ARTICLES

Psychological Manifestations of Celiac Disease
L. B. Smith et al 16

Morbidity and 1-Year Survival of Extreme Preterms
H. J. Stensvold et al 19

E-Cigarettes and “Dripping” Among High-School Youth
S. Krishnan-Sarin et al 23

Alcohol Policies and MVC Fatalities  S. E. Hadland et al 24

Poverty and Common Chronic Disorders  C. D. Pulcini et al 25

Variation in Newborn Sepsis Evaluation
S. Mukhopadhyay et al 28

Hospital Variations in Unexpected Newborn Complications
Y. V. Sebastião et al 31

Bronchiolitis Pathway Adherence and LOS  M. A. Bryan et al 34

Prediction Rule for Rebound Hyperbilirubinemia
P. W. Chang et al 35

Seizures in Children With CP and White Matter Injury
M. S. Cooper et al 38

ACL Tears in School-Aged Children and Adolescents
N. A. Beck et al 39

Complications of Spinal Fusion for Scoliosis
J. G. Berry et al 40

Sexual and Romantic Experiences of Transgender Youth
S. L. Bungener et al 41

Trends in the Diagnosis of Vitamin D Deficiency
E. Basatemur et al 42

Financial Incentives to Maintain Breastfeeding
Y. Washio et al 43

Use of Mental Health Services After Mild TBI
N. Jimenez et al 46

Continued on table of contents and online

PEDIATRICS PERSPECTIVES

The “Late Preterm” Birth—Ten Years Later  T. N. K. Raju 1

Solutions for Asthma Disparities  A. Volerman et al 5

MONTHLY FEATURE

COMSEP High-Value Care  A. V. Holmes et al 12

REVIEW ARTICLES—www.pediatrics.org

Nonoperative Treatment for Acute Appendicitis
R. Georgiou et al 67

Continued on table of contents and online

DIAGNOSTIC DILEMMAS

A 17-Year-Old With Chest Pain  A. Y. Shah et al 72


PDE5 Inhibitors in Children With Pulmonary Hypertension
C. Umebgu et al 80

SPECIAL ARTICLES—www.pediatrics.org

Pediatric Hospital Medicine: A Proposed New Subspecialty
D. J. Barrett et al 81

Continued on table of contents and online

ETHICS ROUNDS

Should Minors Work as Standardized Patients?
E. J. Khoo et al 83

FROM THE AMERICAN ACADEMY OF PEDIATRICS

Counseling Parents and Teens About Marijuana Use
S. A. Ryan, S. D. Ammerman, Committee on Substance Use and Prevention 91

The Need to Optimize Adolescent Immunization  H. H. Bernstein, J. A. Bocchini Jr Committee on Infectious Diseases 97

Practical Approaches to Optimize Adolescent Immunization
H. H. Bernstein, J. A. Bocchini Jr Committee on Infectious Diseases 113

Continued on table of contents on page A17
The content of the journal is intended to encompass the needs of the whole child in his physiologic, mental, emotional, and social structure.

The single word, PEDIATRICS, has been chosen to indicate this catholic intent.

Hugh McCulloch
PEDIATRICS, January 1948
ARTICLES

Psychological Manifestations of Celiac Disease Autoimmunity in Young Children

This study highlights that children with celiac disease autoimmunity may exhibit subtle psychological symptoms before parents are aware of their child’s celiac autoimmunity.

Laura B. Smith, Kristian F. Lynch, Kalle Kurppa, Sibylle Koletzko, Jeffrey Krischer, Edwin Liu, Suzanne Bennett Johnson, Daniel Agardh, The TEDDY study group

Neonatal Morbidity and 1-Year Survival of Extremely Preterm Infants

This is a prospective, population-based cohort study comparing survival and neonatal morbidity in infants born at 22 to 26 weeks’ gestation in Norway in 2013–2014.

Hans Jorgen Stensvold, Claus Klingenberg, Ragnhild Stoen, Dag Moster, Kristin Braekke, Hans Jorgen Gutehe, Henriette Astrup, Siren Rettedal, Morten Gronn, Arild E. Ronnestad, on behalf of the Norwegian Neonatal Network

E-Cigarettes and “Dripping” Among High-School Youth

Using surveys, this study captures rates and reasons for ever use of e-cigarettes for “dripping” among high school youth.

Suchitra Krishnan-Sarin, Meghan Morean, Grace Kong, Krysten W. Bold, Deepa R. Camenga, Dana A. Cavallo, Patricia Simon, Ran Wu
Alcohol Policies and Alcohol-Related Motor Vehicle Crash Fatalities Among Young People in the US

This study examines states’ alcohol policy environments and their relation to motor vehicle crash fatalities among children, adolescents, and underage adults in the United States.

Scott E Hadland, Ziming Xuan, Vishnudas Sarda, Jason Blanchette, Monica H Swahn, Timothy C Heeren, Robert B Voas, Timothy S Naimi

Poverty and Trends in Three Common Chronic Disorders

By investigating trends in national survey data, this study captures the differential impact of poverty on prevalence and co-morbidities of 3 common chronic medical conditions.

Christian D. Pulcini, Bonnie T. Zima, Kelly J. Kelleher, Amy J. Houtrow

Variation in Sepsis Evaluation Across a National Network of Nurseries

Variation exists in risk assessment of early onset sepsis that impacts the level of medical intervention and frequency of mother-infant separation among well-appearing term newborns.

Sagori Mukhopadhyay, James A. Taylor, Isabelle Von Kohorn, Valerie Flaherman, Anthony E. Burgos, Carrie A. Phillipi, Nui Dhepyasuwan, Elizabeth King, Miren Dhudasia, Karen M. Puopolo

Hospital Variations in Unexpected Complications Among Term Newborns

We examined contributing factors and reasons for the large variation in hospital rates of unexpected complications among low-risk term newborns in Florida.

Yuri V. Sebastião, Lindsay S. Womack, Humberto López Castillo, Maya Balakrishnan, Karen Bruder, Paige Altz, Linda A. Detman, Emily A. Bronson, John S. Curran, William M. Sappenfield

Association of Bronchiolitis Clinical Pathway Adherence With Length of Stay and Costs

Higher adherence to a bronchiolitis clinical pathway is associated with decreased length of stay and costs with no increase in readmissions.

Mersine A. Bryan, Arti D. Desai, Lauren Wilson, Davene R. Wright, Rita Mangione-Smith

A Clinical Prediction Rule for Rebound Hyperbilirubinemia Following Inpatient Phototherapy

We describe a model that quantifies the risk of rebound hyperbilirubinemia to help clinicians decide when to discontinue inpatient phototherapy.

Pearl W. Chang, Michael W. Kuzniewicz, Charles E. McCulloch, Thomas B. Newman
ARTICLES (continued)

Seizures in Children With Cerebral Palsy and White Matter Injury 38

- This population-based study reveals that age-limited epileptic syndromes of childhood, with favorable seizure outcome, occur in children with cerebral palsy due to white matter injury.

Monica S. Cooper, Mark T. Mackay, Michael Fahey, Dinah Reddihough, Susan M. Reid, Katrina Williams, A. Simon Harvey

ACL Tears in School-Aged Children and Adolescents Over 20 Years 39

- Through review of insurance billing data, we observed a significant increase in ACL injuries in children and adolescents over the past 20 years.

Nicholas A. Beck, J. Todd R. Lawrence, James D. Nordin, Terese A. DeFor, Marc Tompkins

Comorbidities and Complications of Spinal Fusion for Scoliosis 40

- This study assesses associations of hospital resource use with comorbid conditions and acute events for children with complex neuromuscular and genetic diagnoses undergoing spinal fusion.

Jay G. Berry, Michael Glotzbecker, Jonathan Rodean, Izabela Leahy, Matt Hall, Lynne Ferrari

Sexual and Romantic Experiences of Transgender Youth Before Gender-Affirmative Treatment 41

- Sexual and romantic functioning in transgender youth compared to their same-aged peers: first steps and challenges.

Sara L. Bungener, Thomas D. Steensma, Peggy T. Cohen-Kettenis, Annelou L. C. de Vries

Trends in the Diagnosis of Vitamin D Deficiency 42

- Analysis of UK primary care data reveals a marked increase in the testing and diagnosis of vitamin D deficiency in children over the last decade.

Emre Basatemur, Laura Horsfall, Louise Marston, Greta Rait, Alastair Sutcliffe

Incentive-based Intervention to Maintain Breastfeeding Among Low-income Puerto Rican Mothers 43

- The study provides a proof-of-concept that monthly financial incentives contingent on observed breastfeeding increased breastfeeding rates through 6-month postpartum among low-income Puerto Rican mothers.

Yukiko Washio, Mara Humphreys, Elisa Colchado, Maria Sierra-Ortiz, Zugu Zhang, Bradley N. Collins, Linda M. Kilby, Donna J. Chapman, Stephan T. Higgins, Kimberly C. Kirby

Most of the articles in PEDIATRICS have more content available online at www.pediatrics.org.
Utilization of Mental Health Services After Mild Pediatric Traumatic Brain Injury

This study examines mental health care utilization in children with and without mental health diagnoses prior to a mild TBI and explores differences in mental health care utilization by race/ethnicity.

Nathalia Jimenez, Alex Quistberg, Monica S. Vavilala, Kenneth M. Jaffe, Frederick P. Rivara

Language Outcomes at 7 Years: Early Predictors and Co-Occurring Difficulties

The ability of early factors to predict low language abilities at 7 years is explored together with the degree and nature of co-occurring difficulties present.

Cristina McKean, Sheena Reilly, Edith L. Bavin, Lesley Bretherton, Eileen Cini, Laura Conway, Fallon Cook, Patricia Eadie, Margot Prior, Melissa Wake, Fiona Mensah

Safety of Second-Dose Single-Antigen Varicella Vaccine

We describe reports to the Vaccine Adverse Event Reporting System during 1999–2014 following second dose varicella vaccination among children aged 4–18 years.

John R. Su, Zanie Leroy, Paige W. Lewis, Penina Haber, Mona Marin, Jessica Leung, Emily Jane Woo, Tom T. Shimabukuro

Intimate Partner Violence and Child Behavioral Problems in South Africa

Little research demonstrates the impact of IPV on children in lower to middle income countries. This analysis explores the association of caregiver IPV on child behavior in South Africa.

Pratibha Chander, Jane Kvalsvig, Claude A. Mellins, Shuaib Kauchali, Stephen M. Arpadi, Myra Taylor, Justin R. Knox, Leslie L. Davidson

A Support Program for Somali-born Parents on Children’s Behavioral Problems

This study shows how a culturally tailored parenting intervention could engage and retain immigrant parents and improve their children’s behavioral problems.

Fatumo Osman, Renée Flacking, Ulla-Karin Schön, Marie Klingberg-Allvin

Targeting Sleep, Food, and Activity in Infants for Obesity Prevention: An RCT

An RCT comparing effects of a conventional food and activity intervention versus a sleep behavior intervention on infant growth from birth to 2 years.

Barry J. Taylor, Andrew R. Gray, Barbara C. Galland, Anne-Louise M. Heath, Julie Lawrence, Rachel M. Sayers, Sonya Cameron, Maha Hanna, Kelly Dale, Kirsten J. Coppell, Rachael W. Taylor
## contents

### ARTICLES (continued)

<table>
<thead>
<tr>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safe Storage of Opioid Pain Relievers Among Adults Living in Households With Children</strong></td>
<td>52</td>
</tr>
<tr>
<td>This article explores how adults' opioid storage practices and beliefs may be associated with the age of a child in the home.</td>
<td></td>
</tr>
<tr>
<td>Eileen M. McDonald, Alene Kennedy-Hendricks, Emma E. McGinty, Wendy C. Shields, Colleen L. Barry, Andrea C. Gielen</td>
<td></td>
</tr>
<tr>
<td><strong>Overdose Risk in Young Children of Women Prescribed Opioids</strong></td>
<td>53</td>
</tr>
<tr>
<td>The prescription opioid epidemic affects children. We explored the risk of overdose in young children of women prescribed opioids as opposed with non-opioid analgesics.</td>
<td></td>
</tr>
<tr>
<td>Yaron Finkelstein, Erin M. Macdonald, Alejandro Gonzalez, Marco L. A. Sivilotti, Muhammad M. Mamdani, David N. Juurlink, Canadian Drug Safety and Effectiveness Research Network (CDSERN)</td>
<td></td>
</tr>
<tr>
<td><strong>Pediatric Exposures to Veterinary Pharmaceuticals</strong></td>
<td>54</td>
</tr>
<tr>
<td>From 1999-2013, a regional poison center received 1431 veterinary pharmaceutical-related calls for children ≤19 years of age. This study describes the epidemiology these calls.</td>
<td></td>
</tr>
<tr>
<td>Suzanne Tomasi, Kristin J. Roberts, Jason Stull, Henry A. Spiller, Lara B. McKenzie</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory Morbidity in Infants Born With a Congenital Lung Malformation</strong></td>
<td>55</td>
</tr>
<tr>
<td>In a multicenter cohort of children with congenital lung malformation, this study evaluates the frequency of respiratory symptoms and factors associated to their occurrence.</td>
<td></td>
</tr>
<tr>
<td>Celine Delestrain, Naziha Khen-Dunlop, Alice Hadchouel, Pierrick Cros, Héloïse Ducoin, Michael Foyon, Isabelle Gibertini, André Labbé, Géraldine Labouret, Marie-Noëlle Lebras, Guillaume Lezmi, Fouad Madhi, Guillaume Thouvenin, Caroline Thumerelle, Christophe Delacourt</td>
<td></td>
</tr>
<tr>
<td><strong>Psychiatric Disorders in Adolescents With Single Ventricle Congenital Heart Disease</strong></td>
<td>56</td>
</tr>
<tr>
<td>Examination of adolescents with critical congenital heart disease revealed high risk for certain psychiatric morbidities, providing insight into clinical assessment and management of these youth.</td>
<td></td>
</tr>
<tr>
<td>David R. DeMaso, Johanna Calderon, George A. Taylor, Jennifer E. Holland, Christian Stopp, Matthew T. White, David C. Bellinger, Michael J. Rivkin, David Wypij, Jane W. Newburger</td>
<td></td>
</tr>
</tbody>
</table>
## ARTICLES (continued)

### Decreasing Prescribing Errors During Pediatric Emergencies: A Randomized Simulation Trial

- Precalculated medication doses reduce harmful prescribing errors in emergency situations and should be available in all settings where children could present in critical conditions.

Guylaine Larose, Arielle Levy, Benoit Bailey, Barbara Cummins-McManus, Denis Lebel, Jocelyn Gravel  

### Socioeconomic Attainment of Extremely Low Birth Weight Survivors: The Role of Early Cognition

- This study examined if childhood cognition at age 8 mediated the association between being born at extremely low birth weight and socioeconomic attainment in adulthood.

Kathleen G. Dobson, Mark A. Ferro, Michael H. Boyle, Louis A. Schmidt, Saroj Saigal, Ryan J. Van Lieshout

### Perspectives of Low Socioeconomic Status Mothers of Premature Infants

- Using in-depth interviews, our study explored perspectives of low-income mothers of premature infants, revealing substantial anxiety about discharge and the importance of trust in providers.

Elizabeth Enlow, Laura J. Faherty, Sara Wallace-Keeshen, Ashley E Martin, Judy A. Shea, Scott A. Lorch

### Daptomycin for Complicated Skin Infections: A Randomized Trial

- Randomized, controlled trial evaluating daptomycin for treating Gram-positive complicated skin infections in children. The trial showed that daptomycin was well tolerated, with efficacy comparable to standard-of-care therapy.

John Bradley, Chad Glasser, Hernando Patino, Sandra R. Arnold, Antonio Arrieta, Blaise Congeni, Robert S. Daum, Tsoline Kojaoghlanian, Minjung Yoon, Diane Anastasiou, Dominik J. Wolf, Paula Bokesch


- This study assesses national trends in anthropometric measures among infants aged 6–23 months by using serial cross-sectional data with measured weight and length.

Lara J. Akinbami, Brian K. Kit, Margaret D. Carroll, Tala H.I. Fakhouri, Cynthia L. Ogden

### Hearing Loss in Children With Asymptomatic Congenital Cytomegalovirus Infection

- The prevalence, characteristics, and risk of sensorineural hearing loss are assessed in children with asymptomatic congenital cytomegalovirus infection identified through hospital-based newborn screening managed through 18 years of age.

Tatiana M. Lanzieri, Winnie Chung, Marily Flores, Peggy Blum, A. Chantal Caviness, Stephanie R. Bialek, Scott D. Grosse, Jerry A. Miller, Gail Demmler-Harrison, Congenital Cytomegalovirus Longitudinal Study Group
Parental Health Literacy and Outcomes of Childhood Nephrotic Syndrome

This cohort study investigates the association of parental health literacy with treatment response among children with nephrotic syndrome.

Karlota Borges, Cathryn Sibbald, Neesha Hussain-Shamsy, Jovanka Vasiljevska-Ristovska, Tonny Banh, Viral Patel, Josefine Brooke, Monica Piekut, Michele Reddon, Kimberly Atken-Menezes, Ashley McNaughton, Rachel J. Pear, Valerie Langlois, Seetha Radhakrishnan, Christoph P.B. Licht, Tino D. Piscione, Leo Levin, Damien Noone, Diane Hebert, Rulan S. Parekh

Pediatric Resident Burnout and Attitudes Toward Patients

Burnout is highly prevalent among pediatric residents across multiple programs, and is associated with negative self-reported patient care attitudes and behaviors.

Tamara Elizabeth Baer, Angela M. Feraco, Selin Taysuzoglu Sagalowsky, David Williams, Heather J. Litman, Robert J. Vinci

Celiac Disease, Gut-Brain Axis, and Behavior: Cause, Consequence, or Merely Epiphenomenon?

Alessio Fasano

Extreme Prematurity Outcomes: Have We Really Reached the Limit?

Luigi Gagliardi, Roberto Bellù

Congress Should Adopt a “Do No Harm to Children” Standard in Changes to Public Health Insurance

Benard P. Dreyer

The Well-Appearing Newborn at Risk for Early-Onset Sepsis: We Can Do Better

James J. Cummings

Challenges to Measuring the Quality of Low-Risk Newborns

Scott A. Lorch

Can I Stop Phototherapy for This Baby?

Ian M. Paul, M. Jeffrey Maisels

Should We Pay Mothers Who Receive WIC to Breastfeed?

Lydia Furman

Burnout in Pediatric Residents and Physicians: A Call to Action

John D. Mahan

Most of the articles in PEDIATRICS have more content available online at www.pediatrics.org.
FROM THE AMERICAN ACADEMY OF PEDIATRICS

Clinical Report
Counseling Parents and Teens About Marijuana Use in the Era of Legalization of Marijuana
Sheryl A. Ryan, Seth D. Ammerman, Committee on Substance Use and Prevention

Clinical Report
The Need to Optimize Adolescent Immunization
Henry H. Bernstein, Joseph A. Bocchini Jr, Committee on Infectious Diseases

Clinical Report
Practical Approaches to Optimize Adolescent Immunization
Henry H. Bernstein, Joseph A. Bocchini Jr, Committee on Infectious Diseases

Clinical Report
Care of the Adolescent After an Acute Sexual Assault
James E. Crawford-Jakubiak, Elizabeth M. Alderman, John M. Leventhal, Committee on Child Abuse and Neglect, Committee on Adolescence

Clinical Report
Epinephrine for First-aid Management of Anaphylaxis
Scott H. Sicherer, F. Estelle R. Simons, Section on Allergy and Immunology

Clinical Report
Guidance on Completing a Written Allergy and Anaphylaxis Emergency Plan
Julie Wang, Scott H. Sicherer, Section on Allergy and Immunology

Policy Statement
Recommended Childhood and Adolescent Immunization Schedule—United States, 2017
Committee on Infectious Diseases

Policy Statement
Financing of Pediatric Home Health Care
Edwin Simpser, Mark L. Hudak, Section on Home Care, Committee on Child Health Financing

Policy Statement
A Public Health Response to Opioid Use in Pregnancy
Stephen W. Patrick, Davida M. Schiff, Committee on Substance Use and Prevention

Policy Statement
The Child Witness in the Courtroom
Robert H. Panteil, Committee on Psychosocial Aspects of Child and Family Health

Policy Statement
Expert Witness Participation in Civil and Criminal Proceedings
Stephan R. Paul, Sandeep K. Narang, Committee on Medical Liability and Risk Management

Most of the articles in PEDIATRICS have more content available online at www.pediatrics.org.
## FROM THE AMERICAN ACADEMY OF PEDIATRICS (continued)

**e-Policy Pages**—www.pediatrics.org

**Technical Report**

**Expert Witness Participation in Civil and Criminal Proceedings**

Sandeep K. Narang, Stephan R. Paul, Committee on Medical Liability and Risk Management

**Policy Statement**

**AAP Publications Reaffirmed or Retired**

---

## PEDIATRICS PERSPECTIVES

**The “Late Preterm” Birth—Ten Years Later**

Tonse N. K. Raju

**Solutions for Asthma Disparities**


---

## MONTHLY FEATURE

**We Can Teach How to Bend the Cost Curve:**

Lessons in Pediatric High-Value Health Care

Alison Volpe Holmes, Michele Long, James Stallworth

---

## REVIEW ARTICLES—Online only at www.pediatrics.org

**Efficacy and Safety of Nonoperative Treatment for Acute Appendicitis: A Meta-analysis**

This systematic review of the existing literature with meta-analysis reports on the efficacy and safety of nonoperative treatment of acute uncomplicated appendicitis in children relative to appendectomy.

Roxani Georgiou, Simon Eaton, Michael P. Stanton, Agostino Pierro, Nigel J. Hall

**Inhaled Corticosteroids and Respiratory Infections in Children With Asthma: A Meta-analysis**

Meta-analysis of 31 randomized trials reveals that regular use of ICS may not increase risk of pneumonia or other respiratory infections in children with asthma.

Cristine Cazeiro, Cristina Silva, Susana Mayer, Vanessa Mariany, Claire Elizabeth Wainwright, Linjie Zhang

**NICU-based Interventions To Reduce Maternal Depressive and Anxiety Symptoms: A Meta-analysis**

This systematic review and meta-analysis synthesizes findings on NICU-based interventions to reduce maternal depressive or anxiety symptoms.

Tamar Mendelson, Fallon Cluxton-Keller, Genevieve C. Vulla, S. Darius Tandon, Sassan Noazin
## REVIEW ARTICLES—Online only at www.pediatrics.org (continued)

### Preterm Infant Growth Velocity Calculations: A Systematic Review
- The many different methods used to calculate preterm infant growth velocity make comparisons between studies and with published values difficult if not impossible.

### Minimally Important Differences in Patient or Proxy-Reported Outcome Studies Relevant to Children: A Systematic Review
- Through a rigorous systematic review, this study provides a compendium of MIDs to better interpret the magnitude of treatment effects for PROs relevant to children.

## STATE-OF-THE-ART REVIEW ARTICLE—Online only at www.pediatrics.org

### Pulmonary Hypertension Therapy and a Systematic Review of Efficacy and Safety of PDE-5 Inhibitors
- This systematic review underscores the need for effective therapies for pediatric PH. Data indicate improved oxygenation and hemodynamics in children with PH on PDE5 inhibitors.
- Chinwe Unegbu, Corina Noje, John D. Coulson, Jodi B. Segal, Lewis Romer

## SPECIAL ARTICLES—Online only at www.pediatrics.org

### Pediatric Hospital Medicine: A Proposed New Subspecialty
- This article describes the challenges and opportunities that the American Board of Pediatrics had to consider in its recommendation to the American Board of Medical Specialties to recognize Pediatric Hospital Medicine as a new pediatric subspecialty.
The Sudden Death in the Young Case Registry: Collaborating to Understand and Reduce Mortality

This special article describes the Sudden Death in the Young Case Registry, which provides valuable incidence data and enhances understanding of the characteristics of pediatric deaths to inform prevention efforts.


A 17-Year-Old With Chest Pain

A 17-year-old male presents with severe chest pain, but an extensive interdisciplinary evaluation reveals a rare, underlying diagnosis in time for life-saving treatment.

Ankoor Y. Shah, Megan Jamison, Hansel J. Otero, Lawrence Jung, Lowell H. Frank, Michael F. Guerrera, A. Yasmine Kirkorian

Ethical Concerns When Minors Act as Standardized Patients

Minors are sometimes recruited to help medical educators by acting as standardized patients. Are there risks? Should there be safeguards?

Erwin Jiayuan Khoo, Robert D. Schremmer, Douglas S. Diekema, John D. Lantos

A Multicenter Collaborative to Improve Care of Community Acquired Pneumonia in Hospitalized Children

Through low-cost strategies including collaborative sharing and peer benchmarking, this study increased judicious use of antibiotics in a diverse range of hospitals for pediatric pneumonia.

Kavita Parikh, Eric Biondi, Joanne Nazif, Faiza Wasi, Derek J. Williams, Elizabeth Nichols, Shawn Ralston,Value in Inpatient Pediatrics Network Quality Collaborative For Improving Care in Community Acquired Pneumonia

Increasing Tdap Coverage Among Postpartum Women: A Quality Improvement Intervention

This study describes a quality improvement initiative that increased maternal Tdap immunization in the immediate postpartum period.

Henry H. Bernstein, Mikhaela Monty, Patriot Yang, Amy Cohen
QUALITY REPORTS—Online only at www.pediatrics.org (continued)

Project IMPACT Pilot Report: Feasibility of Implementing a Hospital-to-Home Transition Bundle

- This study describes implementation of a pediatric patient-centered hospital-to-home care transition bundle across 4 sites.

Leah A. Mallory, Snezana Nena Osorio, B. Stephen Prato, Jennifer DiPace, Lisa Schmutter, Paula Soung, Amanda Rogers, William J. Woodall, Kayla Burley, Sandra Gage, David Cooperberg, IMPACT Pilot Study Group

CASE REPORTS—Online only at www.pediatrics.org

Transverse Myelitis as Manifestation of Celiac Disease in a Toddler

- A case of transverse myelitis as manifestation of celiac disease in a 17-month old girl who completely recovered after gluten free diet and methylprednisolone therapy.

Hilde Krom, Fleur Sprangers, René van den Berg, Marc Alexander Benninga, Angelika Kindermann

C septicum Complicating Hemolytic Uremic Syndrome: Survival Without Surgical Intervention

- This case report presents 3 cases of C septicum, a rare complication of HUS, focusing on key diagnostic signs and the importance of early antibiotic initiation.

Rachel M. Engen, Elizabeth Y. Killien, Jessica L. Davis, Jordan M. Symons, Silvia M. Hartmann

Ganglioglioma Arising From Desmoplastic Medulloblastoma: A Case Report and Review of Literature

- This report describes the rare case of a patient with an infantile desmoplastic medulloblastoma maturing into a benign ganglioglioma post-therapy and suggests a role for differentiation therapy in desmoplastic medulloblastoma.

Santosh Valvi, David S. Ziegler

Are Patients With Loeys-Dietz Syndrome Misdiagnosed With Beals Syndrome?

- Beals syndrome, also known as congenital contractural arachnodactyly, due to a FBN2 mutation, shares a number of clinical features with Loeys-Dietz syndrome, though Loeys-Dietz syndrome carries a worse prognosis owing to its cardiac effects.

Rebecca Woolnough, Andrew Dhawan, Kimberly Dow, Jagdeep S. Walia

e-Letters—Online only at www.pediatrics.org

Letters to the Editors

Errata
The “Late Preterm” Birth—Ten Years Later

Tonse N. K. Raju, MD, DCH

It is now 10 years since the phrase late preterm entered the medical lexicon. The impact of this milestone on perinatal patient care and research and a brief note concerning the unresolved issues on this topic are the focus of this Pediatric Perspective.

In 1969, the World Health Organization proposed that a preterm birth should be defined as “childbirth occurring at less than 37 completed weeks, or 259 days of gestation counting from the first day of the last menstrual period in women with regular (28-day) menstrual cycles.” However, in the mid-1970s through the 1980s, researchers began identifying their research participants close to term gestation as “near-term.” Although no specific lower gestational age limits were stated, the implication was that such participants were fully mature and did not differ from full-term infants in any respect.

Coincidentally, the US preterm birth rate, calculated from the last menstrual period, increased 31% between 1981 and 2003 (9.4% in 1981 and 12.3% in 2003). Most of this increase was due to births between 32 and 36 weeks. The distribution of gestational age at delivery had shifted toward lower gestational ages, such that in 2002 the peak gestational age for US singleton births was 39 weeks, compared with 40 weeks in 1991. During this period, for pregnancies between 32 and 36 weeks, there was a 22% increase in medical interventions, defined as inductions or cesarean births in the absence of prolonged rupture of the membranes.

Thus, at the turn of the 21st century, some startling perinatal epidemiologic data had emerged. There was a steady increase in US preterm births. The fastest-growing segment was births between 34 and 36 weeks’ gestation, accounting for 74% of preterm births. The ethnic and racial disparity in US preterm births had continued. In 2008, 8.2% of births were late preterm for non-Hispanic white compared with 11.3% for non-Hispanic black women. There were significantly more medical interventions for deliveries between 32 and 36 weeks’ gestation, with no evident increase in the known causes of prematurity, such as multiple gestation, preeclampsia, or chorioamnionitis.

These trends were alarming. Therefore, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) convened a panel of experts to address issues related to near-term births. The panel reviewed the sparse yet compelling available data and concluded that infants born even a few weeks before term were at
higher risk for short and long-term morbidity and mortality, and calling them “near-term” wrongly implied that they were almost fully mature. The expert panel recommended discontinuing the phrase near-term and replacing it with late preterm, defined as 34 weeks and 0/7 days through 36 weeks and 6/7 days (239th–259th day) of gestation. Research priorities and practice guidelines were offered. 1

The publication of the NICHD executive summary of the workshop proceedings led to a high-impact paradigm shift in many domains. In addition to the milestones noted in Table 1, the national and international research community responded vigorously. More than 500 articles have appeared on this topic since 2007, including observational and case-controlled studies, short-term and long-term follow-up reports, comprehensive and systematic reviews, editorials, and opinion pieces. Most studies underscored the vulnerability of late preterm infants reported by the NICHD workshop panel. 1 They confirmed that late preterm birth per se was associated with higher morbidity in the absence of any identifiable maternal or fetal risk factors. Adverse outcomes included respiratory distress, hypoglycemia, feeding difficulties, problems of temperature control, jaundice, apnea, and seizures during the neonatal period and higher risk for short-term mortality and morbidity. Late preterm infants are also at higher risk for readmission after initial hospital discharge and during infancy and higher risk for pulmonary disorders during childhood and adolescence, and they manifested subtle, minor deficits in cognitive function and learning difficulties compared with their term counterparts at school age. Some of these disorders and deficits persisted into adulthood, probably because of arrested growth of organ systems, neonatal illness, and postnatal care practices. 14

Of particular note, after the NICHD workshop, the US singleton preterm birth rate, calculated based on obstetric estimate documented in birth certificates (as opposed to last menstrual period dating used in earlier reports), which was 10.44% in 2007, dropped to 9.56% in 2014, an 8% drop. 8 The National Center for Health Statistics (NCHS) noted that this drop “may be related to heightened understanding of the increased neonatal risk at these gestational ages.” 8

Although many developments after the 2005 NICHD workshop were positive, there were concerns about unintended consequences. A desire to reduce late preterm births could lead to avoiding indicated late-preterm deliveries altogether, increasing the risks for the mother and her infant. Therefore, to develop guidelines for optimal timing of deliveries, NICHD and the Society for Maternal Fetal Medicine (SMFM) organized a workshop in 2011. Its summary provided practical guidelines for managing indicated late preterm and early term deliveries based on the existing data and expert opinion. 5

In a 2012 workshop convened by NICHD and the SMFM, refinements were recommended for the definition of term pregnancy to help in counseling, clinical management, and research (Table 1). 7 This workshop also had an impact on clinical practice. Between 2006 and 2014, late preterm and early term birth rates decreased in the United States, and a direct association was observed between lower early term birth rates and decreasing clinician-initiated obstetric interventions. 8 This effect could also be secondary to

<table>
<thead>
<tr>
<th>Year</th>
<th>Milestones</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>Introduction of the phrase “late preterm” to replace “near-term,” recommended in an executive summary of a 2005 NICHD workshop. 1</td>
</tr>
<tr>
<td>2007</td>
<td>Practice guidelines are issued by the American Academy of Pediatrics Committee on Fetus and Newborn, and the Committee on Obstetric Practice of the ACOG.</td>
</tr>
<tr>
<td>2007</td>
<td>NCHS begins tracking late preterm birth statistics; the March of Dimes Foundation begins research support and educational activities to prevent non–medically indicated deliveries at late preterm gestations.</td>
</tr>
<tr>
<td>2011</td>
<td>Guidelines to manage “indicated late preterm and early term deliveries” published after an NICHD and SMFM workshop. 6</td>
</tr>
<tr>
<td>2012</td>
<td>Additional classifications published defining and refining the definition of term birth at a working group convened by NICHD, in collaboration with ACOG, the American Academy of Pediatrics, SMFM, the March of Dimes Foundation, the World Health Organization, and the NCHS. The subgroups were “early term” as births between 37 wk 0 d and 38 wk 6 d, “full term” as those at 39 wk 0 d through 40 wk 6 d, “late term” as deliveries at 41 wk 0 d through 41 wk 6 d, and, by implication, “post term” as those at 42 wk and 0 d and beyond. 7</td>
</tr>
<tr>
<td>2014</td>
<td>NCHS continues to note decreases in US singleton preterm and late preterm birth rates beginning in 2007. 5</td>
</tr>
<tr>
<td>2016</td>
<td>From 2007 through October 2016, &gt;500 publications and review articles confirm that late preterm infants are at higher risk for pulmonary, metabolic, and neurologic disorders, feeding difficulties during the neonatal period; elevated risk for hospital readmissions for jaundice and bilirubin-induced brain injury; respiratory syncytial virus and other pulmonary infections during infancy; childhood; cognitive deficits and learning issues at school age; and small but measurable negative effects in adult age groups.</td>
</tr>
<tr>
<td>2016</td>
<td>Decreasing rates of inductions at late preterm and early term pregnancies in 6 high-income countries in North America and Europe. 8</td>
</tr>
<tr>
<td>2016</td>
<td>Attempts to improve fetal pulmonary maturity in late preterm early term gestations for elective cesarean birth and in other clinical settings (reviewed in Kamath-Rayne et al. 10). Publication of a large trial to increase fetal lung maturation with antenatal betamethasone therapy in late preterm pregnancy and endorsement of this practice by the SMFM 12 and ACOG. 13</td>
</tr>
</tbody>
</table>
recommendations by the American Congress of Obstetricians and Gynecologists (ACOG) to avoid non–medically indicated early-term deliveries before 39 weeks.15 In a large multicenter randomized controlled trial, researchers tested whether betamethasone administered to women at risk for late preterm delivery decreased the risks of respiratory and other neonatal morbidities.11 The primary outcome of stillbirth, respiratory morbidities, or postnatal death within 72 hours of age occurred in 165 of 1427 infants (11.6%) in the intervention group and in 202 of 1400 (14.4%) in the placebo group (relative risk in the intervention group and 0.80; 95% confidence interval, 0.66–0.97; P = .02). The number needed to treat to reduce 1 poor primary outcome was 35. The authors recommended administration of betamethasone to women at risk for late preterm delivery to reduce the rate of neonatal respiratory complications.11 However, there are concerns about the routine use of betamethasone in late preterm pregnancies, prompting the SMFM and the ACOG to recommend the use of betamethasone, but with caveats.12,13 Some concerns include a significantly higher prevalence of neonatal hypoglycemia in the steroid-treated group, a need to treat a large number of women to reduce a single poor composite outcome, and the unknown long-term risks of fetal exposures to corticosteroids.10 There are other unresolved issues concerning late preterm births. Compared with the preterm birth rates of 2014, the US rates for 2015 and the first quarter of 2016 have been inching higher, especially among non-Hispanic black and Hispanic women.16,17 These trends must be monitored and their causes explored. Additional studies are needed to understand and prevent persisting high preterm birth rates among non-Hispanic black and Hispanic minority women in the United States.

Evidence-based practice guidelines are needed to refine management guidelines for medically indicated late preterm and early term pregnancies.6 Although maturation is a continuum, the pace and trajectory of maturation vary between organ systems, and we still do not know all the factors that accelerate or impede specific fetal organ maturation. We need to improve methods to accurately date pregnancy duration and fetal organ maturity. Other obstetric and neonatal research and clinical management issues have been reviewed elsewhere.3 In summary, the care of late preterm births has improved since the introduction of the “late preterm” concept.1 Nevertheless, more needs to be done. Reinforcing the awareness among health care teams that all newborn infants are vulnerable and that no specific pregnancy duration is an automatic assurance of full neonatal maturation is needed. Basic and translational research should continue to focus on preventing all preterm births, improving the quality of care, and reducing the short- and long-term burden of morbidity for preterm infants regardless of gestational age at birth.

**ABBREVIATIONS**

ACOG: American Congress of Obstetricians and Gynecologists

NCHS: National Center for Health Statistics

NICHD: Eunice Kennedy Shriver National Institute of Child Health and Human Development

SMFM: Society for Maternal and Fetal Medicine

**REFERENCES**


Solutions for Asthma Disparities

Anna Volerman, MD, a, b Marshall H. Chin, MD, MPH, a Valerie G. Press, MD, MPH a, b

Departments of aMedicine, and bPediatrics, University of Chicago, Chicago, Illinois

Dr Volerman conceptualized and drafted the initial manuscript and revised the manuscript; Drs Chin and Press conceptualized, reviewed, and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

DOI: 10.1542/peds.2016-2546

Accepted for publication Oct 31, 2016

Address correspondence to Anna Volerman, MD, Departments of Medicine and Pediatrics, University of Chicago, 5841 S Maryland Ave, MC 2007, Chicago, IL, 60637. E-mail: avolerman@uchicago.edu

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

Copyright © 2017 by the American Academy of Pediatrics

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

FUNDING: Dr Volerman is supported by the National Center for Advancing Translational Sciences of the National Institutes of Health (KL2TR000431). Dr Chin is supported by the Chicago Center for Diabetes Translation Research (P30 DK092949), a National Institute of Diabetes and Digestive and Kidney Diseases Midcareer Investigator Award in Patient-Oriented Research (K24 DK071933), and the Robert Wood Johnson Foundation Finding Answers: Solving Disparities Through Payment and Delivery System Reform Program Office. Dr Press is supported by the National Heart, Lung, and Blood Institute (K23 HL118151). Funded by the National Institutes of Health (NIH).


Childhood asthma prevalence has plateaued and may have declined for the first time since 1980.1 Although this news is promising, it is important not to lose sight of the significant disparities in asthma outcomes that remain by race, ethnicity, and socioeconomic status. We must reduce these disparities, and health care organizations’ increasing focus on population health presents a prime opportunity to do so. Now is a critical time to invest in research and quality improvement initiatives that directly target the persistent disparities in childhood asthma outcomes.

Disparities in asthma outcomes have been documented since the 1980s. Children of racial or ethnic minorities face higher morbidity and mortality due to asthma when compared with white children. Non-Hispanic African American children have 2 to 3 times higher rates of hospitalization and emergency department visits compared with non-Hispanic white children. African American children face a 4.9-fold higher asthma mortality rate. In addition, Hispanic children are 2 times more likely to visit an emergency department and 1.5 times more likely to die due to asthma when compared with non-Hispanic children.2

Numerous individual- and system-level factors contribute to asthma disparities, including health care policies, health systems operations, and clinician, patient, family, and environmental factors. For example, minority children are less likely to be prescribed a controller medication when indicated and are less likely to adhere to therapy that is prescribed. Additional factors driving disparities include clinic-centric care, indoor allergen exposure, limited primary care and subspecialty access, and poor health literacy.3

Disparities may persist due to the lack of a comprehensive approach for asthma care that is scalable, sustainable, and widely disseminated. Previous programs have provided written action plans for daily management, supplies for home environment remediation, and education to children with asthma and their families. Other initiatives have used case managers or asthma educators, or alternatively partnered with schools and housing authorities. Some efforts have shown positive results on a local level or in the short-term; however, no single program has demonstrated widespread and sustainable reductions in our nation’s asthma disparities.4

Solutions must comprehensively address the medical, environmental, and social drivers of disparities, which is nearly impossible when
interventions are limited to the clinic or home alone. In addition, a one-size-fits-all approach to interventions is unlikely to be generalizable. Programs must be tailored to the unique characteristics of diverse populations and local environments. Lastly, few asthma interventions, other than education curricula, have been broadly disseminated. Interventions may be resource intensive, potentially prohibiting expansion.

Therefore, to impact disparities in asthma outcomes, research must investigate promising comprehensive and sustainable programs. Systematic reviews of the disparities literature indicate characteristics of successful interventions. These interventions target 6 levels of influence, patient/family, provider, microsystem, organization, community, and policy, based on a conceptual model developed by Robert Wood Johnson Foundation’s Finding Answers: Disparities Research for Change Program. This model has effectively examined and designed interventions addressing disparities across adult and pediatric diseases. The model shows it is prudent to move beyond existing interventions that target 1 level to build multilevel, well-integrated programs reaching children across multiple settings. Examples of promising pediatric asthma interventions that reduce disparities and remaining research gaps are outlined in Table 1.

To address disparities in the health care sector, evidence-based guidelines detail essential elements that providers and health care organizations should deliver for high-quality asthma care. However, traditional 15-minute primary care visits do not enable these guidelines to be implemented, contributing to providers not routinely adhering to guidelines. Furthermore, population health management has gained popularity to reduce disparities partly because of its potential to influence health care organizations to address care delivery in the clinic and factors traversing home and school environments. Clinics should adopt streamlined workflows, well-functioning electronic health records, clinical decision support tools, and patient registries to assess asthma control, step-up/down therapy, and ensure appropriate follow-up and preventive care. Health care organizations must also confront health literacy about triggers, symptoms, and care access; medication adherence and proper inhaler technique; and bidirectional coordination with schools. Research and quality improvement efforts should focus on evaluating pragmatic systems for children with asthma to consistently receive high-quality care.

To link asthma care across clinical and nonclinical sectors, emerging work focuses on the multidisciplinary team to reduce disparities. Nonmedical professionals, such as community health workers, play an integral role in new models that engage patients, families, and care providers in the clinic, home, school, and community. Previous studies demonstrate the efficacy of tailored approaches with patients and families to identify needs and address risk factors by using education, home assessments, and community linkages. Many questions remain about how to do this within team-based, integrated programs. Who are key team members? What adaptations are needed for disease severity, risk factors, and local environments? How can social determinants best be addressed across settings? How can these programs be financed to support broad dissemination?

Funders play a critical role in enabling asthma disparities research. The National Institutes of Health disburses $250 million annually for asthma research and recently funded planning phase projects for a clinical trial to evaluate Asthma Care Implementation Programs in diverse populations (Creating Asthma Empowerment Collaborations to Reduce Childhood Asthma Disparities). These programs aim to integrate proven interventions from multiple settings into a comprehensive program, thus adding to the limited knowledge base about multilevel programs. Additional promising aspects include a strong emphasis on reaching children where they are (home, school, and community), rather than only in the clinical setting.

The Patient-Centered Outcomes Research Institute is also bringing evidence into action to improve outcomes for minority children with asthma. This institute uses a novel approach: involving stakeholders in all research aspects and focusing on patient-centered outcomes. Stakeholders are directly engaged in projects from beginning to end, providing an essential and often underrepresented voice to ensure interventions align with community needs and present pragmatic solutions. In addition, the measures of project success emphasize those that are important to patients and families, such as symptom-free days and quality of life, which are complementary to the traditional metrics of emergency department visits and hospital admissions.

Research funding is critical, and health care organizations and payers are also important drivers of the work to reduce disparities. With evolving care delivery and financial systems, health care organizations are increasingly facing global and bundled payments, thus incentivizing them to develop population health management strategies and form partnerships across clinical and
<table>
<thead>
<tr>
<th>Level of Influence and Definition</th>
<th>Examples of Interventions That Improve Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient/family; change in knowledge and/or behavior of children and families</strong></td>
<td></td>
</tr>
<tr>
<td>• Patient education focused on self-management skills and fostered self-monitoring and self-care.</td>
<td></td>
</tr>
<tr>
<td>• Education delivered via interactive web-based computer program with immediate feedback provided.</td>
<td></td>
</tr>
<tr>
<td>• Family education about allergen exposures through repeated home visits (total 5–7).</td>
<td></td>
</tr>
<tr>
<td>• Resources for allergen remediation provided.</td>
<td></td>
</tr>
<tr>
<td>• Intervention tailored to each child’s triggers and risk factors.</td>
<td></td>
</tr>
<tr>
<td>• ~75% African American</td>
<td></td>
</tr>
<tr>
<td>• ~92% public insurance</td>
<td></td>
</tr>
<tr>
<td>• Pediatric primary care clinic in Oakland, CA</td>
<td></td>
</tr>
<tr>
<td>• ~40% African American</td>
<td></td>
</tr>
<tr>
<td>• ~40% Hispanic</td>
<td></td>
</tr>
<tr>
<td>• 7 inner-city locations around United States</td>
<td></td>
</tr>
<tr>
<td>During 90-d follow-up:</td>
<td></td>
</tr>
<tr>
<td>• Decreased activity limitation.</td>
<td></td>
</tr>
<tr>
<td>• Decreased peak flow readings in yellow / red zone.</td>
<td></td>
</tr>
<tr>
<td>• Decreased urgent calls to health provider.</td>
<td></td>
</tr>
<tr>
<td>• Increased medication adherence without reminders.</td>
<td></td>
</tr>
<tr>
<td>• What are the outcomes of care delivered via video or mobile technology?</td>
<td></td>
</tr>
<tr>
<td>• How can technology-based education be accessible to a broader population and in the long-term?</td>
<td></td>
</tr>
<tr>
<td>• How can education consistently be culturally tailored and skill based?</td>
<td></td>
</tr>
<tr>
<td>• What is the necessary frequency of home visits to demonstrate improved outcomes?</td>
<td></td>
</tr>
<tr>
<td><strong>Provider; change in knowledge and/or behavior of providers</strong></td>
<td></td>
</tr>
<tr>
<td>• Comprehensive education (medication management, environment control, ongoing care) individualized to patient/family.</td>
<td></td>
</tr>
<tr>
<td>• Coordination with insurance case manager and school nurse, along with linkages to primary care.</td>
<td></td>
</tr>
<tr>
<td>• Education delivered after emergency department visit, representing a “teachable moment.”</td>
<td></td>
</tr>
<tr>
<td>• Provider education about guideline-based practice, along with patient teaching and communication.</td>
<td></td>
</tr>
<tr>
<td>• 2 interactive seminars with cases and patient materials.</td>
<td></td>
</tr>
<tr>
<td>• Guideline-based recommendations provided to clinician at visit based on previsit assessment of patient’s current symptoms and severity.</td>
<td></td>
</tr>
<tr>
<td>• Primary care pediatricians caring for low-income families (annual income &lt;$20,000)</td>
<td></td>
</tr>
<tr>
<td>• New York, NY and Ann Arbor, MI</td>
<td></td>
</tr>
<tr>
<td>• Primary care pediatricians caring for minority, low-income children</td>
<td></td>
</tr>
<tr>
<td>• 64.2% African American, 26.1% Hispanic</td>
<td></td>
</tr>
<tr>
<td>• 75.2% Medicaid Rochester, NY</td>
<td></td>
</tr>
<tr>
<td>During 2-y follow-up:</td>
<td></td>
</tr>
<tr>
<td>• Fewer symptoms and days with symptoms.</td>
<td></td>
</tr>
<tr>
<td>• Reduction in missed school days.</td>
<td></td>
</tr>
<tr>
<td>• Reduction in disruptions in caretakers’ plans.</td>
<td></td>
</tr>
<tr>
<td>• Reduction in sleep lost by children and caretakers.</td>
<td></td>
</tr>
<tr>
<td>• Fewer unscheduled visits to clinic or emergency department.</td>
<td></td>
</tr>
<tr>
<td>• Greater reduction in allergen levels at home.</td>
<td></td>
</tr>
<tr>
<td>• Increased use of inhaler corticosteroids.</td>
<td></td>
</tr>
<tr>
<td>• Fewer unscheduled visits (emergency department and clinic).</td>
<td></td>
</tr>
<tr>
<td>• Fewer limitations in quality of life.</td>
<td></td>
</tr>
<tr>
<td>• What are the outcomes of care delivered via video or mobile technology?</td>
<td></td>
</tr>
<tr>
<td>• How can technology-based education be accessible to a broader population and in the long-term?</td>
<td></td>
</tr>
<tr>
<td>• How can education consistently be culturally tailored and skill based?</td>
<td></td>
</tr>
<tr>
<td>• What is the necessary frequency of home visits to demonstrate improved outcomes?</td>
<td></td>
</tr>
</tbody>
</table>
TABLE 1 Continued

<table>
<thead>
<tr>
<th>Level of Influence and Definition</th>
<th>Examples of Interventions That Improve Outcomes</th>
<th>Key Features of Intervention</th>
<th>Population</th>
<th>Outcomes (All Statistically Significant)</th>
<th>Ref.</th>
<th>Gaps and Opportunities for Future Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microsystem: team-based care with new members or responsibility modifications</td>
<td>• Ongoing case management for families provided by nurse to ensure adherence with monitoring/medications/appointments and serve as a resource and counselor.</td>
<td>• ~70% African American or Hispanic</td>
<td>During 2-y follow-up: • Reduction in emergency department visits, hospitalizations, and outside-of-health-plan use/spending. • Cost-effective.</td>
<td>12</td>
<td>• Who are the key care team members to foster and reinforce patient and family education? • What is the necessary level of case management needed to impact outcomes and across which settings? • How can team-based care be used on a large scale to impact outcomes, particularly for high-risk patients? • How can team members who are added to the care team be sustainable within new care delivery models?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Community health workers made several home visits to conduct assessments and deliver interactive, tailored, culturally sensitive education to child/family.</td>
<td>• 100% African-American 96% Medicaid</td>
<td>During 1-y follow-up: • Reduced asthma symptoms. • Decreased health resource use and activity-limited days. • Improved caregiver quality of life, knowledge, self-efficacy. • Cost-savings.</td>
<td>13</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Community health workers recruited from targeted community to foster trust.</td>
<td>• Chicago, IL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Linkages made to primary care providers.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health care organization: change in clinical or organizational operations to enhance care delivery</td>
<td>• Children received asthma care in a specialty asthma clinic, as compared with usual primary care.</td>
<td>• Community is predominantly Hispanic and African American (total 95%), low-income (72% below federal poverty level)</td>
<td>During 2-y follow-up: • Fewer emergency department visits and hospital admissions (despite higher asthma severity index). • Cost-effective.</td>
<td>14</td>
<td>• How can clinical and medical operations be optimized to support the appropriate balance of primary and subspecialty care? • What delivery models can facilitate guideline-based care, particularly in communities with limited access to care? • How can technology and electronic medical records support guideline-based care in clinics on a large scale? • How can effective clinical decision-support tools be disseminated broadly within electronic health records and consistently used within clinical workflows?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Specialty clinic provided guideline-based care using team approach over several visits, including intensive education, frequent follow-up, provider availability 24/7, allergen identification, and exposure reduction.</td>
<td>• Harlem and Bronx, NY</td>
<td>• 80+% African American</td>
<td>During 1-y follow-up: • Increased controller medications prescribed and spirometry performed.</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Clinical decision support alerts and reminders presented in workflow to guide clinicians to asthma management tools in electronic health record.</td>
<td>• ~70% Medicaid</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Alerts provided guideline-based and patient-specific guidance (personalized for each patient based on symptoms, diagnosis, and medications).</td>
<td>• 4 urban practices in Children’s Hospital of Philadelphia Pediatric Research Consortium</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Examples of Interventions That Improve Outcomes

<table>
<thead>
<tr>
<th>Level of Influence and Definition</th>
<th>Key Features of Intervention</th>
<th>Population</th>
<th>Outcomes (All Statistically Significant)</th>
<th>Ref.</th>
<th>Gaps and Opportunities for Future Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community; partner with individuals and organizations outside of health care setting</td>
<td>• Supervision of daily controller medication administration in school.</td>
<td>• 91% African American</td>
<td>During 15-mo follow-up, intervention group had:</td>
<td>16</td>
<td>• How can schools effectively and consistently facilitate care that aligns with guidelines and school policies?</td>
</tr>
<tr>
<td></td>
<td>• Intervention fostered medication adherence and developed consistent habits among children.</td>
<td>• 36 schools in Alabama</td>
<td>• Greater improvement in asthma control (based on missed school days, increased quick-relief inhaler use, or peak flow readings).</td>
<td></td>
<td>• How can health care teams and schools successfully coordinate care together in light of limited resources and budgets?</td>
</tr>
<tr>
<td></td>
<td>• Medications provided to children.</td>
<td></td>
<td></td>
<td></td>
<td>• How can social determinants contributing to asthma disparities be addressed by integrating health and non–health sector assets?</td>
</tr>
<tr>
<td></td>
<td>• Public housing redevelopment with homes constructed to reduce moisture, enhance ventilation systems, minimize dust and off-gassing.</td>
<td>• Housing development with 29% African or African American, 29% Asian/Pacific Islander, 85% low income</td>
<td>During 1-y follow-up:</td>
<td>17</td>
<td>• How can public housing be broadly designed and redeveloped to optimize environment and minimize triggers?</td>
</tr>
<tr>
<td></td>
<td>• Home reconstruction remediated and reduced triggers.</td>
<td>• Seattle, WA</td>
<td>• Improvement in night-time symptoms and reduced triggers score (compared with control group).</td>
<td></td>
<td>• How can public housing effectively and consistently facilitate care that aligns with guidelines and school policies?</td>
</tr>
<tr>
<td></td>
<td>• Tenants required to have no smoking or pets in home.</td>
<td></td>
<td>• Improvement in symptom-free days, caretakers’ quality of life, urgent clinic care, asthma control, activity-limited days, rescue medication used days, night-time symptoms, asthma attacks (pre/post–new home).</td>
<td></td>
<td>• How can health care teams and schools successfully coordinate care together in light of limited resources and budgets?</td>
</tr>
<tr>
<td></td>
<td>• Home-based education for both intervention and control group.</td>
<td></td>
<td>• Reduced mold, rodents, moisture exposure and reduced trigger score (pre/post new home).</td>
<td></td>
<td>• How can social determinants contributing to asthma disparities be addressed by integrating health and non–health sector assets?</td>
</tr>
<tr>
<td>Policy; laws and regulations adopted locally, regionally, and nationally</td>
<td>• Enrollment of uninsured children into state health insurance program.</td>
<td>• Children enrolled in health insurance included 26% African American, 49.1% Hispanic</td>
<td>During 1-y follow-up:</td>
<td>18</td>
<td>• How can insurance companies support broad access to care and medications to optimize outcomes?</td>
</tr>
<tr>
<td></td>
<td>• Insurance enrollment fostered usual source of care, medication attainment and compliance, and education.</td>
<td>• New York state</td>
<td>• Improved access to care.</td>
<td></td>
<td>• How do changes in reimbursement regulations impact care delivery across clinical and nonclinical settings?</td>
</tr>
<tr>
<td></td>
<td>• Smoking-free legislation adopted in enclosed public place and workplaces countrywide.</td>
<td>• England</td>
<td>• Fewer asthma-related attacks and medical visits.</td>
<td>19</td>
<td>• How can local, regional, and national laws and regulations support population level changes to improve the environment and decrease triggers?</td>
</tr>
<tr>
<td></td>
<td>• Laws led to decreased exposure of children to secondhand smoke.</td>
<td></td>
<td>• Improved quality of care.</td>
<td></td>
<td>• How do smoke-free laws impact highest-risk children with asthma, including high severity and minority populations?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Improved quality of care and disease severity reported by parents.</td>
<td></td>
<td>• What financial and nonfinancial incentives can reduce disparities in asthma?</td>
</tr>
</tbody>
</table>
nonclinical areas to address the social factors within asthma care. Demonstration projects can build on existing quality improvement efforts to test care transformation models that bridge clinical and community settings. One caveat is that widespread payment policies may not affect all systems equally and care must be taken to avoid widening disparities if financial penalties are on the line. In fact, payment systems should be proactively designed to incentivize and reward the reduction of disparities.24

As we celebrate the stabilization of childhood asthma prevalence, we must not lose sight of the ongoing disparities in morbidity and mortality based on race, ethnicity, and socioeconomic status. Catalyzed by changes in health care payment and delivery, clinicians, researchers, health care organizations, and insurers are in a prime position to partner with those beyond the walls of the hospitals and clinics to reach children with asthma where they live, learn, and play.

**POTENTIAL CONFLICT OF INTEREST:** The authors have indicated they have no potential conflicts of interest to disclose.
REFERENCES


23. Patient-Centered Outcomes Research Institute. What We’ve Funded. Available at: www.pcori.org/research-results/asthma?keywords=asthma

We Can Teach How to Bend the Cost Curve: Lessons in Pediatric High-Value Health Care

Alison Volpe Holmes, MD, MPH, a, b, c Michele Long, MD, d, e James Stallworth, MD f

12 MONTHLY FEATURE

In continuing the series of articles by the Council on Medical Student Education in Pediatrics, we focus on the great clinical teacher’s responsibility to both deliver and explicitly teach about high-value health care. Medical students entering clinical rotations have been introduced to the concept of “too much care” in their coursework, including overdiagnosis, overtreatment, excessive testing, and poor care coordination and communication. 1, 2 As pediatricians committed to eliminating practices and associated expenditures that are not evidence-based and that lack direct patient benefit, we can improve our clinical teaching skills by making our role-modeling of such behaviors explicit. This paper reviews ways to incorporate teaching about common examples of pediatric care of limited or no value by using accessible teaching tools, such as the Choosing Wisely lists. 3 We also introduce 2 efficient teaching aids to help learners incorporate the concept of value into their clinical reasoning and presentations: Prepare, Process, Initiate (PPI), and Subjective, Objective, Assessment, Plan, Value (SOAP-V). 4

EXCESSIVE COSTS OF HEALTH CARE IN THE UNITED STATES: PROPORTION FROM “TOO MUCH CARE”

Despite the modest deceleration in the rate of rise in total US health care expenditures over the last few years, health care spending in the United States vastly exceeds spending in other developed nations, yet our health outcomes are worse. 5 The societal impact is substantial: health care indebtedness is the leading cause of household bankruptcy, and increasing health insurance premiums have eliminated real growth in wages for the past 2 decades. 6, 7 “Too much” care also comes at a personal cost to patients and families, including side effects from unneeded medications and complications from unnecessary procedures.

Approximately half of excess health care cost due to various categories of “waste” in the health care system falls into domains that are under the control of physicians. 2 These include failures of care delivery and coordination, and wasteful excessive care in the form of overdiagnosis, overtesting, and overtreatment. Although pediatrics is not typically viewed as a source of excessive

“We have really good data that show when you take patients and you really inform them about their choices, patients make more frugal choices. They pick more efficient choices than the health care system does.”

Donald Berwick, MD

Dr Holmes conceptualized and designed the article, wrote the initial version, and reviewed and revised the manuscript; Dr Long helped with conceptualization of the manuscript, was the primary author of the table, and reviewed and revised the manuscript; Dr Stallworth helped with conceptualization of the manuscript, developed the Prepare, Process, Initiate model, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

DOI: 10.1542/peds.2016-4016
Accepted for publication Nov 30, 2016
Address correspondence to Alison Volpe Holmes, MD, MPH, 1 Medical Center Dr, Rubin 525, Lebanon, NH 03756. E-mail: alison.v.holmes@hitchcock.org

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).
Copyright © 2017 by the American Academy of Pediatrics

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.

costs, significant opportunities for value improvement in pediatrics exist, and pediatric costs are rising faster than costs in adult health service delivery.\textsuperscript{8,9} Many students who complete pediatric rotations eventually pursue other specialties, but the principles of high-value care are readily transferable.

WHY TEACH ABOUT HEALTH CARE VALUE?

Given the excessive costs in US health care and their effects on patients and families, value and quality require more explicit emphasis in our pediatric teaching. Traditional clinical reasoning instruction results in the generation of extensive and frequently exhaustive differential diagnoses for common presenting complaints. This can have the unintended effect of teaching students and residents that no diagnostic possibility should go unexplored.\textsuperscript{10} Although limiting premature diagnostic closure and ensuring consideration of an accurate differential diagnosis are critical, sound clinical reasoning is also compatible with the teaching of restraint, stepwise decision-making, plans that avoid excess, and the incorporation of patient and family perspectives. When exploring clinical reasoning of learners, we can ask them to explain both the utility and reasoning of learners, we can ask perspectives. When exploring clinical incorporation of patient and family plans that avoid excess, and the restraint, stepwise decision-making, also compatible with the teaching of critical, sound clinical reasoning is accurate differential diagnosis are and ensuring consideration of an premature diagnostic closure

TOOLS FOR TEACHING HIGH-VALUE CARE

Choosing Wisely is a public education campaign whose purpose is to begin conversations between patients and physicians about potentially unnecessary tests and treatments. It highlights specific targets for improving value in pediatric primary care, inpatient, nursery, and select subspecialty settings, providing an excellent starting point for teaching basic pediatric high-value care. Pediatricians should have familiarity with these recommendations and potentially post them in their workrooms, or on course Web sites for easy access by learners and for use in teaching. These resources, which include references and evidence supporting all recommendations, are available at: www.choosingwisely.org.

Clinical teachers should role model honest conversations with families about current evidence-based decision-making, calculated risks versus benefits, and areas of uncertainty in clinical knowledge and practice. By doing so, they engage patients and parents in shared decision-making, and patients will often choose the less invasive, less aggressive approach.\textsuperscript{11}

PPI AND SOAP-V MODELS FOR CLINICAL ENCOUNTERS

PPI is a newly proposed and practical approach for teaching learners to apply the concepts of high-value care in pediatrics. Before a patient encounter, oral presentation, or before writing a note, the preceptor communicates with the learner using the following tool: "Prepare": What are the benefits versus harms of testing, interventions, and treatments related to the presenting problem, in general, but also, more specifically, to this particular patient?

“Process”: What evidence exists pertaining to the presenting problem and the proposed interventions?

“Initiate”: Of the interventions available, which ones will maximize benefit, minimize harm, and be least costly? Here, preceptors emphasize to learners that patients and parents should share in this decision-making.

See Table 1 for examples of how the PPI model applies to common pediatric conditions.

SOAP-V adds “value” to the traditional Subjective-Objective-Assessment-Plan presentation by incorporating 3 value elements in the framing of management plans.\textsuperscript{4} Ask students to include answers to these questions when presenting a plan: (1) Does adding my proposed intervention potentially change management? Does it meaningfully benefit the patient? (2) Have I incorporated patient and family values and circumstances, and considered potential harms? (3) What is known about the cost of the intervention, both immediately and downstream?

VALUE AND ETHICS

Lessons on the principle of nonmaleficence (primum non nocere) are abundantly available in the teaching of high-value care. Although the bioethical principle of beneficence has led some to believe that cost should never be a consideration in treatment decisions, Schroeder and Ralston\textsuperscript{18} have recently illustrated how the bioethical principle of parsimony entreats us to effectively diagnose and treat each patient in the most efficient manner possible, with the efficient approach containing the most benefit for the patient.
**CONCLUSIONS**

With almost half of excess health care costs related to decision-making at the clinician level, opportunities to teach the incorporation of high-value care at the level of the clinical encounter are plentiful. Clinical teachers can bend the healthcare cost curve downward by teaching and role modeling high-value care. The tools presented in this article can help clinical teachers structure lessons in high-value care in daily clinical encounters. Highlighting the underlying bioethical principles and giving thoughtful consideration of options while meeting the best interests of patients and families will assist in incorporating the concept of value in clinical reasoning and medical decision-making. Great clinical teachers are well positioned to demonstrate in both practice and teaching how “doing less” in appropriate situations is safe, family-centered, evidence-based, and ethical.

**ACKNOWLEDGMENTS**

We thank the other members of the Council on Medical Student Education in Pediatrics Curriculum Taskforce subcommittee on teaching high-value pediatrics for stimulating many of the ideas included in this article: Lauren Walker, MD, Marta King, MD, MEd, Starla Martinez, MD, Brian Good, MD, Rukmani Vasan, MD, and Jeanine Ronan, MD. We also thank Alan Schroeder, MD, Matthew Garber, MD, and Gautham Suresh, MD, MPH, for their thoughtful review of this manuscript.

**REFERENCES**


**TABLE 1 Using PPI To Teach Value**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Example</th>
<th>Prepare</th>
<th>Process</th>
<th>Initiate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Office</strong></td>
<td>Parents of a thriving 4-month-old infant ask if she needs medications for her “reflux.”</td>
<td>Could acid suppressing medication help? Are there harms?</td>
<td>Systematic review of articles on acid suppression harms and Choosing Wisely show no benefit and increased risk of infections.</td>
<td>Reassure family that spit-up is normal if growth is fine; come to shared decision not to use medication.</td>
</tr>
<tr>
<td><strong>Office</strong></td>
<td>An immunized 18-month-old child has a normal neurologic exam and a viral exanthem after a simple febrile seizure.</td>
<td>Does this child need more work-up for seizures? Is there potential harm from a CT scan?</td>
<td>AAN/AAP guideline and Choosing Wisely: no EEG or head imaging needed. Consider potential harms of radiation, sedation, inadvertent findings.</td>
<td>Empathize with family on how frightening this was, but explain how it is also common and the absence of long-term effects. Counsel what to do if there is a recurrence.</td>
</tr>
<tr>
<td><strong>Office</strong></td>
<td>A low-risk, 120-hour-old, 41-week gestation girl has a serum bilirubin of 20.1 mg/dL. Mother reports her milk is in, and baby has gained 20 g since the previous day.</td>
<td>Should we initiate phototherapy? Are there side effects to phototherapy, such as impact on bonding?</td>
<td>Measured level is below the AAP guideline phototherapy line; NNT in this category is &gt;3000.</td>
<td>Discuss risks/harms of phototherapy and treatment alternatives, such as a repeat bilirubin level the next day and continued frequent breastfeeding in a comfortable home setting.</td>
</tr>
<tr>
<td><strong>ED</strong></td>
<td>A 3-year-old girl presents with minor closed head injury after falling off a trampoline. She had no LOC and 2 episodes of emesis.</td>
<td>What is this child’s risk of a TBI that needs neurosurgical intervention? What are the harms of a CT scan in terms of radiation, sedation, and costs?</td>
<td>PECARN study risk calculation shows intermediate (0.8%) TBI risk.</td>
<td>Shared decision-making with family on options of observing for a few more hours in the ED for worsening symptoms versus risks of sedation and incidental findings on imaging.</td>
</tr>
<tr>
<td><strong>Inpatient</strong></td>
<td>A 6-year-old initially admitted for peripheral IV antibiotics for acute hematogenous osteomyelitis is now afebrile, clinically improved, and has a significant decline in C-reactive protein.</td>
<td>By what route should additional antibiotics be administered? What are the costs of PICC lines (including placement, risk of clots, infection, mechanical complications) versus oral antibiotics (including concerns about compliance).</td>
<td>Large study showing equivalent cure rates for oral and IV antibiotics, but with higher risks for IV antibiotics administered at home via PICC after discharge.</td>
<td>Shared decision-making with family; they opt for discharge on an oral agent with weekly follow-up.</td>
</tr>
</tbody>
</table>

**ABBREVIATIONS**

PPI: Prepare, Process, Initiate

SOAP-V: Subjective, Objective, Assessment, Plan, Value


18. Ralston SL, Schroeder AR. Doing more vs doing good: aligning our ethical principles from the personal to the societal. JAMA Pediatr. 2015;169(12):1085–1086
Psychological Manifestations of Celiac Disease Autoimmunity in Young Children

Laura B. Smith, PhD, Kristian F. Lynch, PhD, Kalle Kurppa, MD, PhD, Sibylle Koletzko, MD, PhD, Jeffrey Krischer, PhD, Edwin Liu, MD, Suzanne Bennett Johnson, PhD, Daniel Agardh, MD, PhD, The TEDDY study group

abstract

BACKGROUND AND OBJECTIVES: Psychological symptoms can be associated with celiac disease; however, this association has not been studied prospectively in a pediatric cohort. We examined mother report of psychological functioning in children persistently positive for tissue transglutaminase autoantibodies (tTGA), defined as celiac disease autoimmunity (CDA), compared with children without CDA in a screening population of genetically at-risk children. We also investigated differences in psychological symptoms based on mothers’ awareness of their child’s CDA status.

METHODS: The Environmental Determinants of Diabetes in the Young study followed 8676 children to identify triggers of type 1 diabetes and celiac disease. Children were tested for tTGA beginning at 2 years of age. The Achenbach Child Behavior Checklist assessed child psychological functioning at 3.5 and 4.5 years of age.

RESULTS: At 3.5 years, 66 mothers unaware their child had CDA reported more child anxiety and depression, aggressive behavior, and sleep problems than 3651 mothers of children without CDA (all $P_s \leq .03$). Unaware-CDA mothers also reported more child anxiety and depression, withdrawn behavior, aggressive behavior, and sleep problems than 440 mothers aware of their child’s CDA status (all $P_s \leq .04$). At 4.5 years, there were no differences.

CONCLUSIONS: In 3.5-year-old children, CDA is associated with increased reports of child depression and anxiety, aggressive behavior, and sleep problems when mothers are unaware of their child’s CDA status. Mothers’ knowledge of their child’s CDA status is associated with fewer reports of psychological symptoms, suggesting that awareness of the child’s tTGA test results affects reporting of symptoms.

WHAT’S KNOWN ON THIS SUBJECT: Celiac disease may be associated with a variety of psychological symptoms in children, such as depression and attentional problems. Prospective studies in young children examining this relationship do not exist.

WHAT THIS STUDY ADDS: Celiac disease autoimmunity (CDA) is associated with increased parent report of child depression and anxiety, aggression, and sleep problems when mothers are unaware of their child’s CDA status. Knowledge of CDA status is associated with fewer reports of psychological symptoms.
Celiac Disease, Gut-Brain Axis, and Behavior: Cause, Consequence, or Merely Epiphenomenon?

Alessio Fasano, MD

The classic view of celiac disease as a gastrointestinal disorder of childhood has radically changed in the past few decades thanks to a better understanding of its pathogenesis. Celiac disease is now considered an autoimmune enteropathy triggered by the ingestion of gluten-containing grains in genetically susceptible individuals. Although the gastrointestinal tract is the target of the autoimmune insult, celiac disease is a systemic disease, and its presentation can involve any organ or tissue of the body. One of the most fascinating yet poorly understood clinical presentations of celiac disease involve changes in behavior, including short-term memory loss, anxiety, depression, sleep disturbances, cognitive impairment, psychosis, and attention-deficit disorder. The degree to which these symptoms are the consequence of having a chronic disease versus celiac disease itself has not been clear. In this issue of Pediatrics, however, Smith et al provide evidence suggesting that celiac disease may in fact be the cause of these behavioral problems. By assessing the psychological functioning of infants enrolled in the Environmental Determinant of Diabetes in the Young trial and followed prospectively, the authors reported that 3.5-year-old children affected by celiac disease autoimmunity (CDA), defined as positive serology in children at risk, have increased reports of depression/ anxiety, aggressive behavior, and sleep disturbances. Interestingly, these symptoms were significantly greater in the 66 children with CDA whose mothers were unaware of the diagnosis compared with the 440 children with CDA whose mothers were aware of the diagnosis and the 3651 children without CDA, decreasing the chance that the reported behaviors were biased by families’ subjective assessment. However, when older children (4.5 years of age) were reassessed, no relationship between CDA and psychological symptoms was detected, casting some doubts on this interpretation. An alternative explanation offered by the authors is that younger children with limited verbal skills express their physical discomfort with behavioral changes, whereas at later age, they are capable to effectively communicate their symptoms. Although plausible, this interpretation does not take into account that behavioral changes are described as possible clinical manifestations of celiac disease and sometimes as the only presenting symptoms of celiac disease in older children and adult patients, in some cases seriously affecting their lifestyle.

The pathophysiological explanation of why patients with celiac disease can experience psychological symptoms remains a subject of debate. Two not necessarily mutually exclusive explanations suggest that (1) undigested gluten fragments structurally similar to endorphins (“gliadorphins”) cross the gut barrier and the blood-brain barrier to interact with endorphin receptors, causing changes in behavior or (2) undigested...
gluten fragments activate immune cells that in turn migrate to the brain, causing neuroinflammation and ultimately behavioral symptoms. A similar interpretation has been advocated for those children affected by autism spectrum disorders responding with improvement of their behavior to the implementation of a gluten-free diet. Either way, gluten seems to be the key triggering factor for the onset of psychological disturbances as it is for any other symptom experienced by celiac disease patients.

The article from Smith et al also seems to be at odds with this paradigm because these authors reported that neither the implementation of the gluten-free diet nor the antitissue transglutaminase antibody titers were associated with changes in psychological symptoms. This apparent dichotomy can be reconciled by the consideration that in younger children, it is difficult to distinguish between those children who experience behavioral changes as an integral part of their celiac disease clinical presentation versus those children in whom psychological changes represent the somatization of pain and discomfort caused by the celiac disease-associated chronic inflammatory process or by other factors unrelated to celiac disease. Without stratification of these 2 groups, it is conceivable that 2 variables such as the gluten-free diet and serology markers lose statistical power. No matter how the data are interpreted, celiac disease remains one of the most fascinating paradigms of the 2-way gut-brain axis cross-talk in which the combination of neuroendocrine signaling pathways, inflammatory processes, and the ecosystem (microbiome) of the gastrointestinal tract can highly influence brain functions. Prospective studies such as that reported by Smith et al may be a key approach to shedding light on how intestinal factors can influence human behavior and to identifying possible targets to ameliorate psychological symptoms caused by inappropriate gut-brain cross-talk.

**ABBREVIATION**

CDA: celiac disease autoimmunity

**REFERENCES**


Neonatal Morbidity and 1-Year Survival of Extremely Preterm Infants

Hans Jorgen Stensvold, MD,a,b,c Claus Klingenberg, MD, PhD,d,e Ragnhild Stoen, MD, PhD,f,g Dag Moster, MD, PhD,h,i
Kristin Braekke, MD, PhD,h Hans Jorgen Guthe, MD, PhD,h Henriette Astrup, MD,h Siren Rettedal, MD, PhD,j
Morten Gronn, MD, PhD,k Arild E. Ronnestad, MD, PhD,k,l on behalf of the Norwegian Neonatal Network

abstract

OBJECTIVE: To determine 1-year survival and major neonatal morbidities (intracranial hemorrhage grade >2, cystic periventricular leukomalacia, retinopathy of prematurity grade >2, necrotizing enterocolitis, severe bronchopulmonary dysplasia) among extremely preterm infants in Norway in 2013–2014, and to compare the results to the first Norwegian Extreme Prematurity Study 1999–2000 and similar contemporary European population-based studies.

METHODS: Population-based study of all infants born at 22 through 26 weeks’ gestation in Norway in 2013–2014. Prospectively collected data were obtained by linking data in the Norwegian Neonatal Network to the Medical Birth Registry of Norway.

RESULTS: Of 420 infants (incidence 3.5 per 1000 births), 145 were stillborn (34.5%), 275 were live-born (82.3% of the 334 fetuses alive at admission for obstetrical care), and 251 (91.3% of live-born infants) were admitted to a neonatal unit. The survival among live-born infants was 18% at 22 weeks, 29% at 23 weeks, 56% at 24 weeks, 84% at 25 weeks and 90% at 26 weeks (for each week increment in gestational age: odds ratio 3.3; 95% confidence interval, 2.4–4.4). Among infants surviving to 1 year of age, major neonatal morbidity was diagnosed in 55%. Decreasing gestational age was moderately associated with rates of major morbidity (odds ratio 1.6; 95% confidence interval, 1.2–2.2).

CONCLUSIONS: Compared to the previous 1999–2000 cohort, the rate of stillbirth before admission to an obstetrical unit increased, whereas the survival rate among live born infants was similar in our 2013–2014 cohort. Neonatal morbidity rates remain high among extremely preterm infants.

WHAT’S KNOWN ON THIS SUBJECT: Extremely preterm infants have high rates of morbidity and mortality.

**Extreme Prematurity Outcomes: Have We Really Reached the Limit?**

Luigi Gagliardi, MD, MSc, Roberto Bellù, MD

Health care professionals and laypeople alike are convinced that outcomes of very preterm infants have been steadily improving over the years. Yet in an interesting article published in this issue of *Pediatrics*, Stensvold et al challenge this belief. In short, the authors conducted an area-based study in Norway in 2013–2014, collecting data on outcomes of all pregnancies ending either in stillbirth or in a live birth from 22 to 26 weeks of gestation. Compared with an analogous study carried out in 1999–2000, they found an increase in the absolute number of such pregnancies, with an increase of intrauterine deaths before admission to the hospital and no improvement thereafter. These results are both surprising and thought-provoking.

This lack of improvement is surprising in view of the great improvements in obstetric and neonatal care in the past decade, including the widespread use of antenatal corticosteroids even at low gestational weeks, improvements in delivery room management and thermoregulation, and improved ventilatory and nutritional strategies. Many studies, both area-based and not, have shown an improvement in mortality and morbidity over the years, so it is necessary to try to understand the reasons for these disappointing results above and beyond the effect of chance and small numbers (a type II error).

A first consideration is that the 2 populations studied in 1999–2000 and 2013–2014 might differ in some important health care determinant. Differences in ethnic, social, and cultural status are among the likely candidates. As with all other studies with historic controls, we cannot be sure of comparability of populations apart from gestational age.

Even if this was an area-based study, a complete ascertainment of cases does not guarantee against selection bias. In fact, pregnancies were included in this study if they ended in a very narrow window of weeks. If obstetricians/gynecologists have changed attitudes and procedures regarding the management of pregnancies at a gestational age around the “limit of viability” over the past 15 years, then the ability to transform stillbirths at 20 to 21 weeks in 1999–2000 (ie, not contributing data) to deliveries or stillbirths at 22 to 23 weeks (ie, captured in data collection) in 2013–2014 would spuriously increase mortality in the recent cohort. In fact, although the total number of pregnancies in the 2 periods remained the same, those ending at 22 to 24 weeks increased 29%, and it is likely that their features and baseline risk could be different. Moreover, comparing the outcomes at only 22 to 26 weeks is like comparing only a small part of the survival curve. Even if the segment 22 to 26 weeks has the same mortality hazard in the 2 surveys, this does not imply that the overall mortality is the same. In fact, it is not the same: the overall neonatal mortality rates have both almost halved in Norway between 1999–2000 and 2013–2014, with a steady decline during the years considered.
Comparability of populations aside, the key question for all obstetricians and neonatologists is what these results mean from a generalizability standpoint relative to other countries or other periods of time. The great strength of this study, its complete area-based coverage, also represents its weakness. Representativeness is necessary for description but is not sufficient for generalizability. Different countries have different data collection systems, especially at low gestational ages, making comparisons difficult. Moreover, different countries have different health care structures. The size of observation areas matters as well. The population of the study (120,007 total births, 251 infants 22 to 26 weeks out of 423 admitted in 9 NICUs representing approximately 4% of live births) represents approximately half of the population in a region of Italy like Lombardy or in other European regions. In these countries, variability between centers and areas is still wide, and Norwegian results could apply to well-defined areas but not to others.

A final lesson that we can draw from this study is that availability of good data are key to objective measurement of strengths and weaknesses of our own perinatal care. Comparing neonatal outcomes across countries represents a great opportunity for quality improvement. To this aim, neonatal networks are well established worldwide and there is need for sharing a minimum data set and methodology that could ease feasible and meaningful comparisons. Initiatives are going on to accomplish this goal.

Maybe somewhere limits have been reached for the current management of extremely preterm infants, but even in highly developed countries, simple evidence-based effective interventions are not always used and represent "missed opportunities" for a better outcome.

REFERENCES


E-Cigarettes and “Dripping” Among High-School Youth

Suchitra Krishnan-Sarin, PhD, a Meghan Morean, PhD, b Grace Kong, PhD, a Krysten W. Bold, PhD, a Deepa R. Camenga, MD, c Dana A. Cavallo, PhD, a Patricia Simon, PhD, a Ran Wu, MS a

abstract

BACKGROUND: Electronic cigarettes (e-cigarettes) electrically heat and vaporize e-liquids to produce inhalable vapors. These devices are being used to inhale vapors produced by dripping e-liquids directly onto heated atomizers. The current study conducts the first evaluation of the prevalence rates and reasons for using e-cigarettes for dripping among high school students.

METHODS: In the spring of 2015, students from 8 Connecticut high schools (n = 7045) completed anonymous surveys that examined tobacco use behaviors and perceptions. We assessed prevalence rates of ever using e-cigarettes for dripping, reasons for dripping, and predictors of dripping behaviors among those who reported ever use of e-cigarettes.

RESULTS: Among 1080 ever e-cigarette users, 26.1% of students reported ever using e-cigarettes for dripping. Reasons for dripping included produced thicker clouds of vapor (63.5%), made flavors taste better (38.7%), produced a stronger throat hit (27.7%), curiosity (21.6%), and other (7.5%). Logistic regression analyses indicated that male adolescents (odds ratio [OR] = 1.64), whites (OR = 1.46), and those who had tried multiple tobacco products (OR = 1.34) and had greater past-month e-cigarette use frequency (OR = 1.07) were more likely to use dripping (Ps < .05).

CONCLUSIONS: These findings indicate that a substantial portion (~1 in 4) of high school adolescents who had ever used e-cigarettes also report using the device for dripping. Future efforts must examine the progression and toxicity of the use of e-cigarettes for dripping among youth and educate them about the potential dangers of these behaviors.

WHAT’S KNOWN ON THIS SUBJECT: Electronic cigarette (e-cigarette) use is growing among youth. E-cigarettes are also being used to inhale vapors produced by directly dripping e-liquids onto heated coils. There is no information on whether high school youth are participating in this behavior.

WHAT THIS STUDY ADDS: 1 in 4 high school ever e-cigarette users report having used these devices for dripping. E-cigarette users use dripping to produce thicker clouds of vapor, get a stronger throat hit, and make flavors taste better.
Alcohol Policies and Alcohol-Related Motor Vehicle Crash Fatalities Among Young People in the US

Scott E Hadland, MD, MPH, MS, a,b,c Ziming Xuan, ScD, SM, d Vishnudas Sarda, MBBS, MPH, e Jason Blanchette, MPH, f Monica H Swahn, PhD, MPH, g Timothy C Heeren, PhD, h Robert B Voas, PhD, f Timothy S Naimi, MD, MPH i, g

abstract

BACKGROUND: Motor vehicle crashes (MVCs) are a leading cause of death among young people in the United States. We examined the relationship between states’ alcohol policy environments and alcohol-related MVC fatalities among children, adolescents, and young adults under the minimum legal drinking age of 21 years.

METHODS: We used the Alcohol Policy Scale (APS), an assessment of 29 alcohol policies across 50 states and Washington, DC, developed with the assistance of an interdisciplinary Delphi panel. Using the Fatality Analysis Reporting System, we examined APS scores in relation to fatalities of people ≤20 years old from 2000 to 2013 occurring in crashes in which ≥1 involved driver had a blood alcohol content ≥0.08%. Logistic regression was used with a 1-year lag between policies and MVC fatalities and adjusted for potential confounders.

RESULTS: Of 84,756 MVC fatalities of those ≤20 years old during the study period, 23,757 (28.0%) were alcohol related, including deaths of 11,006 (46.3%) drivers, 10,212 (43.0%) passengers, and 2,539 (10.7%) pedestrians, cyclists, and others. People killed in alcohol-related MVCs were predominantly male (72.7%) and older (65.5% were 18–20 years old), and 51.2% were non-Hispanic white. Restrictive policy environments were associated with fewer fatalities (adjusted odds ratio, 0.91 per 10-percentage-point increase in APS score; 95% confidence interval, 0.89–0.94). The association was observed for drivers and passengers, male and female decedents, and children, adolescents, and young adults.

CONCLUSIONS: More restrictive alcohol policies are associated with reduced alcohol-related MVC mortality among young people. Studies should scrutinize the relationship between policies and fatalities to highlight mechanisms.

WHAT’S KNOWN ON THIS SUBJECT: Motor vehicle crashes are a leading cause of death among young people in the United States. Stronger alcohol policies prevent motor vehicle crash deaths, but studies to date have examined only single policies rather than the overall alcohol policy environment.

WHAT THIS STUDY ADDS: We found that >1 in 4 motor vehicle crash fatalities among children, adolescents, and young adults <21 years old were alcohol related and that stronger alcohol policy environments appeared protective for both drivers and passengers regardless of age and sex.
Poverty and Trends in Three Common Chronic Disorders

Christian D. Pulcini, MD, MEd, MPH, a Bonnie T. Zima, MD, MPH, b Kelly J. Kelleher, MD, c Amy J. Houtrow, MD, PhD, MPH a, d

OBJECTIVES: For asthma, attention-deficit/hyperactivity disorder (ADHD), and autism spectrum disorder (ASD), the objectives were to (1) describe the percent increases in prevalence and comorbidity and how these vary by poverty status, and (2) examine the extent to which poverty status is a predictor of higher than average comorbid conditions.

METHODS: Secondary analyses of the National Survey of Children’s Health for years 2003, 2007, and 2011–2012 were conducted to identify trends in parent reported lifetime prevalence and comorbidity among children with asthma, ADHD, and ASD and examine variation by sociodemographic characteristics, poverty status, and insurance coverage. Using 2011–2012 data, multivariable regression was used to examine whether poverty status predicted higher than average comorbid conditions after adjusting for other sociodemographic characteristics.

RESULTS: Parent-reported lifetime prevalence of asthma and ADHD rose 18% and 44%, respectively, whereas the lifetime prevalence of ASD rose almost 400% (from 0.5% to 2%). For asthma, the rise was most prominent among the poor at 25.8%. For ADHD, the percent change by poverty status was similar (<100% federal poverty level [FPL]: 43.20%, 100% to 199% FPL: 52.38%, 200% to 399% FPL: 43.67%), although rise in ASD was associated with being nonpoor (200% to 399% FPL: 43.6%, ≥400% FPL: 36.0%). Publicly insured children with asthma, ADHD, and ASD also had significantly higher odds (1.9×, 1.6×, 3.0×, respectively) of having higher than average comorbidities.

CONCLUSIONS: Poverty status differentially influenced parent-reported lifetime prevalence and comorbidities of these target disorders. Future research is needed to examine parent and system-level characteristics that may further explain poverty’s variable impact.
Congress Should Adopt a “Do No Harm to Children” Standard in Changes to Public Health Insurance

Benard P. Dreyer, MD, FAAP

In 2015, 21% of children, 15 000 000, were living in poverty (<100% of the federal poverty level).1 Forty-three percent of children, 31 000 000, were living below 200% of the federal poverty level, which is a better measure of economic hardship for families in the United States. Children are the poorest age group in our society and more than twice as poor as older adults. It is well documented that poor children are more likely to have poor health outcomes, including chronic conditions such as asthma. They are also at greater risk for poor social, emotional, and behavioral problems, including disobedience, impulsivity, and anxiety.2 Behavioral and mental health problems are common comorbidities of chronic conditions in children living in poverty.

In this issue of Pediatrics, Pulcini et al3 present the results of their secondary analyses of the National Survey of Children’s Health for the years 2003, 2007, and 2011–12. Their purpose was to identify trends in parent-reported lifetime prevalence and comorbidity among children with asthma, attention-deficit/hyperactivity disorder (ADHD), and autism spectrum disorder (ASD). They found that poor and near poor children had a higher lifetime prevalence of asthma and ADHD, but not ASD, and children on public health insurance had higher comorbid conditions for all 3 conditions.

Although these results are not surprising, they substantiate the burden of chronic disease in poor children and the importance of access to health care for this vulnerable population. The contrasting findings for asthma and ADHD versus ASD are likely multifactorial but possibly due to community and family factors that influence asthma and ADHD and are more prevalent in poor children, whereas ASD prevalence is not increased by those factors. Even for ASD, however, children on public insurance were burdened with more comorbidities.

These results raise important health policy considerations. More children are covered by health insurance today than ever before. In 2015, 95% of children were covered by health insurance, due primarily to the expansion of public health insurance through Medicaid and the Children’s Health Insurance Program (CHIP).4

However, the Affordable Care Act (ACA), although primarily insuring nonelderly adults and young adults (19- to 25-year-olds), did help to drive the increases in child health insurance coverage. Parents were offered sign up to public health insurance for their children when they sought insurance for themselves, and some children received health insurance through...
the ACA marketplace. An additional 1.7 million children received health insurance during the period that the major provisions of the ACA were implemented.4 The major advances in health insurance coverage occurred for poor and near poor children, although they still lag behind those at higher income, primarily due to higher uninsured rates among Latino children.

The association of poverty and chronic disease among children is due to more than just health insurance status. As described in a recent American Academy of Pediatrics (AAP) policy on poverty and child health and an accompanied technical report, family, economic, and community factors are powerful social determinants of health outcomes in poor children.5,6 Nevertheless, all children, especially children with chronic diseases, require access to quality health care, for which health insurance is a prerequisite.

Forty-two percent of children, and virtually all poor children, are ensured through public plans, primarily Medicaid and CHIP.7 This year, Congress is deliberating the fate of public health insurance that is essential for the health of children, such as potential cuts or block-granting of Medicaid to the states and an uncertain reauthorization of CHIP. As described here, dramatic changes to the ACA also have the potential to negatively affect children.

We in the AAP, and pediatricians throughout the country, urge Congress to take a “do no harm to children” standard. Any changes in the ACA must not leave children worse off than they are today; there must be no structural changes to Medicaid; and CHIP must be reauthorized and strengthened. As described in the AAP Blueprint for Children,8 anything less will leave the most vulnerable children, who have an increased burden of chronic disease, without access to the essential, comprehensive health services they need to survive and thrive.

ABBREVIATIONS
AAP: American Academy of Pediatrics
ACA: Affordable Care Act
ADHD: attention-deficit/hyperactivity disorder
ASD: autism spectrum disorder
CHIP: Children’s Health Insurance Program

REFERENCES
4. Alker J, Chester A. Children’s Health Insurance Coverage Rate at Historic High of 95 Percent. Washington, DC: Georgetown University Health Policy Institute, Center for Children and Families; 2016
Variation in Sepsis Evaluation Across a National Network of Nurseries

Sagori Mukhopadhyay, MD, MMSc,a James A. Taylor, MD,b Isabelle Von Kohorn, MD, PhD,c Valerie Flaherman, MD, MPH,d Anthony E. Burgos, MD,e Carrie A. Phillipi, MD, PhD,f Nui Dhepyasuwan, MEd,g Elizabeth King, MPP,e Miren Dhudasia, MPH,h Karen M. Puopolo, MD, PhDi

abstract

BACKGROUND AND OBJECTIVES: The extent to which clinicians use currently available guidelines for early-onset sepsis (EOS) screening has not been described. The Better Outcomes through Research for Newborns network represents 97 nurseries in 34 states across the United States. The objective of this study was to describe EOS risk management strategies across a national sample of newborn nurseries.

METHODS: A Web-based survey was sent to each Better Outcomes through Research for Newborns network nursery site representative. Nineteen questions addressed specific practices for assessing and managing well-appearing term newborns identified at risk for EOS.

RESULTS: Responses were received from 81 (83%) of 97 nurseries located in 33 states. Obstetric diagnosis of chorioamnionitis was the most common factor used to identify risk for EOS (79 of 81). Among well-appearing term infants with concern for maternal chorioamnionitis, 51 of 79 sites used American Academy of Pediatrics or Centers for Disease Control and Prevention guidelines to inform clinical care; 11 used a published sepsis risk calculator; and 2 used clinical observation alone. Complete blood cell count (94.8%) and C-reactive protein (36.4%) were the most common laboratory tests obtained and influenced duration of empirical antibiotics at 13% of the sites. Some degree of mother–infant separation was required for EOS evaluation at 95% of centers, and separation for the entire duration of antibiotic therapy was required in 40% of the sites.

CONCLUSIONS: Substantial variation exists in newborn EOS risk assessment, affecting the definition of risk, the level of medical intervention, and ultimately mother–infant separation. Identification of the optimal approach to EOS risk assessment and standardized implementation of such an approach could affect care of a large proportion of newborns.

WHAT’S KNOWN ON THIS SUBJECT: A significant proportion of well-appearing newborns are evaluated for early-onset sepsis (EOS) when following national recommendations for determining EOS risk. The extent to which clinicians use such guidelines and the resulting impact on newborn care have not been described.

WHAT THIS STUDY ADDS: The present study shows that wide variation exists in many aspects of EOS risk management, affecting the frequency and intensity of patient-level intervention. Research is needed to identify the optimal approach to EOS risk management among otherwise well-appearing newborns.

DOI: 10.1542/peds.2016-2845
Accepted for publication Dec 19, 2016
A common question in the newborn nursery is when to do a sepsis evaluation. When one considers pathogens such as group B Streptococcus, the risk of invasive infection is higher in the newborn than at any other time of life. Overall, the incidence of early-onset sepsis (EOS, defined as a positive blood or cerebrospinal fluid culture within the first 72 hours after birth) in infants born at term is estimated to be ~1 per 2000. Although case fatality rates are <2%, the incidence of long-term neurologic sequelae can be as high as 50%. A baseline risk of <1 per 1000 may be too low to justify routine evaluation for EOS, but perinatal factors can significantly increase that risk. Questions then arise: Whom to test, when to treat with antibiotics pending test results, when to perform a lumbar puncture, and how long to treat with antibiotics if cultures remain negative? In an effort to aid the clinician, guidelines and risk-based tools have been developed.

How does the newborn nursery provider use these available resources when managing the well-appearing term infant? The study by Mukhopadhyay et al in this issue of Pediatrics examines this question. In a Web-based survey within a newborn outcome research network of 81 nurseries across the United States, they found wide variation in how well-appearing newborns are assessed and managed for EOS. Although the majority of respondents used 1 of the published guidelines or sepsis risk calculators, >25% relied on local protocols or individual provider discretion. Frequency of intervention varied from doing less to doing more than directed by published resources. Notably, 2 of the 81 responders reported that their site practice was to provide observation and routine newborn care to all well-appearing newborns, without consideration of perinatal sepsis risk factors.

In general, clinical practice guidelines are often not followed; for the healthy-appearing newborn with a low risk of EOS there may also be concern that our current guidelines and risk-based calculators result in too many unnecessary evaluations and antibiotic exposures in infants who do not have EOS. But what is more concerning in the study by Mukhopadhyay et al is the extremes of practice variation, from intervention based solely on fetal tachycardia, neither of which is supported by any of the published guidelines or risk-based models.

The bugbear of chorioamnionitis also looms large in the findings of Mukhopadhyay et al. It was 1 of the 2 most common clinical risk factors that prompted evaluation and treatment; although this finding is consistent with currently published guidelines, neither the guidelines nor the survey provides rigorous criteria for the diagnosis of chorioamnionitis, leaving it to individual interpretation. For respondents who primarily...
used risk-based calculators, most considered an obstetrical diagnosis of chorioamnionitis an additional risk factor, despite the fact that those calculators were specifically designed to avoid such subjective considerations.\(^6\)

Earlier this year, a panel of experts in maternal, fetal, and neonatal care grappled with the vagaries of the term “maternal chorioamnionitis”. In their summary report they recommended a more refined definition of intrauterine inflammation or infection (so-called Triple I), gave criteria for suspected and confirmed Triple I, and emphasized that isolated maternal fever was insufficient to make a diagnosis of Triple I.\(^12\) However, this report is unlikely to change the findings of Mukhopadhyay et al, because almost all cases the newborn provider will have to struggle with will fall into the suspected category, a situation for which the panel recommends that “care should be individualized.” Confirmation of Triple I requires either abnormal amniotic fluid laboratories or placental pathology; amniocentesis is rarely done, and pathology results typically are not available for several days after birth, leaving the newborn provider with no clear direction when evaluating the newly born infant.

The study by Mukhopadhyay et al has the usual shortcomings of survey research. In particular, it is limited by its sample size and depth of inquiry. Still, if such variation was evident among a limited sample, even wider variation is possible from a larger study. In a limited survey we also gain little insight into the barriers to guideline adherence or why providers choose an alternative approach.\(^9\) What the survey by Mukhopadhyay et al does tell us is that assessment and management of the well-appearing newborn at risk for EOS have significant room for improvement, perhaps through a better understanding of the relative risks of harm and benefit for each of our treatment options (observation alone, evaluation and observation, or empirical treatment), the value and limitations of laboratory tests, the barriers that prevent providers from appropriately using available guidelines and risk-based tools, and how our current guidelines can provide better guidance.

### Abbreviation

**EOS**: early-onset sepsis

### References


OBJECTIVES: To examine contributing factors and potential reasons for hospital differences in unexpected newborn complication rates in Florida.

METHODS: We conducted a population-based retrospective cohort study of linked birth certificate and hospital discharge records from 2004 to 2013. The study population included 1,604,774 term, singleton live births in 124 hospitals. Severe and moderate complications were identified via a published algorithm. Logistic mixed-effects models were used to examine risk factors for complications and to estimate the percentage of hospital variation explained by factors. Descriptive analyses were performed to explore reasons for the differences.

RESULTS: Hospital total complication rates varied from 6.7 to 98.6 per 1000 births. No correlation between severe and moderate complication rates by hospital was identified. Leading risk factors for complications included medically indicated early-term delivery, no prenatal care, nulliparity, prepregnancy obesity, tobacco use, and delivery in southern Florida hospitals. Hospital factors such as geographic location, level of care or birth volume, and Medicaid births percentage explained 35% and 27.8% of variation in severe and moderate complication rates, respectively. Individual factors explained an additional 6% of variation in severe complication rates. Different complication subcategories (e.g., infections, hospital transfers) drove the hospital factors that contributed to severe and moderate complications.

CONCLUSIONS: Variation in unexpected complication rates is more likely to be related to hospital rather than patient characteristics in Florida. The high proportion of variation explained by hospital factors suggests potential opportunities for improvement, and identifying specific complication categories may provide focus areas. Some of the opportunities may be related to differences in hospital coding practice.
With rising health care costs in the United States and other countries, there is a growing interest in measuring and improving the value of health care. In addition to programs such as the Choosing Wisely initiative, which identifies wasteful or unnecessary medical tests, pediatrics and perinatal medicine have seen the development of various measures of care quality. Most of these measures assess outpatient practices, such as immunization adequacy or the appropriate use of well care, in which all children are included regardless of their underlying medical complexity. For inpatient practice, however, the available metrics tend to focus on the care of more complex patients, such as the very low birth weight infant. Although this group of patients is important, given their high risk of adverse short- and long-term outcomes and their inherent high treatment costs, metrics focused on the very low birth weight infant (eg, reducing central line–associated bloodstream infections) may not provide insight into the quality of care received by the >85% of low-risk newborns born at term each year.

The results of Sebastiao et al help to fill the knowledge gap about the care received by this understudied group of infants. Using data from 124 Florida hospitals with >100 deliveries annually, they found that “unexpected complications” after delivery were not unusual, with a rate of 37 complications per 1000 deliveries. These complications were not distributed equally among the 124 delivery hospitals studied. Instead, these rates ranged from 6.7 per 1000 births in the hospital with the lowest rate, to 98.6 per 1000 births in the hospital with the highest rate (a 14.7-fold difference). This between-hospital variation was driven primarily by differences in hospital characteristics, such as hospital level, volume, percentage of Medicaid deliveries, and geographic location. Using this information to improve care, however, requires us to understand what this quality measure can and cannot assess for low-risk patients.

The measure used in the study of Sebastiao et al is a composite measure of unexpected newborn complications developed by the California Maternal Quality Care Collaborative. Composite measures are a useful method of combining potential measures of quality that occur rarely into more stable and reliable metrics. Composite metrics, however, have several challenges when applied to an individual hospital. First, we must understand how the various components of the composite measure are combined. As with the unexpected newborn complication measure, many composite measures treat each component equally, with patients triggering the measure if they have any one of a list of outcomes. For this particular measure, a serious complication would be any infant with complications such as death, Apgar score ≤3 at 5 or 10 minutes, sepsis, birth trauma, hypoxia/asphyxia, shock, or intraventricular hemorrhage. It also includes a neonatal transfer to another hospital for any reason and the need for continuous positive airway pressure. As with other composite measures in neonatology, these specific complications have both different short- and long-term...
outcomes in infants (eg, a transfer of a hypoglycemic infant is very different from that of an infant with sepsis or an infant who has died), and these various measures likely assess different aspects of the overall care delivered to laboring women and their newly delivered infant. As a result, hospitals with the same rate of “severe complications” could trigger this metric through an unusually high rate of neonatal death, or a high rate of neonatal transfer. The root causes for such a difference are likely to be substantially different. To further optimize the outcomes of these low-risk deliveries, hospitals, providers, and patients should examine what measures resulted in a hospital achieving the unexpected complication rate that is reported.

The second challenge is the inclusion of measures of hospital utilization in a measure of unexpected complications, specifically the classification of neonatal transfer as a “severe complication.” Perinatal regionalization policies are designed to match hospital capabilities to the needs of a patient. However, our measures of care focus entirely on the hospital, not the larger systems of perinatal care. For rural women, or women residing in areas without nearby access to a hospital with a high-volume/high-level delivery service, a term low-risk delivery at a local, lower level hospital may be appropriate. In this case, a neonatal transfer would be totally appropriate if a condition arose that the delivery hospital was uncomfortable with or unable to manage but otherwise did not reach the level of illness severity suggested by other outcome measures in this complication category. Although a postdelivery transfer is obviously disruptive to families, it is likely more palatable to families who otherwise may have to travel several hours, while the mother is in active labor, to reach a high-level delivery hospital. A similar case can be made for the prolonged length of stay measure in the “moderate complication” category, which could be elevated for a variety of nonmedical indications, including maternal complications of pregnancy or clearance by child protective service agencies. In both cases, hospitals may be unfairly penalized for their geographic location, their position within larger regional structures of perinatal care that overall improve outcomes of infants, and potentially their patient case-mix. It is also a challenge to compare hospitals for which their elevated rates of complications result from hospital utilization versus a defined medical complication.

Finally, it is difficult to interpret hospitals with very low rates of a measure that in general cannot reach 0%. At first glance, having the lowest rate possible may seem desirable, as infants did not experience any of these outcomes that suggest an unwanted medical complication. However, we could imagine that hospitals, attempting to reach a rate of zero, may change their practices to avoid triggering such measures, potentially resulting in an early discharge of a patient or a late transfer of care. Other hospitals may truly be achieving very low rates on this measure but through changes in obstetric practice such as high rates of cesarean delivery. Generally, composite measures include such unwanted changes in practice into the composite to minimize such practice change, such as including neonatal readmission rates when using length of stay in a measure to ostensibly reduce the likelihood that providers will discharge patients too early. Without examining these potential practice changes together with the complication measure, we do not have a sense of what high-performing hospitals may be doing to achieve such a low rate on this metric. Thus, the research by Sebastiao et al provides extremely important insights into the quality and variability of care provided to the vast majority of deliveries in the United States. The paucity of metrics makes such measurement very difficult, particularly when single measure may only provide limited insights into the overall quality of care provided to low-risk populations. The relative rareness of these outcomes in these low-risk populations, however, provides an additional barrier toward understanding the drivers of such variation, particularly when measures of health care use are combined with more tangible measures of illness severity. Continued development and understanding of the drivers of improved performance in measures of the low-risk population will be critical to improving the value of health care in the United States.

REFERENCES

Association of Bronchiolitis Clinical Pathway Adherence With Length of Stay and Costs

Mersine A. Bryan, MD, a,b Arti D. Desai, MD, MSPH, a,b Lauren Wilson, MD, b Davene R. Wright, PhD, a,b Rita Mangione-Smith, MD, MPH a,b

abstract

OBJECTIVES: To examine the associations between the level of adherence to bronchiolitis clinical pathway recommendations, health care use, and costs.

METHODS: We conducted a retrospective cohort study of 267 patients ≤24 months old diagnosed with bronchiolitis from 12/2009 to 7/2012. Clinical pathway adherence was assessed by using a standardized scoring system (0–100) for 18 quality measures obtained by medical record review. Level of adherence was categorized into low, middle, and high tertiles. Generalized linear models were used to examine relationships between adherence tertile and (1) length of stay (LOS) and (2) costs. Logistic regression was used to examine the associations between adherence tertile and probability of inpatient admission and 7-day readmissions.

RESULTS: Mean adherence scores were: ED, 78.8 (SD, 18.1; n = 264), inpatient, 95.0 (SD, 6.3; n = 216), and combined ED/inpatient, 89.1 (SD, 8.1; n = 213). LOS was significantly shorter for cases in the highest versus the lowest adherence tertile (ED, 90 vs 140 minutes, adjusted difference, –51 [95% confidence interval (CI), –73 to –29; P < .05]; inpatient, 3.1 vs 3.8 days, adjusted difference, –0.7 [95% CI, –1.4 to 0.0; P < .05]). Costs were less for cases in the highest adherence tertile (ED, –$84, [95% CI, –$7 to –$161; P < .05], total, –$1296 [95% CI, –126.43 to –2466.03; P < .05]). ED cases in the highest tertile had a lower odds of admission (odds ratio, 0.38 [95% CI, 0.15–0.97; P < .05]). Readmissions did not differ by tertile.

CONCLUSIONS: High adherence to bronchiolitis clinical pathway recommendations across care settings was associated with shorter LOS and lower cost.

WHAT’S KNOWN ON THIS SUBJECT: Clinical practice guidelines and clinical pathways may reduce resource use and within-hospital variation for inpatient care for children admitted for bronchiolitis. The relationship between adherence to pathway processes of care and health care use outcomes has not previously been studied.

WHAT THIS STUDY ADDS: This study demonstrates that, for children with bronchiolitis, higher adherence to standardized clinical processes of care is associated with decreased length of stay and decreased costs in the pediatric emergency department and inpatient settings.
A Clinical Prediction Rule for Rebound Hyperbilirubinemia Following Inpatient Phototherapy

Pearl W. Chang, MD, a Michael W. Kuzniewicz, MD, MPH, b, c Charles E. McCulloch, PhD, d Thomas B. Newman, MD, MPH b, c, d

abstract

OBJECTIVES: The American Academy of Pediatrics provides little guidance on when to discontinue phototherapy in newborns treated for hyperbilirubinemia. We sought to develop a prediction rule to estimate the probability of rebound hyperbilirubinemia after inpatient phototherapy.

METHODS: Subjects for this retrospective cohort study were infants born in 2012 to 2014 at ≥35 weeks’ gestation at 16 Kaiser Permanente Northern California hospitals who received inpatient phototherapy before age 14 days. We defined rebound as the return of total serum bilirubin (TSB) to phototherapy threshold within 72 hours of phototherapy termination. We used stepwise logistic regression to select predictors of rebound hyperbilirubinemia and devised and validated a prediction score by using split sample validation.

RESULTS: Of the 7048 infants treated with inpatient phototherapy, 4.6% had rebound hyperbilirubinemia. Our prediction score consisted of 3 variables: gestational age <38 weeks (adjusted odds ratio [aOR] 4.7; 95% confidence interval [CI], 3.0–7.3), younger age at phototherapy initiation (aOR 0.51 per day; 95% CI, 0.38–0.68), and TSB relative to the treatment threshold at phototherapy termination (aOR 1.5 per mg/dL; 95% CI, 1.4–1.7). The model performed well with an area under the receiver operating characteristic curve of 0.89 (95% CI, 0.86–0.91) in the derivation data set and 0.88 (95% CI, 0.86–0.90) in the validation data set. Approximately 70% of infants had scores <20, which correspond to a <4% probability of rebound hyperbilirubinemia.

CONCLUSIONS: The risk of rebound hyperbilirubinemia can be quantified according to an infant’s gestational age, age at phototherapy initiation, and TSB relative to the treatment threshold at phototherapy termination.

WHAT’S KNOWN ON THIS SUBJECT: There are no standards and little evidence to support decisions about when to discontinue phototherapy in newborns being treated for hyperbilirubinemia.

WHAT THIS STUDY ADDS: We describe a model to quantify the risk of rebound hyperbilirubinemia. This model will enable clinicians to discontinue phototherapy when the risk of rebound hyperbilirubinemia reaches a suitably low level.
Can I Stop Phototherapy for This Baby?
Ian M. Paul, MD, MSc, a, b M. Jeffrey Maisels, MB, BCh, DSc c

The American Academy of Pediatrics (AAP) consensus-based guidelines for the initiation of phototherapy 1, 2 have been universally adopted in the United States and even applied in other countries, 3, 4 whereas several countries have developed their own phototherapy guidelines. 5–8 Substantially less guidance, however, has been provided on when to stop birth hospitalization phototherapy to avoid retreatment. In fact, the AAP Subcommittee on Hyperbilirubinemia has acknowledged that there is no standard for discontinuation. 2 Evidence-based answers to this common clinical question are now provided by Chang et al 9 in this issue of Pediatrics.

From 105,808 neonates born at ≥35 weeks’ gestation at 1 of 17 Kaiser Permanente Northern California hospitals between 2012 and 2014, Chang et al 9 identified a cohort of 7,048 newborns treated with phototherapy. The objective of the study was to identify predictors of “rebound,” defined as a return to treatment threshold levels within 72 hours of discontinuation of a neonate’s first round of phototherapy treatment. These data were then used to create a score that could predict the probability of rebound and help clinicians decide when to discontinue phototherapy. The rich electronic dataset available to the researchers included a number of key variables, including gestational age, sex, birth weight, feeding type, direct antiglobulin test results, and details regarding the initiation, course, and termination of phototherapy. Total serum and direct bilirubin data were also included.

With 4.6% of the sample experiencing a return to treatment threshold after cessation of phototherapy, Chang et al 9 identified multiple significant predictors of rebound hyperbilirubinemia, including Asian race and exclusive breastfeeding, but their parsimonious prediction score was formulated using only 3 variables: gestational age, age at phototherapy initiation, and “relative” total serum bilirubin (level at cessation minus the AAP phototherapy threshold). Specifically, a gestational age of <38 weeks and higher relative serum bilirubin were associated with an increased likelihood of rebound hyperbilirubinemia, whereas older age at phototherapy initiation was protective. These observations are consistent with those of other studies, 10, 11 and the fact that infants with hemolytic disease–associated hyperbilirubinemia are much more likely to both require early phototherapy and experience a rebound. The prediction score calculated from these variables generated thresholds where rebound hyperbilirubinemia was highly unlikely, something that can easily be included in the clinical care of such neonates. Importantly, use of this score could have resulted in a 1-day shorter hospital stay for roughly one-third of those treated with phototherapy, something that would be desirable for all stakeholders.

Numerous previous studies have analyzed the bilirubin rebound after phototherapy, 10–15 but none have approached the sample size studied by Chang et al. 9 In addition, comparisons with these studies are difficult because of differences in the populations studied, the bilirubin
levels chosen for phototherapy termination, and the criteria used to define rebound. In some institutions, about half of the infants receiving phototherapy for the first time are those who are readmitted, a population in whom the primary cause for hyperbilirubinemia is much less likely to be active hemolysis and in whom the risk of rebound is much lower. In the Chang et al study, 62% of infants received their phototherapy during their birth hospitalization. Because of the strong association between older age and less rebound, we assume that many of the older infants were those readmitted for their first course of phototherapy, although the authors do not specifically address this issue. This prediction rule for rebound hyperbilirubinemia comes at a time when innovation around well newborn care has been increasing, providing evidence-based and guideline-based tools to improve patient care. After publication of the Bhutani nomogram for neonatal hyperbilirubinemia, Web-based tools, such as Bilitool (www.bilitool.org), became routinely used in daily clinical care. More recently, the Newborn Sepsis calculator (https://neonatalsepsiscalculator.kaiserpermanente.org/) and Newborn Weight Tool (www.newbornweight.org) have helped clinicians adapt evidence on sepsis risk and newborn weight loss into mobile platforms that can inform clinical care in real-time. The formula used in the new prediction rule for rebound hyperbilirubinemia is simple and easy to use, and has similar potential to influence clinical care for those newborns receiving phototherapy.

**ABBREVIATION**

AAP: American Academy of Pediatrics

**REFERENCES**


3. Fouzas S, Mantagou L, Skylogianni E, Mantagos S, Varvarigou A. Transcutaneous bilirubin levels for the first 120 postnatal hours in healthy neonates. *Pediatrics*. 2010;125(1). Available at: www.pediatrics.org/cgi/content/full/125/1/e52


Seizures in Children With Cerebral Palsy and White Matter Injury

Monica S. Cooper, MBBS, BMedSc,a,b,c Mark T. Mackay, MBBS, PhD,a,b,c Michael Fahey, MBBS, PhD,d Dinah Reddihough, MD,a,b,c Susan M. Reid, PhD,a,b,c Katrina Williams, MBBS, PhD,a,b,c A. Simon Harvey, MDa,b,c

abstract

OBJECTIVE: The goal of this study was to describe the prevalence, syndromes, and evolution of seizure disorders in children with cerebral palsy (CP) due to white matter injury (WMI).

METHODS: For this population-based cohort study, brain MRI scans and medical records were reviewed in children in the Victorian Cerebral Palsy Register born between 1999 and 2006 recorded as having WMI. Children were excluded if they had features of an undiagnosed syndrome, associated cortical malformation or injury, or no medical contact in the preceding year. Included were 166 children with CP and isolated WMI due to presumed vascular insufficiency or hemorrhage; 87 were born preterm. Seizure and CP details were obtained from medical records and interviews, and EEG recordings were reviewed.

RESULTS: Forty-one children (25%) had seizures beyond the neonatal period. Four children had West syndrome, which resolved with treatment. Thirteen children had febrile seizures that they outgrew. Thirty children had focal epilepsy with seizure manifestations and EEG discharges typical of early-onset childhood occipital epilepsy or childhood epilepsy with centrotemporal spikes; 23 have outgrown these seizures. Two children had idiopathic generalized epilepsy; it was ongoing in 1 child. Fourteen children had evolution from 1 epileptic syndrome to another. At last follow-up (median age, 12.7 years; minimum age, 9.7 years), 80% had not had a seizure for >2 years.

CONCLUSIONS: The electroclinical features of seizure disorders associated with CP and WMI are those of the age-limited, epileptic syndromes of childhood, with favorable outcome in the majority. The findings have important implications for counseling and drug treatment.

WHAT’S KNOWN ON THIS SUBJECT: Seizures occur more frequently in children with cerebral palsy (CP) than in typically developing children. Few studies address the heterogeneity of epilepsies in CP. Seizures are often attributed to the underlying brain abnormality, with expected poor prognosis for seizure remission.

WHAT THIS STUDY ADDS: One in 5 children with CP due to white matter injury develops seizures. Seizures occur in the context of age-limited, epileptic syndromes of childhood, with a favorable outcome in the majority. This has implications for counseling and antiepileptic drug treatment.
ACL Tears in School-Aged Children and Adolescents Over 20 Years
Nicholas A. Beck, MD, a J. Todd R. Lawrence, MD, PhD, b James D. Nordin, MD, MPH, c Terese A. DeFor, MS, c Marc Tompkins, MD d

**BACKGROUND:** Anterior cruciate ligament (ACL) tears are thought to occur with increasing frequency in young patients. No study has shown increased incidence over time. We hypothesized the incidence of ACL tears in young patients has increased over the past 20 years.

**METHODS:** This descriptive epidemiology study is a retrospective review of insurance billing data of all patients aged 6 to 18 years with **Current Procedural Terminology**, Fourth Revision codes for ACL tear and reconstruction or **International Classification of Diseases**, Ninth Revision, Clinical Modification codes from 1994 to 2013. Injuries were normalized to persons per year enrolled in the insurance database based on age and sex. Analysis was performed based on sex and age (6–14, 15–16, and 17–18 years).

**RESULTS:** The rate of ACL tears per 100,000 person-years averaged 121 ± 19 (range 92–151). All trends increased significantly except for the male 6- to 14-year-old and 17- to 18-year-old age groups. Overall there was an annual increase of 2.3%. Females had significantly higher incidence except in the 17- to 18-year-olds. Females peaked at age 16 years and males at age 17 years, with rates of 392 ACL tears and 422 ACL tears per 100,000 person-years, respectively.

**CONCLUSIONS:** The incidence of ACL tears in pediatric patients increased over the last 20 years. Females were at higher risk except in the 17- to 18-year-old group. Peak incidence is noted during high school years. These data help target the most at-risk patients for ACL prevention programs.

WHAT’S KNOWN ON THIS SUBJECT: Recent reports of anterior cruciate ligament (ACL) injuries in young patients suggest the incidence is increasing. However, true incidence data are scarce. Female patients are at higher risk of ACL injury than males participating in similar activities.

WHAT THIS STUDY ADDS: We present incidence data for ACL tears in young patients and show that the incidence increased over the past 20 years. Girls exhibit higher risk until age 17. The ages most at risk are 16 for girls and 17 for boys.
Comorbidities and Complications of Spinal Fusion for Scoliosis

Jay G. Berry, MD, MPH, Michael Glotzbecker, MD, Jonathan Rodean, MPP, Izabela Leahy, RN, BSN, Matt Hall, PhD, Lynne Ferrari, MD

abstract

BACKGROUND AND OBJECTIVES: General pediatricians and hospitalists are increasingly summoned to optimize the comorbid conditions of children with medical complexity (CMC) undergoing major surgery. We assessed the relationship between specific chronic conditions of CMC and hospital resource use with spinal fusion for scoliosis, an operation with high cost and morbidity.

METHODS: Retrospective analysis of 7252 children age ≥5 years with an underlying complex chronic condition undergoing spinal fusion between January 1, 2010 through December 31, 2014 in 41 children’s hospitals. Hospital length of stay (LOS), cost, and 30-day readmission rate were compared across comorbid conditions by using linear and logistic regression accounting for demographic characteristics and clustering of patients by hospital.

RESULTS: Fifty-nine percent of children had ≥4 comorbid conditions. As the number of chronic conditions increased from 1–3 to ≥10, median LOS increased 60% (5 [interquartile range (IQR), 4–7] to 8 [IQR, 5–13] days); median hospital cost increased 53% ($52,319 [IQR, $37,937–71,513] to $80,429 [IQR, $58,602–$111,965]); and readmission rates increased 293% (5.4% to 15.8%) (P < .001 for all). In multivariable analysis, conditions strongly associated with LOS and cost were chronic respiratory insufficiency (LOS: +2.1 days; cost: +$12,070; and bladder dysfunction (LOS: +0.8 days; cost: +$4014) (P < .001 for all). Readmission likelihood was highest with bladder dysfunction (odds ratio, 1.5; 95% confidence interval, 1.1–2.0) and epilepsy (odds ratio, 1.2; 95% confidence interval, 1.0–1.5).

CONCLUSIONS: Chronic respiratory insufficiency, bladder dysfunction, and epilepsy had significant associations with hospital resource use for CMC undergoing spinal fusion. Pediatricians, patients, and families may find it useful to consider these conditions when striving to benefit the children’s perioperative health and outcomes.

WHAT’S KNOWN ON THIS SUBJECT: General pediatricians and hospitalists are increasingly summoned to help optimize control of comorbid conditions and contain hospital resource use in children with medical complexity undergoing major surgery, such as spinal fusion for scoliosis.

WHAT THIS STUDY ADDS: Spinal fusion hospital resource use increases with the number of comorbid conditions; chronic respiratory insufficiency, bladder dysfunction, and epilepsy had the strongest associations. Pediatricians assisting with perioperative care may find it useful to consider these conditions.
Sexual and Romantic Experiences of Transgender Youth Before Gender-Affirmative Treatment

Sara L. Bungener, MD,a Thomas D. Steensma, PhD,b Peggy T. Cohen-Kettenis, PhD,b Annelou L.C. de Vries, MD, PhDa

abstract

OBJECTIVE: In various Western countries early medical gender-affirmative treatment has become increasingly available for transgender adolescents. Research conducted before the start of medical gender-affirming treatment has focused on psychological and social functioning, and knowledge about the sexual health of this specific young group is lacking.

METHODS: Gender identity clinics referred 137 adolescents: 60 transgirls (birth-assigned boys, mean age 14.11 years, SD 2.21) and 77 transboys (birth assigned girls, mean age 15.14 years, SD 2.09; \( P = .05 \)). A questionnaire on sexual experiences (kissing, petting while undressed, sexual intercourse), romantic experiences (falling in love, romantic relationships), sexual orientation, negative sexual experiences, and sexual satisfaction was administered. Experiences of the transgender adolescents were compared with data for same-aged youth of a Dutch general population study (\( N = 8520 \)).

RESULTS: Of the transgender adolescents, 77% had fallen in love, 50% had had a romantic relationship, 26% had experienced petting while undressed, and 5% had had sexual intercourse. Transboys had more sexual experience than transgirls. In comparison with the general population, transgender adolescents were both sexually and romantically less experienced.

CONCLUSIONS: Despite challenges, transgender adolescent are sexually active, although to a lesser extent than their peers from the general population.

WHAT’S KNOWN ON THIS SUBJECT: Specialized transgender care clinics are confronted with an increase in the number of referred adolescents. Although it is known that they show psychological and social vulnerabilities, sexuality is an important area of functioning on which little knowledge exists.

WHAT THIS STUDY ADDS: Compared with their same-age peers, transgender adolescents have less sexual and romantic experience before medical gender-affirming treatment is initiated. Sexuality is challenging for them, although many have experienced falling in love and having a romantic relationship.
Trends in the Diagnosis of Vitamin D Deficiency

Emre Basatemur, MBBS, MRCPCH, a Laura Horsfall, PhD, b Louise Marston, PhD, b Greta Rait, MD, b Alastair Sutcliffe, PhD a

abstract

BACKGROUND: Vitamin D has attracted considerable interest in recent years, and health care providers have reported large increases in vitamin D test requests. However, rates of diagnosis of vitamin D deficiency in clinical practice have not been investigated. We examined trends in diagnosis of vitamin D deficiency in children in England over time, and by sociodemographic characteristics.

METHODS: Cohort study using primary care records of 711,788 children aged 0 to 17 years, from the Health Improvement Network database. Incidence rates for diagnosis of vitamin D deficiency were calculated per year between 2000 and 2014. Rate ratios exploring differences by age, sex, ethnicity, and social deprivation were estimated using multivariable Poisson regression.

RESULTS: The crude rate of vitamin D deficiency diagnosis increased from 3.14 per 100,000 person-years in 2000 (95% confidence interval [CI], 1.31–7.54) to 261 per 100,000 person-years in 2014 (95% CI, 241–281). After accounting for changes in demographic characteristics, a 15-fold (95% CI, 10–21) increase in diagnosis was seen between 2008 and 2014. Older age (≥10 years), nonwhite ethnicity, and social deprivation were independently associated with higher rates of diagnosis. In children aged <5 years, diagnosis rates were higher in boys than girls, whereas in children aged ≥10 they were higher in girls.

CONCLUSIONS: There has been a marked increase in diagnosis of vitamin D deficiency in children over the past decade. Future research should explore the drivers for this change in diagnostic behavior and the reasons prompting investigation of vitamin D status in clinical practice.

WHAT'S KNOWN ON THIS SUBJECT: Vitamin D has attracted considerable interest in recent years, and health care providers have reported large increases in vitamin D test requests. However, trends in the diagnosis of vitamin D deficiency in clinical practice have not been investigated.

WHAT THIS STUDY ADDS: There has been a marked increase in testing and diagnosis of vitamin D deficiency among English children over the past decade (15-fold between 2008 and 2014). Older age, nonwhite ethnicity, and social deprivation were associated with higher rates of diagnosis.


Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-2748

*Population, Policy and Practice Programme, UCL Institute of Child Health, London, United Kingdom; and
+Research Department of Primary Care and Population Health, University College London, London, United Kingdom

Dr Basatemur conceptualized and designed the study, conducted the analysis, interpreted the data, drafted the initial manuscript, and wrote the final manuscript. Dr Sutcliffe contributed to the conception and design of the study, the interpretation of data, and critical revision of the manuscript. Drs Rait, Horsfall, and Marston contributed to the design of the study, the interpretation of data, and critical revision of the manuscript; and all authors approved the final version of the manuscript as submitted.

DOI: 10.1542/peds.2016-2748

Accepted for publication Nov 29, 2016

Address correspondence to Emre Basatemur, MBBS, MRCPCH, Population, Policy and Practice Programme, UCL Institute of Child Health, 30 Guilford St, London WC1N 1EH, UK. E-mail: emre.basatemur@ucl.ac.uk

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

Copyright © 2017 by the American Academy of Pediatrics

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.
Incentive-based Intervention to Maintain Breastfeeding Among Low-income Puerto Rican Mothers

Yukiko Washio, PhD; Mara Humphreys, MEd; Elisa Colchado, MEd; Maria Sierra-Ortiz, MSW; Zugui Zhang, PhD; Bradley N. Collins, PhD; Linda M. Kilby, PhD, RD, LDN; Donna J. Chapman, PhD, RD; Stephan T. Higgins, PhD; Kimberly C. Kirby, PhD

BACKGROUND AND OBJECTIVE: Despite maternal and child health benefits, breastfeeding rates are relatively low among low-income Puerto Rican mothers. This study examined the hypothesis that monthly financial incentives would significantly increase the proportion of breastfeeding mothers at 6 months postpartum compared with Supplemental Nutrition Program for Women, Infants, and Children (WIC) services only among Puerto Rican mothers.

METHODS: A randomized, 2-arm parallel-group design, from February 2015 through February 2016. Half of the randomized participants received monthly financial incentives contingent on observed breastfeeding for 6 months (Incentive), and the other half received usual WIC services only (Control). Thirty-six self-identified Puerto Rican women who initiated breastfeeding were enrolled. Monthly cash incentives were contingent on observed breastfeeding increasing the amount given at each month from $20 to $70 for a total possible of $270.

RESULTS: The intent-to-treat analysis showed significantly higher percentages of breastfeeding mothers in the incentive group at each time point compared with those in the control group (89% vs 44%, \(P = .01\) at 1 month; 89% vs 17%, \(P < .001\) at 3 months; 72% vs 0%, \(P < .001\) at 6 months). No significant differences were detected at any time point between study groups for self-reported exclusive breastfeeding rate and infant outcomes (ie, weight, emergency department visits).

CONCLUSIONS: Contingent cash incentives significantly increased breastfeeding through 6-month postpartum among WIC-enrolled Puerto Rican mothers; however, no significant differences between the study groups were observed on exclusive breastfeeding rate and infant outcomes. Larger-scale studies are warranted to examine efficacy, implementation potential, and cost-effectiveness.

WHAT’S KNOWN ON THIS SUBJECT: It has been a major challenge to maintain breastfeeding among low-income Puerto Rican mothers. Professional and peer breastfeeding support has not significantly improved breastfeeding rates at 1 and 3 months.

WHAT THIS STUDY ADDS: The study describes the novel, potentially effective approach of using financial incentives contingent on observed breastfeeding behavior to help low-income Puerto Rican mothers maintain breastfeeding for 6 months.
Should We Pay Mothers Who Receive WIC to Breastfeed?

Lydia Furman, MD

Make no mistake: Dr Washio and colleagues have courageously conducted a trial about which many have whispered but few have dared to have open discussions. Paying women to breastfeed is a strategy that most investigators have assiduously avoided. It is, however, a completely logical intervention because breastfeeding is a profoundly positive public health strategy with enormous health benefits for mothers and infants and huge economic benefits for families and society. This small, unique, proof-of-concept pilot study deserves to be well understood. The authors enrolled 36 Puerto Rican WIC (The Special Supplemental Nutrition Program for Women, Infants and Children) recipients living in Philadelphia who had already initiated breastfeeding. Their aim was to determine if monthly financial incentives contingent on directly observed breastfeeding increased rates of any breastfeeding at 6 months. Half of the group received WIC breastfeeding support, and the other half received this support plus a cash incentive. Novel aspects of the study included both the direct monthly escalating cash payments ($270 maximum possible) and an observed breastfeeding as the outcome (audible swallowing, a suck-swallow-breathe pattern and milk in the infant’s mouth, or pumping with subsequent feeding).

As a small pilot, the authors readily acknowledge that their study was not adequately powered for the outcome measure of any breastfeeding at 6 months. Other limitations are also well described: the study was not blinded, the choice of population (Hispanic Puerto Rican mothers in a large Northeastern urban area) and timing of enrollment (mothers had initiated breastfeeding) make generalizability challenging, and the choice of outcome (duration of any breastfeeding at all, rather than exclusive breastfeeding) can be argued. However, the study was conducted in a respectful manner without deception of participants, comprehensive breastfeeding support was provided to all participants, and each received modest cash payments noncontingent on feeding method for the longer evaluations at study start and at 1, 3, and 6 months.

A chorus of concern identifies ethical issues associated with financial incentives for breastfeeding. Paying low-income women who are receiving WIC to breastfeed makes most people uncomfortable, despite incontrovertible data that this demographic subpopulation is both (1) at higher risk for not breastfeeding and (2) at higher risk for the morbidities that breastfeeding clearly decreases, such as sudden infant death syndrome and maternal cardiovascular disease. Are incentives, most specifically cash incentives to an individual living in poverty, a coercion that negatively and deceitfully influences a woman’s right to choose how she cares for her infant and what she does with her own body? Or is cash a meaningful way to...
incentivize healthy behavior akin to paying women not to smoke during pregnancy? By logical extension, if breastfeeding is so vitally important to the mother’s and infant’s health, should women of all socioeconomic levels be paid to breastfeed? And would such an incentive have to be scaled to the mother’s or to the family’s income to be meaningful? None of these questions have easy answers.

A study that examined 3373 online responses from the general public in the United Kingdom to a proposal to provide financial incentives to support breastfeeding found that most thought incentives were unacceptable and did not address cultural and structural barriers to breastfeeding, so among this large group of respondents, there was recognition of the multiplicity of challenges associated with breastfeeding. Certainly WIC has labored long and hard to support breastfeeding, and kudos to all efforts including the Breastfeeding Peer Helper Program, the Loving Support Program (https://lovingsupport.fns.usda.gov), and the extraordinarily dedicated staff, but even the increased value of WIC’s breastfeeding mother’s food package (over that offered to the mother who accepts formula) has had limited impact, so we cannot pretend that all the answers are in.

Meanwhile, it is fascinating that less concern is generally expressed about the ethics of essentially paying low-income mothers on WIC to give formula to their infants by providing this benefit free of cost. Global research has demonstrated the great potential of conditional cash transfers in promoting maternal and child health. I personally believe that cash incentives paid to WIC recipients for breastfeeding can “level the playing field” with respect to money spent by WIC on the mother-child couple and that they are ethically defensible and socially responsible. Excellent breastfeeding support, as well as continued tackling of structural and environmental barriers to breastfeeding, are critical. I do agree with Dr Washio and colleagues that before any broad program launch, good prospective studies are needed, and additionally that many details, especially those related to privacy and confidentiality surrounding direct observation and verification, need to be carefully and thoughtfully resolved.

ABBREVIATION

WIC: The Special Supplemental Nutrition Program for Women, Infants and Children

REFERENCES


Utilization of Mental Health Services After Mild Pediatric Traumatic Brain Injury

Nathalia Jimenez, MD, MPH,a,b Alex Quistberg, PhD,b Monica S. Vavilala, MD,a,b,c Kenneth M. Jaffe, MD,a,d Frederick P. Rivara, MD, MPH,b,c,e

abstract

BACKGROUND: Mild traumatic brain injury injuries (mTBIs), including concussions, represent >2 million US pediatric emergency department visits annually. Post-mTBI mental health symptoms are prominent and often attributed to the mTBI. This study examined whether individuals seeking post-mTBI mental health care had previous mental health diagnoses or a new onset of such disorders, and determined if mental health care utilization differed by race/ethnicity.

METHODS: Retrospective cohort study, using the Medicaid Marketscan claims national dataset (2007–2012). Utilization of mental health services 1 year before and 1 year after mTBI was compared between children with and without mental health diagnoses before injury. Primary outcome was receipt of post-mTBI outpatient mental health care.

RESULTS: A total of 31,272 children 20 years or younger were included, 8,577 (27%) with mental health diagnoses before their mTBI and 22,695 without one. After injury, children without previous mental health disorders increased mental health services utilization; however, most (86%) postinjury mental health care was received by children with previous mental health disorders. Having a mental health diagnosis pre-mTBI was the most important risk factor for receiving post-mTBI mental health care (odds ratio 7.93, 95% confidence interval 7.40–8.50). Hispanic children were less likely to receive post-mTBI mental health care.

CONCLUSIONS: mTBI was associated with increased utilization of mental health services but most of these services were received by children with previous mental health disorders. Our documentation of racial/ethnic disparities in mental health care utilization reemphasize the importance of providing individualized, culturally, and linguistically competent care to improve outcomes after mTBI for all children.

WHAT'S KNOWN ON THIS SUBJECT: Mental health symptoms after mild traumatic brain injury (mTBI) are prominent and often attributed to the TBI. It remains unclear if utilization of post-mTBI mental health care is related to development of new symptoms or previous illness. No information on mental health care utilization among minority children exists.

WHAT THIS STUDY ADDS: mTBI is associated with increased utilization of mental health services; however, most children seeking mental health care after mTBI had a previous mental health diagnosis. Hispanic children were less likely to receive post-mTBI mental health care.
Language Outcomes at 7 Years: Early Predictors and Co-Occurring Difficulties

Cristina McKean, PhD, a,b Sheena Reilly, PhD, b,c Edith L. Bavin, PhD, d Lesley Bretherton, PhD, b,n,f Eileen Cini, BAppSci, b Laura Conway, BA, b,F Fallon Cook, PhD, b Patricia Eadie, PhD, b Margot Prior, PhD, b Melissa Wake, MD, b,e,f Fiona Mensah, PhD b,e,f

abstract

OBJECTIVE: To examine at 7 years the language abilities of children, the salience of early life factors and language scores as predictors of language outcome, and co-occurring difficulties

METHODS: A longitudinal cohort study of 1910 infants recruited at age 8 to 10 months. Exposures included early life factors (sex, prematurity, birth weight/order, twin birth, socioeconomic status, non–English speaking background,family history of speech/language difficulties); maternal factors (mental health, vocabulary, education, and age); and child language ability at 2 and 4 years. Outcomes were 7-year standardized receptive or expressive language scores (low language: ≥1.25 SD below the mean), and co-occurring difficulties (autism, literacy, social, emotional, and behavioral adjustment, and health-related quality of life).

RESULTS: Almost 19% of children (22/1204;18.9%) met criteria for low language at 7 years. Early life factors explained 9-13% of variation in language scores, increasing to 39-58% when child language scores at ages 2 and 4 were included. Early life factors moderately discriminated between children with and without low language (area under the curve: 0.68–0.72), strengthening to good discrimination with language scores at ages 2 and 4 (area under the curve: 0.85–0.94). Low language at age 7 was associated with concurrent difficulties in literacy, social-emotional and behavioral difficulties, and limitations in school and psychosocial functioning.

CONCLUSIONS: Child language ability at 4 years more accurately predicted low language at 7 than a range of early child, family, and environmental factors. Low language at 7 years was associated with a higher prevalence of co-occurring difficulties.

WHAT’S KNOWN ON THIS SUBJECT: Fluctuating preschool language abilities present challenges for identifying children at risk for later language impairment. Child, family, and environmental factors explain a limited amount of variability in language ability at 4 years, and prediction of low language status is limited.

WHAT THIS STUDY ADDS: Language ability at 4 years predicted language outcomes at 7 years more saliently than child, family, and environmental factors. At 7, low language was associated with higher rates of social-emotional, behavioral, and literacy difficulties and health-related quality of life limitations.

Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-1684

Drs McKean, Reilly, Cook, and Mensah designed the study and completed the data analyses; Drs Bavin, Bretherton, Eadie, Prior, and Wake designed the longitudinal cohort study and revised the manuscript; Ms Cini and Ms Conway designed data collection instruments, carried out preliminary data analyses, coordinated and supervised data collection, and critically reviewed the manuscript, and all authors approved the final manuscript as submitted.

DOI: 10.1542/peds.2016-1684

Accepted for publication Nov 22, 2016

Address correspondence to Sheena Reilly, PhD, Menzies Health Institute Queensland, Griffith University, Queensland, QLD 4222, Australia. E-mail: s.reilly@griffith.edu.au

Safety of Second-Dose Single-Antigen Varicella Vaccine

John R. Su, MD, PhD, MPH, a Zanie Leroy, MD, MPH, b Paige W. Lewis, MSPH, a Penina Haber, MPH, a Mona Marin, MD; Jessica Leung, MPH; Emily Jane Woo, MD, MPH; Tom T. Shimabukuro, MD, MPH, MBA a

BACKGROUND AND OBJECTIVE: In 2006, routine 2-dose varicella vaccination for children was recommended to improve control of varicella. We assessed the safety of second-dose varicella vaccination.

METHODS: We identified second-dose single-antigen varicella vaccine reports in the Vaccine Adverse Event Reporting System during 2006 to 2014 among children aged 4 to 18 years. We analyzed reports by age group (4–6 and 7–18 years), sex, serious or nonserious status, most common adverse events (AEs), and whether other vaccines were administered concomitantly with varicella vaccine. We reviewed serious reports of selected AEs and conducted empirical Bayesian data mining to detect disproportional reporting of AEs.

RESULTS: We identified 14,641 Vaccine Adverse Event Reporting System reports after second-dose varicella vaccination, with 494 (3%) classified as serious. Among nonserious reports, injection site reactions were most common (48% of children aged 4–6 years, 38% of children aged 7–18 years). The most common AEs among serious reports were pyrexia (31%) for children aged 4 to 6 years and headache (28%) and vomiting (27%) for children aged 7 to 18 years. Serious reports of selected AEs included anaphylaxis (83), meningitis (5), encephalitis (16), cellulitis (52), varicella (6), herpes zoster (6), and deaths (7). One immunosuppressed adolescent was reported with vaccine-strain herpes zoster. Only previously known AEs were reported more frequently after second-dose varicella vaccination compared with other vaccines.

CONCLUSIONS: We identified no new or unexpected safety concerns for second-dose varicella vaccination. Robust safety monitoring remains an important component of the national varicella vaccination program.

WHAT’S KNOWN ON THIS SUBJECT: Single-dose vaccination for varicella has proven safe with no unexpected adverse events. A 2-dose vaccination schedule for varicella vaccine was recommended in 2006.

WHAT THIS ANALYSIS ADDS: We identified no unexpected safety concerns. All adverse events reported to the Vaccine Adverse Event Reporting System after the second dose of varicella vaccine were described previously, with frequencies comparable to those occurring after the first dose of varicella vaccine.


Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-2536

*Immunization Safety Office, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, aSchool Health Branch, Division of Population Health, National Center for Chronic Disease Prevention and Health Promotion, and bEpidemiology Branch, Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; and cOffice of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research, US Food and Drug Administration, Silver Springs, MD

Dr Su conceptualized and performed the later descriptive analysis and interpretation of data, and drafted the initial manuscript; Dr Leroy conceptualized and performed the preliminary descriptive analysis and interpretation of data; Ms Lewis performed the query and retrieval of data from the Vaccine Adverse Event Reporting System database; Ms Haber assisted in conceptualization of the descriptive analysis and interpretation of data; Dr Marin and Ms Leung assisted in conceptualization of the descriptive analysis and interpretation of data, and provided expertise on the epidemiology of varicella and the varicella vaccination program; Dr Woo performed and interpreted the disproportionality analysis, and assisted with the descriptive analysis and interpretation of data; Dr Shimabukuro assisted in conceptualization of both preliminary and later descriptive analyses and interpretation of data; and all authors reviewed and revised the manuscript, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.
Intimate Partner Violence and Child Behavioral Problems in South Africa

Pratibha Chander, MPH, Jane Kvalsvig, PhD, Claude A. Mellins, PhD, Shuaib Kauchali, FCPaed (SA), MPhil, Stephen M. Arpadi, MD, MS, Myra Taylor, PhD, Justin R. Knox, PhD, MPH, Leslie L. Davidson, MD, MSc, FAAP, MRCP

abstract

BACKGROUND: Research in high-income countries has repeatedly demonstrated that intimate partner violence (IPV) experienced by women negatively affects the health and behavior of children in their care. However, there is little research on the topic in lower- and middle-income countries. The population-based Asenze Study gathered data on children and their caregivers in KwaZulu-Natal, South Africa. This data analysis explores the association of caregiver IPV on child behavior outcomes in children <12 years old and is the first such study in Africa.

METHODS: This population-based study was set in 5 Zulu tribal areas characterized by poverty, food insecurity, unemployment, and a high HIV prevalence. The Asenze Study interviewed caregivers via validated measures of IPV, alcohol use, caregiver mental health difficulties, and child behavior disorders in their preschool children.

RESULTS: Among the 980 caregivers assessed, 37% had experienced IPV from their current partner. Experience of partner violence (any, physical, or sexual) remained strongly associated with overall child behavior problems (odds ratio range: 2.46–3.10) even after age, HIV status, cohabitation with the partner, alcohol use, and posttraumatic stress disorder were accounted for.

CONCLUSIONS: Childhood behavioral difficulties are associated with their caregiver’s experience of IPV in this population, even after other expected causes of child behavior difficulties are adjusted for. There is a need to investigate the longer-term impact of caregiver partner violence, particularly sexual IPV, on the health and well-being of vulnerable children in lower- and middle-income countries. Studies should also investigate whether preventing IPV reduces the occurrence of childhood behavior difficulties.
A Support Program for Somali-born Parents on Children’s Behavioral Problems

Fatumo Osman, RN, MPH, Renée Flacking, RN, Ulla-Karin Schön, Marie Klingberg-Allvin, RN, RM

abstract

OBJECTIVES: The objectives of this study were to evaluate a culturally tailored parenting support program (Ladnaan) for Somali-born parents and to determine its effectiveness on children’s emotional and behavioral problems.

METHODS: This randomized controlled trial included 120 Somali-born parents with children aged 11 to 16 years. The parents reported self-perceived stress in relation to parenting practices. The intervention consisted of culturally tailored societal information combined with the parenting program Connect. Parents received 12 weeks of intervention, 1 to 2 hours each week, in groups of 12 to 17 parents. Nine group leaders with a Somali background who received a standardized training program delivered the intervention. The primary outcome was a decrease in emotional and behavioral problems based on a Child Behavior Checklist. Parents were randomly allocated either to an intervention group or a wait-list control group. Covariance analyses were conducted according to intention-to-treat principles.

RESULTS: The results showed significant improvement in the children in the intervention group for behavioral problems after a 2-month follow-up. The largest effect sizes according to Cohen’s $d$ were in aggressive behavior (95% confidence interval [CI], 1.06 to 3.07), social problems (95% CI, 0.64 to 1.70), and externalizing problems (95% CI, 0.96 to 3.53).

CONCLUSIONS: The large effect sizes in this study show that this 12-week culturally tailored parenting support program was associated with short-term improvements in children’s behavior. The study adds to the field of parenting interventions by demonstrating how to culturally tailor, engage, and retain parenting programs for immigrant parents.
Targeting Sleep, Food, and Activity in Infants for Obesity Prevention: An RCT

Barry J. Taylor, FRACP; Andrew R. Gray, BCom (Hons); Barbara C. Galland, PhD; Anne-Louise M. Heath, PhD; Julie Lawrence, PhD; Rachel M. Sayers, MHealSc; Sonya Cameron, PhD; Maha Hanna, DPH; Kelly Dale, PhD; Kirsten J. Coppell, FNZCPHM; Rachael W. Taylor, PhD

Abstract

OBJECTIVE: The few existing early-life obesity prevention initiatives have concentrated on nutrition and physical activity, with little examination of sleep.

METHODS: This community-based, randomized controlled trial allocated 802 pregnant women (≥16 years, <34 weeks' gestation) to: control, FAB (food, activity, and breastfeeding), sleep, or combination (both interventions) groups. All groups received standard well-child care. FAB participants received additional support (8 contacts) promoting breastfeeding, healthy eating, and physical activity (antenatal–18 months). Sleep participants received 2 sessions (antenatal, 3 weeks) targeting prevention of sleep problems, as well as a sleep treatment program if requested (6–24 months). Combination participants received both interventions (9 contacts). BMI was measured at 24 months by researchers blinded to group allocation, and secondary outcomes (diet, physical activity, sleep) were assessed by using a questionnaire or accelerometry at multiple time points.

RESULTS: At 2 years, 686 women remained in the study (86%). No significant intervention effect was observed for BMI at 24 months ($P = .086$), but there was an overall group effect for the prevalence of obesity ($P = .027$). Exploratory analyses found a protective effect for obesity among those receiving the “sleep intervention” (sleep and combination compared with FAB and control: odds ratio, 0.54 [95% confidence interval, 0.35–0.82]). No effect was observed for the “FAB intervention” (FAB and combination compared with sleep and control: odds ratio, 1.20 [95% confidence interval, 0.80–1.81]).

CONCLUSIONS: A well-developed food and activity intervention did not seem to affect children's weight status. However, further research on more intensive or longer running sleep interventions is warranted.

WHAT’S KNOWN ON THIS SUBJECT: Obesity prevention in early life has concentrated on changing nutrition and activity in infants, with relatively little success. Although sleep is strongly associated with weight in observational research, few interventions have investigated the effectiveness of sleep modification for obesity prevention.

WHAT THIS STUDY ADDS: An intervention targeting food, activity, and breastfeeding did not seem to affect infants’ weight status. Exploratory analyses of the sleep intervention suggest that further research based on more intensive or longer running sleep interventions is warranted.
Safe Storage of Opioid Pain Relievers Among Adults Living in Households With Children

Eileen M. McDonald, MS, a,b Alene Kennedy-Hendricks, PhD, c,d Emma E. McGinty, PhD, MS, a,c,d,e Wendy C. Shields, MPH, a,d Colleen L. Barry, PhD, MPP, c,d,e Andrea C. Gielen, ScD a,b

abstract

OBJECTIVES: To describe safe storage practices and beliefs among adults who have used a prescription opioid pain reliever (OPR) in the past year; to compare practices and beliefs among those living with younger (<7 years) versus older children (7–17 years).

METHODS: A survey was administered to a nationally representative sample of adults reporting OPR use in the previous 12 months and who had children <18 years old living with them. We used Health Belief Model–derived items to measure beliefs. Safe storage was defined as locked or latched for younger children and as locked for older children. Regression models examined the association between beliefs and safe storage practices.

RESULTS: Among 681 adults who completed our survey and reported having children in their home, safe storage was reported by 32.6% (95% confidence interval [CI], 21.4–43.8) of those with only young children, 11.7% (95% CI, 7.2–16.2) among those with only older children, and 29.0% (95% CI, 18.3–39.8) among those with children in both age groups. Among those asked to answer survey questions thinking about only their oldest child, the odds of reporting safe storage decreased by half as perceived barriers increased (0.505; 95% CI, 0.369–0.692), increased twofold as efficacy increased (2.112; 95% CI, 1.390–3.210), and increased (1.728; 95% CI, 1.374–2.174) as worry increased.

CONCLUSIONS: OPRs are stored unsafely in many households with children. Educational messages should address perceived barriers related to safe storage while emphasizing how it may reduce OPR access among children.

WHAT’S KNOWN ON THIS SUBJECT: The United States is in the midst of an opioid epidemic. Opioids are increasingly implicated in unintentional ingestions among young children. Overdose fatalities related to opioid exposures have more than doubled among adolescents and young adults.

WHAT THIS STUDY ADDS: This study demonstrates that opioid pain reliever (OPR) storage is suboptimal in households with children and adolescents despite most respondents reporting high perceived threats from OPRs and despite high perceived benefits and low perceived barriers to safe OPR storage.
Overdose Risk in Young Children of Women Prescribed Opioids

Yaron Finkelstein, MD, a,b,c,d Erin M. Macdonald, MSc, d Alejandro Gonzalez, MSc, d Marco L.A. Sivilotti, MD, MSc, e,f Muhammad M. Mamdani, PharmD, d,g,h David N. Juurlink, MD, d,i,j Canadian Drug Safety And Effectiveness Research Network (CDSERN)

abstract

BACKGROUND AND OBJECTIVE: Over the past 20 years, the prescribing of opioids has increased dramatically in North America, with parallel increases in opioid addiction, overdose, and associated deaths. We examined whether young children of women prescribed opioids were at increased risk of opioid overdose.

METHODS: We conducted a population-based, nested case control study in Ontario, Canada, between 2002 and 2015. We identified children aged \( \leq 10 \) years, whose mothers received publicly funded prescriptions for an opioid or a nonsteroidal antiinflammatory drug (comparator analgesic) in the preceding year. Cases were children who presented to hospital for or died of opioid overdose. Each case was matched with 4 controls with no opioid overdose. The primary outcome was the risk of opioid overdose.

RESULTS: We identified 103 children who presented to the hospital with opioid overdose and matched them with 412 controls. Half of the children with opioid overdose were <2 years old. Compared with controls, children with an opioid overdose were far more likely to have a mother who received a prescription opioid (unadjusted odds ratio, 2.41; 95% confidence interval, 1.68–3.45) and who was prescribed antidepressants. The most commonly implicated overdose opioids were codeine (53.4%), oxycodone (32.0%), and methadone (15.5%).

CONCLUSIONS: Young children of mothers prescribed opioids are at a markedly increased risk of overdose. Physicians, pharmacists, and parents should take measures to mitigate the risk of opioid-related harm to children, such as prescribing smaller quantities, emphasizing the importance of secure medication storage, and the prompt disposal of unused opioids.

WHAT'S KNOWN ON THIS SUBJECT: The increase in opioid prescribing in North America over the past 2 decades has led to the worst drug overdose epidemic in history. However, the impact of prescription opioids on young children in the home has not been well studied.

WHAT THIS STUDY ADDS: Young children of mothers prescribed opioids are at a markedly increased risk of overdose. Providers should take measures to mitigate the risk of pediatric opioid-related harm, such as prescribing smaller quantities, facilitating secure storage, and prompt disposal of unused opioids.

Drs Finkelstein and Juurlink conceptualized and designed the study, obtained funding, drafted the manuscript, Ms Macdonald and Mr Gonzalez analyzed and interpreted the data and reviewed and revised the manuscript; Drs Sivilotti and Mamdani critically reviewed and revised the manuscript for important intellectual content; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

DOI: 10.1542/peds.2016-2887

Accepted for publication Dec 13, 2016
Pediatric Exposures to Veterinary Pharmaceuticals

Suzanne Tomasi, DVM, MPH,a,b Kristin J. Roberts, MS, MPH,a Jason Stull, VMD, MPVM, PhD, DACVP,a Henry A. Spiller, MS, D.ABAT,c Lara B. McKenzie, PhD, MAa,d,e

abstract

OBJECTIVE: To describe the epidemiology of veterinary pharmaceutical-related exposures to children based on calls to a regional poison control center.

METHODS: A retrospective analysis of pediatric (≤ 19 years of age) exposures to pharmaceutical products intended for animal use, managed by a regional poison control center from 1999 through 2013, was conducted. Case narratives were reviewed and coded for exposure-related circumstances and intended species. Descriptive statistics were generated.

RESULTS: From 1999 through 2013, the Central Ohio Poison Center received 1431 calls that related to a veterinary pharmaceutical exposure for children ≤ 19 years of age. Most of the pediatric calls (87.6%) involved children ≤ 5 years of age. Exploratory behavior was the most common exposure-related circumstance (61.4%) and ingestion accounted for the exposure route in 93% of cases. Substances commonly associated with exposures included: veterinary drugs without human equivalent (17.3%), antimicrobial agents (14.8%), and antiparasitics (14.6%). Based on substance and quantity, the majority of exposures (96.9%) were not expected to result in long-term or lasting health effects and were managed at home (94.1%). A total of 80 cases (5.6%) were referred to a health care facility, and 2 cases resulted in a moderate health effect.

CONCLUSIONS: Children ≤ 5 years of age are most at risk for veterinary pharmaceutical-related exposures. Although most exposures do not result in a serious medical outcome, efforts to increase public awareness, appropriate product dispensing procedures, and attention to home storage practices may reduce the risk of veterinary pharmaceutical exposures to young children.

WHAT’S KNOWN ON THIS SUBJECT: With 74.1 million US households owning at least 1 pet and one-half of households with a child ≤ 19 years of age, unintentional pediatric exposure to pet medication may occur. No previous studies have examined these exposures.

WHAT THIS STUDY ADDS: This study calls attention to the potential risk of pediatric poisonings from veterinary pharmaceutical products and highlights some opportunities for public health officials, pediatricians, pharmacists, and veterinarians to improve education to parents and other childcare providers.


Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-1496

*Center for Injury Research and Policy, The Research Institute, and bCentral Ohio Poison Center, Nationwide Children’s Hospital, Columbus, Ohio; and bDepartment of Veterinary Preventive Medicine, College of Veterinary Medicine, cDepartment of Pediatrics, College of Medicine, and dDivision of Epidemiology, College of Public Health, The Ohio State University, Columbus, Ohio

Dr Tomasi analyzed the data, reviewed the results, helped to draft the initial manuscript, and reviewed drafts of the manuscript; Ms Roberts analyzed the data, reviewed the results, helped to draft the initial manuscript, and reviewed drafts of the manuscript; Dr Stull conceptualized and designed aspects of the study, reviewed the results, and reviewed drafts of the manuscript; Dr Spiller participated in the design of the study, reviewed the results, and reviewed drafts of the manuscript; Dr McKenzie conceptualized and designed aspects of the study, reviewed the results, and reviewed drafts of the manuscript; and all authors approved the final manuscript as submitted.

DOI: 10.1542/peds.2016-1496

Accepted for publication Dec 1, 2016

Address correspondence to Kristin J. Roberts, MS, MPH, Center for Injury Research and Policy, The Research Institute, Nationwide Children’s Hospital, 700 Children’s Dr, Research Building III, 5th Floor, Columbus, OH 43205. E-mail: kristin.roberts@nationwidechildrens.org
Respiratory Morbidity in Infants Born With a Congenital Lung Malformation

Celine Delestrain, MD, Nazia Khen-Dunlop, MD, PhD, Alice Hadchouel, MD, PhD, Pierrick Cros, MD, Héloïse Ducoin, MD, Michael Fayon, MD, PhD, Isabelle Gibertini, MD, André Labbé, PhD, MD, Géraldine Labouret, MD, Marie-Noëlle Lebras, MD, Guillaume Lezmi, MD, Fouad Madhi, MD, Guillaume Thouvenin, MD, Caroline Thumerelle, MD, Christophe Delacourt, MD, PhD

BACKGROUND AND OBJECTIVES: The actual frequency of respiratory symptoms related to congenital pulmonary malformations (CPMs) remains undetermined. The goal of this study was to prospectively evaluate the respiratory symptoms occurring in infants with prenatally diagnosed CPMs, identify factors associated with the occurrence of these symptoms, and evaluate their resolution after surgery.

METHODS: Infectious and noninfectious respiratory symptoms were prospectively collected in a French multicenter cohort of children with CPMs.

RESULTS: Eighty-five children were followed up to the mean age of 2.1 ± 0.4 years. Six children (7%) underwent surgery during the first 28 days of life. Of the 79 remaining children, 33 (42%) had respiratory symptoms during infancy before any surgery. Wheezing was the dominant symptom (24 of 79 [30%]), and only 1 infant had documented infection of the cystic lobe. Symptoms were more frequent in children with noncystic CPMs, prenatally (P < .002) or postnatally (P < .03), and with postnatally hyperlucent CPMs (P < .01). Sixty-six children underwent surgery during the follow-up period, and 40% of them displayed symptoms after the intervention. Six children had documented pneumonia during the postoperative period. At the end of the follow-up, pectus excavatum was observed in 10 children, significantly associated with thoracotomy (P < .02) or with surgery before the age of 6 months (P < .002).

CONCLUSIONS: CPMs are frequently associated with wheezing episodes. Surgery had no significant impact on these symptoms but was associated with a paradoxical increase in pulmonary infections, as well as an increased risk of pectus excavatum after thoracotomy.

WHAT'S KNOWN ON THIS SUBJECT: Poor knowledge regarding the natural history of congenital pulmonary malformations (CPMs) hampers standardized prenatal and postnatal care, with most decisions, including those relating to the need for the surgical removal of asymptomatic malformations, highly dependent on the physician.

WHAT THIS STUDY ADDS: Infants with CPMs had a low rate of infection but a high rate of wheezing episodes, especially when CPMs had a hyperlucent appearance. Surgery had no impact on wheezing prevalence. Our results support a conservative management for noncystic malformations.


DOI: 10.1542/peds.2016-2988

Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-2988

ARTICLE 55

PEDIATRICS Volume 139, number 3, March 2017 e20162988
Psychiatric Disorders in Adolescents With Single Ventricle Congenital Heart Disease

David R. DeMaso, MD,a,b,c Johanna Calderon, PhD,a,c George A. Taylor, BA,a Jennifer E. Holland, BA,a Christian Stopp, MS,a Matthew T. White, PhD,a,c David C. Bellinger, PhD, MSc,a,c,d,e Michael J. Rivkin, MD,a,d,e David Wypij, PhD,b,f Jane W. Newburger, MD, MPHb,g

ABSTRACT

BACKGROUND AND OBJECTIVES: Mental health outcomes for survivors of critical congenital heart disease (CHD) remain under-investigated. We sought to examine psychiatric disorders and psychosocial functioning in adolescents with single ventricle CHD and to explore whether patient-related risk factors predict dysfunction.

METHODS: This cohort study recruited 156 adolescents with single ventricle CHD who underwent the Fontan procedure and 111 healthy referents. Participants underwent comprehensive psychiatric evaluation including a clinician-rated psychiatric interview and parent- and self-report ratings of anxiety, disruptive behavior, including attention-deficit/hyperactivity disorder (ADHD), and depressive symptoms. Risk factors for dysfunction included IQ, medical characteristics, and concurrent brain abnormalities.

RESULTS: Adolescents with single ventricle CHD had higher rates of lifetime psychiatric diagnosis compared with referents (CHD: 65%, referent: 22%; \( P < .001 \)). Specifically, they had higher rates of lifetime anxiety disorder and ADHD (\( P < .001 \) each). The CHD group scored lower on the primary psychosocial functioning measure, the Children's Global Assessment Scale, than referents (CHD median [interquartile range]: 62 [54–66], referent: 85 [73–90]; \( P < .001 \)). The CHD group scored worse on measures of anxiety, disruptive behavior, and depressive symptoms. Genetic comorbidity did not impact most psychiatric outcomes. Risk factors for anxiety disorder, ADHD, and lower psychosocial functioning included lower birth weight, longer duration of deep hypothermic circulatory arrest, lower intellectual functioning, and male gender.

CONCLUSIONS: Adolescents with single ventricle CHD display a high risk of psychiatric morbidity, particularly anxiety disorders and ADHD. Early identification of psychiatric symptoms is critical to the management of patients with CHD.
Decreasing Prescribing Errors During Pediatric Emergencies: A Randomized Simulation Trial

Guylaine Larose, MD, LLM, Arielle Levy, MD, MEd, Benoit Bailey, MD, MSc, Barbara Cummins-McManus, MD, Denis Lebel, MSc, Jocelyn Gravel, MD, MSc

OBJECTIVE: To evaluate whether a clinical aid providing precalculated medication doses decreases prescribing errors among residents during pediatric simulated cardiopulmonary arrest and anaphylaxis.

METHODS: A crossover randomized trial was conducted in a tertiary care hospital simulation center with residents rotating in the pediatric emergency department. The intervention was a reference book providing weight-based precalculated doses. The control group used a card providing milligram-per-kilogram doses. The primary outcome was the presence of a prescribing error, defined as a dose varying by \(\geq 20\%\) from the recommended dose or by incorrect route. Residents were involved in 2 sets of paired scenarios and were their own control group. Primary analysis was the difference in mean prescribing error proportions between both groups.

RESULTS: Forty residents prescribed 1507 medications or defibrillations during 160 scenarios. The numbers of prescribing errors per 100 bolus medications or defibrillations were 5.1 (39 out of 762) and 7.5 (56 out of 745) for the intervention and control, respectively, a difference of 2.4 (95\% confidence interval [CI], −0.1 to 5.0). However, the intervention was highly associated with lower risk of 10-fold error for bolus medications (odds ratio 0.27; 95\% CI, 0.10 to 0.70). For medications administered by infusion, prescribing errors occurred in 3 out of 76 (4\%) scenarios in the intervention group and 13 out of 76 (22.4\%) in the control group, a difference of 13\% (95\% CI, 3 to 23).

CONCLUSIONS: A clinical aid providing precalculated medication doses was not associated with a decrease in overall prescribing error rates but was highly associated with a lower risk of 10-fold error for bolus medications and for medications administered by continuous infusion.

WHAT'S KNOWN ON THIS SUBJECT: Medication errors are common in children. Characteristics of errors during critical situations in the emergency department are ill defined and might be more common than previously thought. However, optimal strategies to eliminate the risk of prescribing errors remain unknown.

WHAT THIS STUDY ADDS: We found that calculating medication doses in critically ill children introduces an unjustifiable risk of committing harmful prescribing errors. Precalculated doses for commonly used medications during emergency situations should be readily accessible for professionals caring for critically ill children.

Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-3200

Dr Larose conceptualized and designed the study, designed the data collection instruments, coordinated and supervised data collection, was in charge of the simulation sessions, and drafted the initial manuscript; Dr Levy conceptualized and designed the study, designed the data collection instruments, coordinated and supervised data collection, and was in charge of the simulation sessions; Dr Bailey and Mr Lebel conceptualized and designed the study; Dr Cummins-McManus conceptualized and designed the study and was in charge of the simulation sessions; Dr Gravel conceptualized and designed the study, designed the data collection instruments, coordinated and supervised data collection, and carried out the initial analyses and statistical analysis, and all authors reviewed, revised, and approved the final manuscript as submitted.

This trial has been registered at www.clinicaltrials.gov (identifier NCT02563912).

DOI: 10.1542/peds.2016-3200
Socioeconomic Attainment of Extremely Low Birth Weight Survivors: The Role of Early Cognition

Kathleen G. Dobson, MSc, a Mark A. Ferro, PhD, b Michael H. Boyle, PhD, c Louis A. Schmidt, PhD, d Saroj Saigal, MD, FRCP (C), e Ryan J. Van Lieshout, MD, PhD, FRCP(C) f

OBJECTIVES: To determine: (1) if childhood cognitive and academic abilities mediate the association between being born at extremely low birth weight (ELBW) and socioeconomic attainment at age 29 to 36 years; (2) which cognitive abilities (IQ, verbal abilities, fluid intelligence, mathematical abilities, or academic achievement) most strongly mediate this association; and (3) if the mediating role of cognition is different in ELBW survivors with significant neurosensory impairment (NSI).

METHODS: A prospective, longitudinal cohort of 100 Canadian ELBW survivors born between 1977 and 1982 and 89 normal birth weight comparison participants were used to examine the mediating role of childhood cognition by using 5 cognitive mediators assessed at age 8 years (overall IQ, verbal IQ, performance IQ, quantitative ability, and academic achievement) on socioeconomic attainment at adulthood. Socioeconomic attainment was defined as personal annual earnings and full-time employment assessed via self-report at age 29 to 36 years.

RESULTS: Mediation models revealed that childhood cognition mediated the association between ELBW status and income attainment, with mathematical abilities and overall IQ each accounting for 26% of the direct effect. Mediated effects were not statistically significant in full-time employment models. For both outcomes, the mediating effect of cognition was stronger for ELBW survivors with NSI.

CONCLUSIONS: Childhood cognitive abilities partially mediate associations between ELBW status and adult income attainment. Early life cognition is a critical predictor of socioeconomic attainment in ELBW survivors, particularly in those born with NSI. Interventions aimed at enhancing early cognition in ELBW survivors may help optimize their later socioeconomic attainment.
Perspectives of Low Socioeconomic Status Mothers of Premature Infants

Elizabeth Enlow, MD, MSHP,a,b,c Laura J. Faherty, MD, MPH, MSHP,c,d Sara Wallace-Keeshen, BSN, RN,e Ashley E Martin, MPH, Ashley J. Shea, PhD,e,f Scott A. Lorch, MD, MSCE,a,b,c

BACKGROUND AND OBJECTIVES: Transitioning premature infants from the NICU to home is a high-risk period with potential for compromised care. Parental stress is high, and families of low socioeconomic status may face additional challenges. Home visiting programs have been used to help this transition, with mixed success. We sought to understand the experiences of at-risk families during this transition to inform interventions.

METHODS: Mothers of infants born at <35 weeks’ gestation, meeting low socioeconomic status criteria, were interviewed by telephone 30 days after discharge to assess caregiver experiences of discharge and perceptions of home visitors (HVs). We generated salient themes by using grounded theory and the constant comparative method. Interviews were conducted until thematic saturation was achieved.

RESULTS: Twenty-seven mothers completed interviews. Eighty-five percent were black, and 81% had Medicaid insurance. Concern about infants’ health and fragility was the primary theme identified, with mothers reporting substantial stress going from a highly monitored NICU to an unmonitored home. Issues with trust and informational consistency were mentioned frequently and could threaten mothers’ willingness to engage with providers. Strong family networks and determination compensated for limited economic resources, although many felt isolated. Mothers appreciated HVs’ ability to address infant health but preferred nurses over lay health workers.

CONCLUSIONS: Low-income mothers experience significant anxiety about the transition from the NICU to home. Families value HVs who are trustworthy and have relevant medical knowledge about prematurity. Interventions to improve transition would benefit by incorporating parental input and facilitating trust and consistency in communication.

WHAT’S KNOWN ON THIS SUBJECT: Discharge from the NICU to home is a time of high parental stress. Interventions to improve the transition have had limited effectiveness. Direct parent input, particularly from those of low socioeconomic status, is often missing when these programs are designed.

WHAT THIS STUDY ADDS: Low socioeconomic status mothers of premature infants worry most about their infant’s health and perceived fragility. Trust and informational consistency are highly valued. During the transition from NICU to home, mothers value services that provide reassurance about infant well-being.
Daptomycin for Complicated Skin Infections: A Randomized Trial

John Bradley, MD, a, b Chad Glasser, PharmD, c Hernando Patino, MD, c Sandra R. Arnold, MD, d Antonio Arrieta, MD, e Blaise Congeni, MD, f Robert S. Daum, MD, g Tsoline Kojaghlilian, MD, h Minjung Yoon, MPH, c Diane Anastasiou, BS, c Dominik J. Wolf, MSc, c Paula Bokesch, MD c

abstract

BACKGROUND: Complicated skin and skin structure infections (cSSSI) are common in children. Due to safety and resistance issues with recommended agents, new treatment options would be advantageous.

METHODS: Multicenter, evaluator-blinded clinical trial. Patients 1 to 17 years old with cSSSI caused by Gram-positive pathogens were randomized 2:1 to intravenous daptomycin or standard-of-care (SOC) treatment for ≤ 14 days. Daptomycin was administered once daily with dosing by patient age: 12 to 17 years, 5 mg/kg; 7 to 11 years, 7 mg/kg; 2 to 6 years, 9 mg/kg; 12 to 23 months, 10 mg/kg. The primary objective was to evaluate daptomycin safety. The secondary objective was to assess the efficacy of daptomycin compared with SOC. The intent-to-treat (ITT) population consisted of all randomized patients with any dose of study drug.

RESULTS: The ITT population comprised 257 daptomycin and 132 SOC patients (primarily clindamycin or vancomycin); 35% had confirmed methicillin-resistant Staphylococcus aureus. The most common adverse events were diarrhea (7% daptomycin, 5% SOC) and increased creatine phosphokinase (6% daptomycin, 5% SOC). The proportions of safety population patients with treatment-related adverse events were similar between the daptomycin (14%) and SOC (17%) groups. Clinical success rates (blinded evaluator-assessed complete/partial resolution of cSSSI signs and symptoms 7–14 days after end-of-treatment) in the ITT population were also similar for the daptomycin (91%) and SOC groups.

CONCLUSIONS: Once-daily daptomycin was well tolerated, with safety and efficacy comparable to SOC in children/adolescents with cSSSI caused by Gram-positive pathogens, including community-acquired methicillin-resistant S aureus.

WHAT’S KNOWN ON THIS SUBJECT: Complicated skin and skin structure infections (cSSSI) caused by community-acquired methicillin-resistant Staphylococcus aureus are common in children. Available treatments (eg, vancomycin, clindamycin, and linezolid) can have important drawbacks, stressing the need for safer, uniformly active, and effective alternatives.

WHAT THIS STUDY ADDS: This randomized, controlled trial evaluating daptomycin for cSSSI in children documents that daptomycin was well tolerated in pediatric patients with Gram-positive cSSSI, with efficacy comparable to standard-of-care therapy (the trial was not powered to confirm noninferiority).


Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-2477

*Division of Infectious Diseases, Department of Pediatrics, University of California San Diego, San Diego, California; aRady Children’s Hospital, San Diego, California; bMerck & Co, Inc, Kenilworth, New Jersey; cUniversity of Tennessee Health Science Center, Le Bonheur Children’s Hospital, Memphis, Tennessee; dChildren’s Hospital of Orange County, Orange, California; eAkon Children’s Hospital, Akron, Ohio; fMRSA Research Center, Department of Pediatrics, University of Chicago, Chicago, Illinois; and gChildren’s Hospital at Montefiore, Bronx, New York

Dr Glasser’s current affiliation is Acceleron Pharma, Cambridge, MA.

Dr Patino’s current affiliation is Janssen Research & Development, Raritan, NJ.

Dr Bradley contributed to the study design, enrolled patients into the clinical trial, was involved in interpretation of the data, was involved in developing the first draft of this manuscript, and revised subsequent drafts based on coauthor comments; Dr Glasser was involved in data analysis, was involved in interpretation of the data, was involved in developing the first draft of the manuscript, and revised subsequent drafts based on coauthor comments; Dr Patino and Ms Yoon contributed to study design, were involved in data analysis, and were involved in interpretation of the data, (continued)

Lara J. Akinbami, MD, a, b Brian K. Kit, MD, MPH, a, b Margaret D. Carroll, MSPH, a Tala H.I. Fakhouri, PhD, MPH, a Cynthia L. Ogden, PhD a

BACKGROUND AND OBJECTIVES: The surveillance of children’s growth reflects a population’s nutritional status and risk for adverse outcomes. This study aimed to describe trends in length-for-age, weight-for-age, weight-for-length, and early childhood weight gain among US children aged 6 to 23 months.


RESULTS: In 2011–2014, the prevalence of low and high length-for-age was 3.3% (SE, 0.8) and 3.7% (SE, 0.8); weight-for-age was 0.6% (SE, 0.3) and 7.0% (SE, 1.1); and weight-for-length was 1.0% (SE, 0.4) and 7.7% (SE, 1.2). The only significant trend was a decrease in high length-for-age (5.5% in 1976–1980 vs 3.7% in 2011–2014; P = .04). Relative weight gain between birth and survey participation did not differ over time, although trends differed by race/Hispanic origin. Non-Hispanic black children gained more weight between birth and survey participation in 2011–2014 versus 1988–1994, versus no change among other groups.

CONCLUSIONS: Between 1976–1980 and 2011–2014, there were no significant trends in low or high weight-for-age and weight-for-length among 6- to 23-month-old children whereas the percent with high length-for-age decreased. A significant trend in relative weight gain between birth and survey participation was observed among non-Hispanic black children.
Hearing Loss in Children With Asymptomatic Congenital Cytomegalovirus Infection

Tatiana M. Lanzieri, MD, MPH,a Winnie Chung, AuD,b Marily Flores, MS,c Peggy Blum, AuD,a A. Chantal Caviness, MD, MPH, PhD,c Stephanie R. Bialek, MD, MPH,a Scott D. Grosse, PhD,b Jerry A. Miller, PhD,c,e Gail Demmler-Harrison, MD,c,d Congenital Cytomegalovirus Longitudinal Study Group

abstract

OBJECTIVES: To assess the prevalence, characteristics, and risk of sensorineural hearing loss (SNHL) in children with congenital cytomegalovirus infection identified through hospital-based newborn screening who were asymptomatic at birth compared with uninfected children.

METHODS: We included 92 case-patients and 51 controls assessed by using auditory brainstem response and behavioral audiometry. We used Kaplan–Meier survival analysis to estimate the prevalence of SNHL, defined as ≥25 dB hearing level at any frequency and Cox proportional hazards regression analyses to compare SNHL risk between groups.

RESULTS: At age 18 years, SNHL prevalence was 25% (95% confidence interval [CI]: 17%–36%) among case-patients and 8% (95% CI: 3%–22%) in controls (hazard ratio [HR]: 4.0; 95% CI: 1.2–14.5; P = .02). Among children without SNHL by age 5 years, the risk of delayed-onset SNHL was not significantly greater for case-patients than for controls (HR: 1.6; 95% CI: 0.4–6.1; P = .5). Among case-patients, the risk of delayed-onset SNHL was significantly greater among those with unilateral congenital/early-onset hearing loss than those without (HR: 6.9; 95% CI: 2.5–19.1; P < .01). The prevalence of severe to profound bilateral SNHL among case-patients was 2% (95% CI: 1%–9%).

CONCLUSIONS: Delayed-onset and progression of SNHL among children with asymptomatic congenital cytomegalovirus infection continued to occur throughout adolescence. However, the risk of developing SNHL after age 5 years among case-patients was not different than in uninfected children. Overall, 2% of case-patients developed SNHL that was severe enough for them to be candidates for cochlear implantation.

WHAT’S KNOWN ON THIS SUBJECT:
The extent to which children with congenital cytomegalovirus infection who are asymptomatic at birth remain at risk for delayed-onset and progressive sensorineural hearing loss throughout childhood is not well established.

WHAT THIS STUDY ADDS:
An estimated 2% of children with asymptomatic congenital cytomegalovirus infection develop severe enough sensorineural hearing loss to meet cochlear implantation candidacy, but their risk of developing hearing loss after age 5 years is not significantly increased compared to uninfected children.


Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-2610

*National Center for Immunization and Respiratory Diseases, and 1National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, Atlanta, Georgia; 2Department of Pediatrics, Baylor College of Medicine, Houston, Texas; 3Texas Children’s Hospital, Houston, Texas; and 4FSS Corporation, San Antonio, Texas

Dr Lanzieri conceptualized and conducted the analysis contained in this report, interpreted the data, and led the writing of the initial manuscript and revised versions; Dr Chung conceptualized the analysis contained in this report, reviewed and interpreted individual audiological data, and critically revised the manuscript; Ms Flores and Dr Miller assisted with data management and quality control for the Longitudinal Congenital CMV Study and critically revised the manuscript; Dr Blum conceptualized and provided audiological follow-up in the Longitudinal Congenital CMV Study and critically revised the manuscript; Dr Caviness was the co-principal investigator for the Longitudinal Congenital CMV Study and critically revised the manuscript; Drs Bialek and Grosse conceptualized the analysis contained in this report, interpreted the data, and critically revised the manuscript; (continued)
Parental Health Literacy and Outcomes of Childhood Nephrotic Syndrome

Karlota Borges, HBSc,a Cathryn Sibbald, MD,b Neesha Hussain-Shamsy, MHS,a Jovanka Vasilevska-Ristovska, MD,a Tonny Banh, HBSc,a Viral Patel, MSc,a Josefina Brooke, BScN,a Monica Piekut, BScN,b Michele Reddon,c Kimerry Aitken-Menezes, BScN,b Ashley McNaughton, BScN,a Rachel J. Pearl, MD,a,c,d Valerie Langlois, MD,a,c Seetha Radhakrishnan, MD,f Christoph P.B. Licht, MD,a,c,d Tino D. Piscione, MD, PhD,a,c,d Leo Levin, MD,b Damien Noone, MB Ch BAO, MSc,a,c,d Diane Hebert, MD,a,c,d Rulan S. Parekh, MD,a,c,d,e

OBJECTIVE: Determine the association of parental health literacy with treatment response among children with nephrotic syndrome.

METHODS: This was a cohort study of children aged 1–18 with nephrotic syndrome and their parent. Health literacy was measured using the validated Short Test of Functional Health Literacy in Adults assessing reading comprehension and numeracy. Outcomes included initial relapse-free period, frequently relapsing disease, relapse rate, second-line medication use, and complete remission after therapy.

RESULTS: Of 190 parents, 80% had adequate health literacy (score >67 of 100), and higher scores were not correlated with higher education. Almost all achieved perfect numeracy scores (>86%); numeracy was not associated with outcomes. After adjusting for immigration, education, and income, higher reading comprehension scores (tertile 3) compared with lower scores (tertile 1) were significantly associated with lower risk of first relapse (hazard ratio 0.67, 95% confidence interval [CI] 0.48–0.94, P trend = .02), lower odds of frequently relapsing disease (odds ratio [OR] 0.38, 95% CI 0.21–0.70, P trend = .002), lower relapse rate (rate ratio 0.77, 95% CI 0.73–0.80, P trend < .001), and higher odds of complete remission after both initial steroids and cyclophosphamide (OR 2.07, 95% CI 1.36–3.16, P trend = .003; OR 5.97, 95% CI 2.42–14.7, P trend < .001).

CONCLUSIONS: Lower parental health literacy, specifically reading comprehension, is associated with higher relapse rates among children with nephrotic syndrome and fewer achieving complete remission. This underscores the importance of assessing and targeting health literacy for chronic management of childhood-onset diseases.

WHAT’S KNOWN ON THIS SUBJECT: Low health literacy is associated with poor outcomes in chronic diseases. The association between parental health literacy and longitudinal outcomes in a pediatric chronic disease has not been studied.

WHAT THIS STUDY ADDS: We demonstrate that poor parental health literacy is associated with more relapses among children with nephrotic syndrome and fewer achieving complete remission. Health professionals should seek to identify parents who may benefit from more focused teaching.

Ms Borges and Dr Sibbald collected data, carried out the analyses, and drafted the initial manuscript; Ms Hussain-Shamsy and Ms Vasilevska-Ristovska designed the data collection instruments, coordinated the study, recruited patients for the study, and reviewed and revised the manuscript; Mr Banh and Mr Patel recruited patients for the study, contributed to analyses, and reviewed and revised the manuscript; Ms Brooke, Ms Piekut, Ms Reddon, Ms Aitken-Menezes, and Ms McNaughton and Drs Pearl, Langlois, Radhakrishnan, Licht, Piscione, Levin, Noone, and Hebert contributed to the conception and design of the study and reviewed and revised the manuscript; Dr Parekh conceptualized and designed the study, reviewed and revised the analysis, and manuscript, and all authors approved the final manuscript as submitted.

Some of the data in this article were presented as a poster presentation at the 2015 Pediatric Academic Societies Annual Meeting, April 25–28, 2015, San Diego, CA.

Pediatric Resident Burnout and Attitudes Toward Patients
Tamara Elizabeth Baer, MD, MPH,a, b Angela M. Feraco, MD, MMSc, b, c, d Selin Tuysuzoğlu Sagalowsky, MD, MPH, e David Williams, PhD, f Heather J. Litman, PhD, f Robert J. Vinci, MD h

abstract

BACKGROUND AND OBJECTIVES: Burnout occurs in up to 75% of resident physicians. Our study objectives were to: (1) determine the prevalence of burnout, and (2) examine the association between burnout and self-reported patient care attitudes and behaviors among pediatric residents.

METHODS: A total of 258 residents (53% response rate) from 11 pediatric residency programs completed a cross-sectional Web-based survey. Burnout was measured with 2 items from the Maslach Burnout Inventory. Patient care attitudes and behaviors were measured with 7 questions from a standardized qualitative survey. \( \chi^2 \) and logistic regression tested the association between burnout and self-reported patient care attitudes and behavior.

RESULTS: A total of 39% of respondents (mean age, 29.4 years ± 2.3 SD; 79% female; 83% white; 35% postgraduate year [PGY] -1, 34% PGY-2, and 31% PGY-3), endorsed burnout. Residents with burnout had significantly greater odds \(( P < .01)\) of reporting suboptimal patient care attitudes and behaviors, including: discharging patients to make the service more manageable (adjusted odds ratio [aOR] 4.2; 95% confidence interval [CI], 1.6–11.1), not fully discussing treatment options or answering questions (aOR 3.5; 95% CI, 1.7–7.1), making treatment or medication errors (aOR 7.1; 95% CI, 2.0–25.8), ignoring the social or personal impact of an illness (aOR 9.6; 95% CI, 3.2–28.9), and feeling guilty about how a patient was treated (aOR 6.0; 95% CI, 1.6–22.1).

CONCLUSIONS: Burnout is highly prevalent among pediatric residents and is associated with self-reported negative patient care attitudes and behaviors. Residency programs should develop interventions addressing burnout and its potential negative impact on patient care.

WHAT’S KNOWN ON THIS SUBJECT: Burnout occurs in up to 75% of resident physicians and has been shown to negatively impact medical knowledge, care quality, and professional conduct among internal medicine residents. Less is known about the impact of burnout among pediatric residents.

WHAT THIS STUDY ADDS: Burnout is highly prevalent among pediatric residents across multiple programs. The self-reported negative patient care attitudes and behaviors that are associated with burnout suggest more careful approaches to improve the work environment of residency programs.

Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-2163

Divisions of aAdolescent/Young Adult Medicine, cHematology/Oncology, and fClinical Research Center, Boston Children’s Hospital, Boston, Massachusetts; bDepartment of Medicine, Harvard Medical School, Boston, Massachusetts; dDepartment of Oncology, Dana-Farber Cancer Institute, Boston, Massachusetts; eDivision of Emergency Medicine, Department of Pediatrics, Columbia University College of Physicians and Surgeons, New York, New York; gDivision of Biostatistics and Epidemiology, Corrona, LLC, Southborough, Massachusetts; and hDepartment of Pediatrics, Boston Medical Center, Boston University School of Medicine, Boston, Massachusetts

Dr Baer was responsible for study design, design of data collection instruments, data collection, performed the literature review, conceptualized and designed the data analysis, and wrote the first draft of the paper; Dr Feraco was responsible for study design, design of data collection instruments, data collection, conceptualized and designed the data analysis, made substantial contributions to data analysis and interpretation, and reviewed and revised the manuscript; Dr Tuysuzoğlu Sagalowsky was responsible for study design, design of data collection instruments, conceptualized and designed the data analysis, and reviewed and revised the manuscript; Drs Litman and Williams were responsible for data analysis and reviewed and revised the manuscript; Dr Vinci was responsible for study design and design of study collection instruments, data collection, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

Burnout in Pediatric Residents and Physicians: A Call to Action

John D. Mahan, MD

The evidence is growing that burnout in trainees, as well as in practicing physicians, comes at a cost to the physicians, those they interact with at home and work, and their patients. In their article in this issue entitled "Pediatric Resident Burnout and Attitudes Toward Patients," Baer et al surveyed pediatric residents at 11 programs in New England to better understand the pathogenesis of burnout in these trainees; the goal was to assist in efforts to develop effective measures to prevent and/or address these maladaptive responses.

It is unsurprising to those who work with trainees that 101 of 258 pediatric residents reported being "burned-out." In fact, many studies show higher rates of burnout in pediatric trainees (40%–75%) depending on site and year of training. In the study by Baer et al., there were no significant differences in burnout rates according to sex, race/ethnicity, and relationship or parental status; younger residents (<30 years of age) were slightly less likely to report burnout than older residents. Residency factors (year of training, program size and location, current rotation schedule, and hours worked in past week) were not associated with burnout. Sleep deprivation did correlate with burnout. Both perceived sleep deprivation and burnout were independent risk factors that predicted poorer self-reported quality of patient care (eg, discharging patients to make the service more manageable, making treatment or medication errors, feeling guilty about how a patient was treated).

THE CONSEQUENCES OF BURNOUT

Burnout is all too common in trainees and practitioners, as well as in all members of the health care team. Burnout in physicians is associated with the following: (1) higher levels of job dissatisfaction and shorter job tenure; (2) more reported medical errors, negative attitudes toward patients, and patient dissatisfaction; and (3) on a personal level, more failed relationships, depression, alcohol abuse, and suicidal ideation. For the physician in training, the personal effects are sobering, including greater rates of neglect of family commitments, dysfunctional relationships, mental health disorders, and self-harm behaviors. Moreover, burnout in physicians is associated with more disruptive behaviors, as well as poorer staff relationships and performance in the workplace.

A particular issue for pediatric trainees and pediatricians is that many especially valued traits, such as compassion, altruism, and perfectionism, also predispose to burnout when clinicians are pushed to mental or physical extremes. Burnout can also be regarded as a byproduct of the culture of medicine, exemplified by an educational system and profession that reward self-denial, persistence, and expert performance under trying conditions, driving learners to perfect clinical abilities with far less attention to the personal-social, leadership, and teamwork skills necessary to achieve success in our complex systems.
THE CALL FOR BETTER SYSTEMS, PERSONAL-SOCIAL SKILLS DEVELOPMENT, AND PERSPECTIVES

These consequences of burnout are not unique to medicine and have been described in many contemporary workplaces related to the increasingly complex tasks and “production facility” mindset that characterize much of modern work. Burnout and its downstream effects must be seen as both a systems issue and an individual issue. Systems issues, such as diminished physician and trainee sense of control, electronic health record burdens, misaligned social and financial rewards, and disengagement of trainees and physicians from workplace governance, are certainly problematic. Thoughtful efforts to address organizational issues with detailed methods that focus on the mismatch between the individual and the work must be part of the solution.10

Ideally, these systems approaches are complemented by person-centered, developmental methods to prevent and/or reduce burnout by building effective self-care skills, social support, and individual resilience in trainees and physicians. We are particularly encouraged with the attention now given to educational programs designed to develop resilience, empathy, self-compassion, and mindfulness. These efforts include: mindfulness training, presented through workshops11 and/or online modules12; CREW (Civility, Respect, and Engagement at Work) training to develop better civility and communication and to mitigate burnout in the workplace13; and comprehensive wellness curricula such as the University of Arizona’s Pediatric Integrative Medicine in Residency Curriculum14 and the American Academy of Pediatrics’ Resilience in the Face of Grief and Loss Resident Curriculum that focus on developing important cognitive and emotional skills of pediatric trainees to help them provide high-quality care while fostering their personal wellness and resilience.15

The Pediatric Residency Burnout–Resilience Study Consortium (www.pedsresresilience.com) was recently formed to provide an innovative research platform to address burnout and promote resilience in a contemporary cohort of pediatric trainees in 41 programs in the United States committed to this work. Burnout is a serious problem with significant effects on pediatric trainees, colleagues, and patients. The problem is clear; the “Call to Action” is for our community to do the hard work to address systems factors and facilitate residents to develop the personal-social skills necessary for resilience in the face of the myriad stresses and difficult outcomes they will inevitably face. Lastly, these efforts will be most effective for trainees and physicians who retain the joy, passion, and purpose of the calling that is pediatrics.16 Modeling and encouraging this appreciation of our work should remain a high priority for all of us who care for our patients and our profession.

REFERENCES

Efficacy and Safety of Nonoperative Treatment for Acute Appendicitis: A Meta-analysis

Roxani Georgiou, MRCS, Simon Eaton, PhD, Michael P. Stanton, MD, Agostino Pierro, FRCS, Nigel J. Hall, PhD

**CONTEXT:** Nonoperative treatment (NOT) with antibiotics alone of acute uncomplicated appendicitis (AUA) in children has been proposed as an alternative to appendectomy.

**OBJECTIVE:** To determine safety and efficacy of NOT based on current literature.

**DATA SOURCES:** Three electronic databases.

**STUDY SELECTION:** All articles reporting NOT for AUA in children.

**DATA EXTRACTION:** Two reviewers independently verified study inclusion and extracted data.

**RESULTS:** Ten articles reporting 413 children receiving NOT were included. Six, including 1 randomized controlled trial, compared NOT with appendectomy. The remaining 4 reported outcomes of children receiving NOT without a comparison group. NOT was effective as the initial treatment in 97% of children (95% confidence interval [CI] 96% to 99%). Initial length of hospital stay was shorter in children treated with appendectomy compared with NOT (mean difference 0.5 days [95% CI 0.2 to 0.8]; \(P = .002\)). At final reported follow-up (range 8 weeks to 4 years), NOT remained effective (no appendectomy performed) in 79% of children (95% CI 73% to 86%). Recurrent appendicitis occurred in 14% (95% CI 7% to 21%). Complications and total length of hospital stay during follow-up were similar for NOT and appendectomy. No serious adverse events related to NOT were reported.

**LIMITATIONS:** The lack of prospective randomized studies limits definitive conclusions to influence clinical practice.

**CONCLUSIONS:** Current data suggest that NOT is safe. It appears effective as initial treatment in 97% of children with AUA, and the rate of recurrent appendicitis is 14%. Longer-term clinical outcomes and cost-effectiveness of NOT compared with appendicectomy require further evaluation, preferably in large randomized trials, to reliably inform decision-making.

Dr Georgiou performed the systematic review and data extraction, performed the analysis, and wrote the draft of the manuscript; Dr Eaton designed the study, performed the systematic review and data extraction, performed the analysis, and revised the manuscript; Dr Stanton designed the study, performed the analysis, and revised the manuscript; Dr Pierro conceived and designed the study and revised the manuscript; Dr Hall conceived and designed the study, performed the systematic review and data extraction, performed the analysis, and wrote the draft of the manuscript; and all authors approved the final manuscript submitted.

This trial has been registered with the PROSPERO International prospective register of systematic reviews (registration CRD42015026994).

**DOI:** 10.1542/peds.2016-3003

Accepted for publication Nov 21, 2016

Inhaled Corticosteroids and Respiratory Infections in Children With Asthma: A Meta-analysis

Cristine Cazeiro, BSN, Cristina Silva, MD, Susana Mayer, MD, Vanessa Mariani, MD, Claire Elizabeth Wainwright, MBBS, MD, Linjie Zhang, MD, PhD

abstract

CONTEXT: Inhaled corticosteroids (ICS) are associated with an increased risk of pneumonia in adult patients with chronic obstructive pulmonary disease.

OBJECTIVE: To assess the association between ICS use and risk of pneumonia and other respiratory infections in children with asthma.

DATA SOURCES: We searched PubMed from inception until May 2015. We also searched clinicaltrials.gov and databases of pharmaceutical manufacturers.

STUDY SELECTION: We selected randomized trials that compared ICS with placebo for at least 4 weeks in children with asthma.

DATA EXTRACTION: We included 39 trials, of which 31 trials with 11,615 patients contributed data to meta-analyses.

RESULTS: The incidence of pneumonia was 0.58% (44/7465) in the ICS group and 1.51% (63/4150) in the placebo group. The meta-analysis of 9 trials that revealed at least 1 event of pneumonia revealed a reduced risk of pneumonia in patients taking ICS (risk ratio [RR]: 0.65; 95% confidence interval [CI]: 0.44 to 0.94). Using risk difference as effect measure, the meta-analysis including all 31 trials revealed no significant difference in the risk of pneumonia between the ICS and placebo groups (risk difference: –0.1%; 95% CI: –0.3% to 0.2%). No significant association was found between ICS and risk of pharyngitis (RR: 1.01; 95% CI: 0.87 to 1.18), otitis media (RR: 1.07; 95% CI: 0.83 to 1.37), and sinusitis (RR: 0.89; 95% CI: 0.76 to 1.05).

LIMITATIONS: Lack of clearly defined criteria for respiratory infections and possible publication bias.

CONCLUSIONS: Regular use of ICS may not increase the risk of pneumonia or other respiratory infections in children with asthma.
NICU-based Interventions To Reduce Maternal Depressive and Anxiety Symptoms: A Meta-analysis

Tamar Mendelson, PhD, a Fallon Cluxton-Keller, PhD, b Genevieve C. Vullo, MHS, c S. Darius Tandon, PhD, d Sassan Noazin, PhD e

abstract

CONTEXT: Parents whose infants are being treated in the NICU are at high risk for depression and anxiety, with negative implications for parenting and infant development.

OBJECTIVE: We conducted a systematic review and meta-analysis of NICU-based interventions to reduce maternal depressive or anxiety symptoms.

DATA SOURCES: PubMed, Embase, PsychInfo, Cochrane, and CINAHL were searched for relevant studies. Reference lists from selected studies were reviewed.

STUDY SELECTION: Inclusion criteria included randomized controlled design, a parent-focused intervention delivered in the NICU, valid maternal depressive or anxiety symptom measures at pre- and postintervention, and publication in a peer-reviewed journal in English.

DATA EXTRACTION: Data extraction was conducted independently by 2 coders.

RESULTS: Twelve studies met inclusion criteria for qualitative review; 2 were excluded from quantitative analyses for high risk of bias. Fixed- and random-effects models, with 7 eligible studies assessing depressive symptoms, indicated an effect of –0.16 (95% confidence interval [CI], –0.32 to –0.002; \( P < .05 \)) and, with 8 studies assessing anxiety symptoms, indicated an effect of –0.12 (95% CI, –0.29 to 0.05; \( P = .17 \)). The subset of interventions using cognitive behavioral therapy significantly reduced depressive symptoms (effect, –0.44; 95% CI, –0.77 to –0.11; \( P = .01 \)).

LIMITATIONS: The small number and methodological shortcomings of studies limit conclusions regarding intervention effects.

CONCLUSIONS: Combined intervention effects significantly reduced maternal depressive but not anxiety symptoms. The evidence is strongest for the impact of cognitive behavioral therapy interventions on maternal depressive symptoms.

Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-1870

Dr Mendelson conceptualized and designed the study, drafted most sections of the initial manuscript, and revised the manuscript; Dr Cluxton-Keller organized and participated in data extraction, selected the risk of bias assessment, conducted analyses, and reviewed and revised the manuscript; Ms Vullo and Dr Tandon participated in data extraction and reviewed and revised the manuscript; Dr Noazin provided guidance and oversight on the analytic strategy and interpretation of findings, conducted analyses to assess publication and other sources of bias, drafted parts of the paper related to statistical analysis, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Preterm Infant Growth Velocity Calculations: A Systematic Review

Tanis R. Fenton, PhD, RD, FDC,a Hilton T. Chan,b Aiswarya Madhu,c Ian J. Griffin, MD,d Angela Hoyos, MDe
Ekhard E. Ziegler, MD,f Sharon Groh-Wargo, PhD, RD,f Susan J. Carlson, MMSc, RD,g
Thibault Senterre, MD, PhD,h Diane Anderson, PhD, RD,i Richard A. Ehrenkranz, MDj

abstract

CONTEXT: Clinicians assess the growth of preterm infants and compare growth velocity using a variety of methods.

OBJECTIVE: We determined the numerical methods used to describe weight, length, and head circumference growth velocity in preterm infants; these methods include grams/kilogram/day (g/kg/d), grams/day (g/d), centimeters/week (cm/week), and change in z scores.

DATA SOURCES: A search was conducted in April 2015 of the Medline database by using PubMed for studies that measured growth as a main outcome in preterm neonates between birth and hospital discharge and/or 40 weeks’ postmenstrual age. English, French, German, and Spanish articles were included. The systematic review was conducted by using Preferred Reporting Items for Systematic Reviews and Meta-analyses methods.

STUDY SELECTION: Of 1543 located studies, 373 (24%) calculated growth velocity.

DATA EXTRACTION: We conducted detailed extraction of the 151 studies that reported g/kg/d weight gain velocity.

RESULTS: A variety of methods were used. The most frequently used method to calculate weight gain velocity reported in the 1543 studies was g/kg/d (40%), followed by g/d (32%); 29% reported change in z score relative to an intrauterine or growth chart. In the g/kg/d studies, 39% began g/kg/d calculations at birth/admission, 20% at the start of the study, 10% at full feedings, and 7% after birth weight regained. The kilogram denominator was not reported for 62%. Of the studies that did report the denominators, the majority used an average of the start and end weights as the denominator (36%) followed by exponential methods (23%); less frequently used denominators included birth weight (10%) and an early weight that was not birth weight (16%). Nineteen percent (67 of 355 studies) made conclusions regarding extrauterine growth restriction or postnatal growth failure. Temporal trends in head circumference growth and length gain changed from predominantly cm/wk to predominantly z scores.

LIMITATIONS AND CONCLUSIONS: The lack of standardization of methods used to calculate preterm infant growth velocity makes comparisons between studies difficult and presents an obstacle to using research results to guide clinical practice.
Minimally Important Differences in Patient or Proxy-Reported Outcome Studies Relevant to Children: A Systematic Review

Shanil Ebrahim, MSc, PhD, Kelsey Vercammen, BSc, Arunima Sivanand, BSc, Gordon H. Guyatt, MD, MSc, Alonso Carrasco-Labra, DDS, PhD, Ricardo M. Fernandes, MD, PhD, Mark W. Crawford, MD, Gihad Nesrallah, MD, MSc, Bradley C. Johnston, PhD

CONTEXT: No study has characterized and appraised all anchor-based minimally important differences (MIDs) associated with patient-reported outcome (PRO) instruments in pediatric studies.

OBJECTIVE: To complete a comprehensive systematic survey and appraisal of published anchor-based MIDs associated with PRO instruments used in children.


STUDY SELECTION: Studies reporting empirical ascertainment of anchor-based MIDs among PROs used in pediatric care.

DATA EXTRACTION: All pertinent data items related to the characteristics of PRO instruments, anchors, and MIDs.

RESULTS: Of 4179 unique citations, 30 studies (including 32 cohorts) proved eligible and reported on 28 unique PROs (8 generic, 13 disease-specific, 5 symptoms-specific, 2 function-specific), with 9 (32%) classified as patient-reported, 11 (39%) proxy-reported, and 8 (29%) both patient- and proxy-reported. Of the 30 studies, we rated 14 (44%) as providing highly credible estimates of the MID. Most cohorts (n = 20, 62%) recorded patients’ direct response to the target PRO and the use of an independent standard of comparison (n = 25, 78%). Most, however, failed to effectively report measurement properties of the anchor (n = 24, 75%).

LIMITATIONS: We have not yet addressed the measurement properties of instrument to measure credibility; our search was restricted to 3 electronic sources, and we used a single data abstractor.

CONCLUSIONS: Our study found 28 PROs that have been developed for children, with fewer than half providing credible estimates. Clinicians, clinical trialists, systematic reviewers, and guideline developers seeking to effectively summarize and interpret results of studies addressing PROs in child health are likely to find our comprehensive compendium of MIDs of use, both in providing best estimates of MIDs and identifying credible estimates.
A 17-Year-Old With Chest Pain
Ankoor Y. Shah, MD, MPH, a Megan Jamison, MD, b Hansel J. Otero, MD, a Lawrence Jung, MD, a Lowell H. Frank, MD, a Michael F. Guerrera, MD, a A. Yasmine Kirkorian, MD a

Two 17-year-old male subjects with a history of deep venous thrombosis (DVT) presented with acute unilateral severe chest pain. Their examination was nonspecific, and vital signs were normal. Their initial laboratory evaluation revealed mild thrombocytopenia, elevated troponin levels, and critically elevated activated partial thromboplastin time. A computed tomography angiogram of the chest revealed a pulmonary embolus, and anticoagulation therapy was initiated. Their course was complicated by the development of multiple thrombi and respiratory failure. Extensive evaluation revealed a rare, underlying diagnosis in time for life-saving treatment to be initiated.

abstract

A 17-year-old male subject with a history of deep venous thrombosis presented with acute unilateral severe chest pain. His examination was nonspecific, and vital signs were normal. His initial laboratory evaluation revealed mild thrombocytopenia, elevated troponin levels, and critically elevated activated partial thromboplastin time. A computed tomography angiogram of the chest revealed a pulmonary embolus, and anticoagulation therapy was initiated. His course was complicated by the development of multiple thrombi and respiratory failure. Extensive evaluation revealed a rare, underlying diagnosis in time for life-saving treatment to be initiated.

CASE HISTORY WITH SUBSPECIALTY INPUT

Ankoor Y. Shah, MD, MPH (Pediatrics, Chief Resident)

A 17-year-old male subject with a history of 2 previous deep vein thromboses (DVTs) presented to a community hospital with rightsided pleuritic chest pain. His initial left lower extremity DVT had been diagnosed 7 months earlier and was treated with rivaroxaban. After discontinuation of anticoagulation therapy, 2 weeks before admission he was diagnosed with a new left lower extremity DVT, and rivaroxaban was restarted. At the community hospital, a right-sided pulmonary embolism (PE) was diagnosed by using a computed tomography (CT) angiogram. Upon transfer to Children’s National Health System, the patient’s respiratory rate was increased, and his heart rate was at the upper limit of normal. His vital signs were otherwise stable (temperature, 37.5°C; blood pressure, 114/79 mm Hg; heart rate, 97 beats per min; respiratory rate, 22 breaths/ min; oxygen saturation, 98% on room air). On physical examination, he had diffuse right-sided chest and nonspecific back pain. His cardiac examination consisted of a regular rhythm, normal S1 and S2, no murmurs or gallops, as well as distal pulses equal in all 4 extremities with no pulsat paradoxus. His lungs were clear to auscultation, with no wheezes or crackles. He had good aeration with minimally increased work of breathing. Chest pain worsened during inspiration, representing a pleuritic pain. The remainder of the patient’s examination was within normal limits as well.

The initial evaluation from the community hospital revealed mild thrombocytopenia with a normal white blood cell count and hemoglobin (Table 1). Hematologic testing revealed elevated prothrombin time and highly elevated activated partial thromboplastin time (aPTT), which are nonspecific in the setting of ongoing rivaroxaban therapy. His D-dimer level was normal at 448 ng/mL.

Dr Frank, the troponin I value was 0.34 ng/mL; is that concerning to you?

Lowell Frank, MD (Pediatric Cardiology)

I am glad you brought this finding up because at the most literal level, an elevated troponin I value simply means there is damage to cardiac muscle. An elevated troponin I

level is not specific to pulmonary emboli in general or to the right ventricle specifically. Troponin elevation in acute PE can result from microinfarctions due to alterations in oxygen supply and demand of the right ventricle. In addition, troponin I elevation has been associated with increased segmental defects in ventilation/perfusion lung scans and may thus be sensitive to minor myocardial damage. Secondly, the value of 0.34 ng/mL, although flagged as abnormal, is not significantly high and not particularly concerning.

In the context of an adolescent patient with chest pain, troponin I can be a confounding test. Recent studies have found little diagnostic value of troponin measurements in pediatric patients presenting with chest pain, as well as little prognostic value for patients with additional symptoms of fever and electrocardiogram (ECG) changes who are subsequently diagnosed with myopericarditis. There are no data available in children regarding the correlation between elevated troponin levels and prognosis, but it has been found to correlate in adults.

**Dr Shah**

What should a cardiac evaluation consist of for this patient?

**Dr Frank**

In this case, in which a PE was already confirmed, the cardiac evaluation should first focus on addressing the hemodynamic stability of the patient and secondarily on assessing right ventricular function. Additional consideration could be given to ordering diagnostic testing that might inform prognosis. The clinical presentation of this patient, with normal vital signs and an overall stable appearance, is the first critical element of the cardiac evaluation. For right ventricular function, a relatively quick and often readily available method of assessment would be an echocardiogram. Although echocardiography has its pitfalls when assessing the right ventricle (compared with the left ventricle), it can provide a good qualitative assessment of right ventricular size and function, as well as usually providing a quantitative assessment of the right ventricular pressure.

Depending on the resources readily available, an ECG may be a reasonable adjunct test but is unlikely to influence acute clinical management with this particular clinical presentation. ECG changes can be associated with a poor outcome in patients with PE, however, recent European Society of Cardiology guidelines did not include ECG in the various tools assessed for prognostic value, perhaps suggesting that despite its availability and low cost that there are better tests available. For a pulmonary embolus, you often think of the “classic” S1Q3T3 pattern on ECG; that is, a deep S wave in lead I, a Q wave in lead III, and an inverted T wave in lead III. However, this finding is neither sensitive nor specific for a pulmonary embolus. Furthermore, despite all the ECG patterns that can suggest right ventricular involvement, the most common finding remains sinus tachycardia, and even that is not particularly sensitive (certainly not specific), with some studies showing no significant differences in the rate of tachycardia between patients with confirmed PE and those without. Therefore, I believe an echocardiogram has more utility in this patient than an ECG.

**Dr Shah**

In this case, an echocardiogram was obtained, with no concerning findings and no evidence of right ventricular dysfunction. Specifically, there was no evidence of a large saddle embolus, total or subtotal occlusion of a branch pulmonary artery, right ventricular dilation, right ventricular systolic dysfunction, or elevated right ventricular pressure.

The patient was admitted to the PICU for pain control and enoxaparin therapy. Dr Guerrera, when would you consider starting an evaluation for an underlying coagulation anomaly?

**Michael F. Guerrera, MD (Pediatric Hematology)**

There is debate among hematologists on whether to evaluate all patients with thrombosis or to evaluate only a select group. We believe that all pediatric patients should have a thrombophilia evaluation with their first thrombosis, especially if it was unprovoked, arterial, involved the central nervous system, or if the patient has a family history of thrombosis. For this patient, we would have recommended thrombophilia testing, with his first DVT 7 months before presentation. Our routine thrombophilia evaluation includes assessment of protein C function, protein S function,
antithrombin level, factor V Leiden, activated protein C resistance, prothrombin gene mutation, factor VIII level, homocysteine, lipoprotein(a), and antiphospholipid antibody testing (which includes lupus anticoagulants, anticardiolipin antibody panel, and β2-glycoprotein-I panel).

**Dr Shah**

During this hospitalization, the patient was diagnosed with an additional occlusive thrombus in the right popliteal vein. Because he remained hemodynamically stable and his thrombus was small and distal, thrombolytic agents were not pursued, and enoxaparin was started. He was eventually discharged on enoxaparin with the plan to switch to warfarin as an outpatient. The thrombophilia evaluation Dr Guerrera recommended was pending at the time of discharge. However, 2 days after discharge, the patient was readmitted to the PICU with severe right-sided chest pain and respiratory distress. The chest pain was caused by a new right pleural effusion, which was treated with placement of a chest tube. The pulmonary CT scan that confirmed the pleural effusion also noted a stable right-sided PE. Although the PE was stable on imaging, the presence of a pleural effusion suggested worsening of his PE, possibly due to microinfarctions resulting in the pleural effusion. During his PICU admission, the patient was started on a heparin drip that was eventually transitioned to enoxaparin, and he was transferred to the general pediatrics ward. After transfer, he continued to have an elevated aPTT. Given this persistent elevation, is there utility in a mixing study for this patient?

**Dr Guerrera**

A mixing study is a useful first test when dealing with an abnormal coagulation screen. Baseline prothrombin time and aPTT should be obtained in all patients before initiating anticoagulation therapy to confirm that the patient does not have an existing coagulopathy and to quickly screen for a potential antiphospholipid antibody. A mixing study involves taking 1 part patient plasma and adding equal part normal pooled plasma (1:1). If the patient has a factor deficiency, the mixing study should correct because factors from the normal pooled plasma can make up for the absent factors in the patient’s plasma. If the patient has a circulating inhibitor such as an antiphospholipid antibody, the mixing study should not correct because the antiphospholipid antibody will affect both patient and normal pooled plasma.

However, it is important to take notice when patients are on anticoagulant agents when the mixing study is performed. Anticoagulant agents inhibit the function of activated factors, which are required to make a clot. A mixing study adds normal plasma to the patient’s plasma; it will correct a deficiency of a factor but cannot correct a medication that blocks coagulation. If the aPTT is prolonged due to the presence of an anticoagulant, the mixing study will not correct, giving a false-positive result suggestive of an antiphospholipid antibody. For example, heparin prolongs the aPTT. It works through antithrombin to inhibit multiple factors (primarily factors Xa and IIa) for anticoagulation therapy. It is important to remember that even in patients not being treated with heparin, a blood sample can be contaminated with heparin if drawn through a heparinized line. Enoxaparin, a fractionated low-molecular-weight heparin, and rivaroxaban, a non–vitamin K oral anticoagulant that is a direct Xa inhibitor, may or may not prolong the aPTT. This outcome is because different aPTT reagents have different sensitivity to enoxaparin and rivaroxaban. In summary, interpretation of results of the mixing study in a patient receiving anticoagulation therapy can be challenging, and confirmation of an antiphospholipid antibody with further testing is indicated.

**Dr Shah**

Thus, for our patient, the aPTT was persistently elevated despite the mixing study. Although there is a potential for a false-positive result as you mentioned, Dr Guerrera, this elevation still suggests an antiphospholipid antibody. But how would you confirm it?

**Dr Guerrera**

Although antiphospholipid antibodies can include lupus anticoagulants, anticardiolipin antibodies, and β2-glycoprotein-I, we would initially repeat the aPTT with reagents more sensitive to lupus anticoagulants. If the aPTT remains prolonged, we then proceed with a series of confirmatory steps to try to rule out a coagulation factor deficiency or heparin contamination. Although anticardiolipin antibodies are more common than lupus anticoagulants, the presence of a lupus anticoagulant puts a person at a higher risk of having a clot than anticardiolipin antibodies alone and is a reason why it is tested for initially.11

**Dr Shah**

Retesting with the more sensitive reagent corroborated a positive lupus anticoagulant in our patient. A diagnosis of antiphospholipid antibody syndrome (APS) was therefore made. However, Dr Guerrera, why does the presence of an antiphospholipid antibody such as a lupus anticoagulant cause a clinical prothrombotic state despite an elevated aPTT in vitro?
Dr Guerrera
In vitro testing of coagulation by the aPTT requires the addition of a finite amount of phospholipids, which are required for proper clot formation. The lupus anticoagulant partially neutralizes these added phospholipids required for clot formation, which prolongs the aPTT. In vivo, the pathophysiology of the lupus anticoagulant is multifactorial and incompletely understood. The lupus anticoagulant activates endothelial cells, monocytes, and platelets, thus leading to a prothrombotic state.

Dr Shah
Later during this second hospitalization, the patient developed an acute-onset rash on his flanks and thighs. Dr Kürkorian, how would you evaluate these skin findings?

A. Yasmine Kürkorian, MD (Pediatric Dermatology)
The patient’s skin is an important clue to his diagnosis. It shows branching and stellate purpura with central necrosis, which were distributed on the bilateral medial thighs and on the right flank (Fig 1). This morphology is called “retiform purpura” and is an indication for skin biopsy.

Understanding the normal vascular anatomy and perfusion of the skin is necessary to understanding the clinical findings. The skin vessels consist of arterioles located in the dermis oriented perpendicularly to the epidermis. Each arteriole divides to form a capillary bed, with the arteriole at the center of the bed. This arrangement gives rise to 1– to 3–cm cones of perfusion, which manifests on the skin as a net-like pattern called livedo reticularis. Livedo reticularis may be physiologic and resolve upon rewarming, particularly in infants, or it may be persistent and associated with underlying systemic disease.

Purpura is defined by visible hemorrhage into the skin. This patient presented with retiform purpura. Clinically, it is helpful to think of retiform purpura as a “broken net” or “puzzle pieces” of livedo reticularis. Retiform purpura is a unique variant of purpura that results from occlusion of cutaneous vessels. Whenever I see this morphology, I begin to search for causes of microvascular occlusion by performing a thorough medical evaluation of the patient and a skin biopsy. The skin biopsy results can help to determine the nature of the microvascular thrombus. Etiologies can include fibrin thrombi secondary to a systemic coagulopathy, microorganisms in the setting of septic emboli, calcium deposits in calciphylaxis, cholesterol emboli, marantic emboli, and other abnormalities in the clotting cascade.

This patient’s skin biopsy specimen (Fig 2) revealed fibrin thrombi in numerous cutaneous arterioles and venules. Taken in the context of the patient’s clinical presentation and laboratory abnormalities, the cutaneous microvascular thrombi were a manifestation of his underlying coagulopathy due to APS.

Dr Shah
At the same time of the presentation of the rash, this patient developed severe generalized abdominal pain with tenderness to palpation. An abdominal CT angiography was obtained to evaluate the cause of this pain (Fig 3). Dr Otero, how would you evaluate this image?

Hansel J. Otero, MD (Pediatric Radiology)
The CT angiography of the abdomen and pelvis shows a new 5-cm right periadrenal collection with stranding of the periadrenal fat extending into the perinephric space, which is the typical CT imaging appearance of an adrenal hemorrhage. The cause of nontraumatic adrenal hemorrhage varies with age; in newborns, it is associated with stress and resulting
hypoxia due to prolonged labor, breech delivery, large birth weight, difficult labor, asphyxia, or sepsis.\textsuperscript{16,17} In older children and adults, adrenal hemorrhage might be the result of other causes of stress, including burns, sepsis, and surgery, as well as underlying tumors and bleeding diathesis or coagulopathy.\textsuperscript{17,18} Acute intratumoral hemorrhage is most common with pheochromocytoma but has also been described in myelolipomas, metastatic lesions, adrenocortical carcinomas, adenomas, and hemangiomas.\textsuperscript{19}

In the present case, there is no suggestion of an underlying lesion in the current or previous imaging studies, and the patient has a known coagulopathy. It is therefore safe to conclude that in this patient, an adrenal vein thrombosis occurred that resulted in a hemorrhagic infarction.\textsuperscript{20}

**Dr Shah**

Because these new thrombi all occurred while the patient was taking enoxaparin, he was transferred back to the PICU and re-started on a heparin drip. Laboratory evaluation at this time demonstrated low complement levels and a positive anti-Sm antibody. While in the PICU, he developed respiratory failure and required intubation and ventilator support. Dr Guerrera, given the events of the most recent hospitalization, is our diagnosis still APS?

**Dr Guerrera**

This patient has APS with the evolution of multiple thrombi over time. He has had a DVT, PE, adrenal hemorrhage due to thrombosis, and cutaneous microvascular thrombi. This presentation with multiorgan thrombi in rapid succession is concerning for probable catastrophic antiphospholipid syndrome (CAPS) (Table 2). He has evidence of thromboses of $\geq 3$ organs, histopathologic confirmation of

---

**FIGURE 2**

Skin biopsy histopathologic results. Histologic sections with hematoxylin-eosin staining at $40\times$ magnification: fibrin thrombi in numerous cutaneous arterioles and venules.

**FIGURE 3**

Patient’s abdomen and pelvis CT angiography. Coronal contrast enhanced CT of the abdomen and pelvis in a 17-year-old male showing a right suprarenal heterogeneously hyperdense collection (arrow), in keeping with an acute adrenal hemorrhage.
small vessel occlusion in the skin, and laboratory confirmation of the presence of antiphospholipid antibodies, specifically the lupus anticoagulant. CAPS is a rare and life-threatening complication of APS. Similar to the concept of a “cytokine storm” during infection, CAPS can be described as a “thrombotic storm” despite adequate anticoagulation, in which thrombi are being formed everywhere. In 2012, Dr Ricard Cervera published an analysis of >400 pediatric and adult patients from the CAPS registry. This analysis showed that 53% of the patients with CAPS have an identified trigger, with the most common being infection (22%) and surgery (10%). Seventy-two percent of the patients were female. Primary APS syndrome was diagnosed in 46%, systemic lupus erythematosus (SLE) in 40%, lupus-like disease in 5%, and other autoimmune diseases in 9%.

**FINAL DIAGNOSIS: CAPS**

**Dr Shah**

Because this patient has a positive lupus anticoagulant, Dr Jung, should we be considering SLE as an underlying diagnosis?

**Lawrence Jung, MD (Pediatric Rheumatology)**

It is plausible that an initial presentation of SLE or an SLE flare could have been the patient’s CAPS trigger. However, diagnosing SLE is a little tricky. The lupus classification criteria of the American College of Rheumatology (ACR) (Table 3), most recently revised in 1997, were designed for the purpose of identifying subjects for clinical studies. A subject with 4 of the 11 clinical criteria serially or simultaneously is considered to be eligible for clinical studies. Although the ACR criteria have been widely used in clinical settings, clinicians need to know that there are pitfalls which lead to diagnostic errors when using the ACR criteria.

The Systemic Lupus International Collaborating Clinics (SLICC) lupus criteria (Table 3) were published in 2012 and compared favorably with the ACR criteria in identifying individuals with lupus. The SLICC criteria were validated in 1 study of pediatric SLE. In that study, the ACR criteria had 76.6% sensitivity and 93.4% specificity, whereas the SLICC criteria had 98.7% sensitivity and 85.3% specificity. Thus, in pediatric lupus, the SLICC criteria are more sensitive (P < .001) but less specific (P < .001) than the ACR criteria.

There are obvious differences in these 2 sets of criteria and how they apply to this patient in particular. This patient meets the SLICC criteria (thrombocytopenia, positive anti-Sm antibody, antiphospholipid antibodies, and low complement levels). However, he does not meet the ACR criteria because low complement level is not considered a classification criterion. Furthermore,****

---

**TABLE 2 Diagnostic Criteria for CAPS**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria 1</td>
<td>Evidence of involvement of ≥3 organs, systems, and/or tissues</td>
</tr>
<tr>
<td>Criteria 2</td>
<td>Development of manifestations simultaneously or in &lt;1 wk</td>
</tr>
<tr>
<td>Criteria 3</td>
<td>Confirmation by histopathology of small vessel occlusion</td>
</tr>
<tr>
<td>Criteria 4</td>
<td>Laboratory confirmation of the presence of antiphospholipid antibodies</td>
</tr>
</tbody>
</table>

**Definite CAPS**

- All 4 criteria present

**Probable CAPS**

- All 4 criteria, except only 2 organs, systems, and/or tissues involved
- All 4 criteria, except for the absence of laboratory confirmation of antiphospholipid antibodies
- Criteria 1, 2, and 4
- Criteria 1, 3, and 4 with the development of a third event >1 wk but within 1 mo of presentation, despite anticoagulation

**TABLE 3 ACR Versus SLICC Classification of SLE**

<table>
<thead>
<tr>
<th>ACR (4 Criteria)</th>
<th>SLICC (4 Criteria With 1 Clinical and 1 Laboratory Finding)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malar rash</td>
<td>Clinical</td>
</tr>
<tr>
<td>Discoid rash</td>
<td>Acute cutaneous lupus</td>
</tr>
<tr>
<td>Photosensitivity</td>
<td>Chronic cutaneous lupus</td>
</tr>
<tr>
<td>Oral ulcers</td>
<td>Oral or nasal ulcers</td>
</tr>
<tr>
<td>Nonerosive arthritis</td>
<td>Nonscarring alopecia</td>
</tr>
<tr>
<td>Pleuritis or pericarditis</td>
<td>Arthritis</td>
</tr>
<tr>
<td>Renal disorder</td>
<td>Serositis</td>
</tr>
<tr>
<td>Neurologic disorder</td>
<td>Neurologic</td>
</tr>
<tr>
<td>Hematologic disorder</td>
<td>Hemolytic anemia</td>
</tr>
<tr>
<td>Immunologic disorder</td>
<td>Leukopenia</td>
</tr>
<tr>
<td>Positive antinuclear antibody</td>
<td>Thrombocytopenia</td>
</tr>
</tbody>
</table>

---

**TABLE 2 Diagnosis Criteria for CAPS**

1. Evidence of involvement of ≥3 organs, systems, and/or tissues
2. Development of manifestations simultaneously or in <1 wk
3. Confirmation by histopathology of small vessel occlusion
4. Laboratory confirmation of the presence of antiphospholipid antibodies

**Definite CAPS**

All 4 criteria present

**Probable CAPS**

All 4 criteria, except only 2 organs, systems, and/or tissues involved

All 4 criteria, except for the absence of laboratory confirmation of antiphospholipid antibodies

Criteria 1, 2, and 4

Criteria 1, 3, and 4 with the development of a third event >1 wk but within 1 mo of presentation, despite anticoagulation

---

**TABLE 3 ACR Versus SLICC Classification of SLE**

<table>
<thead>
<tr>
<th>ACR (4 Criteria)</th>
<th>SLICC (4 Criteria With 1 Clinical and 1 Laboratory Finding)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malar rash</td>
<td>Clinical</td>
</tr>
<tr>
<td>Discoid rash</td>
<td>Acute cutaneous lupus</td>
</tr>
<tr>
<td>Photosensitivity</td>
<td>Chronic cutaneous lupus</td>
</tr>
<tr>
<td>Oral ulcers</td>
<td>Oral or nasal ulcers</td>
</tr>
<tr>
<td>Nonerosive arthritis</td>
<td>Nonscarring alopecia</td>
</tr>
<tr>
<td>Pleuritis or pericarditis</td>
<td>Arthritis</td>
</tr>
<tr>
<td>Renal disorder</td>
<td>Serositis</td>
</tr>
<tr>
<td>Neurologic disorder</td>
<td>Neurologic</td>
</tr>
<tr>
<td>Hematologic disorder</td>
<td>Hemolytic anemia</td>
</tr>
<tr>
<td>Immunologic disorder</td>
<td>Leukopenia</td>
</tr>
<tr>
<td>Positive antinuclear antibody</td>
<td>Thrombocytopenia</td>
</tr>
</tbody>
</table>

---

**TABLE 2 Diagnostic Criteria for CAPS**

1. Evidence of involvement of ≥3 organs, systems, and/or tissues
2. Development of manifestations simultaneously or in <1 wk
3. Confirmation by histopathology of small vessel occlusion
4. Laboratory confirmation of the presence of antiphospholipid antibodies

**Definite CAPS**

- All 4 criteria present

**Probable CAPS**

- All 4 criteria, except only 2 organs, systems, and/or tissues involved
- All 4 criteria, except for the absence of laboratory confirmation of antiphospholipid antibodies
- Criteria 1, 2, and 4
- Criteria 1, 3, and 4 with the development of a third event >1 wk but within 1 mo of presentation, despite anticoagulation

---

**TABLE 3 ACR Versus SLICC Classification of SLE**

<table>
<thead>
<tr>
<th>ACR (4 Criteria)</th>
<th>SLICC (4 Criteria With 1 Clinical and 1 Laboratory Finding)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malar rash</td>
<td>Clinical</td>
</tr>
<tr>
<td>Discoid rash</td>
<td>Acute cutaneous lupus</td>
</tr>
<tr>
<td>Photosensitivity</td>
<td>Chronic cutaneous lupus</td>
</tr>
<tr>
<td>Oral ulcers</td>
<td>Oral or nasal ulcers</td>
</tr>
<tr>
<td>Nonerosive arthritis</td>
<td>Nonscarring alopecia</td>
</tr>
<tr>
<td>Pleuritis or pericarditis</td>
<td>Arthritis</td>
</tr>
<tr>
<td>Renal disorder</td>
<td>Serositis</td>
</tr>
<tr>
<td>Neurologic disorder</td>
<td>Neurologic</td>
</tr>
<tr>
<td>Hematologic disorder</td>
<td>Hemolytic anemia</td>
</tr>
<tr>
<td>Immunologic disorder</td>
<td>Leukopenia</td>
</tr>
<tr>
<td>Positive antinuclear antibody</td>
<td>Thrombocytopenia</td>
</tr>
</tbody>
</table>

---

**TABLE 2 Diagnostic Criteria for CAPS**

1. Evidence of involvement of ≥3 organs, systems, and/or tissues
2. Development of manifestations simultaneously or in <1 wk
3. Confirmation by histopathology of small vessel occlusion
4. Laboratory confirmation of the presence of antiphospholipid antibodies

**Definite CAPS**

- All 4 criteria present

**Probable CAPS**

- All 4 criteria, except only 2 organs, systems, and/or tissues involved
- All 4 criteria, except for the absence of laboratory confirmation of antiphospholipid antibodies
- Criteria 1, 2, and 4
- Criteria 1, 3, and 4 with the development of a third event >1 wk but within 1 mo of presentation, despite anticoagulation

---

**TABLE 3 ACR Versus SLICC Classification of SLE**

<table>
<thead>
<tr>
<th>ACR (4 Criteria)</th>
<th>SLICC (4 Criteria With 1 Clinical and 1 Laboratory Finding)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malar rash</td>
<td>Clinical</td>
</tr>
<tr>
<td>Discoid rash</td>
<td>Acute cutaneous lupus</td>
</tr>
<tr>
<td>Photosensitivity</td>
<td>Chronic cutaneous lupus</td>
</tr>
<tr>
<td>Oral ulcers</td>
<td>Oral or nasal ulcers</td>
</tr>
<tr>
<td>Nonerosive arthritis</td>
<td>Nonscarring alopecia</td>
</tr>
<tr>
<td>Pleuritis or pericarditis</td>
<td>Arthritis</td>
</tr>
<tr>
<td>Renal disorder</td>
<td>Serositis</td>
</tr>
<tr>
<td>Neurologic disorder</td>
<td>Neurologic</td>
</tr>
<tr>
<td>Hematologic disorder</td>
<td>Hemolytic anemia</td>
</tr>
<tr>
<td>Immunologic disorder</td>
<td>Leukopenia</td>
</tr>
<tr>
<td>Positive antinuclear antibody</td>
<td>Thrombocytopenia</td>
</tr>
</tbody>
</table>

---

**TABLE 2 Diagnostic Criteria for CAPS**

1. Evidence of involvement of ≥3 organs, systems, and/or tissues
2. Development of manifestations simultaneously or in <1 wk
3. Confirmation by histopathology of small vessel occlusion
4. Laboratory confirmation of the presence of antiphospholipid antibodies

**Definite CAPS**

- All 4 criteria present

**Probable CAPS**

- All 4 criteria, except only 2 organs, systems, and/or tissues involved
- All 4 criteria, except for the absence of laboratory confirmation of antiphospholipid antibodies
- Criteria 1, 2, and 4
- Criteria 1, 3, and 4 with the development of a third event >1 wk but within 1 mo of presentation, despite anticoagulation

---

**TABLE 3 ACR Versus SLICC Classification of SLE**

<table>
<thead>
<tr>
<th>ACR (4 Criteria)</th>
<th>SLICC (4 Criteria With 1 Clinical and 1 Laboratory Finding)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malar rash</td>
<td>Clinical</td>
</tr>
<tr>
<td>Discoid rash</td>
<td>Acute cutaneous lupus</td>
</tr>
<tr>
<td>Photosensitivity</td>
<td>Chronic cutaneous lupus</td>
</tr>
<tr>
<td>Oral ulcers</td>
<td>Oral or nasal ulcers</td>
</tr>
<tr>
<td>Nonerosive arthritis</td>
<td>Nonscarring alopecia</td>
</tr>
<tr>
<td>Pleuritis or pericarditis</td>
<td>Arthritis</td>
</tr>
<tr>
<td>Renal disorder</td>
<td>Serositis</td>
</tr>
<tr>
<td>Neurologic disorder</td>
<td>Neurologic</td>
</tr>
<tr>
<td>Hematologic disorder</td>
<td>Hemolytic anemia</td>
</tr>
<tr>
<td>Immunologic disorder</td>
<td>Leukopenia</td>
</tr>
<tr>
<td>Positive antinuclear antibody</td>
<td>Thrombocytopenia</td>
</tr>
</tbody>
</table>
his thrombocytopenia may be the result of consumption due to his CAPS and not due to the presence of autoantibodies. The only feature that is lupus-specific is the presence of anti-Sm antibody. Based on the SLICC criteria, we made a presumptive diagnosis of SLE with the understanding that further clinical observation will help to clarify the diagnosis.

Dr Shah

Does this ambiguity change the patient’s acute management?

Dr Jung

Actually, the diagnosis of SLE does not change the acute management in this case. However, for long-term management, he should be given hydroxychloroquine, which is a disease-modifying medication to help keep the suspected lupus activity under control.

Dr Shah

Upon further questioning of the patient’s family, a history of a second cousin with APS and a deceased first cousin with Goodpasture syndrome were discovered. Dr Regier, is there a genetic link to APS?

Debra Regier, MD, PhD (Pediatric Genetics and Metabolism)

In general, autoimmune disorders do have an increased relative risk in family members. There are case reports that show an increase predisposition to CAPS within families.25 CAPS genetic predisposition has low penetrance and is most likely multifactorial, which makes it difficult to identify a clear genetic link. This situation is likely because although the genetic predisposition to CAPS is an inherited trait, clinical symptoms present only when there is a CAPS trigger. Thus, patients without the trigger or inadequate trigger do not have CAPS, and the pedigree seems to have incomplete penetrance.

Dr Shah

This patient was started on high-dose steroids, plasmapheresis, and later on rituximab; he subsequently improved in the PICU. He was weaned off respiratory support and was transferred back to the general pediatrics ward. Dr Guerrera, can you explain why this specific treatment course was successful for this patient?

Dr Guerrera

It is critical to make an early diagnosis of CAPS and to initiate aggressive management because CAPS has a high mortality, and early treatment may be lifesaving. Plasmapheresis has been shown to significantly decrease mortality in CAPS, most likely by removing the high-titer antiphospholipid antibodies as well as other stimulating cytokines. Corticosteroids in combination with plasmapheresis and anticoagulation therapy have been the most successful treatment of CAPS.26 Intravenous immunoglobulin has been added to many regimens to prevent recurrent thrombosis in patients refractory to conventional anticoagulant treatment.27,28 Rituximab was added to reduce the B-lymphocyte population and antibody production, which has been shown to help in autoimmune and alloimmune disorders. In some instances, cyclophosphamide is used when CAPS is associated with underlying SLE.

Dr Shah

On the general pediatric ward, the patient’s respiratory symptoms improved to baseline. In addition to the hydroxychloroquine for SLE mentioned by Dr Jung, what other medications should the patient continue at home?

Dr Guerrera

Given the patient’s history of recurrent thromboses, it is absolutely vital that he continues on warfarin at an international normalized ratio therapeutic range of 2.5 to 3.5. In addition, aspirin should be included in his antithrombotic regimen. Given the patient’s previous treatment with rituximab, he will also need to receive intravenous immunoglobulin monthly to correct his hypogammaglobulinemia.

Dr Shah

Since discharge from the hospital, our patient has continued receiving anticoagulation therapy with warfarin and aspirin, with no further thrombosis or bleeding symptoms. At his last visit 12 months after discharge, the patient is doing well and back to normal activities. Given his improvement, he has been able to return to college. He continues to have chronic, stable occlusion of bilateral popliteal veins. He remains on a low dose of prednisone, which will be discontinued over the next few months. He will remain on hydroxychloroquine.

The survival rate for CAPS is estimated to be 50%.29 Of those who survive, two-thirds remain symptom-free with anticoagulation therapy. In those survivors who have additional thrombotic events, the mortality rate is increased, and 1 in 4 may die. Therefore, even though CAPS is a rare diagnosis, a high level of suspicion is warranted in patients with antiphospholipid syndrome, especially if there is evidence of progression to multiorgan thrombosis. Early diagnosis and aggressive management are paramount to saving the patient’s life. We believe early and aggressive treatment contributed to this patient’s survival. He remains healthy and is doing remarkably well.

ACKNOWLEDGMENTS

We thank Dr Debra Regier for her essential input and advice on this case. We thank Dr Bernard Cohen for the photograph of physiologic...
livedo reticularis in Fig 1 and Gregory Kirkorian for assistance in the creation of Fig 1.

**ABBREVIATIONS**

ACR: American College of Rheumatology

aPTT: activated partial thromboplastin time

CAPS: catastrophic antiphospholipid syndrome

CT: computed tomography

DVT: deep vein thrombosis

ECG: electrocardiogram

PE: pulmonary embolism

SLE: systemic lupus erythematosus

SLICC: Systemic Lupus International Collaborating Clinics

**REFERENCES**


Pulmonary hypertension (PH) is a syndrome that is of growing concern to pediatricians worldwide. Recent data led to concerns about the safety of phosphodiesterase type 5 (PDE5) inhibitors in children and a US Food and Drug Administration safety advisory. Our objective is to provide insight into therapies for PH in children and to systematically review the comparative effectiveness and safety of PDE5 inhibitors in the management of pediatric patients with PH. We searched the following databases through February 2015: Medline, Embase, SCOPUS, and the Cochrane Central Register of Controlled Trials. We included studies that examined PDE5 inhibitor use in children with PH. Allowed comparators were either no medication or other classes of medication for management of PH. Study inclusion was via a 2-stage process with 2 reviewers and a predesigned form. Of 1270 papers identified by literature search, 21 were included: 8 randomized controlled trials and 13 observational studies (9 retrospective, 4 prospective). There is strong evidence that PDE5 inhibitor use improves echocardiography measurements, cardiac catheterization parameters, and oxygenation compared with baseline or placebo in pediatric patients with PH. Evidence suggests that low- and moderate-dose sildenafil are safe regimens for children. There are a relatively small number of randomized controlled trials that address use of PDE5 inhibitors in pediatric patients with PH. PDE5 inhibitors are effective agents for cardiovascular and oxygenation end points in pediatric PH and important components of a multimodal pharmacotherapeutic approach to this growing challenge. Additional studies are needed to define optimal PH therapy in childhood.
Over the past 20 years, hospitalists have emerged as a distinct group of pediatric practitioners. In August of 2014, the American Board of Pediatrics (ABP) received a petition to consider recommending that pediatric hospital medicine (PHM) be recognized as a distinct new subspecialty. PHM as a formal subspecialty raises important considerations related to: (1) quality, cost, and access to pediatric health care; (2) current pediatric residency training; (3) the evolving body of knowledge in pediatrics; and (4) the impact on both primary care generalists and existing subspecialists. After a comprehensive and iterative review process, the ABP recommended that the American Board of Medical Specialties approve PHM as a new subspecialty. This article describes the broad array of challenges and certain unique opportunities that were considered by the ABP in supporting PHM as a new pediatric subspecialty.
The Sudden Death in the Young Case Registry: Collaborating to Understand and Reduce Mortality

Kristin M. Burns, MD, a Lauren Bienemann, BS, b Lena Camperlengo, DrPH, c Carri Cottengim, MA, c Theresa M. Covington, MPH, d Heather Dykstra, MPA, d Meghan Faulkner, MA, d Rosemarie Kobau, MPH, MAPP, d Alexa B. Erick Lambert, MPH, e Heather MacLeod, MS, CGC, e Sharyn E. Parks, PhD, MPH, f Ellen Rosenberg, RN, b Mark W. Russell, MD, b Carrie K. Shapiro-Mendoza, PhD, MPH, b Esther Shaw, MSIS, f Niu Tian, MD, PhD, e Vicky Whittemore, PhD, f Jonathan R. Kaltman, MD, b Sudden Death in the Young Case Registry Steering Committee

Knowledge gaps persist about the incidence of and risk factors for sudden death in the young (SDY). The SDY Case Registry is a collaborative effort between the National Institutes of Health, the Centers for Disease Control and Prevention, and the Michigan Public Health Institute. Its goals are to: (1) describe the incidence of SDY in the United States by using population-based surveillance; (2) compile data from SDY cases to create a resource of information and DNA samples for research; (3) encourage standardized approaches to investigation, autopsy, and categorization of SDY cases; (4) develop partnerships between local, state, and federal stakeholders toward a common goal of understanding and preventing SDY; and (5) support families who have lost loved ones to SDY by providing resources on bereavement and medical evaluation of surviving family members. Built on existing Child Death Review programs and as an expansion of the Sudden Unexpected Infant Death Case Registry, the SDY Case Registry achieves its goals by identifying SDY cases, providing guidance to medical examiners/coroners in conducting comprehensive autopsies, evaluating cases through child death review and an advanced review by clinical specialists, and classifying cases according to a standardized algorithm. The SDY Case Registry also includes a process to obtain informed consent from next-of-kin to save DNA for research, banking, and, in some cases, diagnostic genetic testing. The SDY Case Registry will provide valuable incidence data and will enhance understanding of the characteristics of SDY cases to inform the development of targeted prevention efforts.

Ethical Concerns When Minors Act as Standardized Patients

When minors are asked to assist medical educators by acting as standardized patients (SPs), there is a potential for the minors to be exploited. Minors deserve protection from exploitation. Such protection has been written into regulations governing medical research and into child labor laws. But there are no similar guidelines for minors’ work in medical education. This article addresses the question of whether there should be rules. Should minors be required to give their informed consent or assent? Are there certain practices that could cause harm for the children who become SPs? We present a controversial case and ask a number of experts to consider the ethical issues that arise when minors are asked to act as SPs in medical education.

THE CASE

M.S. is a 6-year-old with hemoglobin E/β thalassemia who lives on a farm who lives on a farm in Indonesia. He was diagnosed at 2 years of age. For his clinical care, he requires frequent transfusions of packed red blood cells. He was started on iron chelators at the age of 5 years. The patient has many of the clinical features of β thalassemia. He is small, pale, has prominent facial bones, and has hepatosplenomegaly. There are multiple subcutaneous injection scars over his abdomen due to the use of the iron chelators.

M.S.’s father and mother are self-employed farmers. Both have the thalassemia trait. M.S. has 2 younger brothers who are well. The family has an income of less than 200 Indonesian Rupees (US $3) per day. They have struggled to make ends meet over the years.

M.S. is followed up in a university hospital. During one of his visits to the clinic there, the hematologist asked M.S.’s mother if she would allow him to be hired as an SP for an undergraduate clinical examination. If she agreed, M.S. would then be one of many patients upon whom medical students would be asked to perform an objective structured clinical examination (OSCE). This examination involves history taking and physical examination by students (examinees) in which they take turns being assessed by examiners. Examinees rotate from station to station with different objectives of competence being assessed. Patients are typically hired because of their

abstract

Medical educators often use simulations and standardized patients (SPs) to improve students’ clinical skills. In pediatrics, children or adolescents may be asked to become SPs. This practice can raise a number of unique ethical issues. Can minors consent to be teaching tools in medical education? Are there certain practices that could cause harm for the children who decide, or whose parents decide, to go this route? In this Ethics Rounds, we present a controversial case and ask a number of experts to consider the ethical issues that arise when minors are asked to act as SPs in medical education.
“interesting” or classic signs of their disease, in which findings cannot be simulated. On the day of OSCE, M.S. would be examined by 24 medical students separately over a period of 12 minutes per student for a total duration of 5 to 6 hours continuously. These examinations will be repeated with a different set of examinees the next day. The students’ performance on these examinations will be used to assess the students’ clinical competence in pediatrics. For being a SP for 2 days, M.S.’s parents will receive a sum of 600 Indonesian Rupees (US $9).

Question: Is it permissible for doctors and educators to request of parents that their child be used to evaluate students’ clinical competence? Are there limits to the sorts of situations in which this undertaking should be permitted?

Erwin Khoo Jiayuan, MRCPCH, MBBS

The involvement of minors as a tool in medical teaching has been a widely overlooked, valued component of medical education. Minors have been used in many professional examinations, including those of the American Board of Medical Specialties, the Medical Council of Canada national licensing examination, and many Royal Colleges around the world. Using SPs in OSCE has become an effective method for evaluating clinical competence in medical education. Even large numbers of child SPs have been made feasible despite the challenging logistics and potential disaster when involving children in such high-stakes clinical examinations.

Sir William Osler said, “to study the phenomenon of disease without books is to sail an uncharted sea, while to study books without patients is not to go to sea at all.” There is no doubt using actual patients is a necessity in medical education for the assessment of students’ learning outcomes. Patient contact provides learners the opportunity to apply their knowledge in real teaching settings and to develop clinical reasoning and enhance cultural diversity. They nurture professionalism and good ethical behavior by fostering empathy. Involvement of child SPs in education improves training and overall societal health care.

The ethical principles of “nonmaleficence versus beneficence” have been invoked to justify the use of minors in medical education. Being an SP increases one’s own knowledge and gives the opportunity to share concerns with a professional, while also gaining enjoyment from these encounters. These experiences also lead to potential psychological and emotional benefits. However, patients involved in education benefit the least when involving younger children using the traditional benefit/burden calculus. A neonate or toddler lacks autonomy and so could be easily coerced or compelled by their parents (or an educational institution) into participating in such educational activities. With no observed direct benefit to these subjects, they are considered noble and self-sacrificing to the production of quality doctors prioritizing the best interest of the community.

The risk of harming a child could be akin to the debatable “July phenomenon” (ie, the increased patient morbidity and mortality related to the influx of new medical trainees). We should also consider the risk of infection or risk of being hurt and being traumatized while trainees were so engrossed in eliciting a sign that they forgot about the child’s discomfort and parent’s anxiety, as well as the potential exhaustion and risk of confusion and embarrassment when cases are presented differently from what the child is actually experiencing.

There are 2 ethical approaches here. Using minors as SPs for the benefit of the institution and society could be compared to using children in research, and be regulated in a similarly stratified manner based on the child’s age. The younger the child is, the greater the risk-to-benefit ratios. The broader societal benefits must be balanced with the rights of the child while retaining the principle of nonmaleficence. When the risk-to-benefit ratio is deemed significant, as in participation of toddlers and newborns, both parents should consent. The “rule of 7” would be a subtle approach to capacity of a minor. Minors aged <7 years, minors aged 7 to 13 years, and minors aged ≥14 years are an important watermark to minors having the capacity and maturity to differentiate decision-making and understanding consent.

The next consideration would be employment of children within the limits of the country’s law. As with simulation as employment in the entertainment industry, appropriate regulations should be in place. The age of the child, the role he or she plays, and the duration of engagement are crucial considerations when regulating such law.

In both ways, parents must be provided with adequate information to enable provision of informed consent before their child’s participation. The concern here is, could minors be exploited where poverty creates personal financial interest? How can children refuse when their parents are asking them to volunteer? If the child refuses, guilt and interfamilial conflict may result. These concerns are similar to concerns that arise in research. Remember that asking for parental consent during a clinic visit can increase pressure on the parent to consent. This persuasion, if not unwittingly, then perhaps by virtue of body language or institutional authority seems unethical.

Sometimes, children may seem to signal dissent, and these objections...
are, of course, overridden by parental instructions. In all these cases, the worry is that the child’s consent, or assent, may not be real when it comes to younger children. We then think of possible reasons for a child’s dissent, and we start to worry about educators taking advantage of children.

In the present case, the question is not whether it is permissible for doctors to request of parents that their child be used as an educational tool. Instead, the key question is how rightfully recommendations are implemented for children to volunteer in medical education. Involvement of minors as SPs remains an educational challenge needing logistic effort, a child advocacy team, and awareness of the minor’s best interest and of any risk of maleficence. For educators, discussions among ethicists or a child advocacy team when minors are too young to express assent are an important first step. As with an institutional review board, such steps ensure that involvement of minors as an education tool is conducted in accordance with institutional and ethical guidelines. Educators should be sensitive to the child’s dissent and be aware of age-appropriate assent. Consent must be sought by an independent team away from clinical responsibility. Parents should be briefed about the details of the OSCE and what is expected during the process. They have the right to refuse participation should be informed of students who learn by examining content and scanning task trainers. SPs compared with students who use other pedagogic techniques.

Using a child in the role of an SP adds further practical challenges. A younger child may not be able to maintain consistency with historical information. He or she may not have the patience to be examined repeatedly and may get bored with the process. A minor cannot consent to being used as an SP, and thus a parent or guardian must provide consent.

Although not often used as true SPs, children are commonly used as patient models for practice or testing of learned skills. This practice is especially common in pediatric point-of-care ultrasound workshops. Children with both normal anatomy and abnormal ultrasound findings (i.e., a peritoneal dialysis patient who mimics a positive focused assessment with sonography in trauma) are asked to lie still while workshop participants scan them repeatedly. The practical portions of these workshops that require child models are usually less than one-half of a day because the rest is spent on didactic content and scanning task trainers.

In the vignette presented, M.S. is asked to be a physical examination model during medical student OSCEs on 2 consecutive 5- to 6-hour days. His mother or father would likely also need to accompany him because he would not be able to provide an accurate history for the students and because his parents would rightly be hesitant to allow their 6-year-old child to be alone in a room with a parade of strangers.

Such a situation raises a number of concerns. The duration of participation and number of examinations proposed are daunting for a 6-year-old. The process may be emotionally stressful. His parents will receive compensation, but there is no mention of a direct incentive for the child, not even lunch during his long days.
Do the benefits for students or for M.S.’s parents outweigh the burdens? One way to sidestep this question would be to imagine other ways of providing similar educational experiences. Technology may render the need for minors as SPs moot. Virtual humans and other forms of artificial intelligence have become much more lifelike due to the advances of the computer chip and networking. Pedagogical educators now use virtual patients in training. Pediatric virtual patients have been developed and have been in use in some locations for >10 years. This modality will likely soon be standard practice. Developing and using virtual patients is expensive, however, and M.S. lives in a resource-limited area; thus, the availability of computing power and networking is not guaranteed. The use of a virtual patient simulator has been reported in at least 1 resource-limited setting, however.

The use of either virtual patients or SPs can improve medical education. Minors can work as SPs with appropriate safeguards in place. If parents judge that a child has the ability to perform the duties asked of him or her, and they consent to the child’s participation, then it is permissible for the child to act as a SP. There should be limits to the duration and number of examinations, however. The child should not be required to undergo any painful or overly embarrassing procedures. But with such safeguards in place, and with careful monitoring for fatigue or other adverse effects, it is ethically permissible to hire children as SPs.

Douglas S. Diekema, MD, MPH, Comments

The situation presented by this case raises ethical issues analogous to those arising in the research context. Like research, the primary purpose of the activity is not to benefit the patient but to contribute to the greater social good, in this case by educating a future generation of physicians. Several well-established ethical principles exist for deciding when and under what conditions enrolling a child in research is appropriate, and I would suggest that deciding whether to allow children to serve as SPs should be subject to the same principles and constraints that we apply to the research context.

Potential risks and benefits are essential elements in determining whether children can participate in research. In most circumstances, children are not permitted to participate in a research project that exceeds minimal risk unless it offers the child sufficient prospect of direct benefit to justify any potential risks involved. A similar rule should apply to children being considered for the role of an SP.

M.S. will be subjected to 48 physical examinations repeated over the course of two 6-hour days. The boredom and unpleasantness of that exercise seem excessive for even the most patient and compliant 6-year-old child. This situation is exacerbated by the relatively passive nature of the role. Even more importantly, M.S. has been specifically selected for his unique visible physical features, features that very possibly alienate him from peers and subject him to teasing. Participation as an SP will highlight the features that make M.S. different from other children and potentially enhance their stigmatizing effect. Although some 6-year-olds might take this all in stride, I suspect most would not. I would be reluctant to characterize that risk as minimal but concede that it might be considered a minor increase over minimal risk in a carefully controlled environment attentive to the boy’s needs.

Does participation provide sufficient direct benefit to M.S. that these potential harms are neutralized? Financial compensation provided to the family is generally not considered to be a direct benefit to the child. Adults would likely argue that the most significant benefit of serving as an SP (beyond the money) resides in the feeling of having contributed to society by enhancing the education of future physicians. An older child might feel similarly, but I would argue that most 6-year-olds are not developmentally capable of reliably enjoying that sense of having contributed to the community. They are much more likely to feel as if they have fulfilled an obligation placed upon them by their parents.

Even if allowing a 6-year-old with potentially stigmatizing physical findings to serve as an SP was deemed to be minimal risk or to offer a reasonable prospect of direct benefit to that particular child, several other ethical obligations exist. First, having young children serve as SPs should occur only when adults or older children are not available to serve that role. If an adult or adolescent with thalassemia and similar physical findings can be recruited, that would be preferable to using a young child.

Second, if the child is allowed to serve as an SP, the welfare of the child must remain paramount and every effort made to minimize potential harm to the child. Frequent breaks should be scheduled. The child should be engaged as much as possible as an active rather than passive participant. Should the child display distress or discomfort at any point, the examination should stop and the needs of the child addressed, including offering the opportunity for a break or for cessation of the activity.

Third, compensation of the parents incentivizes them to consider factors other than their child’s welfare and may hamper their ability to judge the potentially negative impact of this activity on their child. This scenario is most important when the activity may exceed minimal risk. Although the compensation in the
present case seems fair for 2 full days of activity (similar to the parents’ usual income), some consideration should be given to incorporating an independent advocate; the advocate’s role would be to assure that the child’s welfare is optimized during the process.

Finally, there should be an absolute requirement for assent; that is, the active affirmative agreement of the child to participate. Assent serves to remind parents, educators, and students that children are persons with interests and not solely a means to an end. The child should be permitted to revoke assent at any time he or she becomes dissatisfied, and dissent should be respected regardless of whether parental permission has been granted.

John D. Lantos, MD, Comments

SPs are cool. Compared with classroom situations, they allow teaching and learning that more clearly mirrors the situation of an actual doctor talking to and examining an actual patient. To the extent that they improve doctors’ skills, SPs are good for actual patients, who benefit by having trainees who are more skilled and less anxious. When the actors who play SPs are adults, they know what they are getting into and do so voluntarily. When the actors are children, the potential for exploitation exists. Interestingly, this situation may mirror the potential for exploitation among child actors in film and television.

Child actors are granted an exemption from child labor laws because it is understood that the work that they do (ie, playing the part of a child) cannot be done by an adult. In the United States, each state regulates child actors, under guidance from the federal government. In California, minors can only work in theater if the State Labor Commissioner issues a permit. They are not allowed to work >5 consecutive days. They are excused from up to 5 school absences per year, and school districts are to allow pupils to complete all assignments and tests missed during their absence. Courts may require a portion of earnings be set aside for the minor in a trust. Other states have different rules, but all have some rules.16

Children who are used as SPs deserve similar protection. Although the analogy to participation in research is interesting, the analogy to participating in the workforce might also offer valuable guidance as to how this practice should be regulated.

REFERENCES


ABBREVIATIONS
OSCE: objective structured clinical examination
SP: standardized patient
A Multicenter Collaborative to Improve Care of Community Acquired Pneumonia in Hospitalized Children

Kavita Parikh, MD, MSHS, a Eric Biondi, MD, MSBA, b Joanne Nazif, MD, c Faiza Wasif, MPH, d Derek J. Williams, MD, MPH, e Elizabeth Nichols, MS, f Shawn Ralston, MD, MS, g Value in Inpatient Pediatrics

Network Quality Collaborative For Improving Care In Community Acquired Pneumonia

abstract

BACKGROUND AND OBJECTIVES: The Value in Inpatient Pediatrics Network sponsored the Improving Care in Community Acquired Pneumonia collaborative with the goal of increasing evidence-based management of children hospitalized with community acquired pneumonia (CAP). Project aims included: increasing use of narrow-spectrum antibiotics, decreasing use of macrolides, and decreasing concurrent treatment of pneumonia and asthma.

METHODS: Data were collected through chart review across emergency department (ED), inpatient, and discharge settings. Sites reviewed up to 20 charts in each of 6 3-month cycles. Analysis of means with 3-σ control limits was the primary method of assessment for change. The expert panel developed project measures, goals, and interventions. A change package of evidence-based tools to promote judicious use of antibiotics and raise awareness of asthma and pneumonia codiagnosis was disseminated through webinars. Peer coaching and periodic benchmarking were used to motivate change.

RESULTS: Fifty-three hospitals enrolled and 48 (91%) completed the 1-year project (July 2014–June 2015). A total of 3802 charts were reviewed for the project; 1842 during baseline cycles and 1960 during postintervention cycles. The median before and after use of narrow-spectrum antibiotics in the collaborative increased by 67% in the ED, 43% in the inpatient setting, and 25% at discharge. Median before and after use of macrolides decreased by 22% in the ED and 27% in the inpatient setting. A decrease in asthma and CAP codiagnosis was noted, but the change was not sustained.

CONCLUSIONS: Low-cost strategies, including collaborative sharing, peer benchmarking, and coaching, increased judicious use of antibiotics in a diverse range of hospitals for pediatric CAP.
Increasing Tdap Coverage Among Postpartum Women: A Quality Improvement Intervention

Henry H. Bernstein, DO, MHCM, a,b,c Mikhaela Monty, MD, b Patriot Yang, BA, a Amy Cohen, EdM c

General Pediatrics, Cohen Children’s Medical Center of, New York, New Hyde Park, New York; bHofstra Northwell School of Medicine, Hempstead, New York; and cDepartment of Health Policy and Management, Harvard T.H. Chan School of Public Health, Boston, Massachusetts

Dr Bernstein conceptualized and designed this quality improvement project, conducted the analyses, and drafted, critically reviewed, and revised the manuscript; Dr Monty helped with the analysis and interpretation of data, contributed to the initial draft of the manuscript, and critically reviewed the manuscript; Ms Yang made substantial contributions in the conceptualization, design, and coordination of the study and critically reviewed the manuscript; and Ms Cohen helped in the conceptualization, design, analysis, and interpretation of data for the study and critically reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

DOI: 10.1542/peds.2016-0607
Accepted for publication Aug 29, 2016
Address correspondence to Henry H. Bernstein, DO, MHCM, General Pediatrics, 410 Lakeville Rd, Suite 108, New Hyde Park, NY 11042. E-mail: hbernstein@northwell.edu

BACKGROUND AND OBJECTIVE: Infants are at greatest risk for severe disease and death from pertussis; most acquire it from household contacts. Centers for Disease Control and Prevention guidelines recommend tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis, adsorbed (Tdap) vaccination for infant caregivers, especially postpartum women who did not receive it during pregnancy. Our objective was to increase the percentage of women receiving Tdap vaccine before postpartum discharge.

METHODS: An interdisciplinary workgroup identified barriers to improvement of postpartum Tdap vaccination from which a 5-step intervention was created: (1) provide education on Tdap and pertussis; (2) offer Tdap throughout hospitalization; (3) create a Tdap standing order; (4) keep Tdap as floor stock; and (5) document administration. Pre- and postintervention data were collected from monthly chart reviews. Our main outcome measures were the proportion of postpartum women eligible for Tdap and the proportion of those eligible who received Tdap.

RESULTS: Preintervention baseline data (202 charts) described 166 postpartum women eligible to receive Tdap. Of the eligible women, 91 (55%) received the Tdap vaccine. During the 9-month postintervention period, 844 charts were reviewed (average, 93 per month; range, 82–104). Of the 632 women eligible to receive the Tdap vaccine, 462 (73% overall [range, 67%–79%]) received it. Thirty-three percent more postpartum mothers received the Tdap vaccine before discharge in the postintervention period ($P < .01$). The percentage of women eligible decreased from 82% to 75%.

CONCLUSIONS: This quality improvement initiative substantially increased Tdap immunization in the immediate postpartum period. Efforts to increase immunization during pregnancy for passive transfer of maternal antibodies remain preferable.

Full article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2016-0607
abstract

BACKGROUND AND OBJECTIVES: To improve hospital to home transitions, a 4-element pediatric patient-centered transition bundle was developed, including: a transition readiness checklist; predischarge teach-back education; timely and complete written handoff to the primary care provider; and a postdischarge phone call. The objective of this study was to demonstrate the feasibility of bundle implementation and report initial outcomes at 4 pilot sites. Outcome measures included postdischarge caregiver ability to teach-back key home management information and 30-day reuse rates.

METHODS: A multisite, observational time series using multiple planned sequential interventions to implement bundle components with non-technology-supported and technology-supported patients. Data were collected via electronic health record reviews and during postdischarge phone calls. Statistical process control charts were used to assess outcomes.

RESULTS: Four pilot sites implemented the bundle between January 2014 and May 2015 for 2601 patients, of whom 1394 had postdischarge telephone encounters. Improvement was noted in the implementation of all bundle elements with the transitions readiness checklist posing the greatest feasibility challenge. Phone contact connection rates were 69%. Caregiver ability to teach-back essential home management information postdischarge improved from 18% to 82%. No improvement was noted in reuse rates, which differed dramatically between technology-supported and non-technology-supported patients.

CONCLUSIONS: A pediatric care transition bundle was successfully tested and implemented, as demonstrated by improvement in all process measures, as well as caregiver home management skills. Important considerations for successful implementation and evaluation of the discharge bundle include the role of local context, electronic health record integration, and subgroup analysis for technology-supported patients.
Counseling Parents and Teens About Marijuana Use in the Era of Legalization of Marijuana

Sheryl A. Ryan, MD, FAAP, a Seth D. Ammerman, MD, FAAP, b COMMITTEE ON SUBSTANCE USE AND PREVENTION

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.

BACKGROUND

The legalization of medical marijuana in many states and the District of Columbia and the outright legalization of recreational marijuana for adults aged 21 years and older in a few states and the District of Columbia have resulted in changes in the access to and availability of this drug. Most of these states now allow the use of marijuana for a variety of medical conditions in adults as well as in children (with parental permission). In addition, many states have reduced penalties for the recreational use of marijuana; criminal penalties have been reduced from felonies in some cases to misdemeanors or infractions.1 For up-to-date information on the numbers of states allowing these laws related to marijuana use, the reader is referred to www.aap.org/marijuana.

Although there are currently no initiatives to legalize the recreational use of marijuana for minors and marijuana is still a federally controlled substance, changes in the legal status of marijuana, even if limited to adults, may affect use among adolescents by decreasing the perceived risk of harm or through the marketing of legal marijuana, despite restrictions that prohibit marketing and advertising to this age group. The National Survey on Drug

abstract

*Department of Pediatrics/Adolescent Medicine, Yale University School of Medicine, New Haven, Connecticut; and *Department of Pediatrics/Adolescent Medicine, Stanford University School of Medicine, Stanford, California

Drs Ryan and Ammerman were each responsible for all aspects of writing and editing the document and reviewing and responding to questions and comments from reviewers and the Board of Directors.

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.

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: 10.1542/peds.2016-4069

Address correspondence to Sheryl Ryan, MD, FAAP; E-mail: sheryl.ryan@yale.edu

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

Use and Health recently documented a decline in the percentage of 12- to 17-year-olds who perceived that there is “great risk” in smoking marijuana once a month or 1 to 2 times per week, which is concerning, because the same survey has documented that decreases in perceived risk typically precede or occur at the same time as increases in use. The concentration of tetrahydrocannabinol, or THC, the psychoactive substance in the marijuana plant, has increased considerably, from approximately 4% in the early 1980s to upward of 12% in 2012, increasing the risk of adverse effects and the potential for addiction.

Studies have been conducted in adults to research the potential therapeutic effects of the class of chemicals known as cannabinoids (the active compounds in marijuana) administered either as a pharmaceutical preparation or as marijuana leaves, distilled oils, or edibles and drinkables. Cannabinoids have been shown to be helpful for adults in addressing some symptoms, such as increasing appetite and decreasing nausea and vomiting in patients receiving chemotherapy and reducing pain in chronic neuropathic pain syndromes. Cannabinoids may have adverse effects, however, such as dizziness, dysphoria, and clouded sensorium. The only studies that have been published on the use or efficacy of medicinal marijuana in the treatment of refractory seizures have also been documented. These effects may contribute to unintentional deaths and injuries among adolescents, especially those who drive after using marijuana. Negative health effects on lung function associated with smoking marijuana also have been documented; in addition, longitudinal studies linking marijuana use with higher rates of mental health disorders, such as depression and psychosis, recently have been published, raising concerns about longer-term psychiatric effects.

Secondhand marijuana smoke can also be detected in adults who are passively exposed, and new data also suggest that secondhand marijuana smoke may be harmful to children. A recent study found that in an inpatient sample of infants admitted for respiratory compromise, 1 in 6 had detectable traces of marijuana in their systems.

The adolescent brain, particularly the prefrontal cortex areas that control judgment and decision-making, is not fully developed until the early 20s, raising questions about how any substance use may affect the developing brain. Studies examining brain functioning in youth who use cannabis regularly or heavily (defined as using 10–19 times/month or 20 or more times/month, respectively) show potential abnormalities that occur across a number of brain regions including those affecting memory (hippocampus) and executive functioning and planning (prefrontal cortex). Studies assessing the role of marijuana on brain morphology are inconsistent, with 1 study citing increased and decreased volumes of subcortical structures and another citing no effect on structures such as the amygdala and hippocampus. A major study also has shown that long-term marijuana use initiated in adolescence has negative effects on intellectual function and that the deficits in cognitive areas, such as executive function and processing speed, did not recover by adulthood, even when cannabis use was discontinued.

As with other psychoactive substances, the younger an adolescent begins using drugs, including marijuana, the more likely it is that drug dependence or addiction will develop in adulthood. Evidence clearly shows that marijuana is an addictive substance; overall, 9% of those experimenting with marijuana will become addicted; this percentage increases to 17% among those who initiate marijuana use in adolescence and to a range of between 25% and 50% among teenagers who smoke marijuana daily. It should be noted that most teenage patients addicted to marijuana do not have lifelong addiction; however, significant effects on cognitive and psychosocial function may occur during the addiction period.

Marijuana use during pregnancy has adverse effects on the fetus, including growth retardation. Longer-term consequences of prenatal marijuana use that have been reported in infants and children include subtle deficits in learning and memory as well as deficits in executive functions, such as problem-solving skills that require sustained attention, analysis, and integration.

**ROLE OF THE PEDIATRICIAN**

Pediatricians are in an influential position to counteract the perception of teenage marijuana use as benign. Research findings regarding the health effects of marijuana on children and adolescents provide guidance for parents and their children. The office setting provides an excellent opportunity for education and counseling to prevent marijuana use as well as to implement brief interventions and referrals if needed. Parents who use marijuana may not fully realize the problems that their own use may present for their children’s health; the effect that their modeling of
The American Academy of Pediatrics (AAP) recognizes that parents may choose to administer marijuana to children with severely debilitating or severe chronic conditions when other standard therapies have proven inadequate or in compassionate care/end-of-life care situations and that they may seek support for this practice from their child’s pediatrician. However, because marijuana use is still considered a federal offense, there may be legal ramifications for a pediatrician formally recommending the use of medical marijuana in these extenuating circumstances. Awareness of one’s state laws and protections for medical providers is essential, and direct discussion of this issue with one’s state medical board may be appropriate.

The following sections include key facts and suggested talking points for the pediatrician to use in speaking with youth and their parents about marijuana and the effects of its use. For detailed references to the data listed in this statement, the reader is referred to the full technical report published by the AAP.1

### Office Approach to the Adolescent Patient

1. Adolescents and preteens may be screened for substance use and brief intervention, as recommended in the Screening, Brief Intervention, and Referral for Treatment (SBIRT) policy statement.27 The effectiveness of the SBIRT technique has been documented in adults with alcohol use problems; because of the lack of information in the adolescent population, the US Preventive Services Task Force recently gave SBIRT an “I” rating, stating that there was insufficient evidence to recommend either for or against this technique. However, on the basis of the limited evidence available and the low cost of this brief intervention, the AAP and the National Institute on Alcohol Abuse and Alcoholism both recommend that this technique be used in pediatric practices as part of routine care.

2. For adolescents who do not use marijuana, motivational techniques may be helpful in eliciting reasons for abstaining from use and resisting peer pressure in a manner that supports their decision to abstain.

3. Adolescents who use marijuana regularly or heavily are more likely to meet criteria for a substance use disorder. For these teenagers, a brief motivational intervention may be used to target: (1) reducing use and (2) continuing the conversation either with the pediatrician or a mental health or behavioral counselor. Additional advice for gathering information that is helpful to determine the extent and severity of use follows:

   - Ask the adolescent how much and how often he or she uses marijuana. Also ask about the circumstances (ie, where the marijuana is obtained, if use is with others versus alone, if use is before or during school versus on the weekends) and motivations (when stressed, bored, alone, angry, etc) associated with the decision to use the substance. Although teenagers may use marijuana for the positive euphoric effects or for social acceptance, they also may use marijuana for self-medication, such as to relieve negative moods (ie, stress, anxiety, or depression) or for sleep problems. Teenagers who use marijuana for these purposes who meet criteria for a co-occurring mental health disorder may benefit from treatment, including counseling and/or a psychiatric evaluation.

   - Take a detailed history that includes identifying concerns associated with marijuana use. Criteria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (see Table 1), can be useful as a guideline in ruling out problematic marijuana use.29

   - If the adolescent does not report regular use of marijuana and denies any associated problems, offer a “challenge.” Ask the adolescent to quit using the drug for a brief period of time, and see what happens. If the adolescent is able to stop completely, ask whether life was “better, worse, or the same” during the quit period to prompt a discussion of pros and cons of use. If the adolescent was unable to stop

### TABLE 1 DSM-5 Criteria for Marijuana Use Disorder

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Use</td>
<td>Regular or heavy use of marijuana, evidenced by two or more of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use of marijuana is before or during school periods</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use of marijuana is with others versus alone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Use of marijuana is before or during school periods versus on the weekends</td>
<td></td>
</tr>
<tr>
<td>2. Tolerance</td>
<td>Needing more of the substance to get the effect you want</td>
<td></td>
</tr>
<tr>
<td>3. Withdraw symptoms</td>
<td>Development of withdrawal symptoms, which can be relieved by taking more of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>the substance</td>
<td></td>
</tr>
<tr>
<td>4. Cravings or urges</td>
<td>Cravings and urges to use the substance</td>
<td></td>
</tr>
<tr>
<td>5. Time spent</td>
<td>Spending a lot of time getting, using, or recovering from use of the substance</td>
<td></td>
</tr>
<tr>
<td>6. Taking the substance in larger amounts or for longer than you meant</td>
<td>Taking the substance in larger amounts or for longer than you meant to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wanting to cut down or stop using the substance but not managing to</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Spending a lot of time getting, using, or recovering from use of the substance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cravings and urges to use the substance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Not managing to do what you should at work, home, or school because of substance use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Continuing to use, even when it causes problems in relationships</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Giving up important social, occupational, or recreational activities because of substance use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Using substances again and again, even when it puts you in danger</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Continuing to use, even when you know you have a physical or psychological problem that could have been caused or made worse by the substance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Needing more of the substance to get the effect you want (tolerance)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Development of withdrawal symptoms, which can be relieved by taking more of the substance</td>
<td></td>
</tr>
</tbody>
</table>

Each specific substance other than caffeine (which is not a diagnosable substance use disorder) is addressed as a separate use disorder (eg, alcohol use disorder; stimulant use disorder). Nearly all substances use these same overarching criteria. Severity is divided into mild, moderate, or severe: mild = meeting 2–3 criteria; moderate = meeting 4–5 criteria; severe = meeting >6 criteria. DSM-5, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.
completely, explore possible triggers and high-risk situations that were barriers to success. Work with the adolescent to problem-solve and try again. If the adolescent was unwilling to quit, even for a limited period of time, explore the motivations for drug use (see talking point 1) and consider whether any additional interventions or supports may be helpful. Talking points can be introduced as areas of concern but also can be used to trigger engagement and discussion during brief interventions (eg, information about the modeling effect of parental smoking and the current understanding of marijuana effects in teenagers). If there are major concerns for the teenager's safety or the teenager is considered at high risk of adverse consequences, breaking confidentiality and notifying the parents may be advisable to ensure the patient's safety.

TALKING POINTS FOR PARENTS AND TEENS: HANDOUT

1. Marijuana is not a benign drug for teens. The teen brain is still developing, and marijuana may cause abnormal brain development.

2. Teens who use marijuana regularly may develop serious mental health disorders, including addiction, depression, and psychosis.

3. There are no research studies on the use of medical marijuana in teens, so actual indications, appropriate dosing, effects, and side effects are unknown. The only data available on medical marijuana in the pediatric population are limited to its use in children with severe refractory seizures.

4. Recreational use of marijuana by minors and young adults under the age of 21 years is illegal and, if prosecuted, may result in a permanent criminal record, affecting schooling, jobs, etc.

5. Never drive under the influence of marijuana or ride in a car with a driver who is under the influence of marijuana. Adults and teens regularly get into serious and even fatal car accidents while under the influence of marijuana.

6. Marijuana smoke is toxic, similar to secondhand tobacco smoke. The use of vaporizers or hookahs does not eliminate the toxic chemicals in marijuana smoke.

7. For parents: You are role models for your children, and actions speak louder than words. So if you use marijuana in front of your teens, they are more likely to use it themselves, regardless of whether you tell them not to. (See the AAP Healthy Children Web site: www.healthychildren.org/English/ages-stages/teen/substance-abuse/Pages/Drug-Abuse-Prevention-Starts-with-Parents.aspx.)

8. For parents: It is important to keep all marijuana products away from children. As with other medications and toxic products, containers that are child-proof and kept out of reach should be used. For small children, marijuana edibles and drinks can be particularly dangerous.

9. For parents: Remember that intoxication and euphoria are predictable effects of using marijuana products. Being “high” from your own recreational or medical marijuana use may alter your capacity to function safely as a parent or to provide a safe environment for infants and children.30

10. For parents: If your child asks you directly whether you have used marijuana, a brief, honest answer may help the child feel comfortable talking with you about drug use issues. However, it is best to not share your own histories of drug use with your children. Rather, discussion of drug use scenarios, in general, may be a more helpful approach.

SUMMARY AND CONCLUSIONS

Pediatricians are in a unique position to provide parents and teenagers with accurate information and counseling regarding the consequences of marijuana or cannabis use by children, teenagers, and adults. A number of strategies can be used to counsel families about preventing use and to intervene if marijuana is being used either recreationally or medically by the families for whom they provide medical care.

AUTHORS
Sheryl A. Ryan, MD, FAAP
Seth D. Ammerman, MD, FAAP

COMMITTEE ON SUBSTANCE USE AND PREVENTION, 2016–2017
Sheryl A. Ryan, MD, FAAP, Chairperson
Pamela K. Gonzalez, MD, MS, FAAP
Stephen W. Patrick, MD, MPH, MS, FAAP
Joanna Quigley, MD, FAAP
Leslie R. Walker, MD, FAAP

FORMER COMMITTEE MEMBERS
Seth D. Ammerman, MD, FAAP
Sharon Levy, MD, MPH, FAAP
Lorena Siqueira, MD, MSPH, FAAP
Vincent C. Smith, MD, MPH, FAAP

LIAISONS
Vivian B. Faden, PhD – National Institute of Alcohol Abuse and Alcoholism
Gregory Tau, MD, PhD – American Academy of Child and Adolescent Psychiatry

STAFF
Renee Jarrett, MPH

ABBREVIATIONS
AAP: American Academy of Pediatrics
SBIRT: Screening, Brief Intervention, and Referral for Treatment


The Need to Optimize Adolescent Immunization

Henry H. Bernstein, DO, MHCM, FAAP, Joseph A. Bocchini Jr, MD, FAAP, COMMITTEE ON INFECTIOUS DISEASES

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.

Immunization is a key preventive cornerstone of pediatric care. An updated harmonized immunization schedule of the American Academy of Pediatrics (AAP), American Academy of Family Physicians, and Centers for Disease Control and Prevention (CDC) is released each February (www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/
immunization/Schedules/hcp/child-adolescent.html). It currently is formatted as a single schedule for children ages 0 through 18 years, with footnotes that highlight vaccine recommendations for individuals in specific circumstances, including those with high-risk conditions.

The recommended schedule for healthy adolescents includes:

- quadrivalent meningococcal conjugate vaccine (MenACWY): 1 dose at 11 through 12 years of age, with a booster dose at 16 years of age;
- serogroup B meningococcal vaccines (MenB): 16 through 18 years of age (category B recommendation; A Category B recommendation indicates individual counseling and risk benefit evaluation that depends on provider judgment);
- tetanus, diphtheria, and acellular pertussis, absorbed vaccine (Td): 1 dose at 11 through 12 years of age; pregnant adolescents should receive 1 dose during each pregnancy at 27 through 36 weeks of gestation;
- human papillomavirus (HPV) vaccine: 2 doses at 9 through 14 years of age for persons at 0 and 6 to 12 months; 3 doses for persons 15 through 26 years of age and 9 through 26 years of age for immunocompromised at 0, 1 to 2, and 6 months;
- influenza: 1 dose every year.

Figure 1 compares immunization rates for Tdap, MenACWY, and HPV. * Tdap: ≥ 1 Tdap at or after age 10 years; ≥ 1 MenACWY: ≥ 1 dose MenACWY or meningococcal-unknown type vaccine; ≥ 2 doses MenACWY: ≥ 2 doses MenACWY or meningococcal-unknown type vaccine, calculated only among adolescents aged 17 years at the time of the interview (does not include adolescents who received their first dose of MenACWY at or after 16 years of age); ≥ 1 HPV vaccine: ≥ 1 dose HPV vaccine, 9-valent (9vHPV), quadrivalent (4vHPV) or bivalent (2vHPV); ACIP recommends 9vHPV, 4vHPV or 2vHPV for females and 9vHPV or 4vHPV for males (the routine ACIP recommendation was made for females in 2006 and for males in 2011); ≥ 3 HPV vaccine: ≥ 3 doses HPV vaccine. †NIS-Teen implemented a revised APD definition in 2014 and retrospectively applied the revised APD definition to the 2013 data. Estimates using different APD definition may not be directly comparable. APD, adequate provider data; NIS-Teen, National Immunization Survey - Teen. (Source: Centers for Disease Control and Prevention. National and state vaccination coverage among adolescent aged 13-17 years - United States. MMWR Morb Mortal Wkly Rep. 2016;65(33):850-858)

Vaccination rates also vary considerably by vaccine and by state. The National Immunization Survey (NIS)-Teen showed the immunization rates of adolescents receiving at least 1 dose of Tdap ranged from 70% to 97%, whereas rates for at least 1 dose of MenACWY ranged from 55% to 98%. Completion of the 3-dose HPV vaccine series ranged from 24% to 68% in girls and from 16% to 58% in boys. Although HPV vaccination rates are improving slowly, they continue to be far behind Tdap and MenACWY vaccination rates for both boys and girls. Compared with 2014, national vaccination rates in 2015 have increased to 81% for MenACWY but decreased to 86% from 88% for Tdap. Meanwhile, only 63% of girls received at least 1 dose of HPV vaccine, and 42% completed the 3-dose series. Rates for boys were even lower, with 50% of boys having received at least 1 dose of the HPV vaccine series and only 28% having completed the 3-dose series. In addition, there are distinct missed opportunities to administer adolescent vaccines, particularly HPV vaccine. If HPV vaccine had been administered during the same visit at which another recommended vaccine, such as Tdap, was given, the
vaccination rate of 13-year-old girls born in 2000 for at least 1 dose of HPV vaccine would have been 91%. Current data demonstrate a need for improvement in adolescent immunization rates. Understanding the epidemiology and current vaccine recommendations in the adolescent schedule is important to optimize health care for adolescents. Although barriers to optimizing immunization rates persist, familiarity with this information should enable health care providers to create better implementation strategies to enhance vaccine coverage. The increased flexibility created by the recent shift to a 2-dose schedule for HPV vaccine for persons initiating the series at 9 through 14 years of age is anticipated to increase completion rates, but additional efforts will be needed to reach the Healthy People 2020 goal of 80%.

**EPIDEMIOLOGY OF ADOLESCENT VACCINE-PREVENTABLE DISEASES**

**Meningococcal Vaccines**

Meningococcal disease affects all age groups, with increased infection rates seen among infants, adolescents, and the elderly (Fig 2). Complications of meningococcal disease include neurologic sequelae, limb amputation, and death. The case/fatality ratio of meningococcal disease ranges from 10% to 40%. Although the incidence of meningococcal disease has been declining, outbreaks do still occur. Adolescents and their families should be informed about the threat of infection and its complications.

Two polysaccharide-protein conjugate vaccines are currently licensed and recommended as part of the routine immunization schedule for the prevention of meningococcal disease in US adolescents: MenACWY-D (Menactra [Sanofi Pasteur, Swiftwater, PA]) and MenACWY-CRM (Menveo [Novartis Vaccines and Diagnostics, Cambridge, MA]). Both vaccines provide protection against meningococcal serogroups A, C, W, and Y. These vaccines also are indicated for groups at increased risk (ie, those with asplenia, complement deficiencies, or travel to an area where meningococcal disease is prevalent). There is no preferential recommendation for one MenACWY over the other.

In 2005, the Advisory Committee on Immunization Practices (ACIP) recommended immunization against meningococcal disease with a MenACWY conjugate vaccine for individuals 11 through 12 years of age, primarily because the increased incidence of disease begins in late adolescence. In August 2011, the CDC recommended a booster dose of meningococcal vaccine 5 years after primary immunization for all adolescents because of serologic evidence of waning immunity and several cases of breakthrough disease.

Concurrent administration of meningococcal vaccine (MenACWY-CRM) with Tdap and quadrivalent HPV vaccine (4vHPV) yielded similar immune responses when compared with the response of each individual vaccine given independently. There also was no increase in adverse effects when all 3 vaccines were administered together. Similar results have been found for the 9-valent HPV vaccine (9vHPV). This finding has important implications in the clinical setting, encouraging simultaneous administration of these 3 vaccines during the same office visit and thereby increasing timely protection of adolescents against these vaccine-preventable diseases.

With the use of MenACWY vaccines in adolescents and young adults, serogroup B now causes 40% of all meningococcal disease cases in this age group. Most children survive serogroup B meningococcal disease without major sequelae. However, approximately one-tenth have major disabling deficits, and more than one-third have 1 or more deficits in physical, cognitive, and psychological functioning, with
the additional burden of memory deficits and executive function problems. 19 In recent years, ~50 cases of serogroup B meningococcal disease have occurred annually among 11- through 23-year-olds. 20 Approximately one-third of cases of serogroup B meningococcal disease among 18- through 23-year-olds occur in college students, and there have been 10 university-based outbreaks attributable to this serogroup since 2008. 21 Two MenB vaccines have been licensed in recent years, as described below.

During 2013 to 2014, outbreaks of serogroup B meningococcal disease occurred at 2 universities, with a combined 13 cases and 1 death reported. In response, vaccination campaigns were conducted at both universities using a MenB vaccine (Bexsero [Novartis Vaccines and Diagnostics, Cambridge, MA]), which at the time had been investigational in the United States 22 but already had been licensed in Europe, Canada, and Australia. It is not known whether the available MenB vaccines reduce the number of secondary cases. 23

Bexsero was licensed 24 in the United States in January 2015 for use in individuals 10 through 25 years of age. Trumenba (Wyeth Pharmaceuticals, a subsidiary of Pfizer, Philadelphia, PA) was licensed 25 in the United States for use in the same age group in October 2014. The ACIP currently recommends the use of either MenB vaccine for people 10 years and older at increased risk for meningococcal serogroup B disease, including people with persistent complement component deficiencies, people with anatomic or functional asplenia, people receiving eculizumab, microbiologists who work with Neisseria meningitidis, and people in outbreak settings. These MenB vaccines were approved under the surrogate marker of complement-dependent killing of organisms by vaccine-induced antibodies. This surrogate marker has not been established with serum from persistent complement component-deficient subjects, and it is unknown whether such people can expect protection. Bexsero is a 2-dose series administered 1 month apart; Trumenba is approved as a 3-dose series administered at 0, 2, and 6 months and a 2-dose series given at 0 and 6 months. 26 Only the 3-dose series of Trumenba should be used for those at increased risk for meningococcal serogroup B disease or those for whom immediate protection is optimal, such as during an outbreak. Although there is no preference for one MenB vaccine over the other, the same product must be used to complete the series. In June 2015, the ACIP made a Category B recommendation for use of MenB vaccines in 16- through 23-year-old individuals for short-term protection against meningococcal B serogroup strains. Bexsero or the 2-dose Trumenba series can be used. The preferred ages are 16 through 18 years. A Category B recommendation indicates individual counseling and risk benefit evaluation that depends on health care provider judgment and patient preferences. It is covered by the Vaccines for Children (VFC) program and by insurance companies under the Patient Protection and Affordable Care Act (Pub L No. 111-148 [2010]), with no patient out-of-pocket costs. International studies may be useful to consider when evaluating the Category B recommendation in the United States.

Acellular Pertussis Vaccines

There has been increased clinical recognition of pertussis and its associated morbidity and mortality over the past 30 years. Increased awareness, evolving diagnostics, 27 vaccine refusal, and, most importantly, a more rapidly waning immunity after vaccination with acellular products compared with whole-cell pertussis vaccines have contributed to the marked recent increase in pertussis cases in the United States. 28–30 In 2015, 20 762 cases of pertussis were reported among all ages, with 32% of these cases occurring in adolescents 11 to 19 years of age and 9 reported infant deaths. 31, 32 The incidence of pertussis peaked in 2012, with ~48 277 cases across all ages and 20 reported deaths attributable to pertussis. 33

Adolescents serve as an important reservoir for pertussis and are known to transmit the infection to the most vulnerable population: young infants. 28 In 2015, almost 7000 cases of pertussis were reported in the population of adolescents 11 to 19 years of age. 32 Healthy People 2020 has created a goal to have no more than 2000 cases of pertussis in adolescents by 2020. Although most of the deaths are among young infants, older people, including adolescents, experience considerable morbidity attributable to pertussis. Prolonged cough, paroxysms of cough, pneumonia, shortness of breath, a choking sensation, vomiting, rib fractures, and scleral hemorrhages can occur. Adolescents need to be vaccinated to reduce adolescent disease morbidity and to minimize transmission of the disease to infants.

Two Tdap products, Boostrix (GlaxoSmithKline, Research Triangle Park, NC) and Adacel (Sanofi Pasteur), were licensed in the United States in 2005 for use in adolescents to improve pertussis immunity. The ACIP recommended a single Tdap dose at ages 11 through 12 years, with catch-up vaccination at ages 13 through
18 years.34 The Tdap booster is recommended regardless of the interval since the last immunization with a tetanus or diphtheria toxoid–containing vaccine.35 Tdap has also been recommended as a single dose for adults, replacing 1Td booster.36 Beginning in October 2012, the ACIP recommended a dose of Tdap for every pregnant woman during each pregnancy, regardless of immunization history.37 Tdap administration is preferred for pregnant women between 27 and 36 weeks of gestation, with an emphasis on earlier weeks during this preferred period, to enable high titers of the antibody to cross the placenta to provide the longest duration of passive protection to the young infant. The available data do not suggest any increased risk or adverse events in pregnant women who receive Tdap.38

**HPV Vaccines**

HPV can be transmitted with any genital-mucosal contact. The lifetime risk of acquiring an HPV infection is >80%.39 An estimated 79 million people in the United States are currently infected with HPV and approximately half of the 14 million new infections that occur each year are in 15- through 24-year-old individuals.40, 41 Just over 20% percent of a representative sample of the US population of 14- through 19-year-old girls who self-obtained vaginal swabs were found to be colonized with high-risk (oncogenic) HPV types.42 High-risk HPV types are responsible for virtually all cases of cervical cancer and a large percentage of anogenital and oropharyngeal cancers in females and males.43,44 More than 26 000 new cases of HPV-related cancers are diagnosed annually in the United States. With no vaccination among girls 12 years of age and younger, there would be an estimated 168 400 lifetime cases of cervical cancer and 54 100 cervical cancer deaths among this group.45 In fact, comparison of prevaccine (2003–2006) and vaccine era (2009–2012) HPV prevalence showed a 64% decrease in 4vHPV type prevalence among girls 14 through 19 years of age and a 34% decrease among women 20 through 24 years of age, highlighting the impact of the HPV vaccine.46

The HPV vaccine has been included in the annual schedule as a 3-dose series for girls since 2007 and for both boys and girls since 2011 at ages 11 through 12 years. As of October 2016, the ACIP has revised its recommended HPV schedule to be a 2-dose series for persons initiating the vaccine series from 9 through 14 years of age.47 Until recently, 2 HPV vaccines were available in the United States: bivalent human papillomavirus vaccine (2vHPV; Cervarix [GlaxoSmithKline]), which targets HPV types 16 and 18 and is licensed for use in females, and quadrivalent HPV vaccine (4vHPV; Gardasil [Merck & Co Inc, Whitehouse Station, NJ]), which protects against HPV types 6, 11, 16 and 18 and is licensed for use in females and males.48 A 9-valent HPV vaccine (9vHPV; Gardasil-9 [Merck & Co Inc, Whitehouse Station, NJ]) was licensed in December 2014 for use for males through age 26 years.49 Additional data on males through age 26 years were submitted to the FDA, and in December 2015, 9vHPV was licensed for use for males through age 26 years.50

A 2-dose HPV vaccine schedule has the potential to improve completion rates and reduce costs. Data on antibody responses and the effectiveness of 2 doses of 2vHPV and 4vHPV suggest that protection from a 2-dose regimen would be similar to that of a 3-dose series. In 1 Canadian randomized clinical trial, 520 girls aged 9 to 13 years were randomized to receive either 3 doses of 4vHPV at 0, 2, and 6 months or 2 doses of 4vHPV at 0 and 6 months. Researchers found that antibody levels after the 2-dose schedule were noninferior to those after the 3 doses. They also found that antibody titers resulting from the 2-dose and 3-dose schedules were still comparable 36 months after receiving the vaccine.51 Similarly, in a study with over 1500 participants, Iverson et al52

The 9vHPV vaccine was initially licensed in December 2014 for use in females 9 through 26 years of age and males 9 through 15 years of age on the basis of trial results available at the time of Food and Drug Administration (FDA) submission. To evaluate the efficacy and safety of 9vHPV, a randomized, controlled clinical study was conducted in the United States and internationally.49 The 9vHPV was 97% effective in protecting against cervical, vulvar, and vaginal cancer precursor lesions related to the 5 additional types, and antibody response against the 4 types in the 4vHPV vaccine was noninferior.49
found that antibody concentrations achieved in a clinical trial after a 9vHPV 2-dose series administered at 0 and 6 or 12 months to 9- through 14-year-old girls and boys were noninferior compared with the currently licensed 3-dose series in 16- through 26-year-old females. The immune response with a 12-month interval between the 2 doses was more robust than that measured when the interval was only 6 months. Geometric mean antibody titers against all HPV types in the 9vHPV vaccine were higher in the 9- through 14-year-old age groups than in the 16- through 26-year-old women. Although these studies are being extended for 2 more years to evaluate antibody persistence, current data suggesting stronger immune responses in younger individuals may result in routinely recommending HPV vaccination for individuals as young as 9 years of age. The FDA approved the 2-dose schedule for persons 9 through 14 years of age on October 7, 2016, and the ACIP revised its recommendation on October 19, 2016 to vaccinate with 2 doses of 9vHPV vaccine. The second dose should be administered 6 to 12 months after the first. Recommendations for completion of the vaccination series depend on the individual’s age when the HPV vaccination was initiated. For example, if the first dose is given at age 14 years, that individual only needs 1 more dose >6 months later to complete the series, regardless of when the second dose is given.

The rationale for administering the HPV vaccine routinely at the 11- through 12-year-old visit is based on data from vaccine trials, epidemiologic studies of HPV infection, and sexual behavior as well as modeling studies of HPV infection in adolescents that indicate the greatest protection will be achieved by giving the vaccine before the adolescent becomes sexually active. There is remarkably high incidence of HPV infection after sexual initiation. The cumulative incidence of HPV infection was nearly 40% within the first 2 years after first having sexual intercourse among college women and almost 60% among college men, underscoring the importance of early immunization with all 3 HPV vaccine doses. Data reporting that ~24% of adolescent boys and girls report having sexual intercourse by ninth grade and that 58.1% report having sex by 12th grade support targeting HPV vaccination at the 11- through 12-year-old visit. Administration of either 2vHPV, 4vHPV, or 9vHPV leads to greater antibody responses in girls and boys 9 through 15 years of age, compared with those in girls and boys 16- through 26 years of age receiving the respective vaccine. Pre- and postlicensure studies also have demonstrated safety, immunogenicity, and efficacy for the 2vHPV, 4vHPV vaccines. Each vaccine is highly effective, providing type-specific protection against the included HPV types. A recent long-term study of 4vHPV recipients conducted over a period of 8 years has demonstrated safety, immunogenicity, and effectiveness in both girls and boys 9 through 15 years of age.

Currently, the ACIP recommends routine vaccination with the HPV vaccine for individuals 11 through 12 years of age. The vaccine is licensed for use in children beginning at age 9 years, the age at which the World Health Organization recommends starting HPV immunization. In addition, the ACIP recommends HPV vaccination beginning at age 9 years for children and youth with any history of sexual abuse or assault who have not initiated or completed the series. Girls and boys who are victims of sexual abuse or assault should receive the HPV vaccine through the recommended ages if they have not already been vaccinated. Vaccination is also recommended for 13- through 26-year-old females and 13- through 21-year-old males who have not been vaccinated previously or who have not completed the series. Persons who receive the first dose of the vaccine at 15 years of age or older, and persons who are immunocompromised, should complete a 3-dose schedule at 0, 1 to 2, and 6 months. Males 22 through 26 years of age also may receive the vaccine. Men who are immune suppressed, have HIV infection, or have sex with men should be vaccinated through age 26 years. For transgender persons, HPV vaccination is recommended through 26 years for those who were not adequately vaccinated previously. A series begun with 4vHPV can be completed with 9vHPV. A study on the cost-effectiveness of additional 9vHPV vaccination (ie, receiving a full 9vHPV series after receiving a full 4vHPV series) suggests that additional 9vHPV vaccination is not as efficient as other vaccination strategies, such as primary 9vHPV vaccination. Regardless, if a decision is made to give 9vHPV to a person who previously received a 2vHPV or 4vHPV series, the 2- or 3-dose regimen currently recommended for 9vHPV should be followed.

Most female adolescents on commercial and Medicaid health plans are currently not receiving the recommended doses of HPV vaccine by 13 years of age. Medicaid plans have reported significantly higher rates of 3-dose HPV vaccine coverage compared with commercial plans, although the median of adolescent girls receiving 3 doses was only 19%. According to
the 2015 NIS–Teen, just over half (63%) of girls ages 13 through 17 years received ≥1 dose of HPV vaccine, and only 41.9% completed the series. The coverage is even more limited among boys of the same age range, with 49.8% having received ≥1 dose, and 28.1% having completed the series. Compared with non-Hispanic white adolescents or adolescents living at or above the federal poverty level, adolescents who are African American, Hispanic, American Indian/Alaska Native, or living below the federal poverty line have a higher rate of initiation of the HPV vaccine series.8

Health care provider recommendation and physician attitude play a major role in the decision to vaccinate against HPV. On the basis of 2011 NIS–Teen data, Rahman et al63 found that health care provider recommendation independently predicted HPV vaccine initiation and completion. A strong endorsement is more influential than a weak one. Parents prefer clear, unambiguous recommendations; offering the HPV vaccine without strongly recommending it appears to confuse and frustrate parents. One of the most powerful messages that health care providers can transmit is that vaccination against HPV is a critical strategy for cancer prevention. Hull et al64 demonstrated that mothers and adolescent daughters were more willing to receive the HPV vaccine when it was recommended as a routine vaccine that prevents cancer. A study of the impact of maintenance-of-certification participation on HPV vaccination rates revealed that captured opportunities increased after participating health care providers chose to focus on cancer prevention, to use consistent language, and to emphasize vaccination at acute visits. These physicians had a significant relative increase in captured opportunities compared with non–maintenance of certification participants for HPV dose 1 at preventive visits and for doses 1 and 2 at acute visits.65 Mothers also stated that they were less skeptical of the HPV vaccine when it was recommended with other vaccines than when the vaccine was singled out. The "same way, same day" slogan of the CDC promotes the recommendation of HPV vaccine with Tdap and meningococcal vaccines, grouping the 3 vaccines together to avoid singling the HPV vaccine out.66

Influenza Vaccines

Influenza causes annual outbreaks, the timing and severity of which are unpredictable. Both children with high-risk conditions and otherwise healthy children are hospitalized each year because of influenza. Many more require outpatient or emergency department evaluation and management of influenza. A study of influenza-associated deaths from 2004 to 2012 demonstrated that even healthy children are at risk for mortality attributable to influenza.67 During nonpandemic seasons since the 2003–2004 season, reported pediatric deaths have ranged from a low of 37 (2011–2012 season) to a high of 171 (2012–2013 season). Higher pediatric mortality was noted during the 2009–2010 pandemic, with >344 pediatric deaths reported.68 From 2004 through 2012, influenza A virus has accounted for 78% of pediatric influenza-associated deaths.67 In the 2015–2016 influenza season, there were 89 reported influenza-associated pediatric deaths.69 Twenty-two deaths occurred in adolescents 12 through 17 years of age (24.7%) of all pediatric deaths. Approximately 60% of all pediatric deaths occurred in children and adolescents who did not have any underlying high-risk medical conditions (out of 68 with known medical history).69

Influenza immunization rates are much lower in older pediatric patients. On the basis of 2015–2016 NIS influenza vaccine coverage data for children 6 months through 17 years of age, only 46.8% of adolescents 13 through 17 years of age received the vaccine, the lowest uptake of all pediatric age groups. In comparison, 75.3% of infants 6 through 23 months of age received the influenza vaccine in 2015 to 2016.69

Annual vaccination against influenza is recommended for individuals of all ages beginning at 6 months of age, with a specific emphasis on groups at higher risk for complications (eg, children <5 years, the elderly, pregnant women, and those who are immunocompromised).70 In addition, the Committee on Obstetric Practice of the American Congress of Obstetricians and Gynecologists recommends routine influenza vaccination of pregnant women.71

Although vaccine effectiveness varies and is unpredictable from year to year, protection against virologically confirmed influenza illness after immunization with the inactivated influenza vaccine in healthy children >2 years generally ranges between 50% and 60% or higher, depending on the closeness of vaccine strain match with the circulating strains. Given the unpredictable nature of influenza each season, the AAP currently recommends that any licensed and age-appropriate inactivated influenza vaccine available be used. In light of the evidence for poor effectiveness of quadrivalent live attenuated influenza vaccine (LAIV4) documented during the past 3 seasons, LAIV4 should not be used in any setting during the 2016–2017
season. The interim recommendation that LAIV4 not be used in children will be reevaluated for future influenza seasons. Vaccination should not be delayed to obtain a specific product and can be simultaneously administered with another vaccine.72

**Catch-up Immunization and Immunization in Special Circumstances**

Adolescents also may require catch-up of certain immunizations, such as hepatitis B, hepatitis A, measles, mumps, rubella vaccine (MMR), and varicella. Health care providers may choose to test for antibody to hepatitis A and varicella before immunizing against these diseases. Those who are not immunized against hepatitis B should receive a 3-dose series. Alternatively, a 2-dose series (0, 4-6 months) of adult-formulation Recombivax HB is licensed for use in children aged 11 through 15 years. Adolescents who have not been immunized against hepatitis A should receive the 2-dose series with a minimum interval of 6 months. In a 2009 study, the reported rate of adolescents receiving a 1-time dose of hepatitis A was only 42%.73 Adolescents born outside the United States in countries with a hepatitis B surface antigen (HBsAg) prevalence >2% (and those born to mothers born in countries with an HBsAg prevalence >8% who are not immunized at birth) should have documentation of negative HBsAg before immunization with hepatitis B vaccine.72,74

Adolescents who have not received the MMR vaccine as part of the routine schedule should receive a 2-dose series at 11 through 12 years of age. It is particularly important for all adolescents to be up-to-date with the MMR vaccine series, given the recent measles outbreaks in 16 states.75 Furthermore, measles remains a common disease in many parts of the world, and unvaccinated individuals are at risk for becoming infected when they travel internationally.76

**Understanding Barriers to Immunization**

Overcoming barriers to immunization requires understanding the inherent challenges that exist in delivering vaccines to the adolescent population. One of the greatest challenges is health care provider recommendation, which often lacks consistency and urgency. Many health care providers do not universally recommend vaccines to eligible populations and do not offer concomitant vaccination with indicated vaccines during a single patient encounter.78 In a recent study of physicians’ perspectives on the HPV vaccine, only ~60% of pediatricians and family physicians strongly recommend the HPV vaccine for 11- through 12-year-old girls.79 Aligning the vaccine messages communicated by all office personnel is challenging but important (ie, staff should have training on the delivery of vaccine information). A recent randomized clinical trial with 29 pediatric and family practices in North Carolina found that practices trained in an "announcement" (or presumptive) delivery strategy had significant increase in HPV vaccination coverage for individuals 11 or 12 years of age when compared with control practices that did not receive any training. Similar significance was not found in practices trained in a "conversational" delivery strategy.80 From the physician perspective, the barriers are infrequent adolescent well visits or follow-ups and a lack of awareness of the need for vaccines.81 The perception that the patient and parent lack interest is also a reported reason that affects delivery of immunizations and other clinical preventive health services.82 Public and health care personnel have personal

---

**TABLE 1 Parental Perspectives on Vaccines**

<table>
<thead>
<tr>
<th>Perspective</th>
<th>% That Strongly Agreed or Agreed With Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Getting vaccines is a good way to protect my child(ren) from disease.</td>
<td>90</td>
</tr>
<tr>
<td>Generally I do what my doctor recommends about vaccines for my child(ren).</td>
<td>88</td>
</tr>
<tr>
<td>I am concerned about serious adverse effects of vaccines.</td>
<td>54</td>
</tr>
<tr>
<td>New vaccines are recommended only if they are as safe as older vaccines.</td>
<td>51</td>
</tr>
<tr>
<td>Parents should have the right to refuse vaccines that are required for school for any reason.</td>
<td>31</td>
</tr>
<tr>
<td>Some vaccines cause autism in healthy children.</td>
<td>25</td>
</tr>
<tr>
<td>My child(ren) does(do) not need vaccines for diseases that are not common anymore</td>
<td>11</td>
</tr>
</tbody>
</table>

beliefs that also may influence vaccine delivery. In a qualitative meta-analysis of 14 years of influenza-related communications research by the CDC, public and some health care provider perceptions and beliefs were difficult and slow to change. 

A study by Freed et al reported that 11.5% of parents of adolescents refused immunization. The meningococcal vaccine was declined 31.8% of the time and the HPV vaccine was declined 56.4% of the time. The majority of parents who declined either of these vaccines believed that (1) their child was at low risk for acquiring the disease; (2) the risks for adverse effects were “too great”; (3) there was not enough research on the vaccine; and (4) the vaccine had not been on the market “long enough.” The NIS-Teen 2008–2010 data support these findings, including the additional concern about the safety of the HPV vaccine. Table 1 provides an overview of parental perspectives on vaccines. Education about these vaccines will help parents to make informed decisions about vaccinating adolescents.

Other potential barriers to immunization are Internet and media sources that give misinformation about vaccines, especially vaccine safety. Education on the importance of immunizations, infection risk and consequences, and the need to overcome peer-pressure or fear of needles should be key focuses for adolescent patients. Pediatricians provide some of the most important education and recommendations for parents and are their most trusted source of information. Furthermore, parents and adolescents should make decisions together regarding vaccine acceptance. The health care provider should be able to answer parent and patient questions and concerns and should be able to discuss in detail the information in the pertinent vaccine information sheet (VIS).

Racial and ethnic disparities in health care, including immunization coverage, have been demonstrated in the literature. For example, a 2015 study found that HPV vaccination coverage was higher among non-Hispanic black and Hispanic males compared with non-Hispanic white males. Differences in the reasons for not receiving an influenza vaccination also exist between racial and ethnic groups. Black parents were more likely to be concerned about their child getting influenza from the vaccine compared with white and other or multiple-race parents. Focusing on disparities and understanding the cultural needs of a given population will aid in boosting immunization coverage rates. Different forms of written communication may be more effective among certain subpopulations. For example, HPV vaccine–specific brochures were found to be effective in increasing HPV vaccination rates among Hispanic but not among black individuals. In a predominantly Hispanic population in Los Angeles, California, community support for immunization, especially HPV vaccine, strongly affects individual decisions whether to immunize.

In addition, outreach programs and immunization campaigns targeting patients have proven to be effective. For example, churches can be important sources of social support and health information in black communities. Using medical and nonmedical settings (eg, school-based settings) for vaccine administration also may help to increase vaccine awareness. Frequent electronic communications, such as recall/reminders and electronic health record prompts, also are all strategies that can be used by health care providers to improve vaccination rates. Vaccine administrations of all vaccines and in any setting should be entered into the electronic systems.

Financial difficulties affect adolescent immunizations as well. HPV vaccines constitute the most expensive series currently included in the VFC program; private-sector prices are even higher. The CDC vaccine price list reports the following prices of vaccines in the private sector: (1) $193.63 per dose for 9vHPV; (2) $113 to $120 per dose of MenACWY; and (3) $38 to $43 per dose of Tdap. The limited availability of in-network health care providers in some rural jurisdictions and the persistence of some grandfathered plans that are not required to follow the Affordable Care Act preventive care provisions represent the remaining barriers to access. It has been shown that federal- and state-funded vaccine programs assist in boosting rates of office visits for immunizations.

Another potential barrier is having an adequate supply of all vaccines for each patient available in the office. Efforts to work with vaccine manufacturers and the VFC program to maintain an adequate inventory should be considered. Appropriate payment for health care providers also is crucial in having successful immunization programs. Practices need to be up-to-date on current coding, billing, and financing strategies. The AAP has resources on vaccine financing, ordering, and supply that help practices achieve healthy financial margins.

Although barriers to adolescent immunizations exist for all vaccines, HPV vaccination presents a unique set
Barriers to HPV Immunization: Perspectives of Parents and Health Care Providers

<table>
<thead>
<tr>
<th>Barriers Stated by Parents</th>
<th>Barriers Stated by Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines are not offered</td>
<td>Prefer not to give multiple vaccines</td>
</tr>
<tr>
<td>Vaccines are optional or unnecessary</td>
<td>Do not strongly recommend HPV vaccine</td>
</tr>
<tr>
<td>Providers do not encourage vaccination</td>
<td>Cannot predict onset of sexual activity</td>
</tr>
<tr>
<td>Providers do not discuss vaccine safety</td>
<td>Do not have experience with HPV disease</td>
</tr>
<tr>
<td>Providers do not emphasize importance of age at vaccination</td>
<td>Vaccination delays can cause lack of immunization</td>
</tr>
<tr>
<td>Lack of knowledge</td>
<td></td>
</tr>
<tr>
<td>Concerns about vaccine safety</td>
<td></td>
</tr>
</tbody>
</table>


of challenges. A 2009 study based in 2 clinics in a Hispanic community in Los Angeles, California with high cervical cancer rates was aimed at understanding barriers to and facilitators of HPV immunization. Several parental concerns and misconceptions included (1) adolescents do not need vaccination; (2) vaccine programs like VFC were only for infants and young children; (3) the vaccine may increase sexual activity; (4) discomfort toward a new vaccine; and (5) the vaccine is not required for school.

Since the introduction of HPV vaccine, parental acceptance has evolved to become a notable challenge to the immunization of adolescents. The 2010 National Health Survey explored reasons why parents opposed HPV immunization for their child. Approximately 25% of parents stated that there was no need for the vaccine, 19.3% stated concern over vaccine safety, and 16.6% stated they did not have sufficient knowledge about the vaccine. Other reasons include weak or lack of health care provider recommendation and concerns over the effect on adolescents’ sexual behavior. Table 2 summarizes the top reasons why parents did not vaccinate their child against HPV, on the basis of their gender. Table 3 lists barriers to HPV immunization from both health care provider and parental perspectives.

Several studies have focused on whether receipt of the HPV vaccine lowers inhibition for sexual activity. Data show that vaccine receipt does not alter sexual activity. A retrospective cohort study that followed adolescent girls for 3 years after immunization at ages 11 through 12 years did not find any increase in seeking medical attention for outcomes related to sexual activity, including pregnancy, sexually transmitted infection testing or diagnosis, and contraceptive counseling. HPV immunization does not change the vaccine recipient's sexual behavior, such as number of sexual partners or sexually transmitted infections. Although vaccination may not affect sexual behavior, Mather et al found that attitudes toward practicing safe sexual behaviors differed among vaccinated and unvaccinated women. Vaccinated women were found to have more positive attitudes about practicing safe sex. However, both vaccinated and unvaccinated women did not differ in their perceived vulnerability to cervical cancer and need for cervical cancer screening.

Another prominent barrier specific to the completion of the HPV vaccine series used to be its 3-dose schedule. On the basis of 2014 NIS-Teen data, the CDC found 3-dose series completion rates among those who received ≥1 dose of HPV vaccine to be only 69.3% for girls and 57.8% for boys. Coverage with at least 1 dose of HPV vaccine before 13 years of age could have reached 91.3% for girls born in 2000 if opportunities to administer the HPV vaccine when other vaccines were given had not been missed. Scheduling follow-up visits for the second and third doses at the time the initial dose is given, implementing standing orders for vaccination, using every clinical opportunity to evaluate and deliver remaining vaccination doses, using electronic communication, and using recall/reminders are all strategies that can be used by health care providers to improve completion rates. More data are needed to understand the impact of the recently recommended 2-dose schedule.

Reasons that encouraged parents to accept HPV immunization include (1) family history of cervical cancer or HPV infection; (2) family and
community support; (3) education on HPV vaccine; and (4) health care provider access to an immunization registry. Parents who reported Internet use to acquire health information, including on HPV, had significantly better knowledge, had fewer concerns about vaccine safety, and were more likely to accept HPV immunization.108 Health care provider knowledge about the HPV vaccine and promotion of the vaccine as a “routine” vaccine is also an important factor in encouraging parents to get their children vaccinated.96 The impact of health care provider promotion is illustrated by data that noted the reason why parents chose not to immunize their sons against HPV was that no physician or health care provider recommendation for the vaccine was given.109 In another study, ∼55% of parents who received a physician’s recommendation for HPV vaccination had their sons vaccinated versus only 1% of parents who did not receive a recommendation.110 Not surprisingly, health care provider recommendation was found to be the strongest predictor of HPV vaccine initiation.111

CONCLUSIONS

This clinical report highlights each of the vaccines routinely recommended for the healthy adolescent and summarizes the barriers that should be confronted to improve overall rates of immunization, which fall short of the Healthy People 2020 goals. 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. These details are addressed in a separate clinical report, "Practical Approaches to Optimize Adolescent Immunization."112

ACKNOWLEDGEMENT

We acknowledge the significant contributions of Angie L. Hernandez, MD, FAAP, Department of Pediatrics, Hofstra Northwell School of Medicine.

AUTHORS

Henry H. Bernstein, DD, MHCM, FAAP
Joseph A. Bocchini Jr, MD, FAAP

COMMITTEE ON INFECTIOUS DISEASES, 2016–2017

Carrie L. Byington, MD, FAAP, Chairperson
Yvonne A. Maldonado, MD, FAAP, Vice Chairperson
Elizabeth D. Barnett MD, FAAP
James D. Campbell, MD, FAAP
H. Dele Davies, MD, MS, MHCM, FAAP
Ruth Lynfield, MD, FAAP
Flor M. Munoz, MD, FAAP
Dawn Nolt, MD, MPH, FAAP
Ann-Christine Nyquist, MD, MSPH, FAAP
Sean O’Leary, MD, MPH, FAAP
Mobeen H. Rathore, MD, FAAP
Mark H. Sawyer, MD, FAAP
William J. Steinbach, MD, FAAP
Tina Q. Tan, MD, FAAP
Theoklis E. Zaoutis, MD, MSCE, FAAP

FORMER COMMITTEE MEMBERS

Joseph A. Bocchini, Jr, MD, FAAP
Kathryn M. Edwards, MD, FAAP
Dennis L. Murray, MD, FAAP
Gordon E. Schutze, MD, FAAP
Rodney E. Willoughby, MD, FAAP

CONTRIBUTORS

Angie L. Hernandez, MD, FAAP – Department of Pediatrics, Hofstra Northwell School of Medicine
Julia Bratic, BA – Research Assistant, Cohen Children’s Medical Center of New York
Rebecca J. Schneyer, BA – Research Assistant, Cohen Children’s Medical Center of New York
Catherina Yang, BA – Research Assistant, Cohen Children’s Medical Center of New York
Patriot Yang, BA – Research Assistant, Cohen Children’s Medical Center of New York
Tiffany Wang, BA – Research Assistant, Cohen Children’s Medical Center of New York

EX OFFICIO

David W. Kimberlin, MD, FAAP – Red Book Editor
Michael T. Brady, MD, FAAP – Red Book Associate Editor
Mary Anne Jackson, MD, FAAP – Red Book Associate Editor
Sarah S. Long, MD, FAAP – Red Book Associate Editor
Henry H. Bernstein, DD, MHCM, FAAP – Red Book Online Associate Editor
H. Cody Meissner, MD, FAAP – Visual Red Book Associate Editor

ABBREVIATIONS

AAP: American Academy of Pediatrics
ACIP: Advisory Committee on Immunization Practices
CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
HBsAg: hepatitis B surface antigen
HPV: human papillomavirus
LAIV4: quadrivalent live attenuated influenza vaccine
MenACWY: quadrivalent meningococcal conjugate vaccine
MenB: serogroup B meningococcal vaccine
MMR: measles, mumps, rubella vaccine
NIS: National Immunization Survey
Tdap: tetanus, diphtheria, and acellular pertussis vaccine
VFC: Vaccines for Children
2vHPV: bivalent human papillomavirus vaccine
4vHPV: quadrivalent human papillomavirus vaccine
9vHPV: 9-valent human papillomavirus vaccine

STAFF

Jennifer Frantz, MPH

LIAISONS

Douglas Campos-Outcalt, MD, MPA – American Academy of Family Physicians
Amanda C. Cohn, MD, FAAP – Centers for Disease Control and Prevention
Karen M. Fariza, MD – US Food and Drug Administration
Marc Fischer, MD, FAAP – Centers for Disease Control and Prevention
Bruce G. Gellin, MD, MPH – National Vaccine Program Office
Richard L. Gorman, MD, FAAP – National Institutes of Health
Natasha Halasa, MD, MPH, FAAP – Pediatric Infectious Diseases Society
Joan L. Robinson, MD – Canadian Paediatric Society
Jamie Deseda-Tous, MD – Sociedad Latinoamericana de Infectologia Pediatrica (SLIPE)
Geoffrey R. Simon, MD, FAAP – Committee on Practice Ambulatory Medicine
Jeffrey R. Starke, MD, FAAP – American Thoracic Society

AUTHORS

Henry H. Bernstein, DD, MHCM, FAAP
Joseph A. Bocchini Jr, MD, FAAP

COMMITTEE ON INFECTIOUS DISEASES, 2016–2017

Carrie L. Byington, MD, FAAP, Chairperson
Yvonne A. Maldonado, MD, FAAP, Vice Chairperson
Elizabeth D. Barnett MD, FAAP
James D. Campbell, MD, FAAP
H. Dele Davies, MD, MS, MHCM, FAAP
Ruth Lynfield, MD, FAAP
Flor M. Munoz, MD, FAAP
Dawn Nolt, MD, MPH, FAAP
Ann-Christine Nyquist, MD, MSPH, FAAP
Sean O’Leary, MD, MPH, FAAP
Mobeen H. Rathore, MD, FAAP
Mark H. Sawyer, MD, FAAP
William J. Steinbach, MD, FAAP
Tina Q. Tan, MD, FAAP
Theoklis E. Zaoutis, MD, MSCE, FAAP

FORMER COMMITTEE MEMBERS

Joseph A. Bocchini, Jr, MD, FAAP
Kathryn M. Edwards, MD, FAAP
Dennis L. Murray, MD, FAAP
Gordon E. Schutze, MD, FAAP
Rodney E. Willoughby, MD, FAAP

CONTRIBUTORS

Angie L. Hernandez, MD, FAAP – Department of Pediatrics, Hofstra Northwell School of Medicine
Julia Bratic, BA – Research Assistant, Cohen Children’s Medical Center of New York
Rebecca J. Schneyer, BA – Research Assistant, Cohen Children’s Medical Center of New York
Catherina Yang, BA – Research Assistant, Cohen Children’s Medical Center of New York
Patriot Yang, BA – Research Assistant, Cohen Children’s Medical Center of New York
Tiffany Wang, BA – Research Assistant, Cohen Children’s Medical Center of New York

EX OFFICIO

David W. Kimberlin, MD, FAAP – Red Book Editor
Michael T. Brady, MD, FAAP – Red Book Associate Editor
Mary Anne Jackson, MD, FAAP – Red Book Associate Editor
Sarah S. Long, MD, FAAP – Red Book Associate Editor
Henry H. Bernstein, DD, MHCM, FAAP – Red Book Online Associate Editor
H. Cody Meissner, MD, FAAP – Visual Red Book Associate Editor

ABBREVIATIONS

AAP: American Academy of Pediatrics
ACIP: Advisory Committee on Immunization Practices
CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
HBsAg: hepatitis B surface antigen
HPV: human papillomavirus
LAIV4: quadrivalent live attenuated influenza vaccine
MenACWY: quadrivalent meningococcal conjugate vaccine
MenB: serogroup B meningococcal vaccine
MMR: measles, mumps, rubella vaccine
NIS: National Immunization Survey
Tdap: tetanus, diphtheria, and acellular pertussis vaccine
VFC: Vaccines for Children
2vHPV: bivalent human papillomavirus vaccine
4vHPV: quadrivalent human papillomavirus vaccine
9vHPV: 9-valent human papillomavirus vaccine

STAFF

Jennifer Frantz, MPH
REFERENCES


21. National Foundation for Infectious Diseases. Meningococcal serogroup b cases and outbreaks on US college
30. Witt MA, Katz PH, Witt DJ. Unexpectedly
   in preadolescents in a North
   American outbreak. Clin Infect Dis
   2012;54(12):1730–1735

31. Centers for Disease Control and
   Prevention. Notifiable diseases and
   mortality tables. MMWR Morb Mortal
   Wkly Rep. 2016;65(48). Available at:
   https://www.cdc.gov/mmwr/volumes/
   65/wr/mm6548a8.htm. Accessed January
   19, 2017

32. Centers for Disease Control and
   Prevention. 2015 Final pertussis
   Available at: https://www.cdc.gov/
   pertussis/downloads/pertuss-surr-
   January 19, 2017

33. Centers for Disease Control and
   Prevention. 2012 final pertussis
   surveillance report. Available at: www.
   cdc.gov/pertussis/downloads/pertuss-
   2015

34. Broder KR, Cortese MM, Iskander
   JK, et al; Advisory Committee on
   Immunization Practices (ACIP).
   Preventing tetanus, diphtheria, and
   pertussis among adolescents: use of
   tetanus toxoid, reduced diphtheria
   toxoid and acellular pertussis
   vaccines recommendations of the
   Advisory Committee on Immunization
   Practices (ACIP). MMWR Recomm Rep
   2006;55(RR-3):1–34

35. Dempsey AF, Cowan AE, Broder
   KR, Kretsinger K, Stolkey S,
   Clark SJ. Adolescent Tdap
   vaccine use among primary care
   2009;44(4):387–393

36. Centers for Disease Control and
   Prevention (CDC). Updated
   recommendations for use of tetanus
   toxoid, reduced diphtheria toxoid
   and acellular pertussis (Tdap)
   vaccine from the Advisory Committee
   2011;60(13):15–15

37. Gall SA. Vaccines for pertussis and
   influenza: recommendations for use
   2008;51(3):486–497

38. Centers for Disease Control
   and Prevention (CDC). Updated
   recommendations for use of tetanus
   toxoid, reduced diphtheria toxoid,
   and acellular pertussis vaccine (Tdap)
   in pregnant women—Advisory Committee
   on Immunization Practices (ACIP),
   2013;62(7):131–135

39. Association of Reproductive Health
   Professionals. Managing HPV: a new
   era in patient care. Available at: www.
   arhp.org/publications-and-resources/
   clinical-proceedings/Managing-HPV/

40. Markowitz LE, Dunne EF, Saraiya
   M, et al; Centers for Disease
   Control and Prevention (CDC).
   Human papillomavirus vaccination:
   recommendations of the Advisory
   Committee on Immunization
   2014;63(RR-05):1–30

41. Satterwhite CL, Torrone E, Meites E,
   et al. Sexually transmitted infections
   among US women and men: prevalence
   and incidence estimates, 2008. Sex

   papillomavirus among females in the
   United States, the National Health And
   Nutrition Examination Survey, 2003-

43. Centers for Disease Control and
   papillomavirus. Available at: www.
   cdc.gov/vaccines/pubs/pinkbook/
downloads/hpv.pdf. Accessed June 20,
   2016

44. Moscicki AB, Schiffman M, Burchell A,
   et al. Updating the natural history of
   human papillomavirus and anogenital
   cancers. Vaccine. 2012;30(suppl
   5):F24–F33

45. Chesson HW, Ekwueme DU, Saraiya M,
   Dunne EF, Markowitz LE. The estimated
   impact of human papillomavirus
   vaccine coverage on the lifetime
   cervical cancer burden among girls
   currently aged 12 years and younger in
   the United States. Sex Transm Dis.
   2014;41(11):656–659

46. Markowitz LE, Liu G, Hariri S, Steinau M,
   Dunne EF, Unger ER. Prevalence of HPV
   after introduction of the vaccination
   program in the United States.

47. Meites E, Kempe A, Markowitz LE.
   Use of a 2-dose schedule for human
   papillomavirus vaccination – updated


64. Hull PC, Williams EA, Khabele D, Dean C, Bond B, Sanderson M. HPV vaccine use among African American girls: qualitative formative research using a participatory social marketing approach. *Gynecol Oncol.* 2014;132(suppl 1):S13–S20


71. Committee on Obstetric Practice and Immunization Expert Work Group; Centers for Disease Control and Prevention’s Advisory Committee on Immunization, United States; American College of Obstetricians and Gynecologists. Committee opinion no. 608: influenza vaccination during pregnancy. *Obstet Gynecol.* 2014;124(3):648–651


74. Weinbaum CM, Williams I, Mast EE, et al; Centers for Disease Control and Prevention (CDC). Recommendations for identification and public health management of persons with chronic


105. Bednarzcyk RA, Davis R, Ault K, Orenstein W, Omer SB. Sexual activity-related outcomes after human papillomavirus vaccination


Practical Approaches to Optimize Adolescent Immunization

Henry H. Bernstein, DO, MHCM, FAAP,a Joseph A. Bocchini Jr, MD, FAAP,b COMMITTEE ON INFECTIOUS DISEASES

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.

INTRODUCTION

Immunization is a key preventive cornerstone of pediatric care.1 Current data show a need for improvement in adolescent immunization rates.2 Healthy People 2020 lists 3 adolescent health indicators, which focus on the proportion of adolescents who have (1) well visits, (2) medical insurance, and (3) vaccination coverage.3 Unfortunately, there is a notable downward trend in health care utilization from childhood to early adulthood. One study found that the overall rate for any health care utilization was 88%, 83%, and 72% for 0- through 11-year-olds, 12- through 17-year-olds, and 18- through 25-year-olds, respectively.4 Another study documented that early adolescents (11 through 14 years of age) had 3 times more preventive visits than late adolescents.5 Without...
a consistent source of care, young children did not receive the Tdap and meningococcal vaccines, respectively, reported not receiving a recommendation. Nonreceipt of human papillomavirus (HPV) vaccine was associated with a perception that the vaccine was "not necessary." Similarly, a 2013 study revealed that only 64.4% of parents of girls and 41.6% of parents of boys reported receiving a recommendation for the HPV vaccine from their child's health care provider. Table 1 lists the major reasons for not receiving Tdap, meningococcal, and HPV vaccines. Parents were significantly more likely to report the intention to vaccinate their child if they received a health care provider recommendation, compared with parents who received no provider recommendation (48.9% vs 33.6%; P < .001).

The reader is advised to refer to "Suggestions to Improve Your Immunization Services" available at: http://www.immunize.org/catg/d/p2045.pdf. Figure 1 shows the major strategies that can be used to overcome barriers and improve immunization rates in adolescents, which will be discussed in further detail in this report.

**TABLE 1 Major Reasons Parents Report Nonreceipt of Tdap, MenACWY, or HPV Vaccines**

<table>
<thead>
<tr>
<th>Reasons</th>
<th>No Provider Recommendation, % (95% CI)</th>
<th>With Provider Recommendation, % (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tdap</td>
<td>MenACWY</td>
</tr>
<tr>
<td>Provider did not recommend</td>
<td>33.7 (28.3–39.6)</td>
<td>49.1 (46.5–51.7)</td>
</tr>
<tr>
<td>Lack of knowledge</td>
<td>23.7 (18.5–29.9)</td>
<td>19.1 (17.1–21.3)</td>
</tr>
<tr>
<td>Not necessary</td>
<td>20.8 (16.1–26.5)</td>
<td>18.3 (16.2–20.7)</td>
</tr>
<tr>
<td>Not age appropriate</td>
<td>5.8 (3.1–10.4)</td>
<td>4.4 (3.4–5.6)</td>
</tr>
<tr>
<td>Not a school requirement</td>
<td>1.9 (0.9–3.8)</td>
<td>5.7 (4.5–7.2)</td>
</tr>
<tr>
<td>Not sexually active</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Safety concerns</td>
<td>0.9 (0.3–1.9)</td>
<td>0.5 (0.3–0.9)</td>
</tr>
</tbody>
</table>


**STRATEGIES FOR IMPROVING ADOLESCENT VACCINATION RATES**

Every encounter should be viewed as a potential opportunity to immunize. In a 2010 survey, primary care physicians indicated that they often relied on vaccine-only visits and nurse prompts to identify and address vaccine need. Strategies physicians reported they would consider using, but had not implemented, include patient reminder/recall systems and electronic health record prompts. Through advancements in electronic health records, providers can set reminders for immunizations and make a patient’s immunization record accessible during any visit. Providers can also set up a reminder/recall system, which consists of sending reminders about upcoming recommended vaccines to patients along with recalls that encourage patients who are overdue for vaccines to return to the office for appropriate immunization. These population health management activities have the potential to be powerful and cost-effective tools.
Overcoming Vaccine Hesitancy

Vaccine hesitancy in adolescent health care can be challenging to address. The AAP has recently published a clinical report that provides information for pediatricians to address vaccine-hesitant parents. The following are important approaches that providers should use to increase vaccination rates:

1. Strongly endorse all universally recommended vaccines as important for adolescents' health. Offering immunizations as optional opens the door for vaccine dismissal. The health care provider should inform the patient and family about which vaccines are recommended at the current visit. Health care providers also should state the vaccines the adolescent needs without seeming to favor one vaccine over another. Discussion of any concerns or questions can then begin, if needed.

2. When encountering hesitancy toward a vaccine, answer parents' questions and concerns and remain unwavering, as medically appropriate. By asking an open-ended question, such as “What concerns do you have?,” the health care provider can allow for better dialogue. Parents who ask questions may not be hesitant; they may be seeking more information. Health care providers should always remember that immunizations are the core of preventive care. It is important to emphasize, “This is my job in helping you care for your child: to inform you of the recommended vaccines and the diseases they prevent, and thereby protect your child the best way we can.”

3. Focus on the benefits of the vaccine. Educating the patient and family on the diseases that vaccines prevent is key. For example, patients and families are more likely to be receptive if the health care provider informs them and reinforces the fact that HPV vaccine can prevent cancer, that Tdap vaccine can prevent pertussis, and that meningococcal vaccine can prevent meningitis. Up-to-date information on current events and disease outbreaks is a tool to bring into the conversation about vaccines as well. Health care providers also can increase parental confidence and trust in vaccines by mentioning that they...
give the same vaccines to their families.

4. Make the family aware of when the vaccines are needed. In addition to informing the family which vaccines the child needs or why they are needed, it is important for the health care provider to review the appropriate timeline for completing the vaccine series. For example, it is important for parents to be aware of the ages when HPV vaccine can be given, when to return for each dose in the series, and the importance of receiving the vaccine before a teenager is likely to be exposed to HPV through sexual activity. Follow-up immunization visits should be scheduled before the family leaves the care setting.

5. If vaccine refusal occurs, persevere. Although it may be challenging, it is important that health care providers offer the vaccine at the next most appropriate time. Perseverance is critical for vaccine uptake and immunization rates. In the Periodic Survey of Fellows (PS 66) conducted by the AAP in 2006 and a follow-up survey in 2013 (PS 84), pediatricians reported that they were able to convince approximately 30% of parents to vaccinate their children after they initially refused. The other observational study found that up to 47% of parents who were initially resistant ultimately accepted vaccines when providers pursued their original recommendations. The health care provider should document vaccine discussions and any vaccine refusal (http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/not-vacc-risks-color-office.pdf). The AAP clinical reports on responding to parental refusals of immunization are useful resources that may assist physicians in overcoming this challenge. In further exploring the reasons for vaccine hesitancy, health care providers assess for vaccine readiness and the parents’ position and feelings on vaccines, emphasize the benefits of vaccines, clarify misconceptions, and determine whether there is a lack of understanding or education about a specific vaccine. It is also important to consider the beliefs, misperceptions, and concerns among specific ethnic populations and to be aware that culturally tailored, translated information can help inform strategies to improve adolescent vaccine uptake in these populations. Sharing related statistics and educational material can be helpful, but information overload should be avoided. The concept of “chunking and checking” refers to the provision of information in small chunks followed by checking the person’s understanding. This technique contrasts with the common practice of providing much larger amounts of information before checking, which can lead to information overload. Although 1 randomized trial did not show an effect of physician-targeted communication interventions on vaccine hesitancy, these suggestions can be helpful, even though their effects are not proven. Most important, physicians should avoid confrontation, reflect on and summarize the conversation, and schedule follow-up to reinforce the value of immunization. Table 2 lists helpful and unhelpful strategies in navigating a vaccine discussion.

### TABLE 2 Unhelpful and Helpful Strategies

<table>
<thead>
<tr>
<th>Unhelpful</th>
<th>Helpful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directing style: “This is what you should do”</td>
<td>Guiding style: “May I help you?”</td>
</tr>
<tr>
<td>Righting reflex using information and persuasion to achieve change</td>
<td>Care with body language</td>
</tr>
<tr>
<td>Missing cues</td>
<td>Eliciting concerns</td>
</tr>
<tr>
<td>Using jargon</td>
<td>Asking permission to discuss</td>
</tr>
<tr>
<td>Discrediting information source</td>
<td>Acknowledging/listening/empathizing</td>
</tr>
<tr>
<td>Overstating vaccine safety</td>
<td>Determining readiness to change</td>
</tr>
<tr>
<td>Confrontation</td>
<td>Informing about benefits and risks</td>
</tr>
<tr>
<td></td>
<td>Giving or signposting appropriate resources</td>
</tr>
</tbody>
</table>


Approaching the Adolescent Patient in the Office Setting

Adolescents should be encouraged to follow the AAP preventive health care recommendations for routine visits; every visit can be viewed as an opportunity to update and complete an adolescent’s immunizations. Adolescent health visits are enhanced by fostering and maintaining a relationship with both the parent and the adolescent. Education about adolescent health issues should be a highlight of each encounter. A portion of the adolescent visit should be between the health care provider and the adolescent without the presence of a parent. To the extent permitted by applicable law, confidentiality is important and should be emphasized to all adolescents so they feel more comfortable sharing their perspectives. Health care providers can reduce vaccine hesitancy by establishing rapport and a supportive relationship with patients and by providing appropriate education.

Understanding adolescent cognitive development will facilitate the interaction with adolescents and their health care. The adolescent years are a stage in which the mind is developing and adolescents begin to acquire reasoning skills.
Adolescents may not perceive the consequences of risk-taking behavior. They also are in a period in which they seek independence and strive to obtain such independence. It is important to be aware of the aforementioned adolescent framework and to be attuned to the adolescent’s needs during office visits.

Motivational interviewing is a strategy that can be used when approaching the adolescent patient and family. It is “a collaborative, person-centered form of guiding to elicit and strengthen motivation for change.” Motivational interviewing is anticipated to result in changing behavior and encouraging self-reflection. The idea behind motivational interviewing is to allow the patient and parents to come to their own conclusion regarding the importance of and need for immunization. This behavioral change occurs by having the parent reflect on the need to protect the adolescent against preventable diseases (eg, cervical cancer and meningitis). Motivational interviewing can be used to improve vaccine acceptance and overcome hesitancy.

The core skills used in motivational interviewing include the following:

- asking open-ended questions,
- affirming the patient’s efforts and strengths,
- being a reflective listener, and
- assessing readiness to change.

**Approaching the Parent in the Office Setting**

To optimize adolescent immunization, it is necessary to understand the range of parental attitudes toward vaccines. By doing so, providers are then able to address potential dilemmas. Approximately 40% of initially vaccine-hesitant parents stated that health care provider information and reassurance were major reasons why they changed their mind. Table 3 lists Halperin’s 8-step approach in responding to parents when encountering vaccine hesitancy. The best approach to handling vaccine-hesitant parents requires understanding the common reasons for vaccine hesitancy and recognizing the types of vaccine-hesitant parents. This knowledge will then enable the health care provider to navigate and direct the vaccine conversation down different paths depending on the type of hesitancy that is being encountered.

There have been attempts to classify the different types of parental positions toward vaccines. The following is a summary of the different parental positions (Table 4):

1. The parent who accepts, does not question, and may be uninformed, but is open to education on vaccines, is considered to be the unquestioning acceptor or the immunization advocate. These parents may have previously heard about reasons not to immunize but are information seekers and want to hear the counter-argument from a vaccine-supporting health care provider.

2. The well-informed parent who is open-minded. These parents have a fair amount of knowledge and are considered to be “well read” regarding vaccine issues. These parents are willing to vaccinate with the appropriate information and facts. Discussing the risks and benefits thoroughly is necessary to enable vaccine acceptance. Parents may often have “phased agreement to immunization,” meaning that they accept more vaccines over time.

3. The parent who is the cautious acceptor is willing to vaccinate despite their awareness of the rare adverse effect profile of vaccines.

4. The misinformed parent who is open to education and, with the appropriate information, is willing to vaccinate. These parents have some degree of misinformation from the Internet or media, family, or friends and can be “resistant” to dismiss their originally held beliefs but tend to be “correctable” and open to change.

5. The vaccine-hesitant parent has significant concerns about the risks of vaccination. It is important for the health care provider to establish rapport and trust while providing information and answering questions. The parent may not be readily open to vaccine acceptance. This parent may also be viewed as the late or selective vaccinator. This group of parents may “delay or select only some recommended vaccines.”

6. The vaccine refuser is the parent who entirely refuses all vaccines because of either philosophical or religious beliefs. These parents can also be described as “convinced and content” with their belief that immunization is not beneficial, but rather harmful. Parents can also be strong opponents of vaccination and “not appreciate the value of immunization.”

Strategies aimed toward the diverse parental positions include the following (Table 4):

**TABLE 3 Approaches for Responding to Parents Unsure About Immunization**

<table>
<thead>
<tr>
<th></th>
<th>1. Listen, evaluate, and categorize</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.</td>
<td>Recognize legitimate concerns</td>
</tr>
<tr>
<td>3.</td>
<td>Provide context</td>
</tr>
<tr>
<td>4.</td>
<td>Refute misinformation</td>
</tr>
<tr>
<td>5.</td>
<td>Provide valid information</td>
</tr>
<tr>
<td>6.</td>
<td>Recognize that it is the parents’ decision</td>
</tr>
<tr>
<td>7.</td>
<td>Educate about potential consequences</td>
</tr>
<tr>
<td>8.</td>
<td>Make a clear recommendation</td>
</tr>
</tbody>
</table>


**Approaching the Parent in the Office Setting**

To optimize adolescent immunization, it is necessary to understand the range of parental attitudes toward vaccines. By doing so, providers are then able to address potential dilemmas. Approximately 40% of initially vaccine-hesitant parents stated that health care provider information and reassurance were major reasons why they changed their mind.
have been shown. The national schedule has been studied for safety and effectiveness, but nonstandard schedules have not been examined.

Health care providers must establish a way to document parental refusal of vaccines or requests for a nonstandard schedule. The AAP Refusal to Vaccinate Form may be used as a template to document discussion with the parent about the risks of failing to immunize the child (https://www.aap.org/en-us/Documents/immunization_refusaltovaccine.pdf). Health care providers can also create a manual of resources to better address the vaccine-hesitant parent (see Supplemental Information).

Advising for HPV Immunization

It is important to highlight all of the universally recommended vaccines in the adolescent immunization schedule, rates of which vary by vaccine. Indeed, because of various unique barriers, HPV vaccine immunization rates have lagged notably behind those of Tdap and meningococcal vaccines. Therefore, the following is a summary of how to approach HPV vaccination and navigate the encounter (see Supplemental Information):

- Emphasize that HPV immunization prevents cancer. This is a major reason that parents accept the vaccine.
- Discuss the vaccine schedule with parents, particularly the dosing schedule and the ages of administration. In October 2016, a 2-dose schedule for 9-valent HPV was approved by the Advisory Committee on Immunization Practices for individuals 9 through 14 years of age. In a 2014 study by Perkins et al., 13% of parents reported that they thought their daughters were "too young" for the vaccine. Health care providers should instead emphasize that it is preferable to deliver the vaccine at a younger age, especially because this elicits a better immune response. Similarly, in a study of over 1500 participants, Iversen et al. found that geometric mean antibody titers against all HPV types in the 9-valent HPV vaccine were higher in the 9- through 14-year-old female groups than in the 15- through 26-year-old female adolescents and women. On the basis of these data, the HPV vaccine may potentially be recommended for individuals younger than 11 or 12 years of age in the future. The new dosing schedule also provides added flexibility and incentive because individuals younger than 15 years require only 2 shots compared with individuals older than 15 years who need 3 shots. Do not delay vaccination, because this can be detrimental. A recent study cohort showed that both providers and parents tended to delay HPV vaccine until there was a sign that the adolescent was approaching sexual activity.

### TABLE 4 Summary of Parental Attitudes

<table>
<thead>
<tr>
<th>Parental Position</th>
<th>Definition</th>
<th>Targeted Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unquestioning acceptor/immunization advocate</td>
<td>Accepts, does not question, and may be uninformed, but is open to education on vaccines</td>
<td>Build rapport and briefly discuss risks and benefits</td>
</tr>
<tr>
<td>Well-informed</td>
<td>Is open-minded</td>
<td>Discuss the risks and benefits thoroughly</td>
</tr>
<tr>
<td>Cautious acceptor</td>
<td>Willing to vaccinate despite their awareness of the rare adverse effect profile of vaccines</td>
<td>Build rapport and briefly discuss risks and benefits</td>
</tr>
<tr>
<td>Misinformed</td>
<td>Is open to education and, with the appropriate information, is willing to vaccinate</td>
<td>Provide education</td>
</tr>
<tr>
<td>Vaccine-hesitant</td>
<td>Has significant concerns about the risks of vaccination</td>
<td>Establish rapport and trust, provide information, and answer questions; use the guiding style</td>
</tr>
<tr>
<td>Vaccine refuser</td>
<td>Entirely refuses all vaccines either due to philosophical or religious beliefs</td>
<td>Address concerns; use motivational interviewing</td>
</tr>
</tbody>
</table>

Adapted with permission from refs 18, 25, and 26.
However, attempting to predict when the adolescent will become sexually active is difficult and impractical. In addition, it was noted that actual immunization might not occur at a later time as was previously negotiated between the parents and the health care provider. Adolescents are less likely than other patients to follow up. Therefore, health care providers should view the current encounter with a “now or never” mentality when framing their efforts toward immunizing adolescents.

- Coadminister the HPV vaccine with other vaccines, because this can boost HPV immunization rates. Recommending all the adolescent vaccines at the same time increases adherence to the immunization schedule. It is also more practical to give all vaccines at once, because adolescent patients often do not return for medical care and fail to follow up. Adolescents tend to have low rates of immunization, and health care providers are known to overestimate immunization rates.

- State that HPV vaccine is part of the routine immunization schedule. A presumptive delivery strategy is an effective communication approach in which providers present vaccine recommendations as required immunizations to maintain optimal disease prevention. In a randomized clinical trial of 29 pediatric and family medicine clinics in North Carolina, Brewer et al found that practices trained in the presumptive delivery strategy exhibited a significant increase in HPV vaccine coverage for individuals 11 or 12 years of age when compared with the control group that did not receive any additional training. In contrast, a conversational delivery strategy did not exhibit a significant increase when compared with control. The presumptive approach may work well with some parents, however, and pediatricians may use it selectively based on their experience. It is important to overcome the concept that the HPV vaccine is optional. Hull et al demonstrated that mothers and daughters were more receptive to discussion of the HPV vaccine as a routine vaccine that prevents cancer.

- Clarify the misconception that HPV vaccine can promote promiscuity, if that is a parental concern.

- Emphasize that HPV vaccine is a safe vaccine. Approximately 200 million doses have been distributed worldwide between 2006 and 2015, and no serious adverse outcome has been associated with HPV vaccine. The safety of HPV vaccine continues to be monitored through the CDC Vaccine Safety Datalink and the US Food and Drug Administration PRISM programs. The AAP HPV Vaccine Talking Points provides additional information concerning vaccine safety (https://www.aap.org/en-us/my-aap/advocacy/workingwiththemedia/speaking-tips/Pages/HPV-Vaccine.aspx?nfstatus=200&nftoken=177fa0a9-39ac-4bea-ac1d-a5f52c96bc0f&nfstatus=200&nftoken=a5f52c96bd0f&nfstatus=200&nftoken=).

Table 5 lists successful techniques in advocating for HPV immunization.

### Reducing Missed Opportunities

Missed opportunities for adolescent immunizations are relatively common. Therefore, strategies to reduce missed opportunities are key in improving immunization rates. A retrospective study that reviewed electronic health records showed that there was a significant percentage of missed opportunities for immunization: 82% for meningococcal vaccine, 85% for Tdap, and 82% for the first dose of HPV vaccine. The majority of visits that were considered to have a missed opportunity were sick visits or nonpreventive visits. Furthermore, health care providers are more attuned to vaccinating younger adolescents than their older counterparts.

Most health care visits should be viewed as opportunities to review immunization records, provide vaccines that are due, and catch up on missed vaccinations. The concomitant administration of vaccines, when appropriate, is key to reducing missed vaccination opportunities. For example, in youth with special health care needs, vaccine coverage may be lacking, so concomitant administration of adolescent vaccines could reduce missed opportunities for this vulnerable population. The majority of vaccines are administered during well-child visits (eg, sports or camp physicals), and several surveys have shown that health care providers do routinely assess immunization status during such visits. However, acute care visits or sick visits in the patient-centered medical home are also an opportunity to deliver vaccines or to discuss upcoming vaccines. Assessing immunization status during sick and acute care visits is important. The Immunization Action Coalition has a valuable parent questionnaire entitled “Screening Checklist for Contraindications to Vaccines for Children and Teens.”

### TABLE 5 Successful Techniques in Advocating for HPV Vaccine

<table>
<thead>
<tr>
<th>Perspectives of parents</th>
<th>Techniques shared by providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Want to prevent cancer</td>
<td>• Normalize the HPV vaccine</td>
</tr>
<tr>
<td>• Trust provider recommendations</td>
<td>• Coadminister with other vaccines</td>
</tr>
<tr>
<td>• Think benefits outweigh the risks</td>
<td>• Give a strong recommendation</td>
</tr>
</tbody>
</table>

It is feasible for this checklist to be routinely used in the office setting during both well and sick visits. The CDC also has an online quiz for adolescents entitled “What vaccines do you need?”, which is based on 8 questions that yield a list of vaccines the patient should receive when submitted.

The CDC Web site provides guidance on how to display immunization schedules onto a clinic’s Web site, which can serve as a helpful resource for providers, patients, and families (http://www.cdc.gov/vaccines/schedules/syndicate.html#easy-read). In addition, the CDC now has an available application for mobile devices entitled “CDC Vaccine Schedule.” The CDC Web site includes a tool for parents and providers to use to look up school immunization requirements. The AAP immunization Web site includes information for providers about case studies on vaccine hesitancy, resources for communicating with families, immunization technology, and vaccine financing, supply, and ordering (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/default.aspx). Health care providers should promote these resources among their patients and patients’ families.

The College Physicians of Philadelphia has created a Web site on the history of vaccines, which provides many interactive learning tools on vaccines (historyofvaccines.org) and covers the history of antivaccination movements, with a focus on measles-mumps-rubella, the use of thimerosal, and autism. This information can help decrease parental vaccine refusal.

**Using Office-Based Technology**

**Prompts for Health Care Providers**

Health care provider prompts are a useful and effective way to reduce missed opportunities in vaccine delivery.42–44 Prompts can be electronic, paper-based, or generated by immunization information systems (previously known as “registries”). The health care provider will see the prompt and then identify whether the adolescent is a candidate for immunization. If the patient is a candidate, the health care provider should then offer the indicated vaccine(s). It is important for electronic health records to incorporate the recommendations of the harmonized immunization schedule of the AAP, the American Academy of Family Physicians, and the CDC.

It is also important to establish continuity and to enable an adolescent to return for a subsequent vaccine dose. This result can be accomplished by direct communication regarding when the subsequent vaccine dose is needed, scheduling a follow-up visit for immunization during the current visit, and providing an after-visit summary to the patient and parent to serve as a reminder of when to return.

**Prompts for Patients**

Bright Futures handouts can be used in the waiting area or in the examination room to emphasize the value of immunizations in health promotion and disease prevention. The use of tablet computers in the waiting area also has been found to be effective in providing vaccine information to parents, although meaningful engagement with the material was low.35 Vaccine Information Statements from the CDC can be incorporated on a day-to-day basis in the office setting as well. Pediatric offices should also make use of immunization information systems, because they can offer prompts regarding delayed immunization or whether a certain vaccine is indicated. The use of multiple prompts will maximize vaccine delivery. Another important way to improve vaccine delivery is by educating all staff members on the recommended immunization schedule.

It is helpful for the pediatric office to have access to the adolescent’s daily schedule (ie, being attuned to school hours, extracurricular activities, and work hours) and arrange appropriate office hours. Setting up exclusive immunization clinic days or hours is another strategy that can be incorporated.46

**Reminder/Recall Systems for Patients**

Electronic health records and immunization information systems have the capability of running reports listing patients who are due or overdue for immunizations. Delivering reminders via phone call, text, or mail can be a useful way of targeting patients.47 In a managed care organization serving publicly insured patients, adolescents 11 through 17 years of age who received reminders either by mail or telephone had greater immunization rates for quadrivalent meningococcal conjugate vaccine (MenACWY), Tdap, and HPV vaccine compared with adolescents who received no intervention. For adolescents who were not caught up with vaccinations at the start of the study, uptake significantly increased by 21% for mail-reminder groups and by 17% for telephone-reminder groups versus only 13% for control groups.48 A study on HPV vaccination rates, conducted in managed care organizations, found that text message reminders had a modest effect on HPV dose 1 rates for those who were able to receive the text message with valid phone numbers in the database.49 In another study, postal mail, e-mail, or text reminders were used to improve adolescent vaccination rates. All 3 reminder interventions were effective in improving adolescent vaccination rates. Although postal mail reminders were preferred by most parent participants, text messaging and e-mail were the more effective reminder methods.50

In a randomized controlled trial targeting low-income adolescents living in urban neighborhoods,
A text-messaging intervention compared with usual care was associated with an increased rate of influenza vaccination. Matheson et al. showed that 14% of adolescents and young adults who received text message reminders for their second and third HPV vaccine doses completed the vaccine series at the optimal time, compared with 3% who did not receive the intervention. The study also showed patient and parent support and eagerness for text message reminders. Both adolescents and parents reported that they had easy access to phones, preferred text messages, and found it convenient to communicate via phone.

Another successful way of boosting immunization rates was shown by using an immunization navigator intervention in a notable study, which entailed (1) a patient tracking database, (2) a reminder/recall system, and (3) home visits. The patient tracking database allowed the entry of immunizations and well visits for adolescent patients. Staff members would engage in the reminder/recall system by calling families and mailing letters to notify them about upcoming vaccines and well visits. In addition, transportation would be facilitated. If this measure failed, then the final step would be to approach the patient and family via home visits. The overall immunization rate with the use of this intervention was 44.7% compared with 32.4% for the control group. Preventive care visits also increased among the intervention group compared with the control group: 68% versus 55.2%, respectively. Another method of facilitating vaccine delivery is encouraging providers to schedule all follow-up vaccine appointments to complete a vaccine series, such as that required for HPV vaccine.

Extending Care Into School-Based Settings

The use of schools as a pathway to educate and vaccinate adolescents could be helpful to increasing immunization rates. Other vaccination sites that can facilitate immunizing adolescents include pharmacies, mobile vans, clinics for substance abuse or obstetrics/gynecology care, and shelters. Electronic recall/reminder systems may also be used in these alternative vaccination sites. However, all vaccinations in any setting should be documented within the state’s electronic immunization information system.

The School as an Alternative Vaccination Site

School-based sites for vaccine administration offer additional ways of providing preventive care to adolescents and aid in overcoming barriers to access of health care. Models for delivering immunizations in schools include 3 strategies:

- School-based health centers

Although some school-based health centers (SBHCs) can meet the definition of the medical home for their patients, SBHCs, in the context of this clinical report, are being used to improve adolescents’ health by helping to ensure that recommended vaccines are received. The school venue is also capable of being a primary source of health education. A better link between the health and educational departments should be fostered. Schools and health departments should offer routine immunizations at minimal expense to the patient, which can benefit individuals with financial barriers. In turn, schools administering vaccines should communicate with primary care clinics with regard to immunizations given. If an adolescent receives a vaccine outside of his or her medical home, such as at an SBHC, appropriate documentation of immunization should be provided to the adolescent for his or her medical home and entered into the state immunization registry, where possible. The CDC provides a vaccine administration template letter that providers can use (http://www.cdc.gov/flu/school/school_located_vac.htm).

A retrospective study comparing community health centers and SBHCs of the Denver Health System revealed that SBHCs had significantly higher completion rates for the following immunizations in adolescents 12 to 18 years of age: hepatitis B (93% vs 84%), Tdap (71% vs 62%), varicella (20% vs 13%), measles-mumps-rubella (89% vs 83%), HPV vaccine for patients aged 16 through 18 years (18% vs 12%), and the HPV vaccine/Tdap/MenACWY immunization series for female patients aged 16 through 18 years (17% vs 11%). It has also been shown that adolescents who visit SBHCs are more likely to complete the hepatitis B immunization series compared with adolescents who visit hospital-based health centers. SBHCs may represent one means of expanding access to adolescents for vaccinations, and they may serve as a “safety net” for adolescents who do not have reliable access to a medical home elsewhere. Almost two-thirds of juniors in high school who completed a survey about vaccination outside the traditional medical home believe that SBHCs are definitely or probably acceptable locations for vaccinations.

Several surveys have reported that most parents accept the use of SBHCs to provide immunizations. Although most parents (78%) preferred a doctor’s office for adolescent vaccination, a majority were also definitely or probably accepting of vaccination in public health clinics (74%), school health clinics (70%), obstetrics and gynecology clinics (69%), and emergency departments (67%). Surveys of adolescents have also shown that adolescents feel comfortable seeking health care at school, which is especially relevant, because many pediatric patients do not rely on a medical home for care. The socioeconomic factors that are linked with these patients are as
follows: low-income status, lower educational level, Hispanic ethnicity, residence in the western United States, and speaking a language other than English.64,65

- Partnering with local practitioners, community clinics, or other community organizations

Although many schools do not have SBHCs, another model for providing school-located vaccination is partnering schools with public health departments to identify underimmunized adolescents and provide needed vaccines. One study in North Carolina examined the partnership between the school system and the local health department to deliver the HPV vaccine in school-located vaccination clinics. Although HPV vaccine initiation rates among middle school girls did not reach study goals, the involvement of the local health department was key to the success of the school-located vaccination clinic, especially when the school did not have a health center, and the location of the clinic at the host school also increased vaccination rates.66

Another collaboration between Denver Public Schools and Denver Public Health produced a school-located vaccination program in the 2009–2010 and 2010–2011 school years at 27 elementary and middle schools. The vaccination program successfully increased the proportion of enrolled students who received at least 1 dose of vaccine between the first and second years of the program (elementary school: 28%–31%; middle school: 12%–19%).67 Billing and reimbursement can be an issue in school-located vaccination programs, but an alternate study in Denver Public Schools found that billing is feasible, and the program increased the likelihood of receipt of Tdap, MenACWY, and HPV vaccines in adolescents.68 Another program in Florida similarly found that school-located influenza vaccination programs can be economically sustainable by targeting adequate numbers of privately insured children and reducing costs through volunteers and mass vaccination.69

- School nurses

School nurses who are part of a school health program that is enrolled as a Vaccines For Children program provider play an integral role in achieving and maintaining high coverage of adolescent immunizations.70 They can be valuable resources for delivering vaccines because of their knowledge of the school and its students, and access to immunization information systems may help increase their ability to provide vaccines to adolescent students.71 However, school nurses also hold many responsibilities and may not have the time to participate in school-located vaccine programs because of competing job obligations.72

School Vaccination Requirements

It has been shown in the past that immunization requirements can help increase vaccination rates for some vaccines.73,74 Almost all 50 states have implemented immunization requirements for middle school entry, with wide variation. States with vaccine requirements for tetanus-diphtheria (Td)/Tdap and/or MenACWY had significantly higher immunization rates for the respective vaccines compared with states with no vaccination requirements.75,76 Importantly, school entry immunization requirements have also been shown to increase the immunization rates of other vaccines not included in the mandate. For example, states with school entry immunization requirements for Tdap vaccination witnessed approximately a 5% increase in the HPV vaccination rate.77 For more information, the CDC provides a Web site to obtain information on school immunization requirements categorized by child care, kindergarten, middle school, and college/university (http://www2a.cdc.gov/nip/schoolsurv/schImmrqmt.asp). The Immunization Action Coalition also tracks school requirements (http://www.immunize.org/laws/).

The Role of AAP Chapters and the CDC

The CDC and the AAP, including its national and state chapters, have played active roles in helping health care providers boost immunization rates locally, regionally, and nationally. A recent CDC report highlighted that HPV immunization rates have increased for ≥1 or ≥3 doses among females in 7 public health jurisdictions: Illinois, Chicago, District of Columbia, Georgia, Montana, North Carolina, and Utah.78 Four of these jurisdictions received resources in 2013 through the Prevention and Public Health Fund from the CDC to improve HPV vaccination coverage. In addition, the Advisory Committee on Immunization Practices’ recommendation to change from a 3-dose to a 2-dose series for persons aged 9 through 14 years is also expected to improve series completion rates.31 In the District of Columbia, school requirements for HPV vaccination were expanded to include males and females through 12th grade.10 The CDC has launched a useful Web site for health care providers (http://www.cdc.gov/hpv/hcp/index.html), including an important handout entitled “Tips and Time-savers for Talking With Parents About HPV Vaccine.” The CDC recently released a 5-year grant, “Improving Immunization and Enhancing Disease Prevention Through Partnerships With Providers,” to improve HPV immunization rates. The grant uses the following methods: (1) providing outreach and training, (2) expanding on educational materials, and (3) forming strong partnerships.27,39,79 The CDC has also developed the “You Are the Key” program, which provides a number of resources for providers and parents (http://www.cdc.gov/vaccines/ed/hpv/
approaching adolescent patients and their parents in the office to encourage immunizations are important skills for health care providers. The key to increasing immunization rates and decreasing vaccine-preventable diseases among adolescents is to focus on educating adolescents and strengthening health care providers’ recommendations by using all clinical opportunities to assess immunization status and provide needed vaccinations.

ACKNOWLEDGEMENT

We acknowledge the significant contributions of Angie L. Hernandez, MD, FAAP, Department of Pediatrics, Hofstra Northwell School of Medicine.

AUTHORS

Henry H. Bernstein, DO, MHCM, FAAP
Joseph A. Bocchini Jr, MD, FAAP

COMMITTEE ON INFECTIOUS DISEASES, 2016–2017

Carrie L. Byington, MD, FAAP, Chairperson
Yvonne A. Maldonado, MD, FAAP, Vice Chairperson
Elizabeth D. Barnett, MD, FAAP
James D. Campbell, MD, FAAP
H. Dele Davies, MD, MS, MHCM, FAAP
Ruth Lynfield, MD, FAAP
Flor M. Munoz, MD, FAAP
Dawn Nolt, MD, MPH, FAAP
Ann-Christine Nyquist, MD, MSPH, FAAP
Sean O’Leary, MPH, FAAP
Moeen Rathore, MD, MPH, FAAP
William J. Steinbach, MD, FAAP
Tina Q. Tan, MD, FAAP
Theoklis E. Zouzis, MD, MSCE, FAAP

FORMER COMMITTEE MEMBERS

Joseph A. Bocchini Jr, MD, FAAP
Kathryn M. Edwards, MD, FAAP
Dennis L. Murray, MD, FAAP
Gordon E. Schutze, MD, FAAP
Rodney E. Willoughby, MD, FAAP

EX OFFICIO

David W. Kimberlin, MD, FAAP – Red Book Editor
Michael T. Brady, MD, FAAP – Red Book Associate Editor
Mary Anne Jackson, MD, FAAP – Red Book Associate Editor
Sarah S. Long, MD, FAAP – Red Book Associate Editor
Henry H. Bernstein, DO, MHCM, FAAP – Red Book Online Associate Editor

H. Cody Meissner, MD, FAAP – Visual Red Book Associate Editor

CONTRIBUTORS

Angie L. Hernandez, MD, FAAP – Department of Pediatrics, Hofstra Northwell School of Medicine
Julia Bractic, BA – Research Assistant, Cohen Children’s Medical Center of New York
Rebecca J. Schneyer, BA – Research Assistant, Cohen Children’s Medical Center of New York
Catherine Yang, BA – Research Assistant, Cohen Children’s Medical Center of New York
Patriot Yang, BA – Research Assistant, Cohen Children’s Medical Center of New York
Tiffany Yang, BA – Research Assistant, Cohen Children’s Medical Center of New York

LIAISONS

Douglas Campos-Outcalt, MD, MPA – American Academy of Family Physicians
Amanda C. Cohn, MD, FAAP – Centers for Disease Control and Prevention
Karen M. Farizo, MD – US Food and Drug Administration
Marc Fischer, MD, FAAP – Centers for Disease Control and Prevention
Bruce G. Gellin, MD, MPH – National Vaccine Program Office
Richard L. Gorman, MD, FAAP – National Institutes of Health
Natasha Halasa, MD, MPH, FAAP – Pediatric Infectious Diseases Society
Joan L. Robinson, MD – Canadian Paediatric Society
Jamie Deseda-Tous, MD – Sociedad Latinoamericana de Infectologia Pediatrica (SLIPE)
Geoffrey R. Simon, MD, FAAP – Committee on Practice Ambulatory Medicine
Jeffrey R. Starke, MD, FAAP – American Thoracic Society

STAFF

Jennifer Frantz, MPH

ABBREVIATIONS

AAP: American Academy of Pediatrics
AFIX: Assessment, Feedback, Incentives, and eXchange (program)
CDC: Centers for Disease Control and Prevention
HPV: human papillomavirus
MenACWY: quadrivalent meningococcal conjugate vaccine
SBHC: school-based health center
Tdap: tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis, adsorbed
REFERENCES


25. Benin AL, Wisler-Scher DJ, Colson E, Shapiro ED, Holmboe ES. Qualitative analysis of mothers’ decision-making about vaccines for infants:
Care of the Adolescent After an Acute Sexual Assault

James E. Crawford-Jakubiak, MD, FAAP, Elizabeth M. Alderman, MD, FAAP, SAHM, John M. Leventhal, MD, FAAP, COMMITTEE ON CHILD ABUSE AND NEGLECT, COMMITTEE ON ADOLESCENCE

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.

BACKGROUND

For the purposes of this clinical report, “sexual assault” is a comprehensive term that describes any nonconsensual sexual act. Sexual assault includes any situation in which there is nonvoluntary sexual contact, with or without penetration and/or touching of the anogenital area or breasts, that occurs because of physical force, psychological coercion, or incapacitation or impairment (eg, secondary to alcohol or drug use). Sexual assault also occurs when victims cannot consent or understand the consequences of their choice because of their age or because of developmental challenges.1

This report only addresses acute sexual assault in the adolescent age group (including follow-up care and prevention) and not sexual abuse of young children or abuse that might be disclosed long after it occurred. Most jurisdictions define “acute” to reflect an event that occurred in the past 72 hours. Some jurisdictions include events as far out as 7 to 10 days in the “acute” category. For more information about sexual abuse of children and adolescents, please refer to the American Academy of Pediatrics (AAP) clinical report, “The Evaluation of Children in the Primary Care Setting When Sexual Abuse Is Suspected.”2 Available resources and services for adolescents who have been sexually assaulted will vary from community to community. Pediatricians should become familiar with the resources available in their community.
Epidemiology

National data show that teenagers and young adults ages 12 to 34 years have the highest rates of being sexually assaulted of any age group. Annual rates of sexual assault were reported in 2012 (for 2011) by the US Department of Justice to be 0.9 per 1000 persons 12 years and older (male and female). From 2002 to 2011, there has been an overall decrease of 37% in rape/sexual assaults, including a 10% decrease in 2010 to 2011. A survey of 1200 middle- and high-school students identified that 18% of girls and 12% of boys had an unwanted sexual experience during adolescence. In 2010 to 2011, there has been an overall decrease of 37% in rape/sexual assaults, including a 10% decrease of 37% in rape/sexual assaults, including a 10% decrease in 2010 to 2011. In 2014, the White House published a report of a task force appointed to protect college students from sexual assault. Sexual assaults occur frequently on college campuses; a 2009 study showed that 20% of women report being sexually assaulted while in college, typically in their first 2 years. In almost 80% of the cases, the perpetrator is someone the woman knows, rather than a stranger. More recently, the Association of American Universities released a study surveying 27 institutions of higher education, reporting that almost 12% of female and male college students say they experienced nonconsensual sexual contact by threat of physical force, by actual physical force, or while incapacitated. The percentage of female respondents reporting sexual assault or misconduct was 23%. Perpetrators have been classmates, friends, ex-partners, and acquaintances. Statistics on sexual assault may reflect substantial underreporting. In addition, because many victims do not immediately disclose an assault, "past-year surveys" may not reliably capture the actual number of victims and incidents.

Studies have demonstrated that two-thirds to three-quarters of all adolescent sexual assaults are perpetrated by an acquaintance or relative of the adolescent. Older adolescents are most commonly victims during social encounters with assailants, for example, on a date. In younger adolescent victims, the assailant is more likely to be a member of the adolescent’s extended family. In a national study of women and men who experienced sexual assault, approximately 45% of women and 29% of men reported that the assault was from an intimate partner; women, however, were more likely than men to be assaulted by an acquaintance.

The majority of perpetrators of reported sexual assaults are male, regardless of the sex of the victim. Studies of sexual assault of males have demonstrated that up to 90% of the perpetrators of rape are male. Sexual assault of males by females is more commonly reported by older adolescents or young adults, as compared with sexual assault of children or young adolescents.

The circumstances surrounding sexual assaults and subsequent reporting patterns differ when the victim is an adolescent versus an adult. Adolescent rape victims presenting to emergency departments are more likely than adult victims to have used alcohol or drugs and are less likely to incur nonanogenital injury during a rape. Adolescent female victims are also more likely to delay seeking medical care after a sexual assault and are less likely than are adult women to press charges when given a choice.

Although sexual assault is a common occurrence among college and high-school students, only approximately half of high school victims ever tell someone about an incident. As few as 10% of sexual assaults may be reported to authorities, depending on the age and sex of the victim and the circumstances surrounding the assault. When the victim knows the perpetrator, reports to the police are less frequent. In addition, male victims are less likely to report a sexual assault than are female victims.

Substance Use and Sexual Assault

Adults significantly underreport voluntary drug use associated with sexual assault, but adolescents have demonstrated increased disclosure. Alcohol or drug use immediately preceding sexual assault has been reported among more than 40% of adolescent victims and adolescent perpetrators and in approximately 30% of sexual assaults reported by undergraduate females. Cannabis, which may be identified in urine samples days or weeks after its use, has been found in 17% to 35% of systematically collected urine samples of alleged victims of sexual assault. Recreational drug use is common in adolescents and young adults; perpetrators of sexual assault may take advantage of the impaired state of a nonconsensual person who has voluntarily used alcohol or drugs. Substances can also be used inadvertently or coercively for sedation, to decrease inhibition, or to increase libido. Individual state laws generally define the crime as sexual activity with an individual who has been coerced or who has limited decision-making capacity because of intoxication or cognitive limitations and is unable to consent.

Collection of Toxicology Samples

The revised National Protocol for Sexual Assault Medical Forensic Examinations and other published reviews have underscored the widespread use of alcohol and other substances that facilitate sexual assault and the importance of timely collection of toxicology samples to document such use. Collection of toxicology samples usually occurs separately from collection of physical forensic evidence. Toxicology sample collection is recommended when...
the victim presents with symptoms and signs of substance use (eg, fluctuating level of consciousness, physiologic instability, severe intoxication, amnesia of the event) or when concerns of possible drug involvement are raised by the patient or the accompanying persons or witnesses. It is important to obtain informed consent before toxicology sample collection, if possible.\textsuperscript{28} Informed consent can address issues related to confidentiality and discoverability of forensic and medical toxicology results, the value of results for immediate medical care, the influence of timing of specimen collection in the results reported, the limitations of toxicology to identify some drugs, and the responsibility for payment. When patients have ingested a psychoactive substance, confirmation of the details of the alleged crime committed may need to be reviewed at a later time with patients because of their temporarily compromised cognition or memory. An altered state of consciousness can complicate the emotional and physical trauma and make an evaluation even more challenging.

Both forensic and toxicology sample collection should occur in a timely manner and in parallel. In some instances, previously collected samples may be allowed to be discarded at a later time or date. Poison Control Centers, vendor laboratories, and other toxicology resources can be consulted to ensure that specimens are collected and transported correctly. If drug-facilitated sexual assault (DFSA) is suspected, even if the suspected drug may be alcohol, it is ideal to collect the first urine produced after the assault, if possible. It is encouraged that the collection and transport of specimens be coordinated by sexual assault response teams, health care providers, and law enforcement personnel. Documentation of the chain of custody of any specimens is necessary if the sample is to be used in a legal proceeding. To best preserve and minimize the disturbance of forensic evidence from the genitalia and surrounding areas of the body, it is suggested that urination be delayed until other specimens are collected. However, this approach may not be possible and could delay the collection of toxicologic evidence.

### Use of Substances

Voluntary use of alcohol or other drugs proximate to a sexual assault is common and should not influence the perceived legal status of the event or result in reductions in standards of care for presenting victims. Documentation of substance use history may be used by opposing attorneys to undermine the credibility of a victim in court, but may also be used to support the victim’s vulnerability and inability to provide legal consent. The examining physician should attempt to accurately document substance use history relevant to the event. Victims may also “self-medicate” after an assault as a coping mechanism, especially if they have previously experienced a sexual assault. Impairment may influence a victim’s ability to make decisions about interacting with law enforcement professionals and consenting to the collection of forensic evidence. Examiners should consider developing policies regarding handling patients with an altered mental status. At a minimum, if serious medical problems are ruled out, the patient will need to be observed until consent and cooperation can be obtained, which will delay the start of the examination.\textsuperscript{28} Use of substances is one of the factors that may interfere with the reporting and prosecution of cases of sexual assault.

Although alcohol is the most common substance involved in sexual assault, DFSA has been a subject of attention since the 1990s, when increasing rates of adolescent acquaintance rape were allegedly associated with the availability of illegal so-called “date rape drugs.”\textsuperscript{29–32} The most well-known of these drugs is the benzodiazepine sedative/hypnotic flunitrazepam (Rohypnol, Roche Pharmaceuticals, Inc, manufactured outside of the United States). Ketamine and \textgamma\text- hydroxybutyrate (GHB) are also used as date rape drugs.\textsuperscript{33} GHB is more commonly used than flunitrazepam in DFSA because it is less expensive and more easily obtained. Use of any benzodiazepines with alcohol is known to amplify the actions and adverse effects of each individual substance.

Studies of specimens collected when DFSA has been suspected have confirmed the presence of substances in 61% of urine samples tested after an alleged sexual assault. Testing from 3303 samples found occasional confirmation of flunitrazepam (0.33%) and GHB (3.0%) use and higher levels of other benzodiazepines (9.5%). Cocaine (18.6%), amphetamines (6.7%), and cannabis (18.6%) were also found with high frequency, and alcohol was detected in the urine of 41.1% of all samples.\textsuperscript{34} Most of these data were from studies in adults, but a few included older adolescents. In a Canadian study by Du Mont et al of 184 individuals 16 years and older who met the criteria for DFSA, 86% had consumed alcohol before the assault, and one-quarter of the sample had used over-the-counter prescription or street drugs in the 72 hours before the test collection.\textsuperscript{35,36} Unexpected (ie, no known history of drug exposure to the specific drug) positive toxicology results were found in 49% of the suspected DFSA cases; results showed cannabinoids (40%) and cocaine (32%) most frequently. Similar individual studies and systematic reviews\textsuperscript{37} from the United States, Canada, United Kingdom, Australia, and other countries have reported that less than 2% of cases of DFSA...
are associated with common date rape drugs. There may be a greater index of suspicion for such use in geographic areas where flunitrazepam and similar drugs are legal or more accessible (eg, Mexico and near border areas).

Testing for Date Rape Drugs

Date rape drugs and many other drugs of abuse are not included in standard drug-screening panels; flunitrazepam is not identified in routine tests for benzodiazepines. Health care providers are advised to inquire about the presence of suspected drugs and collect the proper specimens from the victim at the time of evaluation. Commonly prescribed benzodiazepines and over-the-counter antihistamines are also being used to facilitate sexual assault, so testing can also be considered for these medications when their use is suspected.

All of these drugs are detectable for only a short time. If there is suspicion that one of them has been used, toxicity screening should be performed as soon as possible, perhaps even before finishing the history and physical examination. The reference concentrations of these drugs are not universally available, and consultation with a sexual assault center, toxicologist, or state forensic laboratory may be required for interpretation of drug testing results. Toxicology screens for drugs of abuse generally are inadmissible in legal settings because false-positive and false-negative results may occur. If a general toxicology screen performed to assess for the possibility of an exposure has a positive result, the same sample should also be sent for confirmatory testing by using gas chromatography or mass spectroscopy.

Substances Increase Vulnerability

Alcohol still is by far the most common date rape drug, and it is advisable to warn adolescents and college students of their increased vulnerability to assault when drinking. Sexual assault in which substance use is involved is likely to be more severe and is associated with assaults by strangers, greater physical injury, greater victimization, and greater likelihood of completed rape. If potential victims’ friends are also drinking, they may not notice that an assault is taking place or be able to respond in a way that maximizes safety and minimizes physical and psychological consequences. After a sexual assault, it is important to address how decreasing or avoiding future alcohol and substance use may decrease vulnerability to subsequent incidents. Such counseling may need to be deferred to a later time, depending on the condition and receptivity of the victim.

SEXUAL ASSAULT OF YOUTH WITH DISABILITIES

Adolescents with developmental disabilities are at an increased risk of sexual assault and acquaintance rape. Between 2009 and 2011, compared with adolescents without disabilities, adolescents with disabilities ages 12 to 15 years had rates of violent victimization that were 2.5 times greater, and those with disabilities ages 16 to 19 years had rates that were more than 3 times greater. Lifetime sexual violence victimization was 3 times higher in males with disabilities compared with males without disabilities (13.9% vs 3.7%, respectively). It is estimated that 68% to 83% of women with developmental disabilities will be sexually assaulted in their lifetime. Those who have milder cognitive disabilities are at the highest risk. In a national sample of adult women, little difference in the risk of sexual assault was seen between women with moderate disabilities and those reporting no disability; women with severe disabilities were 4 times more likely to be sexually assaulted than women with no disabilities.

People with disabilities are likely more vulnerable to sexual assault because of a variety of factors, including a decreased ability to flee or fight off an attacker, an expectation of increased compliance, an increased tolerance of physical intrusion, dependence on others for personal care, deficits in communication skills, and an inability to implement effective safeguards. As is the case for people without disabilities, victims with disabilities often know their perpetrators. Assaults were family members or acquaintances in 32% of cases involving victims with intellectual disabilities. An additional 44% of assailants had a care-providing relationship with the victim (eg, personal care attendants, transportation providers, or residential care staff).

Only approximately 3% of sexual assault cases involving people with developmental disabilities typically have been reported to law enforcement. As many as 25% of girls and women with intellectual disabilities who were referred for contraception had a history of sexual violence, suggesting that screening for sexual assault could increase reporting in this population. Factors that influence whether people with disabilities report a sexual assault include the understanding and significance the victim attaches to the incident, the ability to communicate about what happened, whether the victim perceives there to be a trustworthy and capable person to whom the information may be disclosed, and the level of trust or expectation of being believed and feeling safe. Some of these factors uniquely affect individuals with disabilities, but others are shared by individuals without disabilities as well. It is strongly encouraged that pediatricians be familiar with child abuse resources and programs that
are appropriate for teenagers who are cognitively impaired. Service agencies can provide appropriate genital and pelvic examinations for victims with physical disabilities requiring mobility aids. Finally, it is helpful if pediatricians are aware of sexual violence prevention programs designed for participants with intellectual disabilities.64,65

**ASKING ABOUT SEXUAL ASSAULT**

It is important that pediatricians have an increased awareness that sexual assault is a prevalent issue that can affect any of their patients, regardless of sex. During the high school and college years, a H.E.A.D.S.S. assessment can guide questions about the domains of Home, Education/Employment, Activities, Drugs, Sexuality, and Suicide/Depression. Asking adolescents about exposure to sexual assault (and other types of victimization) is advised during routine health supervision visits in which psychological problems, sexuality issues, contraception, or substance use are discussed. Adolescents can be asked direct questions about their sexual experiences without their parents or partners present. These questions may include the age of their first sexual experience, use of the Internet and other social media to find romantic or sexual partners, and a history of unwanted or forced sexual acts. 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).66

Exploring the perceptions and attitudes of adolescents regarding nonconsensual sexual encounters is important. Because there may have been voluntary participation before an assault occurred, adolescents might think that “consent” cannot be withdrawn. They may worry that their perceptions of assault will not be validated or believed. Teenagers may be reluctant to report an incident for several reasons: feelings of responsibility or guilt for the event, the need to protect, worry about the response of their parents or other authorities, fear of negative consequences, or poor recollection of the assault because of the use of alcohol or other substances. Self-blame, humiliation, and lack of information, understanding, or knowledge about sexual violence may prevent an adolescent from seeking medical care.

**SEXUAL ASSAULT REPORTING**

Specific reporting requirements for parents, child protective services, or law enforcement vary by state or even local jurisdictions. Some states have laws mandating that sexual intercourse or other sexual contact between minors must be reported if certain age differences exist between a minor (usually defined as younger than 18 years) and his or her sex partner (whether minor or adult), even if the sexual act was voluntary and consensual. The age of consent for sex varies from state to state. Depending on the patient's current age, age at time of the event, the identity and relationship to the alleged perpetrator (such as an acquaintance, a relative, teacher/coach, or healthcare provider), it may be mandatory to report the event to law enforcement or child protective services even if the teenager does not want it to be reported.67 Some adolescents may refuse to seek care or disclose personal information because reporting of sexual partners or incidents of sexual violence may be required.68–71 Pediatricians need to know about the specific reporting laws in the states in which they practice. This information is available online through the Child Welfare Information Gateway.72

**SEXUAL ASSAULT EVALUATION**

When an adolescent discloses that an acute sexual assault has occurred, it is incumbent on the health care provider to provide a nonjudgmental response. A supportive environment may encourage the adolescent to provide a clear history of what happened, agree to a timely medical and/or forensic evaluation, and engage in counseling and education to address the sequelae of the event and to help prevent future sexual violence.

It is important to obtain the history of what happened from the adolescent, when possible. As in any other medical encounters, the physician should learn about relevant past medical and social history. Physicians should consider the possibility that the adolescent could be a victim of human trafficking and commercial sexual exploitation and ask appropriate questions, such as “Has anyone ever asked you to have sex in exchange for something you wanted?”66 In addition, the physician should address the physical, psychological, and safety needs of the adolescent victim of sexual violence and be aware that responses to sexual assault can vary. It is advised that adolescents be asked directly whether they have safety concerns related to the perpetrator, the perpetrators' friends, or others. Victims should be asked whether they have been threatened, whether they are afraid of anyone, and whether the perpetrator or the perpetrator's friends have a history of violence and access to weapons.

Most adolescents who disclose an acute sexual assault will consent to a physical evaluation that has a forensic component. The forensic elements of an evaluation are those that pertain to the criminal investigation that occurs after
an assault is disclosed to law enforcement officers (e.g., DNA collection). The adolescent should have a medical examination that assesses and cares for any injury, infection, and pregnancy in addition to addressing mental health and safety issues. It is of paramount importance that patients know they can and will still get the medical care they need related to the assault even if they choose not to have a forensic evaluation. In cases in which reporting is not mandatory, patients can be advised that a forensic evaluation does not require the victim to agree to report or press charges against the perpetrator. Many law enforcement agencies will hold forensic results for 2 or more years, allowing victims to reconsider legal action after the acute period has passed.

A referral for forensic examination and treatment can be made to an emergency department or sexual assault treatment center that has professional staff experienced in treating adolescent assault victims. It is important to note that the young person may have nongenital injuries, the treatment of which may be a priority, depending on their severity. The health care provider should address the adolescent’s immediate health concerns, including any acute injuries, the likelihood of exposure to sexually transmitted infection (STIs), the possibility of pregnancy, and other physical or mental health concerns. Before any forensic examination, victims of acute sexual assault should be asked to not change their clothes, bathe/shower, eat/drink, urinate/defecate, oder douche until they have been examined; however, even if they have done so, they are still encouraged to seek care. The federal Violence Against Women Act (Pub L No. 103–322 [1994]) requires that adolescents be given the option of having a sexual forensic medical examination even if they are uncertain about cooperating with law enforcement at the time of the examination.

A forensic examination is ideally performed by the most qualified health care provider available, such as a pediatric emergency medicine physician, a physician who specializes in child abuse, or a nurse practitioner with sexual assault care training who is working with an experienced physician. A properly maintained chain of evidence and accurate documentation of findings are critical. Details of the required examination and documentation are presented in a handbook published by the American College of Emergency Physicians, Evaluation and Management of the Sexually Assaulted or Sexually Abused Patient. Physicians who treat sexually abused or assaulted patients need to be aware of the legal requirements of their state or locality, including the completion of appropriate forms, maintaining the legal chain of evidence, and reporting to the appropriate local authorities. In many communities, specific medical facilities are designated as the location in which forensic examinations are performed, with specific policies and protocols in place to address the needs of these patients. Physicians should familiarize themselves with the resources and the protocols of the communities in which they practice so that they can refer their patients to the appropriate site.

A forensic medical examination includes a medical history, documentation of physical findings, use of an imaging system (still or video) to record findings and allow for future image review, collection of potential forensic evidence from the patient, and consideration of medications to address issues of possible STI transmission or pregnancy risk. With DNA-amplification techniques, a forensic examination may identify foreign DNA for at least 72 hours after an assault and possibly longer. If the adolescent presents more than 3 days after the reported assault, health care providers should refer to their local protocols regarding evidence collection. After 1 week, examination, counseling, and treatment can take place without the need for forensic collection.

Forensic medical sexual assault examinations can be performed only with the consent of the adolescent. Law enforcement or parents cannot “mandate” that an adolescent have a forensic sexual assault examination. Adolescents must never be forced or coerced to have a forensic sexual assault evaluation. The age at which a patient has the ability to consent legally to a forensic medical sexual assault examination varies from state to state; a list that outlines sexual assault care by state is available from the Center for Adolescent Health and the Law. Pediatricians are advised to become familiar with their state’s laws.

The sexual assault history should be documented and should include verbatim statements whenever possible, important past medical and mental health history, and other areas of risk. The physical examination should include a written description of the findings and detailed drawings as well as photographic or video images whenever feasible. Descriptions of findings should be as clear and precise as possible. Examiners should avoid terms, such as “hymen intact” or “hymen not intact,” but instead use language that objectively describes the appearance of the anatomy. Colposcopy or another appropriate imaging system may assist examiners in detecting and documenting anogenital trauma. Adolescents have appreciated that video colposcopy allowed them to watch their own examination on an adjacent screen. Images from forensic medical sexual assault examinations should be reviewed by the most experienced health
Mental Health Consequences of Sexual Assault

Reactions that adolescents display after sexual assault can include feeling that their trust has been violated, increased self-blame, negative self-concept, and anxiety. Adolescent victims may feel that their actions contributed to the act of rape and can be confused as to whether the incident was forced or consensual. Studies of adolescent girls have found that rape during childhood is associated with a variety of risky behaviors, such as a younger age for the first voluntary intercourse; poor use of contraception; a greater number of pregnancies and abortions; higher rates of STIs; and increased risks of victimization by older partners. Increases are also noted in mental health problems, including higher rates of depression, suicidal ideation and suicide attempts, and other self-harm behaviors, such as self-mutilation and eating disorders, among sexual assault victims.

A history of sexual assault or abuse may also be associated with psychiatric or behavioral problems that are more common in the opposite sex, such as eating disorders in boys and fighting in girls.

All adolescent victims of sexual abuse should be asked about symptoms that would warrant a formal psychiatric assessment, such as suicidal or homicidal ideation or other self-harm behavior. If, for some reason, the pediatrician is not comfortable performing such an inquiry, he or she should refer the patient to a health care provider who is comfortable with such assessments and who can evaluate the patient immediately. Evidence of suicidal or homicidal ideation should be attended to immediately in conjunction with an experienced mental health professional.

The adolescent may be encouraged to share information with a supportive caregiver, counselor, or other qualified and trusted adult. Although adolescents may desire (and be legally entitled to) confidentiality, support from a qualified and capable adult can be valuable, especially when teenagers are being treated in unfamiliar emergency department environments. Involving a support professional also may improve adolescents’ compliance with follow-up recommendations. The support professional also can serve to address concerns or issues expressed or presented by family members. A supportive parent/caregiver may also be enlisted and educated to monitor for and recognize symptoms or problems that develop after the acute care is provided. Parents can be counseled and encouraged to facilitate access to resources that can support their and their teenagers’ mental and physical health needs and not blame themselves or their teenager for the unfortunate event.

Because the risk of suicide may be high after assault, counseling parents to reduce potential access to lethal means of suicide, such as available medications or weapons, is advised. Research evidence has demonstrated that limiting access to firearms reduces the risk of death by suicide, so parents need to be counseled clearly to remove all firearms from the home, and, if that is not possible, to advise that weapons are stored, locked, unloaded, and inaccessible to the adolescent.

Management of Pregnancy and STI Risk After Sexual Assault

Treatment guidelines for STIs from the Centers for Disease Control and Prevention (CDC) include recommendations for comprehensive clinical treatment of victims of sexual assault, including emergency contraception and HIV prophylaxis. Sexual assault is associated with a risk of pregnancy; 1 study reported a national pregnancy rate of 5% per rape among females 12 to 45 years of age. Pregnancy prevention and emergency contraception should be addressed with every adolescent female, including rape and sexual abuse.---

---

For a full PDF of this article, please visit the journal's website.
assault victims. The discussion can include the risks of failure of the preventive measures and options for pregnancy management. It is advised that a baseline urine pregnancy test be performed. Emergency contraception should be offered to females who have been (or may have been) vaginally penetrated or who think that ejaculation has come into contact with their genitalia.28,74,75–77,79 Emergency contraception should be offered within 120 hours of the sexual assault. The AAP outlines the recommended medication doses and guidelines in its policy statement, “Emergency Contraception.”4,110

The most common STIs reported in sexual assault victims are those that are common in the population and include Chlamydia, gonorrhea, and trichomoniasis.79,111 The best approach to collecting specimens for STIs immediately after a sexual assault is debated. A speculum examination may be traumatic, especially for a teenager who has not had one before and may lead to avoidance of reproductive health care in the future. Therefore, nucleic acid–amplification tests (NAATs) that use urine or vaginal specimens for gonorrhea and Chlamydia are preferred to cervical specimens for STI testing in females.79,112 For trichomoniasis, a NAAT vaginal specimen is recommended. Urine NAAT testing is also recommended for males, but additional testing at penetration sites, such as the anus, may be indicated.

Specimen collection for STIs should be discussed with the adolescent, and testing should be performed with the adolescent’s consent. Positive results may indicate an existing infection and may be a result of previous consensual sexual contact. NAATs (or cultures) also may be positive as a result of an assault, even when collected within 72 hours of the event.113–115 All 50 states have laws strictly limiting the use of a victim’s previous sexual or infection history to undermine the credibility of the adolescent’s history of assault.79 If specimens are to be collected, the decision about which specific test is preferred may vary by state. Both NAATs as well as culture typically are accepted by courts. The use of NAATs is preferable to cultures to detect Chlamydia and gonorrhea because the high sensitivity makes it more likely to detect DNA before the end of the incubation period.116 The CDC guidelines also recommend NAATs from vaginal specimens for trichomoniasis. Consequently, NAATs are preferred for diagnostic evaluation of sexual assault victims, even if the site of penetration or attempted penetration is not vaginal.79 Vaginal secretions may be microscopically examined by wet mount for evidence of bacterial vaginosis and candidiasis if vaginal discharge, itching, or odor exists.79

CDC recommendations for sexual assault prophylaxis can be found at www.cdc.gov/std/tg2015/sexual-assault.htm.79 Empirical treatment of Chlamydia, gonorrhea, and trichomoniasis is recommended. If there is a history of alcohol ingestion or if emergency contraception is to be given, metronidazole or tinidazole for trichomoniasis can be provided to be taken later at home to minimize drug interactions and potential gastrointestinal adverse effects. Repeat STI testing after prophylaxis can be offered as indicated. Sexually active adolescents should be counseled to abstain from sexual intercourse until STI prophylactic treatment is completed. If there is no prophylaxis prescribed, then adolescents may be counseled on the symptoms of STIs, and testing is recommended 1 to 2 weeks after the assault. Unfortunately, compliance with follow-up typically is poor.116 Many adolescents will not recall everything said during a sexual assault evaluation, so it is suggested that instructions be provided in writing for later reference.

Serum samples should be obtained for baseline testing for hepatitis B, hepatitis C, syphilis, and HIV.28,74,75,77,79 Teenagers who have not initiated or completed immunization against hepatitis B virus can be offered the hepatitis B vaccine. Although there are currently no CDC recommendations regarding immunization against human papillomavirus (HPV) infections in the context of an acute sexual assault, the AAP recommends initiating the HPV series at 9 years of age and older or continuing/completing the series if all 3 doses have not been received.79,117 Completion of the series can be coordinated with the primary care provider, if possible.

Although HIV transmission has occurred from a single episode of sexual assault, the frequency of transmission is low, given that the risk of HIV transmission in consensual sex is 0.1% to 0.2% for vaginal and 0.5% to 3% for receptive anal intercourse.79,118,119 HIV prophylaxis should be considered and recommended as per the HIV postexposure prophylaxis (PEP) guidelines from the CDC when there is genital or anal penetration with known ejaculation, especially if trauma occurred or if the patient has a known genital infection. The risks and benefits of HIV PEP should be considered. If HIV PEP is started, it is recommended that it begin as quickly as possible. Factors that may indicate a higher risk of HIV infection include chronic sexual abuse, multiple perpetrators, HIV-positive perpetrator(s), a high prevalence of HIV in the geographic area in which the sexual assault occurred, and a perpetrator with a genital lesion.74,75,77,79,120,121 The CDC recommends the following assessment for PEP within 72 hours of sexual assault:79

- Assess the risk of HIV infection in the alleged assailant.
- Evaluate the characteristics of the assault that might increase the risk of transmission.
• Consult with a specialist in HIV treatment.
• Discuss antiretroviral prophylaxis, including the risks of toxicity and the lack of proven benefit.
• Perform baseline complete blood cell count, serum chemistry, and HIV testing.
• Provide enough medication to last 3 to 7 days until the patient returns for assessment of tolerance.

FOLLOW-UP CARE
Because patients treated in emergency departments often do not return for follow-up care,122 the emergency treatment team may refer an adolescent victim to his or her medical home as well as a specialty treatment center, if available in the community. The provision of information related to the evaluation to the primary health care provider or medical home can potentially improve follow-up. Although such communication generally is permitted under federal regulations (Health Insurance Portability and Accountability Act [Pub L No. 104–191 (1996)]), ethical and privacy considerations as well as some states’ confidentiality laws indicate that the treating physician should secure the consent of the adolescent before communicating with the primary care provider or specialty center.123,124

Follow-up usually includes a visit within 1 to 2 weeks of the initial presentation to assess injuries and adherence to medications, determine the victim’s mental health functioning and need for any additional psychological counseling, and arrange for appropriate referrals, if needed.125 Reassessment for STIs may be needed depending on which medications were given at the time of the initial evaluation and/or whether the adolescent has had consensual sexual activity since the assault.114

At 2 weeks, pregnancy testing can be performed.

The CDC recommends that syphilis and fourth-generation HIV testing be repeated at 4 to 6 weeks and at 3 months, and only HIV testing at 6 months after the assault if initial test results were negative and infection in the assailant could not be excluded.79,126–130 Health care providers should be prepared to complete the hepatitis B virus and HPV immunization series.

At follow-up, victims of sexual assault should be assessed for mental health sequelae, as they are at high risk of posttraumatic stress disorder and other posttrauma disorders.131 A 4-item posttraumatic stress disorder screening tool assessing symptoms of startle, physiologic arousal, anger, and emotional numbness has been used with some success by gynecologists in adults ages 22 to 46 years.132 Counseling resources can address this problem as well as additional psychological trauma that may develop after date or acquaintance rape. Psychotropic medications may be required in some instances. It is helpful if the health care provider is knowledgeable about services available in the community that can address these problems and provide initial psychological support. RAINN (Rape, Abuse & Incest National Network, http://centers.rainn.org) is an excellent resource for victims and health care providers.

Studies have shown that trauma-focused cognitive behavioral therapy is useful to aid adolescents who have been sexually assaulted.133 A call or referral to a sexual assault care center may provide the names of mental health professionals experienced in this arena who can provide these services. Under some circumstances, funding may be available to pay for necessary tests and treatments through the Victims of Crime Act (Pub L No. 98–473 [1984]).

SEXUAL ASSAULT PREVENTION
Research data demonstrate that sexual assault of adolescents often occurs in places in which adolescents commonly spend their time and is perpetrated by people with whom the teenager is familiar and may consider “safe.” Perpetrators and victims of sexual assault may be of any sex; therefore, prevention messages for adolescents need to be designed for both males and females.134–136 Adolescents also need to be able to identify and avoid high-risk situations, including attending parties or social activities with unknown people, meeting strangers with whom they have had contact on the Internet, walking alone at night, allowing themselves to be photographed nude or in sexually explicit poses or situations, or sexting. Teenagers should be advised that if they ever are assaulted, they should seek medical care immediately. Factors that may increase the likelihood of assaults (eg, use of drugs or alcohol) and strategies to prevent sexual assaults (eg, “buddying up,” not drinking from a vessel that has been left unattended, abstaining from or moderating alcohol intake, and not accepting drinks from strangers) can be discussed, and associated educational materials can be made available and distributed by pediatricians, particularly during the adolescent years and at the precollege visit.134–136 College health professionals, including physicians, nurses, and health educators, along with specialists in student services/student affairs, can also work with at-risk communities in university settings (eg, athletics, housing, freshmen organizations, Greek life) to provide education and resources to reduce the risks of sexual violence on and beyond campus.

Unfortunately, few effective strategies for the prevention of perpetration of sexual violence have been identified through rigorous
research. Current approaches include aggressive education about sexual violence that seeks to change attitudes, knowledge, and culture, but evidence to identify best practices that reduce sexual violence perpetration is minimal. A recent Cochrane review examined 38 studies of educational or skills-based interventions for preventing relationship and dating violence in adolescents and young adults. The results showed no evidence that the programs enhanced skills to prevent relationship violence or decreased relationship violence. Some of the programs did demonstrate improved understanding and knowledge about relationships after the intervention. Two educational interventions, the Safe Dates program and the building-level intervention of Shifting Boundaries, are universal, school-based dating violence prevention programs that have shown some evidence of effectiveness in preventing relationship violence. Safe Dates includes a 10-session curriculum addressing attitudes, social norms, and healthy relationship skills; a 45-minute student play about dating violence; and a poster contest. Although its effects were modest, students in the intervention group were significantly less likely to be victims or perpetrators of sexual violence involving a dating partner 4 years after participating in the Safe Dates program. The building-level intervention of Shifting Boundaries involves temporary school-based restraining orders, higher levels of adult presence in school areas identified as unsafe, and the use of posters to increase awareness and reporting of sexual violence to school personnel. Shifting Boundaries was effective in reducing the perpetration of sexual harassment and peer sexual violence as well as sexual violence victimization (but not perpetration) by a dating partner.

Recently, there has been increased interest in developing bystander interventions to reduce sexual violence, particularly in university settings. A recent meta-analysis suggested that bystander approaches show promise in changing bystander attitudes and intervention behaviors, if not actual sexual violence perpetration. Two recent studies on college campuses have reported decreased rates of sexual violence perpetration after implementation of bystander interventions, suggesting that these approaches warrant additional attention and evaluation.

CLINICAL GUIDANCE FOR PEDIATRICIANS

1. Pediatricians are encouraged to routinely ask adolescents, including those with disabilities, about a history of sexual violence, dating violence, and sexual assaults. All adolescents who disclose a sexual assault should be asked about commercial sexual exploitation. Identification of sexual assaults may help reduce the risk of such future events, reduce the stigma, and provide victims with appropriate medical, psychological, and supportive care.

2. Pediatricians should be aware of the current reporting requirements related to sexual assault and state laws ensuring the rights of adolescents to obtain medical care at sexual assault or rape crisis centers in their states.

3. Pediatricians should be knowledgeable about the specific resources available to respond to sexual assault and rape in their communities and when and where to refer adolescents for forensic medical examinations and sexual assault care as well as resources for teenagers with disabilities.

4. Pediatricians should be familiar with the CDC guidelines for care of survivors of sexual assault. If the pediatrician does not feel qualified to care for a patient in an acute situation, provisions should be made for the patient to be evaluated immediately by an appropriate experienced provider.

5. Appropriate STI screening, PEP, treatment, and follow-up should be provided per CDC guidelines, including referrals for acute and follow-up testing and care.

6. Emergency contraception should be offered to adolescent girl patients who disclose sexual assault if reported within 120 hours of the assault. Emergency contraception’s safety record allows it to be offered even if the adolescent is not sure whether penetration occurred. Documentation of pregnancy status should occur at the time of the evaluation and at follow-up.

7. Health care providers are advised to consider the possibility that “date rape” drugs may have been used in the context of an assault.

8. Pediatricians should be prepared to offer emotional support, determine the need for counseling and/or urgent mental health interventions, and refer patients and their families for additional evaluation or mental health care. Pediatricians should be aware of services in the community that provide evaluation, management, and counseling for the adolescent patient who has been sexually assaulted.

9. Pediatricians should support evidence-based sexual violence prevention activities in local high schools, colleges, and communities. Pediatricians can work with educators and law enforcement professionals to enhance and expand programs to reduce sexual violence.
REFERENCES


women with disabilities. *Inj Prev.* 2008;14(2):87–90
68. Jones RK, Purcell A, Singh S, Finer LB. Adolescents’ reports of parental knowledge of adolescents’ use of sexual health services and their reactions to mandated parental notification for prescription contraception. *JAMA.* 2005;293(3):340–348
79. Centers for Disease Control and Prevention. 2015 Sexually transmitted diseases treatment guidelines: sexual


89. Association AM. Strategies for the Treatment and Prevention of Sexual Assault. Chicago, IL: American Medical Association; 1995


106. McFarlane J. Pregnancy following partner rape: what we know and what we need to know. Trauma Violence Abuse. 2007;8(2):127–134


123. Parekh V, Brown CB. Follow up of patients who have been recently sexually assaulted. Sex Transm Infect 2003;79(4):349


127. Wiebe ER, Comay SE, McGregor M, Ducceschi S. Offering HIV prophylaxis to people who have been sexually assaulted: 16 months’ experience in a sexual assault service. CMAJ 2000;162(5):841–845


Epinephrine for First-aid Management of Anaphylaxis

Scott H. Sicherer, MD, FAAP, F. Estelle R. Simons, MD, FAAP, SECTION ON ALLERGY AND IMMUNOLOGY

INTRODUCTION

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.

abstract

Anaphylaxis is a severe, generalized allergic or hypersensitivity reaction that is rapid in onset and potentially fatal. 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.


Address correspondence to Scott H. Sicherer, MD. E-mail: scott.sicherer@mssm.edu

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

Copyright © 2017 by the American Academy of Pediatrics

DOI: 10.1542/peds.2016-4006

American Academy of Pediatrics
DEdicated to the Health of All Children®
Clinical presentation and severity can vary among patients and in the same patient from 1 anaphylactic episode to another. Anaphylaxis is the primary initial treatment of anaphylaxis. This clinical report is the primary initial treatment of topic. Amendments to the previous report on this topic. Updates and from the American Academy of Pediatrics (AAP) updates and amplifies the previous report on this topic.

**CLINICAL FEATURES OF ANAPHYLAXIS**

Clinical criteria for anaphylaxis have been proposed and validated. Anaphylaxis is highly likely when any 1 of the following 3 criteria is fulfilled:

1. Acute onset of an illness (minutes to several hours), with involvement of the skin, mucosal tissue, or both (eg, generalized urticaria, itching or flushing, swollen lips/tongue/uvula), and at least 1 of the following: (1) respiratory compromise (eg, dyspnea, wheeze/bronchospasm, stridor, hypoxemia) or (2) reduced blood pressure or associated symptoms of end-organ dysfunction (eg, hypotonia [collapse], syncope, incontinence); OR

2. Two or more of the following that occur suddenly after exposure to a likely allergen for that patient (minutes to several hours): (1) involvement of the skin/mucosal tissue (eg, generalized urticaria, itch/flush, swollen lips/tongue/uvula), (2) respiratory compromise (eg, dyspnea, wheeze/bronchospasm, stridor, hypoxemia), (3) reduced blood pressure or associated symptoms (eg, hypotonia [collapse], syncope, incontinence), or (4) persistent gastrointestinal symptoms (eg, crampy abdominal pain, vomiting); OR

3. Reduced blood pressure after exposure to a known allergen for that patient (minutes to several hours): (1) for infants and children, low systolic blood pressure (age-specific) or greater than 30% decrease in systolic blood pressure, and (2) for teenagers and adults, systolic blood pressure of less than 90 mm Hg or greater than 30% decrease from that person’s baseline. These clinical criteria for the diagnosis of anaphylaxis have been validated in emergency department studies in children, teenagers, and adults. They have high sensitivity (96.7%), reasonable specificity (82.4%), and a high negative predictive value (98%). Disorders such as acute asthma, acute generalized urticaria, aspiration of a foreign body such as a peanut, vasovagal episode, and anxiety or panic attacks can present with some similar symptoms. There are age-related differences in the clinical presentation and differential diagnosis of anaphylaxis. The clinical criteria have not yet been validated in infants.

Foods, especially peanut, tree nuts, milk, eggs, crustacean shellfish, and finned fish, are by far the most common triggers of anaphylaxis in the pediatric population. Insect stings, drugs such as antibiotics, and various other allergens can also trigger anaphylaxis; however, vaccinations to prevent infectious diseases seldom trigger it. Cofactors that lower the threshold at which triggers can cause anaphylaxis include exercise, upper respiratory tract infections, fever, ingestion of nonsteroidal antiinflammatory drugs or ethanol, emotional stress, and perimenstrual status. Fatal anaphylaxis is often associated with adolescence, concomitant asthma (especially if severe or poorly controlled), and failure to inject epinephrine promptly.

**PRIMARY ROLE OF EPINEPHRINE**

Epinephrine is the medication of choice for the first-aid treatment of anaphylaxis. Through vasoconstrictor effects, it prevents or decreases upper airway mucosal edema (laryngeal edema), hypotension, and shock. In addition, it has important bronchodilator effects and cardiac inotropic and chronotropic effects. Delayed epinephrine administration in anaphylaxis is associated with an increased risk of hospitalization and poor outcomes, including hypoxic-ischemic encephalopathy and death. Conversely, prompt prehospital epinephrine injection is associated with a lower risk of hospitalization and fatality.

H₁-antihistamines prevent and relieve itching and hives but do not relieve life-threatening respiratory symptoms, hypotension, or shock; therefore, like H₂-antihistamines and glucocorticoids, they are adjunctive treatments and are not appropriate for use as the initial treatment or the only treatment. For children with concomitant asthma, inhaled β₂-adrenergic agonists (eg, albuterol) can provide additional relief of lower respiratory tract symptoms but, like antihistamines and glucocorticoids, are not appropriate for use as the initial or only treatment in anaphylaxis.

**EPINEPHRINE ADMINISTRATION AND DOSING**

Epinephrine can be life-saving when injected promptly by the intramuscular (IM) route in the mid-outer thigh (vastus lateralis muscle) as soon as anaphylaxis is recognized. For first-aid management of anaphylaxis in health care settings, traditionally an epinephrine dose of 0.01 mg/kg is injected IM, to a maximum of 0.3 mg in a prepubertal child and up to 0.5 mg in a teenager. Epinephrine is injected IM, to a maximum of 0.3 mg in a prepubertal child and up to 0.5 mg in a teenager.
How to recognize anaphylaxis

Anaphylaxis has a sudden onset (minutes to a few hours) after exposure to a food, drug, insect sting, or other trigger. It potentially involves some of the following symptoms and signs:

- skin: itching, redness, hives, or swelling; oral and nasal mucosa: itching, swelling, conjunctivae: itching, swelling, redness;
- respiratory tract: hoarseness, throat itching, throat tightness, stridor, cough, difficulty breathing, chest tightness, wheeze, cyanosis;
- cardiovascular symptoms: tachycardia, chest pain, hypotension, weak pulse, dizziness, collapse, incontinence, shock;
- gastrointestinal tract symptoms: nausea, crampy abdominal pain, persistent vomiting, diarrhea;
- central nervous system: behavioral changes (infants), sense of doom, headache, altered mental status, confusion, tunnel vision.

How to treat anaphylaxis

Be prepared! Have a written anaphylaxis emergency action plan.

When anaphylaxis occurs, promptly assess the patient’s airway, breathing, circulation, and skin and call for help: 911 or EMS in community settings, a resuscitation team in health care settings.

Inject epinephrine (adrenaline) IM in the mid-outer aspect of the thigh by using an EA. If needed, give a second injection 5 to 15 minutes after the first. Place the patient on his or her back or in a position of comfort if there is respiratory distress and/or vomiting. Elevate the lower extremities. Do not allow standing, walking, or running.

Transport the patient to an emergency department, preferably by an EMS vehicle, for further assessment and monitoring. Additional treatment, including supplemental oxygen, intravenous fluids, and other interventions may be needed.

Adapted from refs 1-15

can differ among patients, and even in the same patient from 1 episode to the next. Typically, more than 1 body organ system is involved.

*a Note that only a few anaphylaxis symptoms may be present during an episode. Also, symptoms

autoinjectors (EAs) can be used in health care settings to deliver a 0.15-mg dose in a young child and a 0.3-mg dose in a child or teenager.

If the response to the first epinephrine injection is inadequate, it can be repeated once or twice at 5- to 15-minute intervals.1, 2, 8 From 6% to 19% of pediatric patients treated with a first epinephrine injection in anaphylaxis require a second dose.29-31 A third dose is needed infrequently. Subsequent doses are typically given by a health care professional along with other interventions.1, 2, 4, 8 In a retrospective chart review study in emergency department patients with anaphylaxis, most of whom were children, 17% of those who received 1 epinephrine injection required 1 or more additional doses. The need for subsequent injections did not correlate with obesity or overweight status.31

Subsequent epinephrine doses are needed for severe or rapidly progressive anaphylaxis and for failure to respond to the initial injection because of delayed injection of the initial dose, inadequate initial dose, or administration through a suboptimal route.23 Subsequent doses also might be needed in biphasic anaphylaxis, defined as recurrence of symptoms hours after resolution of initial symptoms despite no further exposure to the trigger, which is reported in up to 11% of pediatric patients. Food-induced anaphylaxis is associated with biphasic anaphylaxis less often than is venom- or drug-induced anaphylaxis.32, 33

Reluctance to inject epinephrine promptly at the onset of anaphylaxis symptoms is best overcome by awareness that the severity of an anaphylactic episode can differ from 1 patient to another and in the same patient from 1 episode to another.21 At the onset, it is impossible to predict whether the patient will respond promptly to treatment, die within minutes, or recover spontaneously because of secretion of endogenous epinephrine.

SAFETY OF EPINEPHRINE

Pharmacologic effects of epinephrine include transient pallor, tremor, anxiety, and palpitations, which, although perceived as adverse effects, are similar to the symptoms caused by increased endogenous epinephrine levels produced in the “fight or flight” response. These effects cannot be dissociated from the beneficial effects of epinephrine.21

Epinephrine given by IM injection achieves peak concentrations faster than that given by subcutaneous injection.20 Epinephrine, 0.3 mg IM, is 10 times safer than epinephrine given as an intravenous bolus.34 Serious adverse effects of IM epinephrine are rare in children. There is no absolute contraindication to epinephrine treatment in anaphylaxis.1, 2, 8, 23

DILEMMAS IN EPINEPHRINE DOSING

Only 2 premeasured, fixed doses of epinephrine, 0.15 mg and 0.3 mg, are currently available in EA formulations in the United States and Canada.35 EA manufacturers advise prescribing the 0.15-mg dose for patients weighing 15 to 30 kg and the 0.3-mg dose for those weighing 30 kg and over. These doses are optimal for many children but not necessarily for all children.

The 0.15-mg dose is high for infants (a twofold dose for those weighing ≤7.5 kg) and for some young children.6, 21 Some EA manufacturers have suggested that an alternative approach for infants is to have caregivers draw up the dose from

---

**TABLE 1 Anaphylaxis: Recognition and First-aid Treatment**

<table>
<thead>
<tr>
<th>How to recognize anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylaxis has a sudden onset (minutes to a few hours) after exposure to a food, drug, insect sting, or other trigger. It potentially involves some of the following symptoms and signs:</td>
</tr>
<tr>
<td>skin: itching, redness, hives, or swelling; oral and nasal mucosa: itching, swelling, conjunctivae: itching, swelling, redness;</td>
</tr>
<tr>
<td>respiratory tract: hoarseness, throat itching, throat tightness, stridor, cough, difficulty breathing, chest tightness, wheeze, cyanosis;</td>
</tr>
<tr>
<td>cardiovascular symptoms: tachycardia, chest pain, hypotension, weak pulse, dizziness, collapse, incontinence, shock;</td>
</tr>
<tr>
<td>gastrointestinal tract symptoms: nausea, crampy abdominal pain, persistent vomiting, diarrhea; and</td>
</tr>
<tr>
<td>central nervous system: behavioral changes (infants), sense of doom, headache, altered mental status, confusion, tunnel vision.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How to treat anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Be prepared! Have a written anaphylaxis emergency action plan.</td>
</tr>
<tr>
<td>When anaphylaxis occurs, promptly assess the patient’s airway, breathing, circulation, and skin and call for help: 911 or EMS in community settings, a resuscitation team in health care settings.</td>
</tr>
<tr>
<td>Inject epinephrine (adrenaline) IM in the mid-outer aspect of the thigh by using an EA. If needed, give a second injection 5 to 15 minutes after the first. Place the patient on his or her back or in a position of comfort if there is respiratory distress and/or vomiting. Elevate the lower extremities. Do not allow standing, walking, or running.</td>
</tr>
<tr>
<td>Transport the patient to an emergency department, preferably by an EMS vehicle, for further assessment and monitoring. Additional treatment, including supplemental oxygen, intravenous fluids, and other interventions may be needed.</td>
</tr>
</tbody>
</table>

Adapted from refs 1-15
a 1-mL ampule by using a 1-mL syringe. However, dose preparation can take laypersons as long as 3 to 4 minutes; moreover, doses typically are inaccurate and can sometimes contain no epinephrine at all when the solution is ejected from the syringe along with the air. Although unsealed 1-mL syringes prefilled by a health care professional with infant epinephrine doses also have been recommended, the doses can be lost, and the epinephrine solution typically degrades within a few months as a result of air exposure.

After consideration of the aforementioned alternatives that potentially lead to delay in dosing, incorrect dosing, or no dose at all and consideration of the favorable benefit-to-risk ratio of epinephrine in young patients with anaphylaxis, many physicians recommend the use of the 0.15-mg EA in infants. Most pediatricians (80%) report that they would prescribe the 0.15-mg EA for an infant or a child weighing 10 kg (22 lb). International guidelines suggest that, when using EAs, patients weighing 7.5 to 25 kg should receive the 0.15-mg dose. Physicians can discuss the benefits and risks of these options with families and prescribe on a case-by-case basis.

On the basis of a pharmacokinetic study and expert consensus, it is appropriate to switch most children from the 0.15-mg dose to the 0.3-mg dose when they reach a body weight of 25 to 30 kg (55–66 lb).

### PRESCRIBING EAS

Most anaphylaxis deaths occur in community settings rather than in health care settings, yet, some physicians fail to prescribe EAs for their patients at risk of anaphylaxis in the community. These patients include those with a history of anaphylaxis who can re-encounter their triggers, such as foods or stinging insects, those with idiopathic anaphylaxis, and those at increased risk of anaphylaxis who might not yet have experienced it (see next paragraph). Including patients living in remote areas with minimal or no access to emergency medical services (EMS). EA prescriptions also can be considered for patients with known sensitization to peanut, tree nuts, cow’s milk, crustacean shellfish, and fish, which potentially are associated with severe and fatal anaphylaxis and can be difficult to avoid (eg, when peanut or milk are hidden ingredients in manufactured foods).

Consideration of prescribing an EA is especially important if the patient has had a previous food-induced allergic reaction, such as generalized acute urticaria, has reacted to trace amounts of a food, or has food allergy and comorbid asthma, which increases the risk of fatality from anaphylaxis. In fact, some experts have suggested that consideration be given to prescribing EAs for all patients with immunoglobulin E–mediated food allergy, because it is difficult or impossible to predict the occurrence or severity of future reactions. It can be beneficial to prescribe EAs for children with a history of acute generalized urticaria after an insect sting, because if re-stung, the risk of a more severe systemic reaction is approximately 5% in this population.

Definitive evaluation by an allergy/immunology specialist can provide confirmation of the diagnosis of anaphylaxis and the trigger and, for patients with idiopathic anaphylaxis, can clarify the diagnosis by performing additional investigations that reveal a trigger or identify comorbidities, such as systemic mastocytosis. Allergy/immunology specialists also initiate comprehensive preventive care: prescription of EAs in the context of written, personalized anaphylaxis emergency action plans; education about anaphylaxis recognition and EA use; detailed information about how to avoid specific allergens; and allergen immunotherapy (eg, venom immunotherapy, if relevant) to prevent the recurrence of insect sting anaphylaxis.

### USING EAS

Guidelines recommend prompt epinephrine injection for the sudden onset of any anaphylaxis symptoms after exposure to an allergen that previously caused anaphylaxis in that patient. Systemic allergic reactions can rapidly progress from mild to life-threatening symptoms, and early treatment before, or at the first sign of, symptoms can sometimes prevent escalation of symptoms. As an example, generalized acute urticaria is not life-threatening; yet, in a community setting, in the context of a known exposure to an allergen (eg, peanut or milk) that previously triggered anaphylaxis, it could be beneficial to inject epinephrine to prevent additional symptoms. It can sometimes be difficult to distinguish anaphylaxis from other diagnostic entities such as acute asthma, acute generalized urticaria, aspiration of a foreign body such as a peanut, a vasovagal episode, or an anxiety or panic attack. In such situations, if unsure, erring on the side of caution and injecting epinephrine, then observing the patient closely, is advised.

Even physicians with years of experience in diagnosing and treating anaphylaxis cannot determine, at the onset of an episode, whether that episode will remain mild or escalate over minutes to become life-threatening. In this situation, although some oral H1-antihistamines relieve itching and hives within 30 or 40 minutes, severe, life-threatening respiratory and/or cardiovascular symptoms can appear suddenly after the hives have disappeared. In community...
settings, patients experiencing anaphylaxis or caregivers without medical training may be so anxious that they cannot assess the situation accurately and remember what to do. It is therefore important that physicians instruct patients and caregivers to err on the side of prompt epinephrine injection.\textsuperscript{1,3,8,35}

Many patients and caregivers fail to carry EAs consistently or to use them when anaphylaxis occurs, even for severe symptoms, including throat tightness, difficulty breathing, wheezing, and loss of consciousness.\textsuperscript{41,45,46} People may have different reasons for not using EAs, including failure to recognize anaphylaxis symptoms, spontaneous recovery from a previous anaphylactic episode and the assumption that this will happen in every episode, reliance on oral H\textsubscript{1}-antihistamines and/or inhaled bronchodilators, no EA available, fear of needles, and concerns about epinephrine adverse effects.\textsuperscript{41,45–48}

Many parents fear using an EA because they worry about hurting or injuring their child or a bad outcome.\textsuperscript{46,47} Unintentional injections into digits and other body parts, with or without injuries,\textsuperscript{48} and lacerations incurred when an inadequately restrained child moves during the injection are reported from pen-type EAs.\textsuperscript{49}

Teenagers are at increased risk of death in anaphylaxis\textsuperscript{16–18} because of high-risk behaviors, including ethanol and/or recreational drug use, failure to recognize triggers, denial of symptoms, and failure to carry their EAs and inject epinephrine promptly when anaphylaxis occurs.\textsuperscript{16–18} Additional efforts to provide anaphylaxis education for adolescents, their peers, and their communities are needed.\textsuperscript{50}

Patients and caregivers need training in how to recognize anaphylaxis and use an EA. Epinephrine injections can be given through clothing, although care must be taken to avoid obstructing seams or items in pockets. Regular review (eg, annually) of anaphylaxis recognition and injection technique is advisable, because errors are common and acquired skills may not be retained permanently.\textsuperscript{51,52} Technique can be practiced at home by using a "trainer." Various EAs may come to market having different mechanisms of activation and variations in ease of use.\textsuperscript{53,54}

Education about anaphylaxis recognition and injection technique is advised to ensure familiarity with the specific device prescribed. After treatment with epinephrine for anaphylaxis in community settings, it is important for patients to be assessed in an emergency department to determine whether additional interventions are needed.\textsuperscript{1,2,8} It may be helpful for families to know they are seeking additional medical care not because of the use of the EA, a safe treatment, but rather to assess and monitor the anaphylactic episode.

PEDIATRICS Volume 139, number 3, March 2017

ANAPHYLAXIS EMERGENCY ACTION PLANS AND MEDICAL IDENTIFICATION

EAs are best prescribed in the context of written, personalized anaphylaxis emergency action plans. Such plans typically list common symptoms and signs of anaphylaxis and outline initial anaphylaxis treatment (Table 1): specifically, prioritize calling for help (911 or EMS), injecting epinephrine from an EA, and positioning the patient supine or in a position of comfort.\textsuperscript{1–3,6,8} Action plans can also provide information such as the individual’s anaphylaxis triggers and, if relevant, any history of severe anaphylaxis and/or comorbid conditions such as asthma. In addition, they can remind readers that H\textsubscript{1}-antihistamines and asthma inhalers should not be used as the initial treatment or only treatment of anaphylaxis.

Patients at risk of anaphylaxis recurrences can wear medical identification jewelry and/or carry a wallet card that states “anaphylaxis” and lists their...
confirmed triggers and relevant comorbidities such as asthma. Knowledge about the recognition and treatment of anaphylaxis increased significantly after brief study of an anaphylaxis wallet card. Plans and medical IDs are best reviewed and updated regularly, such as annually. %n

SPECIAL ISSUES FOR SCHOOLS AND OTHER PUBLIC VENUES
Prevention and treatment of anaphylaxis in schools, child care settings, camps, and other venues for young people are multifaceted and require a comprehensive approach, including awareness training and practical preparation. Approaches are outlined in an AAP clinical report and in guidelines from the Centers for Disease Control and Prevention (http://www.cdc.gov/healthyyouth/foodallergies). In many US schools, unassigned EAs are available for use when anaphylaxis occurs in a student who does not have a personal EA available; clinicians can check with their state legislature regarding such regulations.

SUMMARY
1. Epinephrine is the medication of choice for the initial treatment of anaphylaxis. If injected promptly, it is nearly always effective. Delayed injection can be associated with poor outcomes, including fatality. All other medications, including H1-antihistamines and bronchodilators such as albuterol, provide adjunctive treatment but do not replace epinephrine. After treatment with epinephrine for anaphylaxis in community settings, it is important for patients to be assessed in an emergency department to determine whether additional interventions, including oxygen, intravenous fluids, and adjunctive medications, are needed.
2. When anaphylaxis occurs in health care settings, epinephrine (0.01 mg/kg [maximum dose: 0.3 mg in a prepubertal child and up to 0.5 mg in a teenager]) by IM injection in the mid-outer thigh (vastus lateralis muscle) is recommended. IM epinephrine achieves peak epinephrine concentrations promptly and is safer than an intravenous bolus injection.
3. When anaphylaxis occurs in community settings, EAs are preferred because of their ease of use and accuracy of dosing as compared with the use of an ampule, syringe, and needle by laypersons or the use of an unsealed syringe prefilled with epinephrine. In the United States and Canada, EAs are currently available in only 2 fixed doses: 0.15 mg and 0.3 mg. International guidelines suggest that when using EAs, patients weighing 7.5 kg (16.5 lb) to 25 kg (55 lb) should receive the 0.15-mg dose; although this dose is not ideal for those who weigh less than 15 kg (33 lb), the alternatives are associated with delay in dosing, inaccurate dosing, and potential loss of the dose. It is reasonable to recommend EAs containing a 0.3-mg epinephrine dose for those weighing 25 kg (55 lb) or more.
4. It is beneficial to prescribe EAs for all patients who have experienced anaphylaxis and who may re-encounter their trigger in a community setting. If specific circumstances warrant, EAs may also be prescribed for some high-risk patients without a history of anaphylaxis.
5. Epinephrine is best prescribed in the context of a written, personalized anaphylaxis emergency action plan, developed by the medical home with input from the family. A relevant AAP clinical report provides an example of such a written plan with instructions on completing it. Protocols for the use of unassigned EAs may also be beneficial. Children at risk of anaphylaxis require a comprehensive approach to management. It is important to teach patients and caregivers how to recognize anaphylaxis symptoms; when, why, and how to use an EA; and the rationale for calling 911 or EMS.

LEAD AUTHORS
Scott H. Sicherer, MD, FAAP
F. Estelle R. Simons, MD, FAAP

SECTION ON ALLERGY AND IMMUNOLOGY EXECUTIVE COMMITTEE, 2014–2015
Todd A. Mahr, MD, FAAP, Chair
Stuart L. Abramson, MD, PhD, FAAP
Chitra Dinakar, MD, FAAP
Thomas A. Fleisher, MD, FAAP
Anne-Marie Irani, MD, FAAP
Jennifer S. Kim, MD, FAAP
Elizabeth C. Matsui, MD, FAAP
Scott H. Sicherer, MD, FAAP, Immediate Past Chair

LIAISON TO THE SECTION ON ALLERGY AND IMMUNOLOGY
Paul V. Williams, MD, FAAP – American Academy of Allergy, Asthma, and Immunology

STAFF
Debra L. Burrowes, MHA

ABBREVIATIONS
AAP: American Academy of Pediatrics
EA: epinephrine autoinjector
EMS: emergency medical services
IM: intramuscular(ly)


50. Muraro A, Ageche I, Clark A, et al; European Academy of Allergy and Clinical Immunology. EAACI food allergy and anaphylaxis guidelines: managing patients with food allergy in the community. Allergy. 2014;69(8):1046–1057


56. Simons E, Sicherer SH, Weiss C, Simons FER. Caregivers’ perspectives on timing the transfer of responsibilities for anaphylaxis recognition and treatment from adults to children.


61. Sicherer SH, Mahr T; Section on Allergy and Immunology. Management of food allergy in the school setting. *Pediatrics.* 2010;126(6):1232–1239


Guidance on Completing a Written Allergy and Anaphylaxis Emergency Plan

Julie Wang, MD, FAAP,* Scott H. Sicherer, MD, FAAP,** 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.

INTRODUCTION

Anaphylaxis is a potentially life-threatening, severe allergic reaction. As such, it is a medical emergency that requires an immediate assessment of the patient and administration of epinephrine. Given the unpredictable nature of anaphylaxis, preparedness promotes optimal outcomes. Thus, national and international anaphylaxis guidelines, as well as several American Academy of Pediatrics (AAP) clinical reports (“Self-injectable Epinephrine for First-aid Management of Anaphylaxis,” “Management of Food Allergy in the School Setting,” and “Medical Emergencies Occurring at School”), recommend the provision of emergency action plans to pediatric patients who are at risk of anaphylaxis, in addition to the prescription of epinephrine autoinjectors. Guidance from the Centers for Disease Control and Prevention for managing food allergy in schools and early education programs also supports the inclusion of written emergency plans for the management of children with food allergy.
Written action plans have been shown to improve outcomes for asthma, and similarly, action plans have the potential to improve outcomes of anaphylaxis by reducing the frequency and severity of reactions, improving knowledge of anaphylaxis, improving use of epinephrine autoinjectors, and reducing anxiety of patients and caregivers. Action plans serve as an important tool for anaphylaxis education and treatment.

Currently, several different anaphylaxis action plans are available, but variations exist in content and treatment recommendations, which can lead to confusion. A survey of AAP Section on Allergy and Immunology members found that there is wide variation in terms of which plans are used by pediatric allergy specialists. Therefore, a universal plan for pediatric patients could be beneficial to patients, families, health care professionals, and schools to facilitate care for children at risk of anaphylaxis. The AAP Allergy and Anaphylaxis Emergency Plan associated with this clinical report was developed with the support and advice of various committees, councils, and sections within the AAP. It is available online (www.aap.org/aaep) and shown in Fig 1. This plan takes into consideration several aspects of anaphylaxis emergency care, including the recognition of signs and symptoms and treatment. This clinical report focuses on providing guidance to the clinician to complete the plan. The guidance in this clinical report has not undergone a systematic review nor a strict weighing of the evidence and, as such, should not be considered a practice guideline. Clinical guidance regarding treatment with epinephrine in the first-aid management of anaphylaxis is covered in a separate clinical report.

**WHEN TO PROVIDE A WRITTEN EMERGENCY PLAN**

An allergy and anaphylaxis emergency plan, developed by the health care provider, is a document written in simple lay terms that can guide the patient, family and nonfamily caregivers, and school personnel in the event that the child experiences an allergic reaction. Allergic reactions can occur anywhere and at any time, and health care providers may not be present at the time a child has an allergic reaction. Therefore, the emergency action plan serves as a guide for the patient, caregiver, and/or school personnel to determine how to treat allergic reactions.

It is beneficial to provide an allergy and anaphylaxis emergency plan when there is a diagnosis of an allergic disorder that places the child at risk of anaphylaxis (eg, food allergy, insect sting allergy). A new written plan can be provided, for example, annually at the beginning of the school year, to address any need for adjustment of medication doses or whenever there is any change in allergic triggers, comorbid conditions, or any new medical information that would warrant a change in the plan.

**COMPLETING THE ALLERGY AND ANAPHYLAXIS EMERGENCY PLAN**

**Demographic Information and Allergy History**

The initial section is completed with the child’s demographic information, including name, date of birth, and age, as a personalized plan for the child. The plan should be dated so that it is easy to determine when the health care provider created the emergency plan. Allergic triggers can be listed in the space provided. It is advisable to include the weight of the child at the time the plan was created to allow confirmation of correct medication dosages.

Having a history of asthma and/or of anaphylaxis is associated with a higher risk of severe reactions and, as such, these should be noted. The presence of asthma is associated with an increased likelihood of having respiratory symptoms during an allergic reaction and can cause the reaction to be more difficult to treat. In a recent study of anaphylaxis-related hospitalizations over 2 decades in the United Kingdom, 75% of patients with fatal food-induced anaphylaxis were noted to have concurrent asthma.

A child’s ability to self-carry emergency medications and/or self-administer medications can be indicated. This ability will depend on the age and maturity of the child. All states have laws to allow self-carry by students in schools; however, some states require a student’s physician and parents to sign a form stating the student has the maturity to self-administer relevant medications. Although no specific guidelines exist to determine when it would be appropriate for a child to self-carry and/or self-administer epinephrine autoinjectors, a survey of members of the AAP Section on Allergy and Immunology found that most pediatric allergy specialists begin to expect children 9 through 11 years of age to be able to recognize signs and symptoms of anaphylaxis and expect children 12 through 14 years of age to self-carry epinephrine autoinjectors and self-administer the device. In a study of family and nonfamily caregivers of children with food allergy, most expected the child to be able to recognize anaphylaxis at approximately 6 through 8 years of age and believed that epinephrine autoinjector use was appropriate for children 6 through 11 years of age. Thus, these decisions may benefit from personalization with the input of the family. Of note, if it is determined that self-carrying/self-administration is appropriate, it is important to designate adults...
to be additionally and primarily responsible for treatment, because the child may not be depended on to self-treat if he or she is panicked or severely symptomatic.

**Treatment Pathways**

Epinephrine is the first-line treatment of anaphylaxis; therefore, the form indicates that if there is any uncertainty about whether anaphylaxis is occurring, epinephrine should be administered immediately. The early use of epinephrine has been shown to be associated with better outcomes. In studies of fatal and near-fatal anaphylaxis, delayed or lack of administration of epinephrine was noted in the majority of cases. Studies have shown that the early use of epinephrine in the treatment of food-induced anaphylaxis was associated with a decreased likelihood the child would require hospital admission.

Therefore, the plan instructs on prompt treatment with epinephrine for symptoms of anaphylaxis.

When allergic reactions are suspected, the caregiver or school personnel should observe for signs and symptoms of an allergic reaction and determine the appropriate treatment pathway as outlined on the allergy and anaphylaxis emergency plan (Fig 1). If any severe symptom develops, anaphylaxis is highly likely, and epinephrine should be injected immediately.

Epinephrine administration should be followed by activation of emergency medical services (calling 911), monitoring of the child, and consideration of adjunctive treatment with oral antihistamines and/or bronchodilators for known asthmatics or in the presence of respiratory symptoms, including wheezing or shortness of breath.

In some circumstances, it may be beneficial to treat with epinephrine even if anaphylaxis is not occurring, such as when anaphylaxis is likely to develop after an exposure or when it may be difficult to determine by the observer. Therefore, the plan provides options that can be selected at the physician’s discretion to address these possibilities. For example, if the child has a history of very severe anaphylaxis, such as with respiratory distress, hypoxia, hypotension, or neurologic compromise after exposure to specific allergen(s), then the health care provider may consider recommending epinephrine to be administered immediately after a likely ingestion or sting at the onset of the first symptom (even mild ones, such as itchiness of the face/mouth, a few hives, or mild symptoms of stomach discomfort or nausea), because severe reactions can progress rapidly.

Other scenarios in which to consider immediate epinephrine use after definitive ingestion or sting when only mild symptoms are present (assuming additional doses are available, should symptoms emerge and progress) may include a child who has a history of repeated anaphylaxis with exposure to the specific allergen(s), a child who has a history of significant reactions with trace exposures, or a child with comorbid asthma that is poorly controlled. The allergen(s) can be listed as a “special situation” (box within the “For Severe Allergy and Anaphylaxis” box on the left-hand side of the form). Although controversial, there may be situations in which the health care provider may consider recommending epinephrine to be administered immediately after a definite ingestion or sting and before symptoms develop (manually write in “no” in place of “mild”), because severe reactions can occur suddenly without significant warning signs.

An example is if a child has had a history of severe cardiovascular collapse to a specific allergen. These suggestions are based on expert opinion, not from data acquired through controlled trials.

In some situations, licensed health care providers will not be available in a school setting and there is a desire to simplify the instructions for delegates or designated individuals. In these cases, the health care provider can indicate that definitive allergen exposures would require immediate treatment with epinephrine. If the administration of antihistamine by delegates or designated individuals is not permitted by school or local regulations, this scenario would be another in which the health care provider should consider instructing epinephrine to be used in the event of a definite allergen exposure even if mild symptoms occur (see below for more details on the completion of the form for no permission to use antihistamine).

If there is a mild symptom alone, an oral antihistamine may be administered first. If additional symptoms are observed after oral antihistamine has been administered or if more than 1 organ system is involved, then epinephrine is indicated. Education about anaphylaxis and epinephrine is helpful, and additional advice about the administration of epinephrine is provided in another AAP clinical report.

The use of antihistamine is included as an option because this plan provides instructions for managing allergic reactions with a range of severities. Several studies have examined allergic reactions attributable to accidental or intentional exposures in food-allergic children and noted that 30% to 70% of reactions are characterized as mild in severity.

In a cohort of 512 young children (3–15 months at enrollment) with allergies to milk, egg, and/or peanut followed over 3 years, 70% of the 1171 reactions occurring during the study time frame were considered to be mild (defined as skin and/or oral symptoms and/or upper...
respiratory symptoms, but not all 3 organ systems). In a study in 88 children with milk allergy (median age: 32.5 months) followed for 1 year, 53% of reported reactions were mild (defined as cutaneous symptoms [angioedema excluded], rhinitis, or conjunctivitis). A recent Canadian study of accidental exposures to peanut in 1941 children (mean age: 7 years) with confirmed peanut allergy reported that 30% of exposures resulted only in mild symptoms (defined as involving only pruritus, urticaria, flushing, or rhinoconjunctivitis). Therefore, in the event of a mild allergic reaction involving isolated skin symptoms, mild facial or oral symptoms, or mild gastrointestinal tract discomfort, none of which meet the criteria for anaphylaxis, the use of oral antihistamines may be an option.

Another concern is that epinephrine is stipulated in all cases of allergic reaction regardless of severity, a child may be hesitant to voice any symptoms for fear of epinephrine autoinjector use. Thus, emphasizing the option to observe and also having the option of using antihistamines for mild allergic reactions allows the plan to be individualized according to the child’s history. However, it is not possible to know the eventuality of any allergic reaction, and consideration can be given to use epinephrine liberally. If an option is needed, where antihistamine alone is not permitted (eg, if school or local policies do not permit delegates or designated individuals to administer antihistamines), then no antihistamine would be listed under medications. In this situation, mild symptoms would not be treated and close observation and watching for possible progression would be indicated. However, there is an option to list all of the allergens under “special situation” to indicate that any symptoms would require the administration of epinephrine.

After initiating treatment, additional instructions for contacting emergency medical services (calling 911) and monitoring for progression of symptoms are provided on the plan. For those who are initially treated with epinephrine, a second dose of epinephrine can be given if symptoms persist or recur. For those who are observed only or for those who receive antihistamines as the first treatment, any progression of symptoms would warrant epinephrine use, and the use of an antihistamine should not delay the administration of epinephrine.

In some severe cases of anaphylaxis, rapid vasodilation and extravasation of fluid have been reported, resulting in a decrease of up to a 35% in circulating blood volume within minutes. Upright posture in cases of food-induced anaphylactic shock has been reported to be associated with fatalities. This “empty ventricle syndrome” has not been reported in children; however, it would be prudent to place the child in the supine position to prevent pooling of blood in the lower extremities after epinephrine is administered. This position may not be tolerated in some circumstances, such as if a child is vomiting or having difficulty breathing. In these situations, the child can be placed in the lateral decubitus position (lying on his or her side).

**Medications**

Medications, specifying dosage, should be clearly indicated at the bottom of the form. Standard dosing for epinephrine in the treatment of anaphylaxis in health care settings is 0.01 mg/kg intramuscularly, with the use of a 1:1000 dilution (maximum of 0.3 mg in a prepubertal child and 0.5 mg in a teenager). Intramuscular injection of epinephrine in the lateral thigh is the preferred route of administration because it results in higher and faster peak plasma concentrations than subcutaneous or intramuscular injection in the deltoid.

Providing epinephrine ampules, needles, and syringes to patients and families for weight-based dosing is often not practical and subject to human error; therefore, epinephrine autoinjectors are prescribed for use in the community setting. Currently, only 2 epinephrine autoinjector dosing options exist, 0.15 mg or 0.3 mg. Package inserts state that the 0.15-mg dose is appropriate for children weighing 15 to 30 kg, and the 0.3-mg dose should be prescribed for those who weigh greater than or equal to 30 kg. On the basis of the lack of readily available alternatives and the favorable benefit-versus-risk ratio, prescription of the 0.15-mg autoinjector can be considered for those weighing 7.5 to 15 kg. Because of the concern of underdosing in children nearing 30 kg, expert consensus suggests that children be switched to the 0.3-mg dose autoinjector when they reach 25 kg, with consideration of switching to this higher dose at a lower weight if the child has asthma or other risk factors for severe reaction.

Physicians can discuss the rationale for selecting autoinjector doses with each individual family. Two epinephrine autoinjectors should be available at all times, because a second administration may be needed if there is not a quick or adequate response to the first dose of epinephrine.

$H_1$ antihistamines are effective for the treatment of acute cutaneous symptoms, such as pruritus and urticaria, associated with allergy. Therefore, in cases of isolated mild symptoms, the use of oral antihistamines may be appropriate. Diphenhydramine is the most commonly used $H_1$ antihistamine. Standard dosing is 1 mg/kg, up to 50 mg. First-generation $H_1$ antihistamines, such as diphenhydramine, cross the blood-brain barrier, causing
sedation and impairment in cognitive function. These side effects can potentially complicate the neurologic assessment of a child who is experiencing an allergic reaction. These adverse effects are significantly less likely to occur for second-generation H1 antihistamines, because these medications cross the blood-brain barrier to a much lesser extent.26 In a randomized double-blind study of 70 allergic reactions during oral food challenge, cetirizine (second-generation H1 antihistamine) was shown to have a similar efficacy and onset of action compared with diphenhydramine in treating cutaneous symptoms during acute food-induced allergic reactions. Given these findings, in addition to the longer duration of action compared with diphenhydramine, cetirizine is a good option to consider for the treatment of isolated mild symptoms of an allergic reaction.27

Additional Instructions Regarding Completion of the Emergency Plan

Space is provided for parents’ and health care providers’ signatures as an additional measure to indicate parental understanding and agreement with the allergy and anaphylaxis emergency plan. Space is provided to indicate the dates of the parents’ and health care providers’ signatures.

The second page provides space for additional instructions, such as statements of disability. Space is provided to include contact information for health care providers, parents/guardians, and other caregivers.

There is blank space on the second page that can be used to provide information specific to the school or child or illustrations of using the autoinjector.

The plan is given to the patient and his or her family so they may review it and share it with the school or other child care facility or caregivers. The health care provider may speak to the family regarding the benefits of permitting 2-way sharing of information between the school and the health care provider and completing any forms that would be required to allow this exchange of information.

In addition to providing this allergy and anaphylaxis emergency plan, the patient should have updated prescriptions for emergency medications. It is also helpful for the health care provider to review with the patient and/or family members instructions for, and show the proper use of, epinephrine autoinjectors by using a training device that has the same mechanism but does not contain medication or the needle. Patients and family members should be reminded to check expiration dates on their epinephrine autoinjectors and be familiar with proper storage conditions. Additional information about anaphylaxis management is reviewed in another AAP clinical report.5

SUMMARY

1. National and international guidelines support the use of a written allergy and anaphylaxis emergency plan to enhance the care of children at risk of anaphylaxis. Although several plans are currently available, they differ in content and treatment recommendations, potentially leading to confusion. Thus, a universal plan may be beneficial to patients, families, health care professionals, and schools.

2. An allergy and anaphylaxis emergency plan, developed by the health care provider, would be beneficial for patients who are at risk of anaphylaxis and those who have been prescribed an epinephrine autoinjector.

3. The written plan may serve as a guide for patients, family and nonfamily caregivers, and school personnel in the management of allergic reactions.

4. Epinephrine is the medication of choice for the initial treatment of anaphylaxis, and early administration is associated with optimal outcomes. In the event of a definite exposure to an allergen that has previously caused a severe reaction, or if anaphylaxis develops, immediate use of epinephrine is warranted. If exposure to an allergen triggers only a mild symptom, observation only or initiating treatment with an antihistamine may be appropriate.

5. This allergy and anaphylaxis emergency plan allows health care providers the opportunity to individualize the treatment plan according to the child’s history, family input, and local regulations. Options and considerations for completing the plan are reviewed in this clinical report.

AUTHORS
Julie Wang, MD, FAAP
Scott H. Sicherer, MD, FAAP

SECTION ON ALLERGY AND IMMUNOLOGY EXECUTIVE COMMITTEE, 2015–2016
Elizabeth Matsui, MD, FAAP, Chair
Stuart Abramson, MD, PhD, FAAP
Chitra Dinakar, MD, FAAP
Anne-Marie Irani, MD, FAAP
Jennifer S. Kim, MD, FAAP
Todd A. Mahr, MD, FAAP, Immediate Past Chair
Michael Pistiner, MD, FAAP
Julie Wang, MD, FAAP

LIAISON
Paul V. Williams, MD, FAAP – American Academy of Allergy, Asthma, and Immunology

STAFF
Debra Burrowes, MHA

ABBREVIATION
AAP: American Academy of Pediatrics
Allergy and Anaphylaxis Emergency Plan

Child’s name: ___________________________ Date of plan: ___________________________

Date of birth: ____/____/______ Age ____ Weight: ________ kg

Child has allergy to _____________________________________________________________

Child has asthma. □ Yes □ No (If yes, higher chance severe reaction)
Child has had anaphylaxis. □ Yes □ No
Child may carry medicine. □ Yes □ No
Child may give him/herself medicine. □ Yes □ No (If child refuses/is unable to self-treat, an adult must give medicine)

IMPORTANT REMINDER
Anaphylaxis is a potentially life-threatening, severe allergic reaction. If in doubt, give epinephrine.

For Severe Allergy and Anaphylaxis

What to look for

If child has ANY of these severe symptoms after eating the food or having a sting, give epinephrine.

- Shortness of breath, wheezing, or coughing
- Skin color is pale or has a bluish color
- Weak pulse
- Fainting or dizziness
- Tight or hoarse throat
- Trouble breathing or swallowing
- Swelling of lips or tongue that bother breathing
- Vomiting or diarrhea (If severe or combined with other symptoms)
- Many hives or redness over body
- Feeling of “doom,” confusion, altered consciousness, or agitation

□ SPECIAL SITUATION: If this box is checked, child has an extremely severe allergy to an insect sting or the following food(s): _____________________________. Even if child has MILD symptoms after a sting or eating these foods, give epinephrine.

Give epinephrine!

What to do

1. Inject epinephrine right away! Note time when epinephrine was given.
2. Call 911.
   - Ask for ambulance with epinephrine.
   - Tell rescue squad when epinephrine was given.
3. Stay with child and:
   - Call parents and child’s doctor.
   - Give a second dose of epinephrine, if symptoms get worse, continue, or do not get better in 5 minutes.
   - Keep child lying on back. If the child vomits or has trouble breathing, keep child lying on his or her side.
4. Give other medicine, if prescribed. Do not use other medicine in place of epinephrine.
   - Antihistamine
   - Inhaler/bronchodilator

For Mild Allergic Reaction

What to look for

If child has had any mild symptoms, monitor child.

Symptoms may include:

- Itchy nose, sneezing, itchy mouth
- A few hives
- Mild stomach nausea or discomfort

Monitor child

What to do

Stay with child and:

- Watch child closely.
- Give antihistamine (if prescribed).
- Call parents and child’s doctor.
- If symptoms of severe allergy/anaphylaxis develop, use epinephrine. (See “For Severe Allergy and Anaphylaxis.”)

Medicines/Doses

Epinephrine, intramuscular (list type): __________________________ Dose: □ 0.15 mg □ 0.30 mg (weight more than 25 kg)
Antihistamine, by mouth (type and dose): __________________________
Other (for example, inhaler/bronchodilator if child has asthma): __________________________

Parent/Guardian Authorization Signature __________________________ Date ____________
Physician/HCP Authorization Signature __________________________ Date ____________

© 2017 American Academy of Pediatrics. All rights reserved. Your child’s doctor will tell you to do what’s best for your child. This information should not take the place of talking with your child’s doctor. Page 1 of 2.
Allergy and Anaphylaxis Emergency Plan

Additional Instructions:

Contacts

Call 911 / Rescue squad: (___) ____-_______

Doctor: _______________________________ Phone: (___) ____-_______

Parent/Guardian: _______________________________ Phone: (___) ____-_______

Parent/Guardian: _______________________________ Phone: (___) ____-_______

Other Emergency Contacts

Name/Relationship: _______________________________ Phone: (___) ____-_______

Name/Relationship: _______________________________ Phone: (___) ____-_______

© 2017 American Academy of Pediatrics. All rights reserved. Your child’s doctor will tell you to do what’s best for your child. This information should not take the place of talking with your child’s doctor. Page 2 of 2.

FIGURE 1
Continued
REFERENCES


The 2017 recommended childhood and adolescent immunization schedules have been approved by the American Academy of Pediatrics, the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists. The schedules are revised annually to reflect current recommendations for the use of vaccines licensed by the US Food and Drug Administration.

The 2017 format of Fig 1 is similar to the 2016 schedule consisting of a single table for persons from birth through 18 years of age. The yellow bars indicate the recommended age range for all children and contain a notation indicating the recommended dose number by age. The green bars indicate the recommended catch-up age. The purple bars designate the range for immunization for certain groups at high risk. The blue bars indicate the range of recommended doses for persons in non–high-risk groups who may receive a vaccine, subject to individual decision-making. The white boxes show the ages at which a vaccine is not recommended routinely. The columns that begin with a gray-shaded box indicate vaccine recommendations for school entry and at adolescent visits. The following specific changes have been made to the 2017 schedule:

- A column has been added for adolescents at 16 years of age. This age group has been separated from 17- to 18-year-olds to emphasize the need for a meningococcal conjugate vaccine (MenACWY) booster dose at age 16.
- Reference to live attenuated influenza vaccine (LAIV) has been removed from the influenza vaccine row.
- A blue bar has been added to the human papillomavirus (HPV) vaccine row at 9 to 10 years to indicate that, even in the absence of a high-risk condition, children may receive HPV vaccine series at this age.

To cite: AAP COMMITTEE ON INFECTIOUS DISEASES. Recommended Childhood and Adolescent Immunization Schedule—United States, 2017. Pediatrics. 2017;139(3):e20164007
Figure 2 is the catch-up immunization schedule offering recommendations for children and adolescents who start late or are >1 month behind. As in previous years, the catch-up schedule is divided into sections for children ages 4 months through 6 years and children and adolescents ages 7 through 18 years. No changes have been made to the 2017 catch-up immunization figure. Tables (job aids) are available to assist in the clarification of the recommended use of Haemophilus influenzae type b, pneumococcal, and pertussis-containing vaccines as a function of age; the number of doses previously administered; and the time interval since the last dose.

Figure 3 is a new table that addresses which vaccines may be indicated for persons aged 0 through 18 years who have a specific medical indication. This figure indicates vaccines that may be administered during pregnancy or to children and adolescents with an immunocompromising condition; kidney, heart, or liver disease; a cochlear implant; a cerebrospinal fluid leak; asplenia; a complement deficiency; or diabetes. Figure 3 in the childhood/adolescent schedule is similar to Fig 2 in the adult immunization schedule.

Footnotes contain recommendations for routine vaccination, for catch-up vaccination, as well as for vaccination of children and adolescents with high-risk conditions or in special circumstances. Recommendations in the figures should be read with the corresponding footnotes. Changes have been made to the following footnotes:

- Hepatitis B. Updated recommendations reflect that a monovalent birth dose should be administered to all newborns within 24 hours of birth. Revised wording indicates that infants born to hepatitis B surface antigen (HBsAg)-positive mothers should be tested for HBsAg and antibody to HBsAg at 9 through 12 months (rather than 9 through 18 months).
- Haemophilus influenzae type b. Comvax vaccine (Merck, Whitehouse Station, NJ) has been removed because the vaccine is no longer commercially available and all available doses have expired. Hiberix (GlanxSmithKline Biologicals, Rixensart, Belgium) has been added to the list of vaccines that may be used for a primary vaccination series.
- Pneumococcal conjugate. References to PCV7 vaccine have been removed because all children who may have received PCV7 as part of a primary series have now aged out of the recommendation for pneumococcal vaccine.
- Influenza. Wording has been added to indicate that LAIV is not recommended for the 2016–2017 influenza season.
- Meningococcal ACWY. Recommendations now include vaccination of children with HIV infection.
- Meningococcal B. Wording has been modified to note that persons aged 16 through 23 years may be vaccinated on the basis of clinical discretion. Updated recommendations regarding a 2-dose Trumenba (Wyeth Pharmaceuticals, Philadelphia, PA) schedule have been added.
- Tdap. Revised wording indicates a preference for administration of 1 dose for pregnant adolescents, and this dose should be administered as early as possible in the 27- to 36-week gestational age period. Wording is changed to indicate that for children aged 7 through 10 years who receive Tdap as part of a catch-up series, either Tdap or Td may be administered for the adolescent dose at 11 through 12 years.
- Human papillomavirus. Wording reflects that the number of recommended doses is based on age at administration of the first dose. Two doses are recommended for persons starting the series before their 15th birthday, whereas 3 doses are recommended for those who start the series on or after their 15th birthday and for persons with certain immunocompromising conditions. 2vHPV (Cervarix; GlaxoSmithKline Biologicals, Rixensart, Belgium) has been removed from the schedule because this vaccine is no longer available and all available doses expired before January 1, 2017.

In addition to publication of the schedules in this issue of Pediatrics, the 2017 version of Figs 1 through 3, the catch-up schedule, the footnotes, and job aids are available at the AAP Web site (http://redbook.solutions.aap.org/selfserve/ssPage.aspx?SelfServeContentTypeId=Immunization_Schedules) and the Centers for Disease Control and Prevention Web site (https://www.cdc.gov/vaccines/schedules/). A parent-friendly vaccine schedule for children and adolescents is available at http://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.

Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS 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 Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention that contain detailed recommendations for individual vaccines, including recommendations for children with high-risk conditions, are available.
at www.cdc.gov/vaccines/pubs/ACIP-list.htm. 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 and www.cdc.gov/vaccines/pubs/ACIP-list.htm.

COMMITTEE ON INFECTIOUS DISEASE, 2016-2017
Carrie L. Byington, MD, FAAP, Chairperson
Yvonne A. Maldonado, MD, FAAP, Vice Chairperson
Elizabeth D. Barnett, MD, FAAP
James D. Campbell, MD, FAAP
H. Dele Davies, MD, MS, MHCM, FAAP
Ruth Lynfield, MD, FAAP
Flor M. Munoz, MD, FAAP
Dawn Nolt, MD, MPH, FAAP
Ann Christine Nyquist, MD, MSPH, FAAP
Sean O’Leary, MD, MPH, FAAP
Mobeen H. Rathore, MD, FAAP
Mark H. Sawyer, MD, FAAP
William J. Steinbach, MD, FAAP
Tina Q. Tan, MD, FAAP
Theoklis E. Zaoutis, MD, MSCE, FAAP

EX OFFICIO
David W. Kimberlin, MD, FAAP – Red Book Editor
Michael T. Brady, MD, FAAP – Red Book Associate Editor
Mary Anne Jackson, MD, FAAP – Red Book Associate Editor
Sarah S. Long, MD, FAAP – Red Book Associate Editor
Henry H. Bernstein, DO, MHCM, FAAP – Red Book Online Associate Editor
H. Cody Meissner, MD, FAAP – Visual Red Book Associate Editor

LIAISONS
Douglas Campos-Outcalt, MD, MPA – American Academy of Family Physicians
Amanda C. Cohn, MD, FAAP – Centers for Disease Control and Prevention
Karen M. Farizo, MD – US Food and Drug Administration
Marc Fischer, MD, FAAP – Centers for Disease Control and Prevention
Bruce G. Gellin, MD, MPH – National Vaccine Program Office
Richard L. Gorman, MD, FAAP – National Institutes of Health
Natasha Halasa, MD, MPH, FAAP – Pediatric Infectious Diseases Society
Joan L. Robinson, MD – Canadian Paediatric Society
Jamie Deseda-Tous, MD – Sociedad Latinoamericana de Infectologia Pediatrica (SLIPE)
Geoffrey R. Simon, MD, FAAP – Committee on Practice Ambulatory Medicine
Jeffrey R. Starke, MD, FAAP – American Thoracic Society

STAFF
Jennifer M. Frantz, MPH
Financing of Pediatric Home Health Care

Edwin Simpser, MD, FAAP, a Mark L. Hudak, MD, FAAP, b SECTION ON HOME CARE, COMMITTEE ON CHILD HEALTH FINANCING

aSt. Mary’s Healthcare System for Children, Bayside, New York; and bDepartment of Pediatrics, University of Florida College of Medicine—Jacksonville, Jacksonville, Florida

Drs Hudak and Simpser were each responsible for all aspects of writing and editing the document and reviewing and responding to questions and comments from reviewers and the Board of Directors.

This document is copyrighted and is the 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. Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (American Academy of Pediatrics) 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: 10.1542/peds.2016-4202

Address correspondence to Mark L. Hudak, MD, FAAP. E-mail: mark.hudak@jax.ufl.edu

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).
Copyright © 2017 by the American Academy of Pediatrics

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.

INTRODUCTION

The home of the pediatric patient can be an appropriate, and is often the preferred, site for the provision of health care services to address a wide range of serious and complex medical needs or developmental disabilities. Indeed, many pediatricians believe that the patient’s home provides a healing environment and offers psychological benefit for the child and family. In the United States, almost 500,000 children and
youth with special health care needs require a range of medical and therapeutic services in their home.\textsuperscript{1} Although cross-sectional data on the demographic characteristics and needs of this population are limited, what is known is that children receiving home health care are more likely to have serious or complex medical conditions and functional limitations and be insured by a Medicaid plan, by a Children’s Health Insurance Program (CHIP) plan, or by both a private insurance and a Medicaid/CHIP plan.

Over the past several decades, a number of factors have affected the scope of pediatric home health care services, including the following: higher rates of survival of extremely preterm infants; more children with serious or life-limiting complex medical conditions, including those recovering from physical trauma; the miniaturization and simplification of life-sustaining medical equipment; the deinstitutionalization of children with severe medical and mental health needs; family preferences for care in the home instead of in the hospital; and cost-containment pressures to prevent or shorten hospital stays. Home care for children involves a broad array of professional and paraprofessional services, including the following: nurses; physical, occupational, and speech-language therapists; respiratory therapists; medical social workers; psychologists; dietitians; and home health or personal care aides. Private duty (also known as extended-hours) nursing is necessary for a subset of children with complex and frequently technology-dependent conditions. A recent study of the utilization of postacute services in children found that almost one-half of pediatric patients discharged from the hospital from acute care hospital settings are neonates.\textsuperscript{2} This study also noted that home health services seem to be infrequently and variably used in children compared with adults, even when assessing use in children with multiple chronic conditions and technology assistance. In addition, significant state-to-state utilization disparities exist across the United States.

Family members assume significant responsibility and are often the primary providers of home health services to children. Family members often facilitate needed communication between service providers, case managers, and payer sources. Many family members who care for their children at home report significant physical, emotional, social, and financial burdens.\textsuperscript{3} The National Survey of Children with Special Health Care Needs found that a significant percentage of families provide greater than 21 hours per week of health care at home and spend upward of 11 hours per week on care coordination.\textsuperscript{1} This survey also reported that 25% of families curtail work or leave their jobs to care for their children. These consequences can significantly impair family functioning and quality of life. A recent study found that parents self-reported poorer physical health and cognitive function when their medically complex, technology-dependent children received care in the home compared with medical day care or long-term care facility settings.\textsuperscript{4} Maintaining all care in the home setting required tremendous emotional, financial, and time investment by the parents that compromised their social lives and employment.

Since 1989, federal regulations have specified that children aged younger than 21 years who are enrolled in Medicaid are entitled to Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) benefits, which the American Academy of Pediatrics (AAP) believes are the standard for comprehensive essential medical services for these children. Home health services, including private duty nursing services, personal care services, primary care case coordination, and hospice care, are federally mandated Medicaid EPSDT benefits “when necessary to correct or ameliorate a mental or physical illness or condition.”\textsuperscript{5–7} National health expenditure data reveal that pediatric home health costs rose steadily from 2002–2010 and totaled $6.7 billion in 2010. This total represented 9% of all home health expenditures and 2% of all children’s health expenditures. The vast majority of these expenditures ($6.2 billion) were funded by Medicaid.\textsuperscript{8} Among children with more complex medical conditions, home care costs can exceed 10% of health care expenditures. For example, in the Florida Ped-I-Care program (a Medicaid provider-sponsored network for children and youth with special health care needs), home health care expenses for 2012–2014 averaged $190.60 per member per month, or 22.7% of the total expenditure for children receiving Title XIX benefits. For children insured by Medicaid in Clinical Risk Groups 5b through 9 in outpatient centers participating in a Children’s Hospital Association project funded by the Centers for Medicare & Medicaid Innovation, an analysis by Truven Health Analytics demonstrated that home health care expenditures averaged 26% of the total cost (data used with approval).

The AAP advocates for home health care as a patient- and family-centered delivery system that can be integrated within a comprehensive care program and linked to the full resources of the medical home, medical and surgical specialties, rehabilitative and habilitative therapies, hospice and respite care, care coordination, other related community-based supports, and hospitals. Each child can benefit from a readily accessible and comprehensive written plan of care that represents a consensus among the family, the patient, and...
the caregivers. The ability of the medical home and other specialty providers to interact with the child, family, and home health providers using telehealth technologies has the potential to optimize care, to minimize family disruption, and to avoid unnecessary medical utilization. Children who require home care represent the very population for whom the potential for benefit and cost savings is highest through prevention of excessive emergency department and inpatient hospital utilization.

**PROBLEM STATEMENT**

The Medicaid program permits each state to define the medical necessity for evaluation and treatment and allows latitude in establishing the duration and/or scope of a medically necessary treatment or benefit. In practice, state Medicaid agencies differ with respect to decisions regarding eligibility for benefits, duration and scope of benefits, the amount of payment, the required provider expertise for service provision, and provider documentation requirements. These differences lead to inconsistent provision of home care services across states. The increasing outsourcing of care to Medicaid managed care organizations has exacerbated problems with home health care services because of a number of factors that include dilution of pediatric expertise, limited provider networks, burdensome procedures for prior authorization, and potential payments at less than state Medicaid rates. Eligibility criteria for EPSDT services are not uniformly interpreted, particularly when essential treatments required by a child (e.g., home care, hospice care) differ from or exceed those routinely covered for adults by private insurers and Medicare. Appeals to reverse state-level Medicaid denials for home care services often require a considerable time investment by a family and the child’s physician, without any federally based oversight or ombudsman-like support mechanism.

Access to pediatric home care services also is affected by financial factors that affect the availability of qualified pediatric home health care providers. Among the most significant is the lack of private health insurance benefits for extended home health services, including nursing, rehabilitation/habilitation, durable medical equipment (DME), and respite care. Medicaid payments may be less than the actual total cost of the prescribed service, discouraging providers from caring for these children in the home setting. In particular, low Medicaid payments for skilled private duty nursing can impede the ability of home health agencies to offer staffing with sufficient skilled nurses to care for medically complex children. As a result, children will remain in the hospital or be placed in inpatient or residential facilities. In some states, thousands of children are on waiting lists for home health services. Many private insurers and CHIP plans have limited home health benefits for children, critically affecting those children with medical complexity who require longer term services. Coverage for DME often is inadequate, especially when it is bundled into payment for visits or into prospective payment arrangements. Such systems of bundled payments create disincentives or delays in obtaining coverage for DME.

Both private and public insurance offer limited or no physician payment for pediatric care coordination, home care management, or telehealth, although these are recognized key components to quality care delivery for children with complex medical needs. Lack of payment for these services limits access to medical home practices and qualified pediatric home health providers. Additional costs incurred to comply with and document adherence to regulatory requirements represent an unfunded mandate that exacerbates home care providers’ financial burdens. The reduction and elimination of pediatric capacity in many home health agencies and hospital-run home health programs are widespread and have led to decreased access to quality home care services in many communities.

Family members are often the primary providers of home care to children, and many are forced to choose between continuing employment and caring for their child at home. Partnership with professionals is essential, as is information, education, training, resources, and support so that families can provide the skilled care their children need. However, the resources to train and support family caregivers are limited. Although there are opportunities for Consumer Directed Personal Assistance Programs, many states do not participate in these plans, and funding for a parent (as opposed to a relative or a stranger) through these programs is not available. Parents can likely be the best caregivers, but without such support, many parents must maintain employment and delegate care of their children to other in-home providers or to residential facilities.

Because policies that regulate the delivery and financing of health care are developed most often with the needs of aging adults in mind, existing standards have become increasingly irrelevant to pediatric home health care, given the disparate needs of children with medical complexity or developmental disabilities. In many states, agencies are not required to provide pediatric-specific training or to develop pediatric-specific competencies. Because of the lack of pediatric-specific home health regulations
and payment structure, children requiring home health services may not receive the necessary expert care at home. They may experience life-threatening disease and other medical complications, risk of serious injury, more frequent readmission to hospitals with attendant accrual of higher health care costs, and excessive family burden. Children remain hospitalized or are placed in residential facilities at a much higher cost because pediatric home health care services are inadequate to allow home discharge. Certain medical complications are more likely when children are in the hospital or long-term inpatient facilities rather than in an appropriately supervised home care setting.

States and payers are, at times, working together to build new models of care designed to contain cost and improve quality. However, most of these delivery reforms and the standards associated with them concentrate on adults with chronic conditions and not on children.

**CONCLUSIONS**

Pediatric home care involves the delivery of medical care in the home to children with serious and often complex medical conditions or with developmental disabilities. Some of these children depend on technological assistance for survival. The number of children who can benefit from home health services is steadily increasing as medical providers and parents express concerns about significant gaps in existing services. To advocate for continued improvements in pediatric home care, the AAP has developed the following set of recommendations pertaining to regulatory oversight, care delivery systems and payment, and further research. Implementation of these recommendations is critical so that children and families will have enhanced access to high-quality medically necessary services and all the benefits that essential pediatric home care provides.

**RECOMMENDATIONS**

**Regulatory**

1. The Centers for Medicare & Medicaid Services (CMS) should explicitly recognize the full breadth of pediatric home health care services as elements of pediatric services, the 10th category of essential benefits listed in the Patient Protection and Affordable Care Act (Pub L No. 111-148 [2010]).

2. All public and private payers should incorporate pediatric home health care services into their essential health benefits.

3. The US Department of Health and Human Services should provide regulatory guidance to the states establishing their essential health benefit standards to ensure inclusion of the full range of pediatric home health care services, clearer specific guidance on medical necessity in children, and flexibility in prescribing the duration and frequency of services in consideration of the evolving status of the individual child. The US Department of Health and Human Services should also take steps to ensure that home health care networks attract a provider base that is sufficient in number and skill sets to meet the needs of children. The EPSDT criteria for essential services for children should be endorsed as the standard definition.

4. CMS should appoint a federal ombudsman program to compile and evaluate provider and patient complaints regarding access to care in the Medicaid program. This program would monitor state-level denials for EPSDT-mandated home health care services, DME, and assistive technology to identify and redress patterns of unwarranted denials for necessary care.

5. Federal and state health agencies should develop home health care regulations that address the unique needs of children. In this process, family knowledge and experience related to the need for and the impact of home care on the family should be integrated into the regulatory processes that seek to develop policies or to establish other program or resource requirements.

6. Pediatric home care should be delivered consistent with a written plan of care developed by the child’s medical care providers in consultation with the child’s family and, as appropriate, the child. Physicians, home health agencies, third-party payers, and managed care plans can use the recommendations published by the AAP in *Guidelines for Pediatric Home Health Care* for the purpose of determining the frequency and duration of home health services. Physicians have a special responsibility to prescribe the types, quantity, and intensity of home health services that are appropriate for the needs of the individual child and family. Physicians should modify their prescriptions when there is a change in the child’s needs or when the goal of therapeutic services has transitioned from habilitation or rehabilitation to maintenance of function. Home health agencies should communicate such changes to the prescribing physician in a timely manner.

7. Personnel responsible for direct care should be properly credentialed, licensed, or certified.

**Care Delivery and Payment**

1. Medical necessity for pediatric home health care should be more clearly defined to include services that assist in achieving...
maintaining, or restoring health and functional capacity and that are appropriate for the age and developmental status and take into account the needs of the individual child. Because few scientific studies have examined the effectiveness of home health care for specific pediatric conditions, medical necessity standards should be based on professional standards of care for children or on a consensus of best pediatric practice. Coverage of home health care should not be denied in the absence of conclusive scientific evidence.13

2. Payment for services should be adequate to support the appropriate depth and expertise needed to ensure the provision of high-quality pediatric home health care. To accomplish this goal, payments should be at levels that permit home health agencies to attract and retain appropriately credentialed and skilled clinicians and ancillary personnel for pediatric intermittent care and shift/private duty care as well as to cover the indirect costs of clinical management and support of in-home staff. Payment adjustments should also take into account the costs associated with preparation and continuing education of nurses in pediatric competencies, intensive care, and technological skills.

3. Public and private payers should pay physicians for care coordination, case management, and telehealth encounters to ensure comprehensive and continuous care for children within the medical home.14 Payers should recognize that many children with medically complex conditions benefit from concurrent standard medical and hospice care.

4. Expansion of current consumer-directed personal assistance programs is warranted, and all states should be encouraged to participate. Such expansion should include the development of care and payment standards for all family caregivers, including parents, who assume significant home nursing or personal care responsibilities for their children. Appropriate preparation, training, and support for family caregivers should be available.

5. To lessen disincentives or barriers to coverage of medically necessary DME in the course of planning transitions to home care, payment for DME should not be bundled into payment for visits or into prospective payment arrangements for intermittent care and should include first-dollar coverage for appropriate and necessary DME.

Research and Demonstrations

1. CMS should analyze Medicaid pediatric home health care payment rates across all states to ensure that eligible children have access to medically necessary services nationwide.

2. CMS should analyze the net actuarial impact of adequate funding of pediatric home health care services and project the effect on state Medicaid funding.

3. CMS should analyze opportunities to expand eligibility for long-term care coverage for children under the new Community Living Assistance Services and Supports Act (Title VIII of the Patient Protection and Affordable Care Act), which was established as part of health care reform.

4. Among populations of children for whom telehealth technologies become integrated into medical home care protocols as a consequence of payment reform, payers should fund prospective studies that evaluate the effects of telehealth on health outcomes, patient and family experience of care, and total health care expenditures.
REFERENCES


FINANCIAL DISCLOSURE: Dr Hudak reported consulting income as a member of an advisory board for Aerogen. Dr Simpser has indicated he has 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.
A Public Health Response to Opioid Use in Pregnancy

Stephen W. Patrick, MD, MPH, MS, FAAP,a,b,c,d,e  Davida M. Schiff, MD, FAAP,f COMMITTEE ON SUBSTANCE USE AND PREVENTION

aDepartments of Pediatrics and bHealth Policy, cMildred Stahlman Division of Neonatology, dVanderbilt Center for Health Services Research, and eVanderbilt Center for Addiction Research, Vanderbilt University, Nashville, Tennessee; and fDepartment of Pediatrics, Boston Medical Center and Boston University School of Medicine, Boston, Massachusetts

Dr Schiff conceptualized and drafted the initial manuscript and critically reviewed the revised manuscript; Dr Patrick conceptualized the manuscript and critically reviewed and revised the manuscript; and both 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. 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: 10.1542/peds.2016-4070

Address correspondence to Stephen W. Patrick, MD, MPH, MS, FAAP. E-mail: stephen.patrick@vanderbilt.edu

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

Copyright © 2017 by the American Academy of Pediatrics

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).

INTRODUCTION

Substance use during pregnancy occurs commonly in the United States. In 2009, the Substance Abuse and Mental Health Administration estimated that 400,000 infants each year are exposed to alcohol or illicit drugs in utero.1 Although concern regarding substance use in pregnancy is not new, it has recently increased among health care providers, the public, and policy makers as the opioid epidemic’s impact reached an increasing portion of the US population, including pregnant women and their infants.2,3 Several recent studies highlighted an increase in prescription opioid use among women of childbearing age4 and among pregnant women.5,6 As opioid use among pregnant women increased, the rate of infants in the United States experiencing opioid withdrawal after...
birth, known as neonatal abstinence syndrome (NAS), grew nearly fivefold over the past decade.\(^2,7\) By 2012 in the United States, on average, 1 infant was born every 25 minutes experiencing signs of withdrawal, accounting for an estimated $1.5 billion in hospital charges.\(^2\) The issues surrounding substance use in pregnancy are complex and merit a thoughtful public health response focused on prevention, expansion of treatment to women with substance use disorder, and improved funding for child welfare systems to improve the health of the substance-exposed mother-infant dyad.

**Primary Prevention**

A public health approach to substance use in pregnancy should begin with primary prevention: preventing substance and opioid misuse before pregnancy. In 2011, the White House Office of National Drug Control Policy released a plan to respond to the prescription opioid epidemic that has 4 main pillars: (1) improve public and provider education about the abuse potential of opioids, (2) reduce the abuse of prescription opioids by bolstering prescription drug monitoring programs, (3) ensure that unused opioids are properly disposed, and (4) provide law enforcement with the tools needed to stop illegal prescribing or dispensing of opioids.\(^8\) Public health and policy approaches to the prescription opioid epidemic will help eliminate the burden of opioid use disorder before pregnancy begins.

Preconception and interconception (between pregnancies) care plays an important role in improving outcomes for pregnant women. Counseling during these crucial periods may play a role in identifying and mitigating risk to mothers and their infants.\(^9\) Although 31% to 47% of US pregnancies are unintended, research suggests that, for women with opioid use disorder, the proportion of unintended pregnancies was higher than 85%.\(^10\) Education and expansion of access to effective contraception, particularly long-acting reversible contraception (LARC) methods,\(^11\) are important components of primary prevention. Access to LARC methods is supported by both the American Academy of Family Physicians (AAFP) and the American College of Obstetricians and Gynecologists (ACOG)\(^12,13\) during both the pre- and interconception periods. However, there remain barriers to highly effective contraception in many states. For example, the ACOG supports placement of LARC devices during the immediate postpartum period to improve the use of LARC among postpartum women\(^13\); however, bundled payments for delivery create a relative financial disincentive to place LARC devices at the time of delivery. State Medicaid programs play a critical role in ensuring access to highly effective contraception at the time when it is desired, including the time of delivery. However, recent research suggests that states are variable in aligning financial incentives to ensure access to LARC methods if elected at the time of delivery.\(^14\)

**Improved Identification and Access to Treatment**

The early identification of women who use illicit substances during pregnancy is vital to improving outcomes for both mothers and infants. Routine universal screening through brief questionnaires for drug, alcohol, and tobacco use before and throughout pregnancy is recommended by the ACOG and AAFP.\(^9,15,16\) The ACOG recommends that screening consist of a mutual dialogue between clinician and patient and be performed in partnership with the woman with the use of validated screening tools,\(^17,18\) with her consent, and screening should be applied equally to all women, regardless of their age, race, ethnicity, or socioeconomic status.\(^19\)

The benefits of drug testing in addition to screening during pregnancy remain uncertain. Targeted urine drug-testing programs have been shown to disproportionately affect low-income women of racial or ethnic minorities,\(^20-22\) prompting some to develop universal urine toxicology testing protocols at the time of delivery.\(^24\) Although urine toxicology tests can provide objective evidence of drug use at 1 point in time, they do not enable providers to determine the frequency of use or to characterize the frequency or degree of use.\(^25,26\) Studies comparing the difference between verbal screening and urine drug testing are mixed; 1 study found superior identification with verbal screening and another identified individuals with positive urine drug test results who were not previously known to have used opioids.\(^17,24\) Consistent with ACOG policy, informed consent should occur at the time of drug testing and a woman should be informed how a positive test result will be used for both medical treatment and reporting to child welfare agencies.\(^19\)

Drug screening and testing in pregnancy should be used to identify women with substance use disorder and enable access to comprehensive treatment. Access to comprehensive prenatal care and treatment of women with substance use disorders is associated with fewer preterm deliveries, small-for-gestational-age infants, and infants with low birth weight.\(^27-30\) The literature suggests that pregnancy can motivate women with substance use disorders to seek treatment.\(^31\) However, there remains a dearth of comprehensive treatment programs geared toward pregnant and parenting women. Only 19 states have treatment programs specifically designed for pregnant women.\(^32\) Furthermore, only 15% of current treatment centers across
the country offer specific services for pregnant women with substance use disorders, and the majority of these are located in urban areas. Women with substance use disorder report high rates of past trauma, including physical and sexual abuse, and need access to gender-specific, family-friendly addiction treatment programs, psychosocial services, and mental health treatment. Trauma-informed services should be framed by an understanding of the effects of interpersonal violence and victimization of women with substance use disorders, with a focus on creating a strengths-based environment to foster resiliency and to minimize the possibility of retraumatization. In addition, pregnant and parenting women are likely to remain in treatment if on-site child care and child services are provided and staff work to develop collaborative and nonjudgmental therapeutic alliances through the use of trauma-informed care approaches. Positive outcomes of treatment in pregnant and parenting women who complete treatment programs include employment, less engagement in criminal activity, and lower risk of relapse.

For women with opioid use disorder, the abrupt discontinuation of opioids in pregnancy can result in preterm labor, fetal distress, or fetal demise. Furthermore, medically supervised withdrawal from opioids in opioid-dependent women is currently not recommended during pregnancy, because the literature suggests that withdrawal is associated with high relapse rates. Opioid agonist therapy, also known as medication-assisted treatment, with methadone or buprenorphine has emerged as the standard for pregnant women with opioid use disorder. Opioid agonist therapy has been shown to be safe and effective in pregnancy and is associated with improved maternal and infant outcomes.

Knowledge of substance use during pregnancy is vital to the pediatrician’s ability to effectively provide care for substance-exposed infants. For example, exposure to opioids in utero may lead to an infant developing NAS. The presentation of NAS may be delayed for several days depending on several factors (eg, timing of maternal drug use, drug type, infant metabolism), and clinical signs of NAS can be vague (eg, irritability, poor feeding). Each of these factors creates the possibility that a diagnosis of NAS may be missed without the knowledge of opioid exposure, potentially leading to poor outcomes for infants.

Teamwork between all health care providers, including but not limited to obstetric, pediatric, family, and addiction medicine, is vital to optimal care of substance-exposed infants. When inadequate information about drug exposure exists, testing an infant’s urine, meconium, or umbilical cord tissue can be important in ensuring the optimal care of the infant.

Criminal Justice Approaches to Substance Use in Pregnancy

In recent years, a number of state legislatures have passed new laws or applied existing child endangerment laws to prosecute pregnant women for illicit drug use during pregnancy. The American Academy of Pediatrics (AAP) first published recommendations on substance-exposed infants in 1990 and reaffirmed its position in 1995 that “punitive measures taken toward pregnant women, such as criminal prosecution and incarceration, have no proven benefits for infant health” and argued that “the public must be assured of nonpunitive access to comprehensive care that meets the needs of the substance-abusing pregnant woman and her infant.”

More than 20 national organizations have since published statements against the prosecution and punishment of pregnant women who use illicit substances: these include the American Medical Association, the AAFP, the ACOG, the American Public Health Association, the American Nurses Association, the American Psychiatric Association, the National Perinatal Association, the American Society of Addiction Medicine, the March of Dimes, and the Association of Women’s Health, Obstetric and Neonatal Nurses. Despite the strong consensus from the medical and public health communities affirming that a punitive approach during pregnancy is ineffective and potentially harmful, there has been a recent increase in the number of states passing and considering criminal prosecution laws that selectively target pregnant women with substance use disorders.

The existing literature supports the position that punitive approaches to substance use in pregnancy are ineffective and may have detrimental effects on both maternal and child health. Qualitative research performed in pregnant women with substance use disorders shows that women may avoid prenatal care for fear of being reported to the police and child protective services. In addition, surveys of pregnant women found that punitive laws targeted at pregnant women who use drugs are a significant deterrent to obtaining regular prenatal care and agreeing to drug testing, and women who deliver without receiving any prenatal care are more likely have a history of substance use. For these reasons, the AAP supports an approach toward substance use in pregnancy that focuses on a public health approach of primary prevention, improving access to treatment, and promoting the provider-patient relationship rather than punitive
measures through the criminal justice system.

**Role of Child Welfare Systems**

The Child Abuse Protection and Treatment Act mandates that states have in place “policies and procedures to address the needs of infants born with and identified as being affected by illegal substance abuse or withdrawal symptoms from prenatal drug exposure.”69 Reporting requirements for in utero illicit substance exposure to child welfare systems have been interpreted differently by each state. More than 25% of states currently have statutes that consider illicit substance use during pregnancy to be reportable as child abuse or neglect.32 Health care providers caring for pregnant women with substance use disorders and their infants should be knowledgeable about their state requirements and be able to educate women during pregnancy. Notably, although the incidence of NAS has increased in recent years,27 federal funding for child welfare systems has not changed,70 even as some state child welfare systems are reporting an increased workload attributable to NAS.71 In recent years, Congress has addressed the issue of substance-exposed infants in child welfare systems; however, there has not been a substantial increase in funding to state child welfare systems to bolster the response to the growing number of opioid-exposed infants. There is an urgent need for improved funding to child welfare systems to ensure the safety of infants and to promote the well-being of families.

**RECOMMENDATIONS**

Opioid use in pregnancy is increasingly common, with an associated increase in opioid-exposed infants. This critical public health issue demands a public health approach grounded in science. For these reasons, the AAP recommends the following:

1. The treatment of pregnant women with substance use disorder requires a coordinated, evidence-based, public health approach. The AAP reaffirms its position that punitive measures taken toward pregnant women are not in the best interest of the health of the mother-infant dyad.

2. Primary prevention strategies should be bolstered to educate the public about the addictive potential of prescription opioids and enhance access to reproductive health services, including effective forms of contraception such as LARC.

3. The ACOG policy that universal substance use screening of all pregnant women via validated screening tools such as questionnaires should occur at routine health care visits and at several points throughout prenatal care and be applied equally to all women, regardless of age, race, ethnicity, or socioeconomic status, should be supported. If urine drug testing is performed, a reasonable effort to obtain a woman’s informed consent should be made before collecting the sample, and the woman should be aware of the results and who will have access to the results.

4. Access should be improved to comprehensive prenatal care for pregnant women with substance use disorders, including medication-assisted treatment and gender-specific substance use treatment programs that provide nonjudgmental, trauma-informed services.

5. Health care providers caring for women who use substances during pregnancy should be knowledgeable about their state’s reporting mandates around illicit drug use and educate pregnant women prenatally about these requirements. In addition, states should clarify which substances constitute mandated reporting and explicitly define the health care provider’s role in reporting.

6. To adequately ensure the safety of substance-exposed infants and to provide optimal care to families, social support services and child welfare systems are in need of additional funding.

The American College of Obstetricians and Gynecologists supports the value of this clinical document as an educational tool (December 2016).

**AUTHORS**

Stephen W. Patrick, MD, MPH, MS, FAAP  
Davida M. Schiff, MD, FAAP

**COMMITTEE ON SUBSTANCE USE AND PREVENTION, 2016–2017**

Sheryl A. Ryan, MD, FAAP, Chairperson  
Joanna Quigley, MD, FAAP  
Pamela K. Gonzalez, MD, MS, FAAP  
Stephen W. Patrick, MD, MPH, MS, FAAP  
Leslie R. Walker, MD, FAAP

**FORMER COMMITTEE MEMBERS**

Sharon J.L. Levy, MD, MPH, FAAP  
Lorena Siqueira, MD, MSPH

**LIAISONS**

Vivian B. Faden, PhD – National Institute on Alcohol Abuse and Alcoholism  
Gregory Tau, MD, PhD – American Academy of Child and Adolescent Psychiatry

**STAFF**

Renee Jarrett, MPH

**ABBREVIATIONS**

| AAFP | American Academy of Family Physicians |
| ACOG | American College of Obstetricians and Gynecologists |
| LARC | long-acting reversible contraception |
| NAS | neonatal abstinence syndrome |
REFERENCES


39. Brady TM. *Women in Substance Abuse Treatment: Results From the Alcohol and Drug Services Study (ADSS).* Rockville, MD: Substance Abuse and Mental Health Services Administration, Office of Applied Studies; 2005


47. Hudak ML, Tan RC; Committee on Drugs; Committee on Fetus and Newborn. Clinical report: neonatal drug withdrawal. *Pediatrics.* 2012;129(2). Available at: www.pediatrics.org/cgi/content/full/129/2/e540


The Child Witness in the Courtroom

Robert H. Pantell, MD, FAAP, COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH

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.

BACKGROUND

Children were first allowed to provide courtroom testimony with the 1895 US Supreme Court decision allowing a 5.5-year-old to serve as a witness. It is now estimated that substantially more than 100,000 children appear in court each year. With growing awareness of child abuse and a continual increase in reported abuse cases, a 1982 Presidential Task Force on Victims of Crime recommended 62 reforms.
including some intended to benefit child victims. However, despite the task force’s recommendations, “children remained unheard and re-victimized in criminal and delinquency courts."

A growing body of scientific literature on the psychological and physiologic consequences of children witnessing and experiencing violence, as well as appearing in court, has supported modifications of courtroom procedures.3–7 To decrease the stress experienced by children appearing in courts, various accommodations were developed, ranging from allowing children to hold comforting objects to being accompanied by a support person while testifying. Recently, specially trained facility dogs have been allowed to offer comfort for witnesses (www.courthousedogs.com). These accommodations have been challenged legally, particularly those attempting to allow children to testify outside the presence of the accused. Notably, in the 1988 decision Coy v Iowa,8 the US Supreme Court ruled that a screen between a child witness and defendant violated the confrontation clause of the sixth amendment. However, in 1990, in Maryland v Craig,9 the US Supreme Court ruled that closed-circuit televised testimony is acceptable when there is a “case specific finding of necessity.” Also in 1990 came the passage of the Victims of Child Abuse Act,10 which has been subsequently modified and provides protection to both child victims and witnesses.11 Guidelines from the US Attorney General followed in 2005,12 which state that “A primary goal of such (justice department) officials, therefore, shall be to reduce the trauma to child victims and witnesses caused by their contact with the criminal justice system.” Although the federal statute and guidelines offer substantial protection for children who are victims or witnesses of a crime, particularly live testimony by 2-way closed-circuit television or videotaped testimony, most cases are tried not in federal court but rather in courts under state jurisdiction. The National Conference of Commissioners on Uniform State Laws drafted The Uniform Child Witness by Alternative Methods Act in 2002,13 which encouraged states to allow victims and witnesses younger than 13 years to testify by alternative (closed-circuit) methods, which, to date, has only been enacted in a small number of states. However, all states have laws to minimize the impact on children of appearing in court through allowing support people or comfort objects or provisions for excluding the press. However, some states, such as California, have codes that apply only to victims of physical and sexual abuse and exclude children who witness violence; these children are covered by the federal statute.

To further protect the rights of child victims and witnesses, the 2005 Attorney General’s report provided for the appointment and payment of a guardian ad litem (GAL) to protect the interests of the child.7 However, title 1811 provides for GALs only in cases involving child abuse or exploitation in child welfare proceedings and criminal cases but does not address children witnessing other violent crimes, such as murder of a mother by a father. Nevertheless, some states have expanded the provisions set by the federal code to offer services to children witnessing violence. (For more information about state laws, contact the American Academy of Pediatrics [AAP] Division of State Government Affairs at stgov@aap.org.) In addition to GALs, a network of nearly 1000 community programs train and support citizen volunteers to advocate for the best interests of abused and neglected children in courtrooms and communities as court-appointed special advocates (www.casaforchildren.org). Violence in the home and directed toward children is responsible for a substantial proportion of court actions involving children. The National Child Abuse and Neglect Data System reported 3.4 million child protective service referrals, 686,000 substantiated unique instances of abuse, 146,000 removals from the home (in 44 states), and 1640 deaths in 2012. Whether confirmed reports of child abuse reach court is highly variable. In the United States, 21.4% cases of child abuse reach court, ranging from 3.2% of cases in Mississippi to 56.0% of cases in New Hampshire.14 The number of these cases in which children testify is unknown. The percentage of children with court-appointed representation also is highly variable, with a national average of 17.0%, but only 0.7% in Virginia compared with 69.7% in Arizona and 49.4% in Hawai.14

In addition, the number of cases being tried in which children are not victims but witnesses to violence is unknown. In 2009, it was reported that one-quarter of children in the United States had witnessed violence and 9.8% had witnessed intrafamilial violence.15

**COMPETENCE**

The purpose of child testimony in court is to provide trustworthy evidence. The qualifications for a child to provide testimony include the following:

- sufficient intelligence, understanding, and ability to observe, recall, and communicate events;
- an ability to comprehend the seriousness of an oath; and
- an appreciation of the necessity to tell the truth.

The ability of children to provide trustworthy testimony must be considered in terms of a developmental context as well as
the circumstances of the event precipitating a court appearance, the ongoing influences in the current home, and the environment and processes leading up to and including appearance in the courtroom. The ability to recall events evolves throughout childhood, as does the ability to understand and contextualize these events, including the ability to distinguish an experience and thoughts as one's own or someone else's. Truthfulness and lying also have different meanings throughout an individual's moral development. Building on the work of Piaget and Kohlberg, Ekman has developed a comprehensive view of lying as a developmental process. The development of abstract thinking and moral development continues throughout childhood and adolescence and into adulthood. Indeed, the US Supreme Court's recognition that brain maturation and cognitive development continue well into adulthood was part of the basis for its decisions prohibiting capital punishment (Roper v Simmons) and mandatory life imprisonment without parole (Miller v Alabama) for individuals younger than 18 years.

Substantial research has been conducted on the abilities of children to provide trustworthy testimony. The following are some of the findings.

- **Memory: Memory development** begins at birth as infants quickly develop the abilities to recognize the faces and voices of their caregivers. Memory underscores basic language development as older infants and toddlers develop the ability to associate words with objects and actions, and children as young as 3 years can recall and articulate experiences. For purposes of court testimony, there is an extensive experimental literature on the validity and reliability of children's recall of events, with a study of a medically invasive event being recalled reliably by 3- to 7-year-olds (mean age: 5.3 years). However, over time and under variable external circumstances, information provided in interviews can change. Ceci and Bruck pointed out that memory may change over time as a result of constructive processes that serve to fill in the gaps that occur as the original memory weakens. Some of this change occurs because, as children gather more experience, they may embellish an event with circumstances that occurred in a similar, although unrelated event. In experimental studies, the accuracy of information retained over time is challenging for both children and adults, because of the wide variability in recall, predictors of accuracy could not be determined.

- **Assessing children's memories** of their maltreatment, especially sexual abuse, has substantial methodologic challenges. Nevertheless, Goodman et al indicate that “maltreatment should lead to enhanced memory for negative emotionally laden or stressful information in most individuals, but also that certain subsets of maltreated individuals may have memory deficits for negative or traumatic experiences.” These subsets include individuals with dissociative symptoms and individuals who experienced particularly severe abuse. A major research challenge is to develop a valid and reliable predictive tool for the accuracy of children's recall of their maltreatment.

- **Suggestibility: Suggestibility, as** defined by Ceci and Bruck, “refers to the degree to which children's encoding, storage, retrieval and reporting of events can be influenced by a range of social and psychological factors.” Experimental studies showed that young children can be induced to recall events that did not occur and that they are less likely to deny events that did occur. In a classic experiment, “the Sam Stone study,” which took place over 10 weeks, 3- to 4-year-olds in a control group had excellent recall, and only 10% assented to false statements. However, if the character in the study was stereotyped with “clumsiness,” 42% of children assented to false statements; adding questioning suggestive to stereotyping raised the false assenting rate to 72%. Older children 6 to 8 years of age had a false assenting rate only half as high as that in 3- to 5-year-olds and followed a similar stepwise pattern. Substantial experimental literature exists on children being subject to suggestibility by parents and authority figures as well as intimidation during police or courtroom procedures.

- **Lying:** Ekman has defined lying as when “one person intends to mislead another, doing so deliberately” and has stated, “there are two primary ways to lie: to conceal and to falsify.” He points out that all children (and adults) lie and that making statements that are knowingly untruthful occurs in children as young as 3 years but that the underlying motivation for and understanding of lying differs according to age, stage of moral development, and external factors. Experimental studies have documented that 3- to 4-year-olds lie and that they are more likely to lie to cover up the misbehavior of a friend than a stranger. If caught doing something they were
that has been documented to improve the accuracy of children's testimony (http://www.nichdprotocol.com/the-nichd-protocol). Various states have adopted specific forensic interviewing protocols to ensure uniformity of practice. These forensic interviews generally are conducted within Child Advocacy Centers, known in some states as Child Justice Centers. The American Bar Association Center on Children and the Law also has issued a handbook discussing the language capabilities of children for use during court procedures.

**IMPACT OF TESTIFYING**

The support of children after they have provided testimony, although critically important, has received insufficient attention. Assessing the consequences of children testifying in court has many methodologic challenges; however, long-term studies have documented a number of issues, which are summarized here. Studies have established clearly that children experience anxiety surrounding court appearances and that the main fear is facing the defendant. Other fears include being hurt by the defendant, embarrassment about crying or not being able to answer questions, and going to jail. The more frightened a child is, the less he or she is able to answer questions. The greatest predictors of inadequate responses are young age and severity of abuse. Postponements cause emotional difficulties, and having to testify more than once is associated with long-term mental health problems. The use of shielding procedures, such as testifying via a 2-way video-monitoring system, is less stressful for children than court appearances, and children providing shielded testimony give more accurate and detailed information. Although mock trials indicate that juries do not provide different verdicts for shielded or courtroom testimony, some studies have suggested that jurors are less likely to believe child witnesses who give shielded testimony. It also has been documented that children have more long-term emotional problems if the assailant receives a light sentence; this finding is especially true for children who did not testify. Therefore, testifying may improve outcomes for some children. For older children, experience as a witness in court has a negative effect on their view of legal system. International studies have documented that with substantial preparation of children for trial, emotional consequences are not different between those testifying inside the courtroom and those testifying outside the courtroom. For short-term consequences, in a matched control study in 218 children, those who testified, compared with those who did not testify, were more likely to experience anxiety and indicated that delay in testifying increased their anxiety. Anxiety diminished after the trial, except for those without maternal support. Documented and theoretical benefits for children testifying in court include decreased anxiety, feeling less victimized, and having a greater sense of control. A child’s anxiety can be decreased through the use of child advocates and other support people.

In a study of long-term consequences, 176 children were interviewed 12 years after testifying. Children who testified when they were younger had more severe externalizing symptoms. Testifying repeatedly was associated with worse mental health outcomes, and testifying about severe abuse had higher levels of trauma-related problems. Children who did not testify had worse outcomes if the accused received a light sentence. These studies indicate the need for ongoing psychosocial support and counseling, not only for any
victimization that may have occurred but also for children’s experiences of testifying at trial. The recognition of these consequences and the provision of postwitness counseling services can be provided through existing public resources, privately funded organizations, and volunteer organizations.

IMMIGRATION COURTS

Current AAP policy asserts that no child, under any circumstance, should be required to represent himself or herself in an immigration proceeding. However, by some estimates, nearly 70% of unaccompanied children and >70% of families with children must represent themselves, without attorneys, in immigration court. Not surprisingly, children without counsel are far more likely to be deported. Although federal regulations require that immigration courts provide interpreters for children who prefer languages other than English, children may also experience difficulties in understanding proceedings as a result of age, development, culture, and a history of trauma. Similar to recommendations involving children in other courtroom proceedings, recommendations for immigration court cases involving unaccompanied alien children offer strategies that courts can use to support children in immigration proceedings, including preparation of children, use of child-sensitive questioning, allowing a young child to bring a toy or personal item into the courtroom, permitting the child to testify while seated next to an adult or friend, and removal of the judge’s robe.

Although immigration courts do not appoint GALs for children placed in removal proceedings, a personal representative or a GAL has the potential to increase children’s understanding of proceedings and offer support for children in the courtroom.

ROLE OF THE PEDIATRICIAN

The pediatrician can help a child who is scheduled to appear in court in a number of ways, as follows:

1. If a pediatrician becomes aware of an impending divorce and potential custody dispute in which a child will be testifying, advising the parents to be aware of the stress and potential impact on the child’s mental health is appropriate. Referring the child for mental health services, advising the parents not to use the child as a pawn or a messenger, and suggesting family counseling all may be appropriate, depending on the circumstances.

2. If, in the course of caring for a child, the pediatrician learns of a pending appearance in court, he or she can elicit the child’s concerns, assure the child that he or she will not be judged for truthful answers, and help refer the family to individuals who can arrange an advance court visit. Court-appointed victims’ advocates and GALs generally can arrange these services. Some states allow, and others mandate, special child advocates, including GALs, who may be lawyers. (For more information on your state, contact the AAP Division of State Government Affairs at stgov@aap.org.)

3. A referral to a mental health provider is strongly recommended for the event causing the court appearance as well as to help deal with the stress of encountering the legal system.

4. The pediatrician can make efforts to request coordination of interviews to lessen fatigue on the child. Coordination of interviews is mandated in federal legislation but varies across states. The function of Children’s Advocacy Centers is to bring the various investigative groups together to witness a single interview by a skilled forensic interviewer. They are specifically designed for the purpose of reducing the number of interviews, providing support to child victims, and eliciting forensic information.

5. When a child will appear in court, it should be encouraged, in states where it is allowed, for the child to be permitted accompaniment by support people and comfort objects. Pediatricians can encourage supportive family/friends to attend court to reduce the child’s unfamiliarity with surroundings.

6. The pediatrician is encouraged to become aware of state statutory accommodations and judicial allowances if a patient is to appear in court. These include potential exclusion of the press and nonessential people, shielding of witness identity, and limiting repetition of questions. Depending on state law, judges may have substantial discretion in what will be allowed. Pediatricians...
can work with the attorneys in the case (whether prosecutor, child’s attorney, GAL, etc) and ask that they petition for these accommodations.

7. Appeals are common and may lead to retrials. Children experience anxiety while waiting to learn whether there will be a second trial and whether they will need to endure testifying in court again. This situation creates continuing stress and an emotional rollercoaster for children. Consequently, ongoing and long-term follow-up by the pediatrician is necessary to monitor a child for depression, sleep disorders, and changes in school functioning, with appropriate referral for counseling and mental health services. Being alert to parent/guardian depression also is important because of the potential impact on the child.

8. As a child advocate, the pediatrician may encourage the parent, guardian, or GAL to obtain for the child witness all of the special accommodations, services, and judicial allowances available under federal and state law (eg, coordination of interviews, comfort objects, exclusion of the press and nonessential people from court, shielding of witnesses’ identity, attendance by supportive people). By assuming a supportive role, the pediatrician not only promotes the best possible and least traumatizing court experience for the child but also, by allowing the child to accurately provide information, potentially contributes to the integrity of the legal process.

9. Pediatricians are likely to encounter children traumatized in a variety of situations. In addition to being aware of and able to recognize psychological trauma, they should be willing to respond. Psychologists experienced in trauma management are available in many communities and can be a valuable resource for pediatricians. In addition, the AAP resource “Helping Foster and Adoptive Families Cope With Trauma” may be helpful for children in foster or adoptive families who must testify in court.

AAP POLICY RECOMMENDATIONS


2. The AAP, in concurrence with portions of the federal guidelines, encourages state chapters to support state legislation expanding rights currently granted to sexually and physically abused witnesses to all children who have witnessed violent acts and who are testifying in court.

3. The AAP urges state chapters to advocate that state courts do whatever is necessary, within the framework of existing state laws and resources, to prevent psychological harm to the child victim/witness as a result of participating in the judicial process.

4. The AAP supports expanding specific statutory and judicial accommodations, consistent with the development of new evidence that supports the ability of child witnesses to provide accurate information, to support their well-being during and after a trial. A supportive interview enhances the accuracy of a child’s testimony and accurate testimony by a child, in turn, supports the best interests of society and adults involved in the legal proceeding.

5. Given the complexities of the legal system and the documented stresses experienced by children in the courtroom, the AAP recommends that state chapters advocate for the judicial system to appoint and pay for GALs routinely to represent the best interests of children during all legal procedures.

6. In forensic interviews preceding a trial, the use of a validated format for interviewing, such as that of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, is strongly recommended. As new validated instruments are developed, the AAP recommends state chapters ensure that such measures are used appropriately in the court system.

7. The AAP recommends the application of developmentally appropriate and scientifically effective methods for addressing children who are to be witnesses; questions should be developmentally appropriate, nonambiguous, and nonthreatening. To limit fatigue and improve the accuracy and reliability of child responses, there should be a limited number of questions per hour, specified breaks consistent with age, and prohibition of irrelevant questions designed to embarrass the child or that are demeaning or imply the child is incompetent. In addition, it is recommended that only individuals with qualifications and experience working with child witnesses be allowed to question children.

8. The AAP recommends that confidentiality be maintained with respect to child witnesses before, during, and after any courtroom appearance. Publicity and loss of privacy may prolong the child’s sense of shame and
stigma stemming from the abuse beyond the immediate courtroom appearance. Furthermore, public disclosure of events precipitating a school-aged child’s appearance in court has the potential to lead to exclusionary behavior and bullying by other children.47

9. On the basis of studies of the psychological consequences of children testifying, the AAP recommends mandatory state-funded, evidence-based therapies for traumatized children, including child victims and child witnesses. In federal court, these services should be supported similarly.

10. State chapters should consider identifying an individual with expertise in children testifying (child abuse pediatrician or individual with legal, legislative, or related experience) who is willing to assist with advocacy issues and to consult with pediatricians and parents about the process of helping children who will become or already are witnesses in court.

11. Given the substantial gaps in knowledge despite important work by several groups of investigators, funding of research should be increased by states to improve and ensure the ability of children to provide accurate information in court. Federal funding also should be made available to develop interventions to improve outcomes for children appearing in court.

12. For immigrant children facing deportation proceedings that include serving as a child witness, the AAP supports universal access to pro bono legal representation and recommends that GALs or community-based court advocates be encouraged to support them.

FUTURE RESEARCH
Substantial gaps exist in our knowledge of how to optimize the care of children in the courtroom. A limited number of long-term follow-up studies on the adverse consequences of child testimony have been conducted, and no prospective studies on the benefits of specific system improvements to benefit the child or the legal system have been performed. Adding questions to ongoing national and longitudinal data collection efforts would be invaluable in providing partial answers to some of these questions. Because a number of accommodations for courtroom appearances have been implemented by some states, a natural study of comparative effectiveness could be accomplished by comparing interstate data. Finally, with advances in technology and changes in law, interventions should be developed and tested for their ability to reduce adverse consequences and improve outcomes for children interacting with the judicial system.

ADDITIONAL RESOURCES
American Academy of Pediatrics. helping foster and adoptive families cope with trauma. Available at: www.aap.org/traumaguide
American Bar Association, Center on Children and the Law. Bar-youth empowerment. Available at: www.americanbar.org/groups/child_law

ACKNOWLEDGMENTS
We are grateful for the thoughtful contributions on early drafts by Charene Mack, RN, Laura Rosenbury, JD, and Lois Weithorn, JD, PhD.

AUTHOR
Robert H. Pantell, MD, FAAP

CONTRIBUTORS
Julie Linton, MD, FAAP
Marsha Griffin, MD, FAAP

COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH, 2016–2017
Michael Yogman, MD, FAAP, Chairperson
Benjamin S. Siegel, MD, FAAP, Past Chairperson (2009-2014), Committee Member (2004-2009)
Thresia Gambon, MD, FAAP
Arthur Lavin, MD, FAAP
Gerri Mattson, MD, FAAP
Jason Richard Rafferty, MD, MPH, EdM
Lawrence Sagin Wissow, MD, MPH, FAAP

CONSULTANT
George J. Cohen, MD, FAAP – National Consortium for Child and Adolescent Mental Health Services

LIAISONS
Sharon Berry, PhD – Society of Pediatric Psychology
Terry Carmichael, MSW – National Association of Social Workers
Edward R. Christopherson, PhD, FAAP – Society of Pediatric Psychology
Norah Johnson, PhD, RN, CPNP-BC – National Association of Pediatric Nurse Practitioners
L. Read Sulik, MD – American Academy of Child and Adolescent Psychiatry

STAFF
Stephanie Domain, MS

ABBREVIATIONS
AAP: American Academy of Pediatrics
GAL: guardian ad litem

POTENTIAL CONFLICT OF INTEREST: The author has indicated he has no potential conflicts of interest to disclose.
REFERENCES


3. 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

4. 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


Expert Witness Participation in Civil and Criminal Proceedings

Stephan R. Paul, MD, JD, FAAP,* Sandeep K. Narang, MD, JD, FAAP,b,c
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.

BACKGROUND

The American Academy of Pediatrics (AAP) first articulated policy on appropriate medical expert witness testimony in 1989 and was among the first medical specialty societies to do so. The statement was revised in 1994 to incorporate additional provisions on expert witness testimony guidelines from the Council of Medical Specialty Societies. A 2002 revision outlined responsible practices that physicians should follow to safeguard their objectivity in preparing and presenting expert witness testimony. Key legal concepts were explained, and the role of the expert witness in the litigation process (pretrial and trial) was described. A 2009 iteration of this statement expanded the requirements and qualifications for experts testifying in civil and criminal cases, the latter primarily relating to cases involving alleged child abuse and/or neglect. The importance of expert witness testimony in the process of determining civil liability, child safety, or criminal culpability and its unique significance in pediatric cases also were stressed. This policy statement replaces the previous policy statement. In addition, it bolsters the requirements for expert testimony and provides new guidance on ways to prevent irresponsible testimony in medical liability proceedings as well as in child abuse cases. This policy statement applies to medical expert witness consultation or testimony in all legal venues including...
Implementing the relevant recommendations of this statement through legislative or regulatory reform (eg, relevant qualifications and standards of testimony).

2. Educating pediatricians (during residency training and through continuing medical education), via both didactic and experiential learning methods, about the skills and knowledge base necessary for providing objective, scientific, and ethical expert witness testimony in legal proceedings.

3. Implementing additional specialized education, as well as oversight safeguards, for experts participating in the criminal law process because of heightened concerns for convictions based on inaccurate expert testimony in criminal cases.

**Relevant Qualifications**

The AAP believes that the establishment of certain minimal qualifications for physicians who serve as expert witnesses will improve the quality of testimony and promote just and equitable verdicts. Physicians should limit their participation as medical experts to cases only in which they have genuine expertise. To demonstrate the relevant education, certification, and experience, physicians should have the following qualifications:

1. Hold a current, valid, and unrestricted medical license in the state in which they practice medicine.

2. Be board certified by the relevant board (American Board of Medical Specialties or a board recognized by the American Osteopathic Association) or a board with equivalent standards. Alternatively, be capable of demonstrating sufficient training and clinical experience in the clinical area at issue to be qualified and accepted as an expert by the relevant specialty board(s).

3. Be actively and meaningfully engaged in clinical practice in the medical specialty or area of medicine about which they testify, including knowledge of or experience in performing the skills and practices at issue to the lawsuit.

4. If retired from clinical practice, remain knowledgeable of the current standard of care and clinical literature in the field before rendering expert opinions on cases.

5. Not give false, misleading, or misrepresentative details about their qualifications.

6. Be subspecialty-trained pediatricians for evaluation and expert testimony in child abuse cases, whenever feasible.

**Standards of Testimony**

Physician expert witnesses should take all necessary steps to provide thorough, fair, objective, and impartial review of the medical facts. To meet that obligation, physicians who agree to testify as experts in legal cases should conduct themselves as follows:

1. Lend their knowledge, experience, and best judgment to all relevant facts of the case regardless of the source of the request for testimony (plaintiff/prosecutor or defendant).

2. Render an opinion only after reviewing sufficient medical records and documents to enable the formation of unbiased and accurate conclusions. If all medical records are unavailable for review, recuse themselves from serving in an expert capacity or acknowledge that their expert opinion is based on limited information.

3. Not exclude relevant information for any reason and certainly not to create a perspective that favors either the plaintiff/prosecutor or the defendant.

4. Provide objective, valid opinions that are well supported by their
clinical experience and the best evidence-based medical literature, regardless of whether it is to be used by the plaintiff/prosecutor or defendant.

5. Testify to matters only within their expertise. If asked about matters outside of their expertise, refrain from testifying on those matters.

6. Testify in cases of child abuse and neglect when they have special knowledge and/or extensive experience in the field. When lacking such or uncomfortable with testimony in such cases, may consult with subspecialists in child-abuse pediatrics.

Providing Proper Testimony

Physician expert witnesses:

1. Must take all necessary steps to provide expert work that is relevant, reliable, honest, unbiased, and based on sound scientific principles.

2. Be willing to submit his or her testimony to scrutiny, if requested, by professional organizations, hospitals, peer review bodies, and state medical and/or licensing boards, as appropriate, and be willing to participate in expert witness review programs.

3. State candidly and clearly when a variety of reasonable and acceptable treatment modalities exist.

4. Not condemn performance that clearly falls within generally accepted practice standards or condone performance that clearly falls outside accepted practice standards.

5. Respect the privacy and confidentiality of the process, as required by law.

6. Contact their employers to ascertain the organization’s policy regarding participation in these activities before agreeing to serve as expert witness pediatricians, pediatric medical subspecialists, or pediatric surgical subspecialists.

Voluntary Affirmation Statement

Because the use of expert witness voluntary affirmation statement is a useful tool for those involved in the legal system and medical associations, the AAP recommends the following:

1. AAP members should offer to provide a certified expert witness affirmation statement to the legal counsel that secured their services.

2. Legal counsel should routinely inquire whether an expert witness has executed a voluntary Expert Witness Affirmation Statement and use its existence or absence.

Standard of Care

Physician expert witnesses should be familiar with the medical standard of care at the time of the incident at issue. Those unfamiliar with the medical standard of care do not meet the recommended qualifications of an expert.

1. Thoroughly review and understand the current concepts and practices related to that standard as well as the concepts and practices related to that standard at the time of the incident that led to the legal proceeding before testifying.

2. Present testimony that reflects the generally accepted standard within the specialty or area of practice, including those standards held by a significant minority.

3. State candidly and clearly when a variety of reasonable and acceptable treatment modalities exist.

4. Not condemn performance that clearly falls within generally accepted practice standards or condone performance that clearly falls outside accepted practice standards.

5. Accept compensation for expert witness work that is reasonable and commensurate with the time and effort involved at the prevailing market value.

6. Not enter into agreements in which compensation for expert witness work is contingent on the outcome of the case.

6. Contact their professional liability insurance carrier to ascertain the need for additional coverage for these activities.

Ethical Business Practices

It is important that expert witnesses conduct the business practices (eg, marketing, contractual agreements, and payment for services) associated with provision of their testimony in a manner conducive to remaining nonpartisan and objective throughout the legal proceedings. To that end, the AAP recommends that expert witnesses do the following:

1. Not participate in advertising or solicit employment as expert witnesses in which such advertising or solicitation contains inaccurate or outdated representations about their qualifications, experience, titles, or background.

2. Structure contractual agreements between physician expert witnesses and attorneys in a way that promotes fairness, accuracy, completeness, and objectivity.

3. Accept compensation for expert witness work that is reasonable

4. Not enter into agreements in which compensation for expert witness work is contingent on the outcome of the case.

5. Contact their professional liability insurance carrier to ascertain the need for additional coverage for these activities.

6. Contact their employers to ascertain the organization’s policy regarding participation in these activities before agreeing to serve as expert witness pediatricians, pediatric medical subspecialists, or pediatric surgical subspecialists.

Voluntary Affirmation Statement

Because the use of expert witness voluntary affirmation statement is a useful tool for those involved in the legal system and medical associations, the AAP recommends the following:

1. AAP members should offer to provide a certified expert witness affirmation statement to the legal counsel that secured their services.

2. Legal counsel should routinely inquire whether an expert witness has executed a voluntary Expert Witness Affirmation Statement and use its existence or absence.

AUTHORS

Stephan R. Paul, MD, JD, FAAP
Sandeep K. Narang, MD, JD, FAAP

COMMITTEE ON MEDICAL LIABILITY AND RISK MANAGEMENT, 2014–2015

William M. McDonnell, MD, JD, FAAP, Chairperson
Robin L. Altman, MD, FAAP
Steven A. Bondi, JD, MD, FAAP
Jon Mark Fanaroff, MD, JD, FAAP
Sandeep K. Narang, MD, JD, FAAP
Richard L. Oken, MD, FAAP
John W. Rusher, MD, JD, FAAP
Karen A. Santucci, MD, FAAP
James P. Scibilia, MD, FAAP
Susan M. Scott, MD, JD, FAAP

FORMER MEMBERS OF THE COMMITTEE

Jay P. Goldsmith, MD, FAAP
Stephan R. Paul, MD, JD, FAAP

STAFF

Julie Kersten Ake

ABBREVIATION

AAP: American Academy of Pediatrics
REFERENCES


