegiate Athletic Association, American Medical Society for Sports Medicine, National Association of Collegiate Directors of Athletics, and National Association of Intercollegiate Athletics (7/13)

LONG-TERM CARDIOVASCULAR TOXICITY IN CHILDREN, ADOLESCENTS, AND YOUNG ADULTS WHO RECEIVE CANCER THERAPY: PATHOPHYSIOLOGY, COURSE, MONITORING, MANAGEMENT, PREVENTION, AND RESEARCH DIRECTIONS; A SCIENTIFIC STATEMENT FROM THE AMERICAN HEART ASSOCIATION

American Heart Association (5/13)

MEETING OF THE STRATEGIC ADVISORY GROUP OF EXPERTS ON IMMUNIZATION, APRIL 2012–CONCLUSIONS AND RECOMMENDATIONS

World Health Organization (5/12) (The AAP endorses the recommendation pertaining to the use of thimerosal in vaccines.)

MENSTRUATION IN GIRLS AND ADOLESCENTS: USING THE MENSTRUAL CYCLE AS A VITAL SIGN

American College of Obstetricians and Gynecologists Committee on Adolescent Health Care

ABSTRACT. Despite variations worldwide and within the U.S. population, median age at menarche has remained relatively stable—between 12 years and 13 years—across well-nourished populations in developed countries. Environmental factors, including socioeconomic conditions, nutrition, and access to preventive health care, may influence the timing and progression of puberty. A number of medical conditions can cause abnormal uterine bleeding, characterized by unpredictable timing and variable amount of flow. Clinicians should educate girls and their caretakers (eg, parents or guardians) about what to expect of a first menstrual period and the range for normal cycle length of subsequent menses. Identification of abnormal menstrual patterns in adolescence may improve early identification of potential health concerns for adulthood. It is important for clinicians to have an understanding of the menstrual patterns of adolescent girls, the ability to differentiate between normal and abnormal menstruation, and the skill to know how to evaluate the adolescent girl patient. By including an evaluation of the menstrual cycle as an additional vital sign, clinicians reinforce its importance in assessing overall health status for patients and caretakers. (12/15)

MULTILINGUAL CHILDREN: BEYOND MYTHS AND TOWARD BEST PRACTICES

Society for Research in Child Development

ABSTRACT. Multilingualism is an international fact of life and increasing in the United States. Multilingual families are exceedingly diverse, and policies relevant to them should take this into account. The quantity and quality of a child's exposure to responsive conversation spoken by fluent adults predicts both monolingual and multilingual language and literacy achievement. Contexts supporting optimal multilingualism involve early exposure to high quality conversation in each language, along with continued support for speaking both languages. Parents who are not fluent in English should not be told to speak English instead of their native language to their children; children require fluent input, and fluent input in another language will transfer to learning a second or third language. Messages regarding optimal multilingual practices should be made available to families using any and all available methods for delivering such information, including home visitation programs, healthcare settings, center-based early childhood programs, and mass media. (2013)

NATIONAL ADOPTION CENTER: OPEN RECORDS

National Adoption Center

The National Adoption Center believes that it is an inalienable right of all citizens, including adopted adults, to have unencumbered access to their original birth certificates. In keeping with this position, we believe that copies of both the original and the amended birth certificate should be given to the adoptive family at the time of finalization unless specifically denied by the birthparents. In any case, the National Adoption Center advocates that the adoptee, at age 18, be granted access to his/her original birth certificate. (6/00)

NEONATAL ENCEPHALOPATHY AND NEUROLOGIC OUTCOME, SECOND EDITION

American College of Obstetricians and Gynecologists Task Force on Neonatal Encephalopathy

In the first edition of this report, the Task Force on Neonatal Encephalopathy and Cerebral Palsy outlined criteria deemed essential to establish a causal link between intrapartum hypoxic events and cerebral palsy. It is now known that there are multiple potential causal pathways that lead to cerebral palsy in term infants, and the signs and symptoms of neonatal encephalopathy may range from mild to severe, depending on the nature and timing of the brain injury. Thus, for the current edition, the Task Force on Neonatal Encephalopathy determined that a broader perspective may be more fruitful. This conclusion reflects the sober recognition that knowledge gaps still preclude a definitive test or set of markers that accurately identifies, with high sensitivity and specificity, an infant in whom neonatal encephalopathy is attributable to an acute intrapartum event. The information necessary for assessment of likelihood can be derived from a comprehensive evaluation of all potential contributing factors in cases of neonatal encephalopathy. This is the broader perspective championed in the current report. If a comprehensive etiologic evaluation is not possible, the term hypoxic–ischemic encephalopathy should best be replaced by neonatal encephalopathy because neither hypoxia nor ischemia can be assumed to have been the unique initiating causal mechanism. The title of this report has been changed from *Neonatal Encephalopathy and Cerebral Palsy: Defining the Pathogenesis and Pathophysiology* to *Neonatal Encephalopathy and Neurologic Outcome* to indicate that an array of developmental outcomes may arise after neonatal encephalopathy in addition to cerebral palsy. (4/14)

NEURODEVELOPMENTAL OUTCOMES IN CHILDREN WITH CONGENITAL HEART DISEASE: EVALUATION AND MANAGEMENT; A SCIENTIFIC STATEMENT FROM THE AMERICAN HEART ASSOCIATION

American Heart Association (7/12)

THE NEUROLOGIST'S ROLE IN SUPPORTING TRANSITION TO ADULT HEALTH CARE

Lawrence W. Brown, MD; Peter Camfield, MD, FRCPC; Melissa Capers, MA; Greg Cascino, MD; Mary Ciccarelli, MD; Claudio M. de Gusmao, MD; Stephen M. Downs, MD; Annette Majnemer, PhD, FCAHS; Amy Brin Miller, MSN; Christina SanInocencio, MS; Rebecca Schultz, PhD; Anne Tilton, MD; Annick Winokur, BS; and Mary Zupanc, MD

ABSTRACT. The child neurologist has a critical role in planning and coordinating the successful transition from the pediatric to adult health care system for youth with neurologic conditions. Leadership in appropriately planning a youth's transition and in care coordination among health care, educational, vocational, and community services providers may assist in preventing gaps in care, delayed entry into the adult care system, and/or health crises for their adolescent patients. Youth whose neurologic conditions result in cognitive or physical disability and their families may need additional support during this transition, given the legal and financial considerations that may be required. Eight common principles that define the child neurologist's role in a successful transition process have been outlined by a multidisciplinary panel convened by the Child Neurology Foundation are introduced and described. The authors of this consensus statement recognize the current paucity of evidence for successful transition models and outline areas for future consideration. *Neurology.* 2016;87:1–6. (7/16)

NONINHERITED RISK FACTORS AND CONGENITAL CARDIOVASCULAR DEFECTS: CURRENT KNOWLEDGE

American Heart Association

ABSTRACT. Prevention of congenital cardiovascular defects has been hampered by a lack of information about modifiable risk factors for abnormalities in cardiac development. Over the past decade, there have been major breakthroughs in the understanding of inherited causes of congenital heart disease, including the identification of specific genetic abnormalities for some types of malformations. Although relatively less information has been available on noninherited modifiable factors that may have an adverse effect on the fetal heart, there is a growing body of epidemiological literature on this topic. This statement summarizes the currently available literature on potential fetal exposures that might alter risk for cardiovascular defects. Information is summarized for periconceptional multivitamin or folic acid intake, which may reduce the risk of cardiac disease in the fetus, and for additional types of potential exposures that may increase the risk, including maternal illnesses, maternal therapeutic and nontherapeutic drug exposures, environmental exposures, and paternal exposures. Information is highlighted regarding definitive risk factors such as maternal rubella; phenylketonuria; pregestational diabetes; exposure to thalidomide, vitamin A cogeners, or retinoids; and indomethacin tocolysis. Caveats regarding interpretation of possible exposure-outcome relationships from case-control studies are given because this type of study has provided most of the available information. Guidelines for prospective parents that could reduce the likelihood that their child will have a major cardiac malformation are given. Issues related to pregnancy monitoring are discussed. Knowledge gaps and future sources of new information on risk factors are described. (*Circulation.* 2007;115:2995–3014.) (6/07)

NUSINERSEN USE IN SPINAL MUSCULAR ATROPHY

David Michelson, MD; Emma Ciafaloni, MD; Stephen Ashwal, MD; Elliot Lewis, Pushpa Narayanaswami, MBBS; Maryam Oskoui, MD, MSc; Melissa J. Armstrong, MD, MSc; and American Academy of Neurology

ABSTRACT. *Objective.* To identify the level of evidence for use of nusinersen to treat spinal muscular atrophy (SMA) and review clinical considerations regarding use.

Methods. The author panel systematically reviewed nusinersen clinical trials for patients with SMA and assigned level of evidence statements based on the American Academy of Neurology's 2017 therapeutic classification of evidence scheme. Safety information, regulatory decisions, and clinical context were also reviewed.

Results. Four published clinical trials were identified, 3 of which were rated above Class IV. There is Class III evidence that in infants with homozygous deletions or mutations of *SMN1,* nusinersen improves the probability of permanent ventilation-free survival at 24 months vs a well-defined historical cohort. There is Class I evidence that in term infants with SMA and 2 copies of *SMN2,* treatment with nusinersen started in individuals younger than 7 months results in a better motor milestone response and higher rates of event-free survival than sham control. There is Class I evidence that in children aged 2–12 years with SMA symptom onset after 6 months of age, nusinersen results in greater improvement in motor function at 15 months than sham control. Nusinersen was safe and well-tolerated.

Clinical context. Evidence of efficacy is currently highest for treatment of infantile- and childhood-onset SMA in the early and middle symptomatic phases. While approved indications for nusinersen use in North America and Europe are broad, payer coverage for populations outside those in clinical trials remain variable. Evidence, availability, cost, and patient preferences all influence decision-making regarding nusinersen use. (10/18)

ORTHOPTISTS AS PHYSICIAN EXTENDERS

American Association for Pediatric Ophthalmology and Strabismus (5/15)

PERINATAL PALLIATIVE CARE

American College of Obstetricians and Gynecologists

ABSTRACT. Perinatal palliative care refers to a coordinated care strategy that comprises options for obstetric and newborn care that include a focus on maximizing quality of life and comfort for newborns with a variety of conditions considered to be life-limiting in early infancy. With a dual focus on ameliorating suffering and honoring patient values, perinatal palliative care can be provided concurrently with life-prolonging treatment. The focus of this document, however, involves the provision of exclusively palliative care without intent to prolong life in the context of a life-limiting condition, otherwise known as perinatal palliative comfort care. Once a life-limiting diagnosis is suspected antenatally, the tenets of informed consent require that the pregnant patient be given information of sufficient depth and breadth to make an informed, voluntary choice for her care. Health care providers are encouraged to model effective, compassionate communication that respects patient cultural beliefs and values and to promote shared decision making with patients. Perinatal palliative comfort care is one of several options along a spectrum of care, which includes pregnancy termination (abortion) and full neonatal resuscitation and treatment, that should be presented to pregnant patients faced with pregnancies complicated by life-limiting fetal conditions. If a patient opts to pursue perinatal palliative comfort care, a multidisciplinary team should be identified with the infrastructure and support to administer this care. The perinatal palliative care team should prepare families for the possibility that there may be differences of opinion between family members before and after the delivery of the infant, and that there may be differences between parents and the neonatal care providers about appropriate postnatal therapies, especially if the postnatal diagnosis and prognosis differ substantially from antenatal predictions. Procedures for resolving such differences should be discussed with families ahead of time. (8/19)

A PRACTICAL GUIDE FOR PRIMARY CARE PHYSICIANS: INSTRUMENT-BASED VISION SCREENING IN CHILDREN

Children's Eye Foundation

SUMMARY. In January 2016 a new joint policy statement from the American Academy of Pediatrics (AAP), American Academy of Ophthalmology (AAO), American Association

for Pediatric Ophthalmology and Strabismus (AAPOS) and American Association of Certified Orthoptists (AACO) regarding the pediatric eye examination was published. The updated policy statement, published in the journal *Pediatrics,* incorporates earlier and routine visual assessments using instrument-based screening to help identify children who may benefit from early intervention to improve vision (or correct vision problems). Instrument-based screening technology is revolutionizing early detection and prevention of amblyopia by allowing screening of more children and at a younger age.

This guide for primary care physicians is produced by the Children's Eye Foundation of AAPOS to provide information regarding instrument-based screening. Early detection and treatment of amblyopia is key to preventing unnecessary blindness, and primary care physicians play a critical role in its detection through vision screening in the preschool and school age groups. (2016)

PREVENTION AND CONTROL OF MENINGOCOCCAL DISEASE: RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention

SUMMARY. Meningococcal disease describes the spectrum of infections caused by *Neisseria meningitidis,* including meningitidis, bacteremia, and bacteremic pneumonia. Two quadrivalent meningococcal polysaccharide-protein conjugate vaccines that provide protection against meningococcal serogroups A, C, W, and Y (MenACWY-D [Menactra, manufactured by Sanofi Pasteur, Inc., Swiftwater, Pennsylvania] and MenACWY-CRM [Menveo, manufactured by Novartis Vaccines, Cambridge, Massachusetts]) are licensed in the United States for use among persons aged 2 through 55 years. MenACWY-D also is licensed for use among infants and toddlers aged 9 through 23 months. Quadrivalent meningococcal polysaccharide vaccine (MPSV4 [Menommune, manufactured by Sanofi Pasteur, Inc., Swiftwater, Pennsylvania]) is the only vaccine licensed for use among persons aged ≥56 years. A bivalent meningococcal polysaccharide protein conjugate vaccine that provides protection against meningococcal serogroups C and Y along with *Haemophilus influenzae* type b (Hib) (Hib-MenCY-TT [MenHibrix, manufactured by GlaxoSmithKline Biologicals, Rixensart, Belgium]) is licensed for use in children aged 6 weeks through 18 months.

This report compiles and summarizes all recommendations from CDC's Advisory Committee on Immunization Practices (ACIP) regarding prevention and control of meningococcal disease in the United States, specifically the changes in the recommendations published since 2005 (CDC. Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices [ACIP]. *MMWR* 2005;54 Adobe PDF file [No. RR-7]). As a comprehensive summary of previously published recommendations, this report does not contain any new recommendations; it is intended for use by clinicians as a resource. ACIP recommends routine vaccination with a quadrivalent meningococcal conjugate vaccine (MenACWY) for adolescents aged 11 or 12 years, with a booster dose at age 16 years. ACIP also recommends routine vaccination for persons at increased risk for meningococcal disease (i.e., persons who have persistent complement component deficiencies, persons who have anatomic or functional asplenia, microbiologists who routinely are exposed to isolates of *N. meningitidis,* military recruits, and persons who travel to or reside in areas in which meningococcal disease is hyperendemic or epidemic). Guidelines for antimicrobial chemoprophylaxis and for evaluation and management of suspected outbreaks of meningococcal disease also are provided. (3/13)

PREVENTION OF GROUP B STREPTOCOCCAL EARLY-ONSET DISEASE IN NEWBORNS

American College of Obstetricians and Gynecologists Committee on Obstetric Practice

ABSTRACT. Group B streptococcus (GBS) is the leading cause of newborn infection (1). The primary risk factor for neonatal GBS early-onset disease (EOD) is maternal colonization of the genitourinary and gastrointestinal tracts. Approximately 50% of women who are colonized with GBS will transmit the bacteria to their newborns. Vertical transmission usually occurs during labor or after rupture of membranes. In the absence of intrapartum antibiotic prophylaxis, 1–2% of those newborns will develop GBS EOD. Other risk factors include gestational age of less than 37 weeks, very low birth weight, prolonged rupture of membranes, intraamniotic infection, young maternal age, and maternal black race. The key obstetric measures necessary for effective prevention of GBS EOD continue to include universal prenatal screening by vaginal–rectal culture, correct specimen collection and processing, appropriate implementation of intrapartum antibiotic prophylaxis, and coordination with pediatric care providers. The American College of Obstetricians and Gynecologists now recommends performing universal GBS screening between 36 0/7 and 37 6/7 weeks of gestation. All women whose vaginal–rectal cultures at 36 0/7 and 37 6/7 weeks of gestation are positive for GBS should receive appropriate intrapartum antibiotic prophylaxis unless a prelabor cesarean birth is performed in the setting of intact membranes. Although a shorter duration of recommended intrapartum antibiotics is less effective than 4 or more hours of prophylaxis, 2 hours of antibiotic exposure has been shown to reduce GBS vaginal colony counts and decrease the frequency of a clinical neonatal sepsis diagnosis. Obstetric interventions, when necessary, should not be delayed solely to provide 4 hours of antibiotic administration before birth. This Committee Opinion, including Table 1, Box 2, and Figures 1–3, updates and replaces the obstetric components of the CDC 2010 guidelines, "Prevention of Perinatal Group B Streptococcal Disease: Revised Guidelines From CDC, 2010." (6/19)

RECOMMENDED AMOUNT OF SLEEP FOR PEDIATRIC POPULATIONS: A CONSENSUS STATEMENT OF THE AMERICAN ACADEMY OF SLEEP MEDICINE

Shalini Paruthi, MD; Lee J. Brooks, MD; Carolyn D'Ambrosio, MD; Wendy A. Hall, PhD, RN; Suresh Kotagal, MD; Robin M. Lloyd, MD; Beth A. Malow, MD, MS; Kiran Maski, MD; Cynthia Nichols, PhD; Stuart F. Quan, MD; Carol L. Rosen, MD; Matthew M. Troester, DO; and Merrill S. Wise, MD

Background and Methodology. Healthy sleep requires adequate duration, appropriate timing, good quality, regularity, and the absence of sleep disturbances or disorders. Sleep duration is a frequently investigated sleep measure in relation to health. A panel of 13 experts in sleep medicine and research used a modified RAND Appropriateness Method to develop recommendations regarding the sleep duration range that promotes optimal health in children aged 0–18 years. The expert panel reviewed published scientific evidence addressing the relationship between sleep duration and health using a broad set of National Library of Medicine Medical Subject Headings (MeSH) terms and no date restrictions, which resulted in a total of 864 scientific articles. The process was further guided by the Oxford grading system. The panel focused on seven health categories with the best available evidence in relation to sleep duration: general health, cardiovascular health, metabolic health, mental health, immunologic function, developmental health, and human performance. Consistent with the RAND Appropriateness Method, multiple rounds of evidence review, discussion, and voting were conducted to arrive at the final recommendations. The process to

develop these recommendations was conducted over a 10-month period and concluded with a meeting held February 19–21, 2016, in Chicago, Illinois. (6/16)

SCREENING CHILDREN AT RISK FOR RETINOBLASTOMA: CONSENSUS REPORT FROM THE AMERICAN ASSOCIATION OF OPHTHALMIC ONCOLOGISTS AND PATHOLOGISTS

Alison H. Skalet, MD, PhD; Dan S. Gombos, MD; Brenda L. Gallie, MD; Jonathan W. Kim, MD; Carol L. Shields, MD; Brian P. Marr, MD; Sharon E. Plon, MD, PhD; and Patricia Chévez-Barrios, MD

Purpose: To provide a set of surveillance guidelines for children at risk for development of retinoblastoma.

Design: Consensus panel.

Participants: Expert panel of ophthalmic oncologists, pathologists, and geneticists.

Methods: A group of members of the American Association of Ophthalmic Oncologists and Pathologists (AAOOP) with support of the American Association for Pediatric Ophthalmology and Strabismus and the American Academy of Pediatrics (AAP) was convened. The panel included representative ophthalmic oncologists, pathologists, and geneticists from retinoblastoma referral centers located in various geographic regions who met and discussed screening approaches for retinoblastoma. A patient "at risk" was defined as a person with a family history of retinoblastoma in a parent, sibling, or first- or second-degree relative.

Main Outcome Measures: Screening recommendations for children at risk for retinoblastoma.

Results: Consensus statement from the panel: (1) Dedicated ophthalmic screening is recommended for all children at risk for retinoblastoma above the population risk. (2) Frequency of examinations is adjusted on the basis of expected risk for *RB1* mutation. (3) Genetic counseling and testing clarify the risk for retinoblastoma in children with a family history of the disease. (4) Examination schedules are stratified on the basis of high-, intermediate-, and low-risk children. (5) Children at high risk for retinoblastoma require more frequent screening, which may preferentially be examinations under anesthesia.

Conclusions: Risk stratification including genetic testing and counseling serves as the basis for screening of children at elevated risk for development of retinoblastoma. (10/17)

SCREENING FOR IDIOPATHIC SCOLIOSIS IN ADOLESCENTS—POSITION STATEMENT

American Academy of Orthopedic Surgeons, Scoliosis Research Society, and Pediatric Orthopedic Society of North America

ABSTRACT. The Scoliosis Research Society (SRS), American Academy of Orthopedic Surgeons (AAOS), Pediatric Orthopedic Society of North America (POSNA), and American Academy of Pediatrics (AAP) believe that there has been additional useful research in the early detection and management of adolescent idiopathic scoliosis (AIS) since the review performed by the United States Preventive Services Task Force (USPSTF) in 2004. This information should be available for use by patients, treating health care providers, and policy makers in assessing the relative risks and benefits of the early identification and management of AIS.

The AAOS, SRS, POSNA, and AAP believe that there are documented benefits of earlier detection and non-surgical management of AIS, earlier identification of severe deformities that are surgically treated, and of incorporating screening of children for AIS by knowledgeable health care providers as a part of their care. (9/15)

SKIING AND SNOWBOARDING INJURY PREVENTION

Canadian Paediatric Society

ABSTRACT. Skiing and snowboarding are popular recreational and competitive sport activities for children and youth. Injuries associated with both activities are frequent and can be serious. There is new evidence documenting the benefit of wearing helmets while skiing and snowboarding, as well as data refuting suggestions that helmet use may increase the risk of neck injury. There is also evidence to support using wrist guards while snowboarding. There is poor uptake of effective preventive measures such as protective equipment use and related policy. Physicians should have the information required to counsel children, youth and families regarding safer snow sport participation, including helmet use, wearing wrist guards for snowboarding, training and supervision, the importance of proper equipment fitting and binding adjustment, sun safety and avoiding substance use while on the slopes. (1/12, reaffirmed 1/20)

SPINAL MOTION RESTRICTION IN THE TRAUMA PATIENT—A JOINT POSITION STATEMENT

Peter E. Fischer, MD, MS; Debra G. Perina, MD; Theodore R. Delbridge, MD, MPH; Mary E. Fallat, MD; Jeffrey P. Salomone, MD; Jimm Dodd, MS, MA; Eileen M. Bulger, MD; and Mark L. Gestring, MD

ABSTRACT. The American College of Surgeons Committee on Trauma (ACS-COT), American College of Emergency Physicians (ACEP), and the National Association of EMS Physicians (NAEMSP) have previously offered varied guidance on the role of backboards and spinal immobilization in out-of-hospital situations. This updated consensus statement on spinal motion restriction in the trauma patient represents the collective positions of the ACS-COT, ACEP and NAEMSP. It has further been formally endorsed by a number of national stakeholder organizations. This updated uniform guidance is intended for use by emergency medical services (EMS) personnel, EMS medical directors, emergency physicians, trauma surgeons, and nurses as they strive to improve the care of trauma victims within their respective domains. (8/18)

SUPPLEMENT TO THE JCIH 2007 POSITION STATEMENT: PRINCIPLES AND GUIDELINES FOR EARLY INTERVENTION AFTER CONFIRMATION THAT A CHILD IS DEAF OR HARD OF HEARING

Joint Committee on Infant Hearing

PREFACE. This document is a supplement to the recommendations in the year 2007 position statement of the Joint Committee on Infant Hearing (JCIH) and provides comprehensive guidelines for early hearing detection and intervention (EHDI) programs on establishing strong early intervention (EI) systems with appropriate expertise to meet the needs of children who are deaf or hard of hearing (D/HH).

EI services represent the purpose and goal of the entire EHDI process. Screening and confirmation that a child is D/HH are largely meaningless without appropriate, individualized, targeted and high-quality intervention. For the infant or young child who is D/HH to reach his or her full potential, carefully designed individualized intervention must be implemented promptly, utilizing service providers with optimal knowledge and skill levels and providing services on the basis of research, best practices, and proven models.

The delivery of EI services is complex and requires individualization to meet the identified needs of the child and family. Because of the diverse needs of the population of children who are D/HH and their families, well-controlled intervention studies are challenging. At this time, few comparative effectiveness studies have been conducted. Randomized controlled trials are particularly difficult for ethical reasons, making it challenging

to establish causal links between interventions and outcomes. EI systems must partner with colleagues in research to document what works for children and families and to strengthen the evidence base supporting practices.

Despite limitations and gaps in the evidence, the literature does contain research studies in which all children who were D/HH had access to the same well-defined EI service. These studies indicate that positive outcomes are possible, and they provide guidance about key program components that appear to promote these outcomes. This EI services document, drafted by teams of professionals with extensive expertise in EI programs for children who are D/HH and their families, relied on literature searches, existing systematic reviews, and recent professional consensus statements in developing this set of guidelines.

Terminology presented a challenge throughout document development. The committee noted that many of the frequently occurring terms necessary within the supplement may not reflect the most contemporary understanding and/or could convey inaccurate meaning. Rather than add to the lack of clarity or consensus and to avoid introducing new terminology to stakeholders, the committee opted to use currently recognized terms consistently herein and will monitor the emergence and/or development of new descriptors before the next JCIH consensus statement.

For purposes of this supplement:

- *Language* refers to all spoken and signed languages.
- *Early intervention* (EI), according to part C of the Individuals with Disabilities Education Improvement Act (IDEA) of 2004, is the process of providing services, education, and support to young children who are deemed to have an established condition, those who are evaluated and deemed to have a diagnosed physical or mental condition (with a high probability of resulting in a developmental delay), those who have an existing delay, or those who are at risk of developing a delay or special need that may affect their development or impede their education.
- *Communication* is used in lieu of terms such as communication options, methods, opportunities, approaches, etc.
- *Deaf or hard of hearing* (D/HH) is intended to be inclusive of all children with congenital and acquired hearing loss, unilateral and bilateral hearing loss, all degrees of hearing loss from minimal to profound, and all types of hearing loss (sensorineural, auditory neuropathy spectrum disorder, permanent conductive, and mixed).
- *Core knowledge and skills* is used to describe the expertise needed to provide appropriate EI that will optimize the development and well-being of infants/children and their families. Core knowledge and skills will differ according to the roles of individuals within the EI system (eg, service coordinator or EI provider).

This supplement to JCIH 2007 focuses on the practices of EI providers outside of the primary medical care and specialty medical care realms, rather than including the full spectrum of necessary medical, audiologic, and educational interventions. For more information about the recommendations for medical follow-up, primary care surveillance for related medical conditions, and specialty medical care and monitoring, the reader is encouraged to reference the year 2007 position statement of the JCIH as well as any subsequent revision. When an infant is confirmed to be D/HH, the importance of ongoing medical and audiologic management and surveillance both in the medical home and with the hearing health professionals, the otolaryngologist and the audiologist, cannot be overstated. A comprehensive discussion of those services is beyond the scope of this document. (3/13)

TIMING OF UMBILICAL CORD CLAMPING AFTER BIRTH

American College of Obstetricians and Gynecologists Committee on Obstetric Practice (12/12)

WEIGHING ALL PATIENTS IN KILOGRAMS

Emergency Nurses Association (9/16)

YEAR 2007 POSITION STATEMENT: PRINCIPLES AND GUIDELINES FOR EARLY HEARING DETECTION AND INTERVENTION PROGRAMS

Joint Committee on Infant Hearing

ABSTRACT. The Joint Committee on Infant Hearing (JCIH) endorses early detection of and intervention for infants with hearing loss. The goal of early hearing detection and intervention (EHDI) is to maximize linguistic competence and literacy development for children who are deaf or hard of hearing. Without appropriate opportunities to learn language, these children will fall behind their hearing peers in communication, cognition, reading, and social-emotional development. Such delays may result in lower educational and employment levels in adulthood. To maximize the outcome for infants who are deaf or hard of hearing, the hearing of all infants should be screened at no later than 1 month of age. Those who do not pass screening should have a comprehensive audiological evaluation at no later than 3 months of age. Infants with confirmed hearing loss should receive appropriate intervention at no later than 6 months of age from health care and education professionals with expertise in hearing loss and deafness in infants and young children. Regardless of previous hearing-screening outcomes, all infants with or without risk factors should receive ongoing surveillance of communicative development beginning at 2 months of age during well-child visits in the medical home. EHDI systems should guarantee seamless transitions for infants and their families through this process. (10/07)

APPENDIX 1

PPI: AAP Partnership for Policy Implementation

BACKGROUND

The American Academy of Pediatrics (AAP) develops policies that promote optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. These documents are valued highly not only by clinicians who provide direct health care to children but by members of other organizations who share similar goals and by parents, payers, and legislators. To increase clarity and action of AAP clinical guidance and recommendations for physicians at the point of care, the AAP formed the Partnership for Policy Implementation (PPI). The PPI is a group of pediatric medical informaticians who partner with authors of AAP clinical practice guidelines and clinical reports to assure that clinical recommendations are stated with the precision needed to implement them in an electronic health record (EHR) system. Partnership for Policy Implementation volunteers focus on helping content experts develop clinical guidance that specifies exactly who is to do what, for whom, and under what circumstances.

VISION

The vision of the PPI is that all AAP clinical recommendations include clear guidance on how pediatricians can implement those recommendations into their patient care and that AAP clinical guidance can be easily incorporated within EHR decision-support systems.

MISSION

The mission of the PPI is to facilitate implementation of AAP recommendations at the point of care by ensuring that AAP documents are written in a practical, action-oriented fashion with unambiguous recommendations.

WHAT THE PPI IS

The PPI is a network of pediatric informaticians who work with AAP authors and clinical practice guideline subcommittees throughout the writing process.

Contributions of the PPI to the AAP writing process include disambiguation and specification; development of clear definitions; clearly defined logic; implementation techniques; action-oriented recommendations, including clinical algorithms; transparency of the evidence base for recommendations; and health information technology (HIT) standard development.

WHAT THE PPI HAS ACCOMPLISHED

Since inception of the PPI, more than 30 statements have been published using the PPI process, covering a wide variety of child health topics, including attention-deficit/hyperactivity disorder in children and adolescents (*Pediatrics.* 2019;144[4]:e20192528), influenza prevention and control (*Pediatrics.* 2020;146[4]:e2020024588), infantile hemangiomas (*Pediatrics.* 2019;143[1]:e20183475), maintenance intravenous fluids (*Pediatrics.* 2018;142[6]:e20183083), child passenger safety (*Pediatrics.* 2018;142[5]:e20182460), and high blood pressure in children and adolescents (*Pediatrics.* 2018;142[3]:e20182096).

One example of how a statement developed using the PPI process has gained broader acceptance is the AAP annual influenza statement. Since 2007, the Centers for Disease Control and Prevention has adopted components of the PPI statement (specifically, the clinical algorithm) within its own statement on the same topic.

WHAT THE PPI IS DOING NOW

In addition to creating practical, action-oriented guidance that pediatricians can use at the point of care, the PPI works to make it easier for these recommendations to be incorporated into electronic systems. To date, the PPI has focused its involvement on the statement development process. Involvement of the PPI during the writing process helps produce a clear, more concise document. As these standards of care become well documented, the PPI can begin to focus on building or mapping pediatric vocabulary; once solidified, this vocabulary can be built into EHR systems. The standards of care can also be matched to various logical and functional HIT standards that already exist today. Through this work, the PPI improves AAP policy documents by providing specific guidance to pediatricians at the point of care, helping ensure that EHRs are designed to assist pediatricians in providing optimal care for children. The PPI developed a short video that provides an overview of its mission and process. This video is available on the PPI website (https://www.aap.org/en-us/professional-resources/quality-improvement/Pages/Partnership-for-Policy-Implementation.aspx) as well as the AAP YouTube channel at www.youtube.com/watch?v=woTfeoNcxn4.

The PPI continues to expand and mentor new members. For more information on the application process and about the PPI, please visit its website (https://www.aap.org/en-us/professional-resources/quality-improvement/Pages/Partnership-for-Policy-Implementation.aspx) or contact Kymika Okechukwu (kokechukwu@aap.org or 630/626-6317).

APPENDIX 2

American Academy of Pediatrics Acronyms

AACAP	American Academy of Child and Adolescent Psychiatry
AAFP	American Academy of Family Physicians
AAMC	Association of American Medical Colleges
AAOS	American Academy of Orthopaedic Surgeons
AAP	American Academy of Pediatrics
AAPD	American Academy of Pediatric Dentistry
ABM	Academy of Breastfeeding Medicine
ABMS	American Board of Medical Specialties
ABP	American Board of Pediatrics
ACCME	Accreditation Council for Continuing Medical Education
ACEP	American College of Emergency Physicians
ACGME	Accreditation Council for Graduate Medical Education
ACIP	Advisory Committee on Immunization Practices
ACMG	American College of Medical Genetics
ACO	Accountable Care Organization
ACOG	American College of Obstetricians and Gynecologists
ACOP	American College of Osteopathic Pediatricians
ACP	American College of Physicians
ADAMHA	Alcohol, Drug Abuse, and Mental Health Administration
AG-M	Action Group—Multidisciplinary (Section Forum)
AG-M1	Action Group—Medical 1 (Section Forum)
AG-M2	Action Group—Medical 2 (Section Forum)
AG-S	Action Group—Surgical (Section Forum)
AHA	American Heart Association
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
ALF	Annual Leadership Forum
AMA	American Medical Association
AMCHP	Association of Maternal and Child Health Programs
AMSA	American Medical Student Association
AMSPDC	Association of Medical School Pediatric Department Chairs
AMWA	American Medical Women's Association
APA	Academic Pediatric Association
APHA	American Public Health Association
APLS	Advanced Pediatric Life Support
APPD	Association of Pediatric Program Directors
APQ	Alliance for Pediatric Quality
APS	American Pediatric Society
AQA	Ambulatory Care Quality Alliance
ASHG	American Society of Human Genetics
ASPHO	American Society of Pediatric Hematology/Oncology
ASPN	American Society of Pediatric Nephrology
ASTM	American Society of Testing and Materials
BHP	Bureau of Health Professions
BIA	Bureau of Indian Affairs
BLAST	Babysitter Lessons and Safety Training
BOD	Board of Directors
BPC	Breastfeeding Promotion Consortium
CAG	Corporate Advisory Group
CAMLWG	Children, Adolescents, and Media Leadership Workgroup
CAP	College of American Pathologists
CAQI	Chapter Alliance for Quality Improvement
CATCH	Community Access to Child Health
CDC	Centers for Disease Control and Prevention
CESP	Confederation of European Specialty Pediatrics
CFMC	Chapter Forum Management Committee
CFT	Cross Functional Team
CHA	Children's Hospital Association
CHIC	Child Health Informatics Center
CHIP	Children's Health Insurance Program
CISP	Childhood Immunization Support Program
CMC	Council Management Committee
CME	Continuing Medical Education
CMS	Centers for Medicare & Medicaid Services
CMSS	Council of Medical Specialty Societies
CnF	Council Forum
COA	Committee on Adolescence
COB	Committee on Bioethics
COCAN	Council on Child Abuse and Neglect
COCHF	Committee on Child Health Financing
COCIT	Council on Clinical Information Technology
COCM	Council on Communications and Media
COCME	Committee on Continuing Medical Education
COCN	Committee on Coding and Nomenclature
COCP	Council on Community Pediatrics
COCWD	Council on Children With Disabilities
COD	Committee on Drugs
CODe	Committee on Development
COEC	Council on Early Childhood
COEH	Council on Environmental Health
CoF	Committee Forum
COFCAKC	Council on Foster Care, Adoption, and Kinship Care
COFGA	Committee on Federal Government Affairs
CoFMC	Committee Forum Management Committee
COFN	Committee on Fetus and Newborn
COG	Committee on Genetics
COGME	Council on Graduate Medical Education (DHHS/HRSA)
COHC	Committee on Hospital Care
COICFH	Council on Immigrant Child and Family Health
COID	Committee on Infectious Diseases
COIVPP	Council on Injury, Violence, and Poison Prevention

COMLRM	Committee on Medical Liability and Risk Management
COMSEP	Council on Medical Student Education in Pediatrics (AMSPDC)
CON	Committee on Nutrition
CONACH	Committee on Native American Child Health
COPA	Committee on Pediatric AIDS
COPACFH	Committee on Psychosocial Aspects of Child and Family Health
COPAM	Committee on Practice and Ambulatory Medicine
COPE	Committee on Pediatric Education
COPEM	Committee on Pediatric Emergency Medicine
COPR	Committee on Pediatric Research
COPW	Committee on Pediatric Workforce
COQIPS	Council on Quality Improvement and Patient Safety
CORS	Committee on Residency Scholarships
COSGA	Committee on State Government Affairs
COSH	Council on School Health
COSMF	Council on Sports Medicine and Fitness
COSUP	Committee on Substance Use and Prevention
CPS	Canadian Paediatric Society
CPTI	Community Pediatrics Training Initiative
CQN	Chapter Quality Network
CSHCN	Children With Special Health Care Needs
DHHS	Department of Health and Human Services
DOD	Department of Defense
DVC	District Vice Chairperson
EBCDLWG	Early Brain and Child Development Leadership Workgroup
EC	Executive Committee
ECHO	Expanding Capacity for Health Outcomes
ELWG	Epigenetics Leadership Workgroup
EMSC	Emergency Medical Services for Children
EPA	Environmental Protection Agency
EQIPP	Education in Quality Improvement for Pediatric Practice
eTACC	Electronic Translation of Academy Clinical Content
FAAN	Federal Advocacy Action Network
FASD	Fetal Alcohol Spectrum Disorder
FCF	Friends of Children Fund
FDA	Food and Drug Administration
FERPA	Family Educational Rights and Privacy Act
FOPE II	Future of Pediatric Education II
FOPO	Federation of Pediatric Organizations
FPN	Family Partnerships Network
FTC	Federal Trade Commission
GME	Graduate Medical Education
HAAC	Historical Archives Advisory Committee
HBB	Helping Babies Breathe
HBSPG	Helping Babies Survive Planning Group
HCCA	Healthy Child Care America
HEDIS	Healthcare Effectiveness Data and Information Set
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health Maintenance Organization
HOF	Headquarters of the Future
HQA	Hospital Quality Alliance
HRSA	Health Resources and Services Administration
HTC	Help the Children
HTPCP	Healthy Tomorrows Partnership for Children Program
IHS	Indian Health Service
IMG	International Medical Graduate
IPA	International Pediatric Association
IPC	International Pediatric Congress
IRB	Institutional Review Board
LLLI	La Leche League International
LWG	Leadership Workgroup
MCAN	Merck Childhood Asthma Network
MCH	Maternal and Child Health
MCHB	Maternal and Child Health Bureau
MCN	Migrant Clinicians Network
MHICSN-PAC	Medical Home Initiatives for Children With Special Needs Project Advisory Committee
MHLWG	Mental Health Leadership Work Group
MOC	Maintenance of Certification
MRT	Media Resource Team
NACHC	National Association of Community Health Centers
NAEMSP	National Association of EMS Physicians
NAEPP	National Asthma Education and Prevention Program
NAM	National Academy of Medicine
NAPNAP	National Association of Pediatric Nurse Practitioners
NASPGHAN	North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition
NAWD	National Association of WIC Directors
NBME	National Board of Medical Examiners
NCBDDD	National Center on Birth Defects and Developmental Disabilities
NCE	National Conference & Exhibition
NCEPG	National Conference & Exhibition Planning Group
NCQA	National Committee for Quality Assurance
NHLBI	National Heart, Lung, and Blood Institute
NHMA	National Hispanic Medical Association
NHTSA	National Highway Traffic Safety Administration
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NICHD	National Institute of Child Health and Human Development
NICHQ	National Initiative for Children's Health Quality
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NMA	National Medical Association
NNC	National Nominating Committee
NQF	National Quality Forum
NRHA	National Rural Health Association
NRMP	National Resident Matching Program
NRP	Neonatal Resuscitation Program
NSC	National Safety Council
NVAC	National Vaccine Advisory Committee
ODPHP	Office of Disease Prevention and Health Promotion
OED	Office of the Executive Director
OHISC	Oral Health Initiative Steering Committee
OLWG	Obesity Leadership Workgroup
P4P	Pay for Performance
PAAC	Payer Advocacy Advisory Committee
PAC	Project Advisory Committee
PAHO	Pan American Health Organization
PALS	Pediatric Advanced Life Support
PAS	Pediatric Academic Societies
PCO	*Pediatric Care Online*™
PCOC	Primary Care Organizations Consortium
PCPCC	Patient-Centered Primary Care Collaborative

PCPI	Physician Consortium on Performance Improvement
PEAC	Practice Expense Advisory Committee
PECOS	Pediatric Education in Community and Office Settings
PECS	Pediatric Education in Community Settings
PEPP	Pediatric Education for Prehospital Professionals
PIR	*Pediatrics in Review*
PLA	Pediatric Leadership Alliance
PPAAC	Private Payer Advocacy Advisory Committee (COCHF Subcommittee)
PPAC	Past President's Advisory Committee
PPC-PCMH	Physician Practice Connections—Patient-Centered Medical Home (NCQA)
PPI	Partnership for Policy Implementation
PREP	Pediatric Review and Education Program
PROS	Pediatric Research in Office Settings
PUPVS	Project Universal Preschool Vision Screening
QA	Quality Assurance
QI	Quality Improvement
QuIIN	Quality Improvement Innovation Network
RBPE	Resource-Based Practice Expense
RBRVS	Resource-Based Relative Value Scale
RCAC	Richmond Center Advisory Committee
RCE	Richmond Center of Excellence
RRC	Residency Review Committee (ACGME)
RUC	AMA/Specialty Society Relative Value Scale Update Committee
RVU	Relative Value Unit
SAM	Society for Adolescent Medicine
SAMHSA	Substance Abuse and Mental Health Services Administration
SCHIP	State Children's Health Insurance Program
SDBP	Society for Developmental and Behavioral Pediatrics
SF	Section Forum
SFMC	Section Forum Management Committee
SLGBTHW	Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness
SOA	Section on Anesthesiology and Pain Medicine
SOAC	Subcommittee on Access to Care
SOAH	Section on Adolescent Health
SOAI	Section on Allergy and Immunology
SOAPM	Section on Administration and Practice Management
SOATT	Section on Advances in Therapeutics and Technology
SOB	Section on Bioethics
SOBr	Section on Breastfeeding
SOCAN	Section on Child Abuse and Neglect
SOCC	Section on Critical Care
SOCCS	Section on Cardiology and Cardiac Surgery
SOCDRP	Section on Child Death Review and Prevention
SOCPT	Section on Clinical Pharmacology and Therapeutics
SOD	Section on Dermatology
SODBP	Section on Developmental and Behavioral Pediatrics
SOECP	Section on Early Career Physicians
SOEM	Section on Emergency Medicine
SOEn	Section on Endocrinology
SOEPHE	Section on Epidemiology, Public Health, and Evidence
SOGBD	Section on Genetics and Birth Defects
SOGHN	Section on Gastroenterology, Hepatology, and Nutrition
SOHCa	Section on Home Care
SOHM	Section on Hospital Medicine
SOHO	Section on Hematology/Oncology
SOHPM	Section on Hospice and Palliative Medicine
SOICH	Section on International Child Health
SOID	Section on Infectious Diseases
SOIM	Section on Integrative Medicine
SOIMG	Section on International Medical Graduates
SOIMP	Section on Internal Medicine/Pediatrics
SOMHEI	Section on Minority Health, Equity, and Inclusion
SOMP	Section on Medicine-Pediatrics
SONp	Section on Nephrology
SONPM	Section on Neonatal-Perinatal Medicine
SONS	Section on Neurological Surgery
SONu	Section on Neurology
SOOb	Section on Obesity
SOOH	Section on Oral Health
SOOHNS	Section on Otolaryngology—Head and Neck Surgery
SOOp	Section on Ophthalmology
SOOPe	Section on Osteopathic Pediatricians
SOOr	Section on Orthopaedics
SOPPSM	Section on Pediatric Pulmonology and Sleep Medicine
SOPS	Section on Plastic Surgery
SOPT	Section on Pediatric Trainees
SORa	Section on Radiology
SORh	Section on Rheumatology
SOSILM	Section on Simulation and Innovative Learning Methods
SOSM	Section on Senior Members
SOSu	Section on Surgery
SOTC	Section on Telehealth Care
SOTCo	Section on Tobacco Control
SOTM	Section on Transport Medicine
SOU	Section on Urology
SOUCM	Section on Urgent Care Medicine
SOUS	Section on Uniformed Services
SPR	Society for Pediatric Research
SPWG	Strategic Planning Work Group
TA	Technical Assistance
TA	Technology Assessment
TFOA	Task Force on Access (also known as Task Force on Health Insurance Coverage and Access to Care)
TFOABD	Task Force on Addressing Bias and Discrimination
TFOC	Task Force on Circumcision
TFODI	Task Force on Diversity and Inclusion
TFOSIDS	Task Force on Sudden Infant Death Syndrome
TIPP	The Injury Prevention Program
TJC	The Joint Commission
UNICEF	United Nations Children's Fund
UNOS	United Network for Organ Sharing
USDA	US Department of Agriculture
VIP	Value in Inpatient Pediatrics
WHO	World Health Organization
WIC	Special Supplemental Nutrition Program for Women, Infants, and Children

Subject Index

Page numbers followed by *f* indicate a figure.
Page numbers followed by *t* indicate a table.

A

B

C

D

E

F

G

H

I

J

K

L

M

N

O

P

Q

R

S

T

U

V

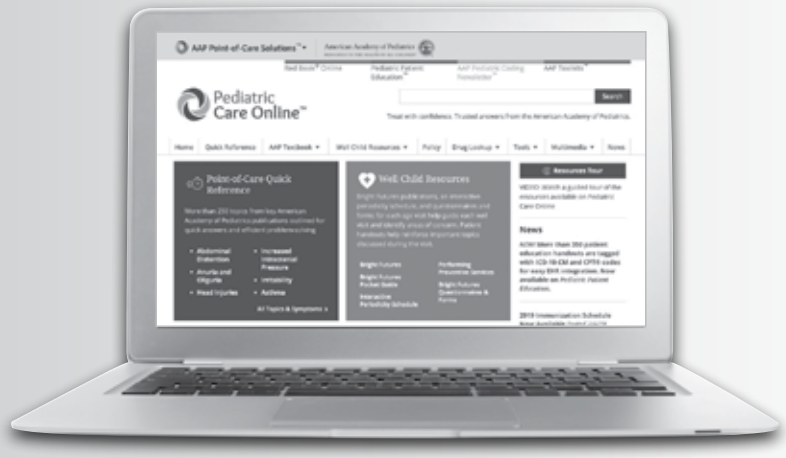
W

X

Y

Pediatric Care Online provides instant access to the most essential practice resources in pediatrics today.

Pediatric Care Online™



pediatriccare.solutions.aap.org

Exclusive AAP toolkits included in every *PCO* subscription

- *Addressing Mental Health Concerns in Pediatrics: A Practical Resource Toolkit for Clinicians,* 2nd Edition
- *Bright Futures Tool and Resource Kit,* 2nd Edition
- *Caring for Children With ADHD: A Practical Resource Toolkit for Clinicians,* 3rd Edition
- *Caring for Children With Autism Spectrum Disorder: A Practical Resource Toolkit for Clinicians,* 3rd Edition

Don't wait—Subscribe today!

shopAAP
shop.aap.org

FREE TRIAL AVAILABLE!
Pediatricians can request a free 1-month trial.
Visit **aap.org/pcotrial** today.

Founding Sponsor

Mead Johnson Nutrition

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

American Academy of Pediatrics

Pediatric Clinical Practice Guidelines & Policies

A Compendium of Evidence-based Research for Pediatric Practice
21st Edition

eBook access included!

Clinical practice guidelines have long provided physicians with an evidence-based decision-making tool for managing common pediatric conditions. Policies issued and endorsed by the American Academy of Pediatrics (AAP) represent the AAP position on child health care issues.

More than 40 clinical practice guidelines and more than 600 policy statements, clinical reports, and technical reports have been combined into this 21st edition of *Pediatric Clinical Practice Guidelines & Policies* book and eBook, giving you even easier access to the important clinical and policy information you need.

Manual includes

- Complete AAP clinical practice guidelines
- Complete 2020 AAP policy statements and clinical and technical reports
- Appendixes on the AAP Partnership for Policy Implementation and AAP acronyms
- Quick Reference Tools, including coding tips, patient education handouts, and more
- Five-section organization for ease of use

Clinical practice guidelines included in this edition cover the following pediatric conditions:

- Attention-deficit/hyperactivity disorder
- Autism spectrum disorder
- Brief resolved unexplained events
- Bronchiolitis
- Cardiovascular health
- Cerebral palsy
- Cerumen impaction
- Congenital muscular dystrophy
- Depression
- Diabetes
- Duchenne muscular dystrophy
- Dysplasia of the hip
- Febrile seizures
- Food allergy
- Hemorrhage
- High blood pressure
- HIV
- Hyperbilirubinemia
- Infantile hemangiomas
- Infantile spasms
- Intravascular catheter-related infections
- Intravenous fluids
- Medullary thyroid carcinoma
- Migraine headache
- Nosebleed (epistaxis)—***New!***
- Otitis media
- Palliative care
- Positional plagiocephaly
- Rhinoplasty
- Seizure
- Septic shock and sepsis-associated organ dysfunction—***New!***
- Sinusitis
- Sleep apnea
- Status epilepticus
- Telehealth
- Thyroid nodules and differentiated thyroid cancer
- Tobacco use
- Turner syndrome
- Urinary tract infection

Organization of *Pediatric Clinical Practice Guidelines & Policies*, 21st Edition

Section 1:	Clinical Practice Guidelines From the American Academy of Pediatrics
Section 2:	Endorsed Clinical Practice Guidelines
Section 3:	2020 Policies From the American Academy of Pediatrics
Section 4:	Current Policies From the American Academy of Pediatrics
Section 5:	Endorsed Policies
Appendix 1:	PPI: AAP Partnership for Policy Implementation
Appendix 2:	American Academy of Pediatrics Acronyms

Pediatric Clinical Practice Guidelines & Policies, 21st Edition, is the perfect practical reference book for primary care physicians, nurses, and allied health professionals.

To order other pediatric resources, visit **shop.aap.org/books.**

shopAAP
shop.aap.org

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

ISBN: 978-1-61002-502-7
ISSN: 1942-2024
MA1016

ISBN 978-1-61002-502-7
90000>
9 781610 025027