CONTEMPORARY PEDIATRICS MAY 2013, VOL. 30 NO.5 INTIMATE PARTNER VIOLENCE ■ A PRACTICAL APPROACH TO ACNE MANAGEMENT ■ WINNING THE PEDIATRIC OFFICE PAPER CHASE ■ IMPACT OF TRAUMA ON CHILDREN'S HEALTH

CONTEMPORARY Pediatrics

IPV THE PEDE'S UNIQUE ROLE

MAY 2013
VOL. 30 | NO. 5

Expert Clinical Advice for Today's Pediatrician

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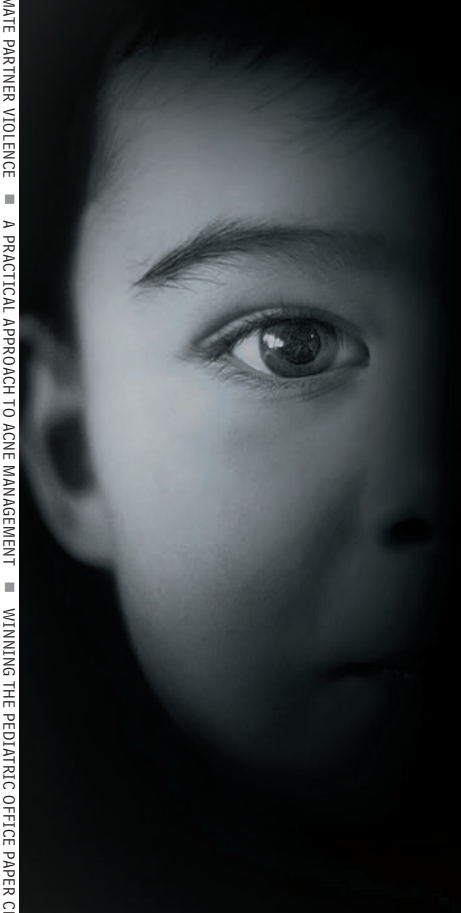

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What can Auvi-Q™ (epinephrine injection, USP), a new epinephrine auto-injector, offer my patients at risk for anaphylaxis?

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Light

Unique Size and Shape

Auvi-Q measures just 3 3/8" high, 2" wide, and 5/8" thick.

Indication

Auvi-Q™ (epinephrine injection, USP) is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to allergens, idiopathic and exercise-induced anaphylaxis. Auvi-Q is intended for individuals with a history of anaphylaxis or who are at risk for anaphylactic reactions.

Important Safety Information

Auvi-Q should **ONLY** be injected into the anterolateral aspect of the thigh. DO NOT INJECT INTO BUTTOCK OR INTRAVENOUSLY.

Epinephrine should be administered with caution to patients with certain heart diseases, and in patients who are on medications that may sensitize the heart to arrhythmias, because it may precipitate or aggravate angina pectoris and produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or taking cardiac glycosides or diuretics. Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid

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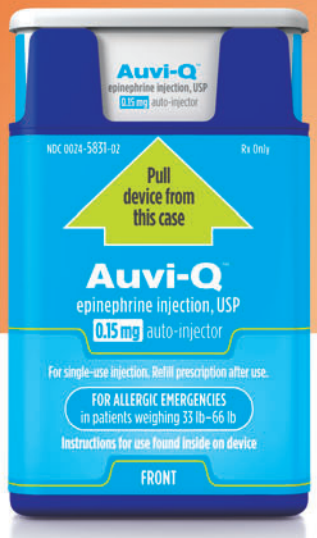

I talk.

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Press-and-Hold Injection Process

Auvi-Q has a "Press-and-Hold" action with a 5-second hold time. The needle retracts automatically once the injection is complete.

Retractable Needle

Two Dosage Strengths

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0.15 mg for patients 33 lb - 66 lb

0.3 mg for patients over 66 lb

Important Safety Information (continued)

disorders, diabetes, and hypertension, may be at greater risk for adverse reactions. Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

Auvi-Q is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical or hospital care.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see brief summary of Prescribing Information on the next page.

Auvi-Q™
epinephrine injection, USP
0.15 mg/0.3 mg auto-injectors
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(epinephrine injection, USP) 0.3 mg, 0.15 mg Auto-Injector

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

Auvi-Q™ is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., order Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Auvi-Q™ is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions.

Anaphylactic reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thready or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

Auvi-Q™ is intended for immediate self-administration as emergency supportive therapy only and is not a substitute for immediate medical care.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 EMERGENCY TREATMENT

Auvi-Q™ is not intended as a substitute for immediate medical care. **In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care.** More than two sequential doses of epinephrine should only be administered under direct medical supervision [*see INDICATIONS AND USAGE (1), DOSAGE AND ADMINISTRATION (2) and PATIENT COUNSELING INFORMATION (17.1 in the full prescribing information)*].

5.2 INCORRECT LOCATIONS OF INJECTION

Auvi-Q™ should **ONLY** be injected into the anterolateral aspect of the thigh [*see DOSAGE AND ADMINISTRATION (2) and PATIENT COUNSELING INFORMATION (17.1 in the full prescribing information)*].

- **Do not inject intravenously.** Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine if there is such inadvertent administration.
- **Do not inject into buttock.** Injection into the buttock may not provide effective treatment of anaphylaxis. Advise the patient to go immediately to the nearest emergency room for further treatment of anaphylaxis.
- **Do not inject into digits, hands or feet.** Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection. Treatment of such inadvertent administration should consist of vasodilation, in addition to further appropriate treatment of anaphylaxis [*see ADVERSE REACTIONS (6)*].

5.3 ALLERGIC REACTIONS ASSOCIATED WITH SULFITE

Epinephrine is the preferred treatment for serious allergic reactions or other emergency situations even though this product contains sodium bisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons.

The presence of a sulfite in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive.

The alternatives to using epinephrine in a life-threatening situation may not be satisfactory.

5.4 DISEASE INTERACTIONS

Some patients may be at greater risk for developing adverse reactions after epinephrine administration. Despite these concerns, it should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation. Therefore, patients with these conditions, and/or any other person who might be in a position to administer Auvi-Q™ to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under which epinephrine should be used.

- Patients with Heart Disease
  Epinephrine should be administered with caution to patients who have heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias [*see DRUG INTERACTIONS (7) and ADVERSE REACTIONS (6)*].
- Other Patients and Diseases
  Epinephrine should be administered with caution to patients with hyperthyroidism, diabetes, elderly individuals, and pregnant women. Patients with Parkinson's disease may notice a temporary worsening of symptoms.

6 ADVERSE REACTIONS

Adverse reactions to epinephrine include anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea and vomiting; headache; and/or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism [*see WARNINGS AND PRECAUTIONS (5.4)*].

Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs [*see WARNINGS AND PRECAUTIONS (5.4) and DRUG INTERACTIONS (7)*].

Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease [*see WARNINGS AND PRECAUTIONS (5.4)*].

Angina may occur in patients with coronary artery disease [*see WARNINGS AND PRECAUTIONS (5.4)*].

Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area [*see WARNINGS AND PRECAUTIONS (5.2)*].

Adverse events experienced as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypoesthesia or injury at the injection site resulting in bruising, bleeding, discoloration, erythema or skeletal injury.

7 DRUG INTERACTIONS

Patients who receive epinephrine while concomitantly taking cardiac glycosides, diuretics, or anti-arrhythmics should be observed carefully for the development of cardiac arrhythmias [*see WARNINGS AND PRECAUTIONS (5.4)*].

The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, and certain antihistamines, notably chlorpheniramine, tripelennamine, and diphenhydramine.

The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs, such as propranolol.

The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine.

Ergot alkaloids may also reverse the pressor effects of epinephrine.

8 USE IN SPECIFIC POPULATIONS

8.1 PREGNANCY

Teratogenic Effects: Pregnancy Category C.

There are no adequate and well controlled studies of the acute effect of epinephrine in pregnant women.

Epinephrine was teratogenic in rabbits, mice and hamsters. Epinephrine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus (fetal anoxia, spontaneous abortion, or both).

Epinephrine has been shown to have teratogenic effects when administered subcutaneously in rabbits at approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal dose of 1.2 mg/kg/day for two to three days), in mice at approximately 7 times the maximum daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal subcutaneous dose of 1 mg/kg/day for 10 days), and in hamsters at approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a maternal subcutaneous dose of 0.5 mg/kg/day for 4 days).

These effects were not seen in mice at approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose (on a mg/m^2 basis at a subcutaneous maternal dose of 0.5 mg/kg/day for 10 days).

8.3 NURSING MOTHERS

It is not known whether epinephrine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Auvi-Q™ is administered to a nursing woman.

8.4 PEDIATRIC USE

Auvi-Q™ may be given safely to pediatric patients at a dosage appropriate to body weight [*see DOSAGE AND ADMINISTRATION (2)*]. However, studies in pediatric patients weighing less than 15 kg (33 pounds) have not been conducted.

8.5 GERIATRIC USE

Clinical studies of Auvi-Q™ did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Epinephrine should be administered with caution in elderly individuals, who may be at greater risk for developing adverse reactions after epinephrine administration [*see WARNINGS AND PRECAUTIONS (5.4), OVERDOSAGE (10)*].

10 OVERDOSAGE

Overdosage of epinephrine may produce extremely elevated arterial pressure, which may result in cerebrovascular hemorrhage, particularly in elderly patients. Overdosage may also result in pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Treatment consists of rapidly acting vasodilators or alpha-adrenergic blocking drugs and/or respiratory support.

Epinephrine overdosage can also cause transient bradycardia followed by tachycardia, and these may be accompanied by potentially fatal cardiac arrhythmias. Premature ventricular contractions may appear within one minute after injection and may be followed by multifocal ventricular tachycardia (prefibrillation rhythm). Subsidence of the ventricular effects may be followed by atrial tachycardia and occasionally by atrioventricular block. Treatment of arrhythmias consists of administration of a beta-adrenergic blocking drug such as propranolol.

Overdosage sometimes results in extreme pallor and coldness of the skin, metabolic acidosis, and kidney failure. Suitable corrective measures must be taken in such situations.

Revised September 2012

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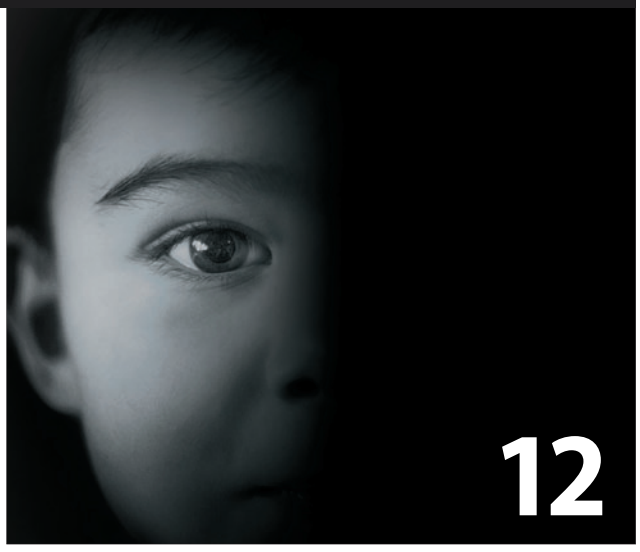

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Contemporary Pediatrics (Print ISSN: 8750-0507, Digital ISSN: 2150-6345) is published monthly by Advanstar Communications, Inc., 131 W. 1st Street, Duluth, MN 55802. Subscription rates: one year $89, two years $150 in the United States & Possessions, $105 for one year, $189 for two years in Canada and Mexico; all other countries $105 for one year, $189 for two years. Single copies (prepaid only) $18 in the United States; $22 in Canada and Mexico, and $24 in all other countries. Include $6.50 per order plus $2.00 per additional copy for U.S. postage and handling. **Periodicals postage paid** at Duluth, MN 55806 and additional mailing offices. POSTMASTER: Please send address changes to *Contemporary Pediatrics*, PO Box 6083, Duluth, MN 55806-6083. Canadian GST number: R-124213133RT001. Publications Mail Agreement Number 40612608. Return Undeliverable Canadian Addresses to: Pitney Bowes, P. O. Box 25542, London, ON N6C 6B2, CANADA . Printed in the U.S.A.

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References: 1. Wigal T, Greenhill L, Chuang S, et al. Safety and tolerability of methylphenidate in preschool children with ADHD. *J Am Acad Child Adolesc Psychiatry.* 2006;45:1294-1303. **2.** Swanson J, Greenhill L, Wigal T, et al. Stimulant-related reductions of growth rates in the PATS. *J Am Acad Child Adolesc Psychiatry.* 2006;45:1304-1313. **3.** Faraone SV, Biederman J, Monuteaux M, Spencer T. Long-term effects of extended-release mixed amphetamine salts treatment of attention-deficit/hyperactivity disorder on growth. *J Child Adolesc Psychopharmacol.* 2005;15:191-202. **4.** Zachor DA, Roberts AW, Hodgens JB, Isaacs JS, Merrick J. Effects of long-term psychostimulant medication on growth of children with ADHD. *Res Dev Disabil.* 2006;27:162-174.

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JONATHAN THACKERAY, MD

INTIMATE PARTNER VIOLENCE
WHY ABUSE OF WOMEN IS A PEDIATRIC ISSUE

As a medical student, my education on intimate partner violence (IPV) was limited to resources available in the community (which were few) and reasons why physicians don't talk to their patients about IPV (which were many). As a resident, IPV was presented almost exclusively as an adult issue that affected grown women.

I trained in a combined internal medicine/pediatrics program and early on developed an interest in the various aspects of family violence. With my internal medicine hat on, I planned a rotation at our community shelter to learn more about the "adult issues" of IPV.

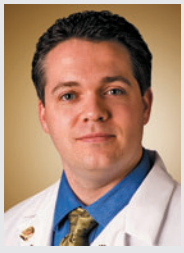
I remember my first day vividly. Within my first few minutes there, I turned the corner and was greeted by a child running full speed with an armful of books. The collision was harmless, and as we shared a laugh and started to collect the books strewn across the floor, I still recall my first thought—a naïve one at that: "What is a child doing in a shelter for victims of IPV? They never taught us that victims have children."

But they do, of course—15 million children by recent estimates. The American Academy of Pediatrics (AAP) advises pediatricians that "the abuse of women is a pediatric issue." I applaud the authors of this month's cover article "Screening and intervention for intimate partner violence: A practical apprach," for reminding us of this and for presenting an excellent summary of IPV to an audience of pediatricians who provide care to these children.

Rates of IPV are disproportionately higher in homes with young children. The magnitude of childhood exposure to IPV described in this article (twice as common as childhood asthma!) should make pediatricians sit up and take notice.

I often wonder how many children who present to the pediatrician with "bad behavior" are being raised in homes with violence. I wonder how many caregivers confide in their pediatricians about a child's school difficulties and then return home only to scream and throw punches at each other over some disagreement. I suspect many of us evaluating these children unfortunately "spin our wheels" diagnosing various disorders and providing various treatments without ever identifying the true heart of the issue in many of our patients' homes.

Once rarely ever mentioned as a consequence of IPV, the effects of childhood exposure to IPV (and other toxic stressors) are now a foremost area of medical and behavioral health research. We now know that the infant brain exposed to IPV develops with a different architecture than the infant not exposed to violence. This abnormal brain development is the



JONATHAN THACKERAY, MD, is medical director of the Center for Family Safety and Healing in Columbus, Ohio, and chief of the Division of Child and Family Advocacy at Nationwide Children's Hospital, Columbus. He is active in the American Academy of Pediatrics (AAP) Section on Child Abuse and Neglect and the Ray E Helfer Society; is a member of the American Board of Pediatrics Subboard on Child Abuse Pediatrics; and is board certified in child abuse pediatrics, general pediatrics, and internal medicine. He is co-author of the 2010 AAP clinical report "Intimate partner violence: the role of the pediatrician" *(Pediatrics.* 2010;125(5):1094-1100).

nidus for a cascade of cognitive and developmental problems that can ultimately lead to early mortality, with a host of social, medical, and behavioral health consequences in between.

It is important to acknowledge with colleagues that IPV is not an inherently easy subject to discuss. In fact, I suspect it is nearly impossible for pediatricians to generate an acceptable level of comfort with the topic unless they practice having this discussion with caregivers regularly.

As pediatricians, however, we discuss the most sensitive of other subjects with our patients and their families, from delivering a diagnosis of cancer in a child to his or her parents, to obtaining the most personal of sexual histories from teenagers, to routinely discussing issues related to drug and alcohol use. Why then should the issue of IPV be any more difficult?

We can approach these conversations armed with the support of the AAP, the Institute of Medicine, and other major medical organizations. We can feel confident that we are practicing evidence-based medicine in accordance with the US Preventive Services Task Force, which endorses screening women of childbearing age for IPV.

I think it is equally important to recognize that screening is not a one-time discrete event but rather an ongoing conversation between the pediatrician and the caregiver. "Caregivers lie to me," I'm often told. Perhaps, but by initiating a discussion on IPV, you have told the caregiver that your office is a safe place to discuss the topic if and when she is comfortable doing so. Remember that with our relatively frequent contacts in the context of well-child and sick visits, we are in a unique position to having ongoing discussions with the caregiver.

If we know that IPV is frighteningly common and we know that the adverse effects on the child are innumerable and undeniable, I will argue then that it is no longer acceptable for pediatricians to simply ignore the issue. When discussing IPV screening by pediatricians, it is time for the conversation to shift from "why don't I ask?" to "how could I not ask?" cp

AHRQ reports on impact of trauma on children's health

KATHRYN FOXHALL

When children are exposed to trauma, our knowledge of what helps and what does not is very limited, according to a comparative effectiveness review prepared for the Agency for Healthcare Research and Quality (AHRQ).

The report, from the RTI International-University of North Carolina at Chapel Hill Evidence-based Practice Center, looked only at interventions for children exposed to trauma other than maltreatment or family violence and concluded, "Our findings may be interpreted as a call to action: Psychotherapeutic intervention may be beneficial relative to no treatment, but far more research is required to produce definitive guidance on the comparative effectiveness of psychotherapeutic or pharmacological interventions targeting children exposed to trauma, some of whom already have symptoms."

In a commentary on the current report in *Pediatrics*, Denise Dowd, MD, MPH, calls this evidence "indeed paltry," pointing out that it comes in the face of exponential growth in understanding of the impact of childhood trauma exposure on physical and mental health.

The AHRQ-sponsored study notes that although nearly two-thirds of children and adolescents go through at least 1 traumatic event and most do not suffer a long-term impact, some do develop traumatic stress syndromes, including posttraumatic stress disorder (PTSD).

After looking at a total of 6,647 articles from standard databases and sources, the authors excluded all but 506. They then excluded most of the others for reasons such as a high risk of bias or wrong population or publication type. They finally included 22 studies in the review.

One reason for the exclusion of many studies, the authors noted, was that they did not look at children whose source of trauma was not maltreatment or family violence. Even among those 22 studies, there was such a variety of components, including medication dose and frequency, family member involvement, and mode and method of delivery, that it challenged "attempts to combine or categorize interventions," they said. In addition, each of the studies looked at a unique intervention, so there was no replication of findings.

"No pharmacotherapy intervention demonstrated effectiveness," the authors said.

Some school-based treatments that included elements of cognitive behavioral therapy (CBT) appear promising in terms of "the magnitude and precision of effects found." However, there was less compelling evidence for interventions for children who already had symptoms, even though those interventions did have elements of CBT.

With most studies looking at short-term outcomes, there was no insight on interventions' impact on long-term development. Also, there was little evidence on how effectiveness might vary by child characteristics, and none on treatment characteristics or setting.

In addition, the authors said, "We also found almost no evidence on harms associated with psychological treatments. Only pharmacological interventions attempted to assess harms in this vulnerable population."

The authors suggest that given this preliminary evidence, clinicians and policymakers may want to focus on therapies that have some evidence of effectiveness, and clinicians may want to "create patient-centered treatments composed of specific components of several interventions that have particular theoretical, evidence-based, or anecdotal benefits."

Dowd, the commentary writer who is professor and injury researcher at the University of Missouri-Kansas City, said that professionals, including social workers, psychologists, physicians, and educators, identify and intervene when children are exposed to trauma but added, "They fail to take advantage of the depth and breadth of each other's knowledge and insight."

The report, "Child and Adolescent Exposure to Trauma: Comparative Effectiveness of Interventions, Addressing Trauma Other Than Maltreatment or Family Violence," is available on the AHRQ Web site, www.effectivehealthcare.ahrq.gov. CP

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†*P*=0.0001

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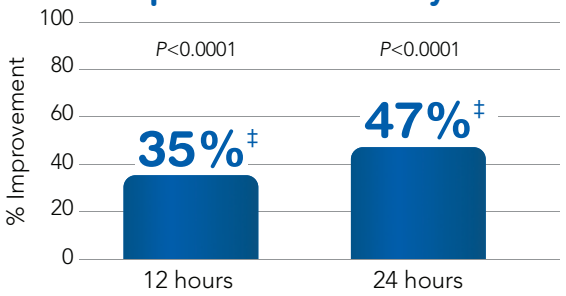

‡Efficacy and safety assessments were performed by a trained evaluator at baseline, and at 12 and 24 hours post-baseline (N=57). Subjects (2-36 months of age) must have received an "Overall Severity Score" of >1.5 as determined by evaluator at enrollment. Diaper rash severity was assessed using a 0- to 3-point scale (0=none; 3.0=severe).

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References: 1. Data on file. **2.** Brown WM, Berg JE, Li Q, Kohut BE. A clinical study to evaluate the efficacy of two marketed zinc oxide-based diaper rash ointments in children with diaper dermatitis. Poster presented at: Clinical Dermatology Conference; October 6-9, 2006; Las Vegas, NV. **3.** Product monograph. 68 FR 33377, June 4, 2003.

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Federal court lifts age restriction for emergency contraceptives

A federal judge has ruled that emergency contraceptives (ECs) be available in pharmacies over the counter without age restriction, allowing easier access to girls aged younger than 17 years who previously required a prescription from a health care provider for the medications.

The American Academy of Pediatrics (AAP), the American College of Obstetricians and Gynecologists (ACOG), and the Society of Adolescent Health and Medicine (SAHM) commended the order that overruled the US Department of Health and Human Services' decision in 2011 to restrict availability of drugs that prevent pregnancy after sexual intercourse from young girls.

In his decision, Judge Edward R. Korman of the US District Court for the Eastern District of New York concluded that restricting ECs for girls aged younger than 17 years was not based on scientific evidence.

The AAP, ACOG, and SAHM have contended that pregnancy carries greater safety risks for adolescents and young teenagers than the "morning-after" pill. In a press release, they said the court's decision "reflects the overwhelming evidence that emergency contraception is safe and effective for all women of reproductive age." In addition, ECs taken up to 120 hours after intercourse can help to prevent unintended pregnancies after contraceptive failures, unprotected sex, or sexual assaults.

"While pediatricians recommend that teens delay sexual activity until they fully understand its consequences, we strongly encourage the use of contraception—including emergency contraception— to protect the health of our adolescent patients who are sexually active," said AAP President Thomas K. McInerney, MD, FAAP.

The US Food and Drug Administration has 30 days to appeal the ruling.

ABUSE AT HOME A FACTOR FOR REPEAT SUICIDE ATTEMPTS

Children who have been so severely maltreated that they have been legally removed from their parents' homes are twice as likely to repeat a suicide attempt as their peers in the general population, new research from Canada has found.

Researchers from the Suicide Studies Research Unit at St. Michael's Hospital, Toronto, looked at data for 6,484 children aged 12 to 17 years who were seen in an emergency department (ED) for first incidence of suicide-related behavior (SRB) between January 2004 and December 2008 and documented repeat visits for SRB in these patients through December 2010. A total of 179 study participants had been legally removed from their parental homes because of substantiated maltreatment. These children and population-based peers were analyzed for demographic, social, and clinical factors and for repetition-free SRB probabilities over time.

GIRLS AGED 12 TO 13 YEARS were more likely to attempt another suicide than both boys and children aged older than 13 years.

Children who had been abused and removed from their homes were 2 times more likely to repeat suicide attempts than their peers after adjusting for age, sex, neighborhood size, income, presence of mental disorder, and severity of the first SRB visit to an ED. Children at risk for repetition also had a high prevalence of mental disorders. Girls aged 12 to 13 years were more likely to attempt another suicide than both boys and children aged older than 13 years.

Findings highlight the importance of assessing a child's family situation and whether he or she has a mental disorder when evaluating for repeat SRBs. The researchers suggest that clinicians work closely with social workers, child welfare agencies, and those with expertise in child maltreatment to guide treatment plans that will be effective in preventing repeat attempts of suicide among these vulnerable pediatric patients.

Rhodes AE, Boyle MH, Bethell J, et al. Child maltreatment and repeat presentations to the emergency department for suicide-related behaviors. *Child Abuse Negl.* 2013;37(2-3):139-149.

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SCREENING AND INTERVENTION FOR INTIMATE PARTNER VIOLENCE

MARIO CRUZ, MD, AND **MEGAN H BAIR-MERRITT, MD, MSCE**

Fifteen million children are exposed to intimate partner violence in their homes each year, and all pediatricians, whether they are aware of it or not, have cared for families in which there is overt or hidden physical or sexual abuse. Well-child visits are the best times for pediatricians to screen for this preventable public health issue.

Introduction

Screening and intervention for intimate partner violence (IPV) may provide pediatricians with the opportunity to protect their patients from years of exposure to violence. Many pediatricians avoid this topic because of a lack of knowledge or comfort in addressing the issue. This article summarizes research and guidelines that have emerged over the past 10 years, with the goal of providing pediatricians with the knowledge and tools necessary to comfortably address IPV with the families for whom they provide care.

IPV: Adult problem affects children

Whether they recognize it or not, all pediatricians have cared for families affected by IPV. In a recent study from the Centers for Disease Control and Prevention, 36% of adult women reported being physically or sexually assaulted by an intimate partner at 1 point in their lives.[1] Six percent had been victimized within the past year. The prevalence of IPV in these population-based surveys differs from what has been described in specific clinical settings.

For example, in a survey of 133 Baltimore women accompanying their children to an ambulatory pediatric visit, Bair-Merritt found that 23% of the women disclosed having experienced IPV during the past year.[2] Another survey of 553 women in a private pediatric practice in Falmouth, Massachusetts, found the current prevalence of IPV to be 2.5%.[3]

It is important to recognize that IPV is not isolated to inner-city environments; rather, IPV occurs in all communities. In fact, when controlling for

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employment status and poverty, the prevalence rates of IPV among black, Hispanic, and white women are nearly identical.[4] Social stigma and reporting bias, however, can make it more difficult to identify IPV in more affluent communities and in men.

Rates of IPV are disproportionately high in families with a child aged younger than 5 years.[5] This finding is particularly salient for pediatric providers because women of childbearing age rarely see their own providers, but they frequently bring their infants and toddlers to pediatric visits.[6]

Women between the ages of 18 and 24 years are at the greatest risk for IPV victimization.[7] Low socioeconomic status, unmarried status,[3] multiple children in the family (especially if they are younger than 5 years),[5] maternal depression,[8] and economic instability[9] also place women at higher risk for abuse.

All told, up to 15 million children witness IPV in their homes every year.[10] To put this number into perspective, childhood IPV exposure in the United States is twice as common as the prevalence of childhood asthma. Thus, what was once considered a "women's issue" has been increasingly recognized as a preventable pediatric public health issue.

IPV defined, exposure to children

Intimate partner violence has been defined as "a pattern of coercive behaviors that may include repeated battering and injury, psychological abuse, sexual assault, progressive social isolation, deprivation and intimidation. These behaviors are perpetrated by someone who is or was involved in an intimate relationship with the victim."[11] IPV can affect males or females and can take place within same- or opposite-sex relationships. Abusive behaviors can take many forms (Table 1),[12,13] including physical abuse (eg, smacking, pushing, kicking, punching, or choking), sexual abuse (eg, forced intercourse), emotional abuse (eg, isolation from family and friends, yelling, and belittling), and financial abuse (eg, controlling financial resources).

More recently, pregnancy coercion[14] and technology abuse (also known as cyber-stalking or electronic monitoring)[13] have emerged in the medical literature. In pregnancy coercion, the abusive partner sabotages contraceptive techniques with the goal of forcing an unintentional pregnancy upon the woman. In technology abuse, the perpetrator uses cell phone technology, the Internet, and social networking sites such as Facebook to harass, stalk, intimidate, and humiliate. Some of the more recently defined types of violence (eg, pregnancy coercion and technology abuse) may not affect children in the same way as witnessing physical or sexual abuse; however, they can produce secondary impacts on children that result from having an anxious, fearful, or depressed parent.

Children can be directly and indirectly exposed to IPV. The most common indirect IPV exposure comes from overhearing abuse that takes place behind closed doors (eg, shouting, hitting, and the sound of objects breaking). Children are also exposed to the aftermath of an abusive episode (eg, a tearful parent with visible bruising, broken objects or walls, a parent who suddenly leaves the house and slams the door on the way out).

Direct exposure to IPV occurs when physical, sexual, emotional, or other forms of violence take place in the presence of the child. On occasion, children can be caught "in the crossfire" during an abusive episode.[15] For example, infants being held by a parent may be struck by an abusive partner during an argument. In addition, many older children and adolescents will attempt to defend a parent from the abuser and become threatened or injured in the process.

Impact on children

Not all children who witness IPV are equally affected. Factors such as the duration and severity of the abuse, maternal mental health, and parenting skills can all influence a child's resiliency.[16]

CHILD ABUSE

It is important to recognize that child abuse and IPV are not synonymous. Unlike child abuse, IPV involves the child's caregiver as the primary victim. Not surprisingly, the relationship between child abuse, in which the child is the direct victim of maltreatment, and IPV is quite strong. In fact, IPV is one of the most preventable and identifiable correlates of child abuse. Studies have demonstrated

TABLE 1 Four major categories of abusive behavior experienced by victims of intimate partner violence

Category	Abusive actions
Physical abuse	Punching, shoving, kicking, biting, grabbing, slapping, choking, injuring with objects, burning, scratching, shaking, restraining, attempting to kill, causing death.
Sexual abuse	Forcing unwanted sexual acts, intentionally infecting with a sexually transmitted infection, sabotaging or removing contraceptives, coercing a pregnancy, leaving large visible "hickeys" (subcutaneous ecchymosis from forceful kissing).
Emotional abuse	Blaming the victim for a child's behavioral or health issues, threatening to remove custody of the children, threatening to harm the victim or her children, name-calling, humiliation, withholding of information, social isolation, making negative statements to children about the victim, stalking, threatening deportation, forcing the victim to engage in illegal activities.
Financial, technology, and other forms of abuse	Identity theft, depleting a bank account, damaging a credit record, withholding access to money, causing poor work performance (eg, by hiding the car keys, slashing tires, leaving embarrassing bruises), harassing the victim at work, using social media or a cell phone's GPS device to stalk, breaking into one's email.

Abbreviation: GPS, global positioning system.
Adapted from Saltzman LE, et al[12]; Tjaden P, et al.[13]

that the coexistence of IPV and child abuse is 29% to 60%.[17] As a result, many child advocacy organizations, including the American Academy of Pediatrics (AAP),[6] have advocated IPV screening and intervention as a method for the primary prevention of child abuse.

HEALTH CARE USE

In all age groups, children who have witnessed IPV use health care services (especially the emergency department and mental health settings) more often than their peers and subsequently incur greater health care costs. This increase in health care costs persists even after the abuse has ended.[18]

EMOTIONAL AND PHYSICAL HEALTH

Although IPV is most prevalent in homes with children aged younger than 5 years, many parents and providers erroneously believe that IPV does not affect young children because "they are too little to understand what is going on." On the contrary, infants and toddlers are perhaps at greatest risk for adverse health effects related to IPV exposure. Children in this age group are experiencing a period of rapid brain growth (this is what allows them to learn to talk and walk within a short span of time). Although the traumatic experience of observing IPV is not stored in conscious memory, children's developing brains are exquisitely sensitive to traumatic experiences in the social environment. A growing body of literature suggests that this type of early trauma can lead to changes in brain structure that may affect learning and emotional regulation.[19,20]

Young children living in violent homes may experience disruption of eating and sleeping cycles. They often have nightmares, night terrors, excessive clinginess, and separation anxiety.[21] In addition, children living with IPV have a higher likelihood of internalizing and externalizing behavior problems (including temper tantrums and aggressive behavior) and are at risk for developmental delays and impaired school readiness.[22]

Although the mechanism is not completely understood, pregnant women who experience IPV are more likely to lack prenatal care and are at greater risk for delivering premature infants.[23] Young children exposed to IPV are more likely to be delayed with immunization and are less likely to receive on-time well-child care.[24] Obesity rates[25] and asthma incidence[26] are also higher in IPV-exposed children.

IPV-exposed school-aged children often exhibit aggressive behaviors both at home and at school and have higher rates of involvement with bullying, both as bullies and as victims.[27] Academic underperformance is common,[28] as are distractibility and hyperactivity (which can be misdiagnosed as attention-deficit/hyperactivity disorder), posttraumatic stress disorder, depression, and anxiety.[21] Nightmares and sleep difficulties may

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persist into the school-aged years, and somatic complaints such as headache, backache, and abdominal pain are frequently reported by IPV-exposed children.[29]

Approximately 20% of adolescent girls have been victimized by dating violence (IPV that occurs within the context of an adolescent relationship).[30] Adolescents experiencing dating violence have higher rates of risk-taking behaviors such as drug use, smoking, unsafe sexual behaviors, suicide attempts, and fighting.[30,31]

Impact of IPV exposure is long lasting

The Adverse Childhood Experiences (ACE) studies, conducted by Felitti and colleagues, highlight how ACEs such as childhood IPV exposure, parental substance abuse, and parental mental health problems can negatively affect health across the life course.[32] In a sample of more than 17,000 adults enrolled in a Kaiser Permanente health plan in California, two-thirds had experienced some form of ACE. In this landmark study, the authors documented that ACEs were related in a dose-dependent manner to a variety of poor adult health outcomes, including smoking, anxiety, obesity, sexual promiscuity, chronic obstructive pulmonary disease, and cancer. Even when controlling for other ACEs, the frequency of childhood IPV exposure was independently and positively correlated with alcoholism, substance abuse, and depression as an adult.[33] The impact of these studies cannot be overstated because they solidify the notion that childhood IPV exposure, especially when combined with other ACEs, is a public health issue that can affect physical and mental health throughout life.

Mechanism for IPV exposure and damage to children

Stress is a common experience for children and adults, and tolerable stress helps to build one's ability to cope with challenging situations. However, IPV-exposed children live with a phenomenon termed toxic stress.[19,20] Toxic stress is defined as the chronic, unpredictable, and uncontrollable exposure to adverse experiences without access to the buffering effects of a stable and responsive caregiver relationship.[19] Childhood IPV exposure meets all the criteria for being a toxic stressor. For most families, the violence is chronic and unpredictable, and children are not able to stop or prevent the violence. Furthermore, IPV often makes effective, positive parenting more difficult. For example, parents with IPV histories are more likely to use corporal punishment and are less likely to use positive disciplinary strategies than are parents who have not experienced IPV.[34] These parents may be anxious, preoccupied, and depressed, and therefore may be less likely to engage their children in activities that require uninterrupted attention, such as reading.[35]

Toxic stress causes frequent and prolonged activation and dysregulation of the autonomic nervous system and the hypothalamic-pituitary-adrenocortical axis. When children are exposed to IPV, they chronically mount their fight-or-flight response. Although this response is adaptive in the short term, repetitive activation alters neuroendocrine systems, with an adverse impact on the developing brain and organ systems.[20]

In a 2012 policy report, the AAP stated that it was "committed to leveraging science to inform the development of innovative strategies to reduce the precipitants of toxic stress in young children and to mitigate their negative effects on the course of development and health across the life span."[36] The AAP also recommended that pediatricians routinely screen caregivers for toxic stressors.

Screening for IPV

Several professional organizations endorse routine IPV screening of women of childbearing age, including the AAP,[6] the Institute of Medicine,[37] the American College of Obstetricians and Gynecologists,[38] and the American Academy of Family Physicians.[39] The US Preventive Services Task Force stated that IPV screening and intervention may improve some of the aforementioned health outcomes while having a minimal risk of harm and therefore gave IPV screening a "B" rating.[40]

Despite the recommendations of professional organizations, many health care providers find IPV

screening to be challenging or impractical. The barriers most commonly identified in the medical literature include not recognizing that IPV is a pediatric issue, forgetting to screen, feeling uncomfortable screening, having insufficient time, lacking a relevant protocol, and lacking resources for IPV victims.[35,41] Preparing your office to screen for IPV requires the use of "champions" who can dedicate their energy toward developing effective strategies to overcome these barriers (Table 2).[41]

Use of the RADAR screen

RADAR (**R**outinely screen, **A**sk, **D**ocument, **A**ssess, **R**efer/**R**esources) has been proposed as a mnemonic to facilitate screening for IPV.[42]

ROUTINELY SCREEN

IPV screening should take place as routinely as possible because this destigmatizes the issue for providers and for patients and helps identify those individuals who do not have obvious red flags for abuse. For example, although many physicians recognize that a woman with a black eye should be screened for IPV, it is rare for someone to present to the office with visible bruising. Routine screening also provides practice for providers who are looking to improve their screening approach. Pediatric offices may consider providing parents with a handout that describes their practice philosophy on the issues of psychosocial screening (eg, depression, substance use, IPV) and confidentiality.

Even if some practices are unable to offer routine IPV screening, it is imperative that they screen the following high-risk populations of women: those involved in a new relationship, those with visible signs of abuse, those who have children with aggressive behaviors or previous victimization by abuse, or those who have been noted in your practice to have had public arguments with their partners. Pediatricians should also screen for IPV in adolescent girls, especially during pregnancy and postpartum.

SCREENING DOES NOT GUARANTEE DISCLOSURE

One possible explanation for lack of disclosure of IPV involves the transtheoretical model of behavior change (ie, the "stages of change" model). This model proposes that individuals experiencing IPV progress through stages of behavior change (eg, precontemplation, contemplation, preparation, action, maintenance, and relapse) and that asking about IPV during a precontemplative stage might result in a negative response.[43,44] In addition, women often must be asked multiple times before they

TABLE 2 Barriers to screening for intimate partner violence and strategies to overcome them

Barrier to screening	Potential strategies
Not recognizing that IPV is a pediatric issue; believing IPV is not an issue in your community of patients	• Ensure that all your staff members (including nurses, medical assistants, and clerical staff) become educated about IPV. Your regional IPV agencies may be able to provide free training.[a] In addition, IPV training opportunities are available online at: www.leapsf.org and www.dveducation.ca.
Not comfortable screening; fear of offending patients	• The medical literature suggests that most parents (>85%) appreciate being screened for IPV. As with any sensitive issue, it is likely that at some point you will make an awkward statement. Do not be discouraged because this is part of the learning process. • Training on IPV should have a role-play component so that your providers can have the opportunity to practice and receive immediate feedback.
Forgetting to screen	• Post IPV signage in your office.[a] • Incorporate IPV-screening prompts within your encounter forms.
Not enough time to screen	• Consider using previsit written screening questionnaires, such as the HITS or the Partner Violence Screen (Table 3[47]).
Not sure what to do with a positive screen; lack of resources for IPV victims	• Develop an office protocol for IPV screening and intervention. • Protocol specifics will vary depending on the availability of immediate resources at your site.

Abbreviations: HITS, Hurt, Insult, Threaten, Scream; IPV, intimate partner violence.
[a]The national IPV hotline, 1-800-799-SAFE(7233), may be able to provide a listing of local IPV agencies that can assist with training for your staff, free IPV signage for your office, and intervention for IPV victims identified in your setting.
Adapted from McColgan MD, et al.[41]

TABLE 3 Commonly used self-administered screening tools for intimate partner violence

Screening tool	Specific questions	Scoring	Pros and cons
HITS (Hurt, Insult, Threaten, Scream)	How often does your partner: **1.** Hit you? **2.** Insult you? **3.** Threaten you with harm? **4.** Scream at you?	The following scale is used for each question: **1.** Never **2.** Rarely **3.** Sometimes **4.** Fairly often **5.** Frequently A score of 10 or more is suggestive of abuse.	**Pros:** Addresses physical and emotional abuse **Cons:** Only applies to individuals who are currently in a relationship; requires a complex scoring system; does not address sexual abuse, financial abuse, or other forms of abuse
Partner Violence Screen	**1.** Have you been hit, kicked, punched, or otherwise hurt by someone in the past year? **2.** Do you feel safe in your current relationship? **3.** Is there a partner from a previous relationship who is making you feel unsafe now?	Answers are scored as "yes" or "no." A score of yes on any item indicates abuse.	**Pros:** Simple to score; asks about current and previous relationships; addresses physical and emotional abuse **Cons:** Does not address sexual abuse, financial abuse, or other forms of abuse

Adapted from Rabin RF, et al.[47]

disclose; they must trust the person to whom they disclose; and they must believe that that person will be able to provide them with a menu of options from which to find a solution. A negative IPV screen should never be seen as a low-yield exercise, but instead as a statement to the mother that if she ever finds herself in an abusive relationship, you and your colleagues are available as resources.

The manner of screening for IPV also may affect a victim's likelihood of disclosing abuse to you. Rhodes and colleagues determined that patients experiencing IPV were less likely to disclose abuse to physicians who screened in an awkward or perfunctory manner and were more likely to disclose abuse to physicians who allowed for open-ended answers and who asked probing follow-up questions.[45]

WHY VICTIMS REMAIN

Although each person experiencing IPV has unique circumstances, it is fair to say that most have made a calculated decision that the benefits of remaining in an abusive relationship (eg, financial stability, father figure for their children) outweigh the risks and losses associated with leaving (eg, life in a shelter, humiliation, fear of losing custody of their children). They may not choose to leave until this balance changes. Other reasons for remaining in an abusive relationship include fear of the unknown, lack of family or social support, cultural norms that prohibit divorce, concerns about losing legal immigration status, love for the abuser, depression, and fear that leaving might result in injury or death.[44,46]

ASK DIRECT QUESTIONS

Experts disagree about whether IPV screening should be self-administered (written or computer assisted; Table 3)[47] or verbally administered by a health care professional (Table 4). Many patients have reported that self-administered screening is less awkward and more private, and research shows that it has better psychometric properties than verbal screening.[48] On the other hand, verbal screening can be tailored to the parent's unique situation and allows immediate response from a provider.

All experts agree, however, that IPV screening questions must be direct and have strong psychometric properties. Psychometric properties refer to the ability of a screening tool to accurately and reliably perform its intended function. In the case of IPV

TABLE 4 Common screening scenarios for intimate partner violence

Scenario	Dialogue	Key point
Scenario 1: You are seeing a mother with her 6-month-old daughter for well-child care.	**Provider:** Because abuse in the home is so frequent, I have begun to ask all my families about this issue. Have you ever been in a relationship where your partner has hit, kicked, or punched you? **Mother:** Oh, no! Why would you ask that? **Provider:** Well, unfortunately, we see many families in that situation and unless we ask we would never find out. Violence in the home can be very harmful to children's health and well-being. **Mother:** Yes, you are right. I know a few people in that situation. Thanks for asking.	Empirical evidence and clinical practice suggest that only a small percentage of parents will be surprised or offended by IPV screening. When this is the case, simply explaining why screening is so important generally leads to understanding and, often, appreciation.
Scenario 2: You are seeing a mother with her 8-year-old child. She is concerned about attention-deficit/ hyperactivity disorder.	**Provider:** You are right to be concerned about these behaviors. Sometimes children misbehave when they are stressed about issues at home. One question that I ask all families when they are concerned about this type of behavior is: Are there any issues at home—such as violence or frequent arguments—that your child might be reacting to or worrying about? **Mother:** (Pauses) Well, yes. Sometimes his father and I get into really bad arguments and our children see it. (Mother is visibly upset.) **Provider:** (Pause) I am really sorry that you are going through this. (Pause for response.) I'd like to spend a few minutes discussing this with you alone. Would it be all right if your son waited for a few minutes with one of our staff members?	Behavior changes and unexplained somatic complaints are risk factors for IPV.
Scenario 3: You are seeing a mother and father with a newborn for their first well-child visit. You decide not to screen for IPV.	—	Confidentiality is essential for IPV screening. Unless the father leaves the room for a prolonged and predictable amount of time, IPV screening should be deferred to the next opportunity. There are, however, clever ways to get around this issue if you have time. For example, you can send the father to the checkout desk to arrange the next appointment while the mother remains in the room with the baby.

Abbreviation: IPV, intimate partner violence.

screening, one is most interested in the sensitivity and positive predictive value of the screening tool. Unfortunately, one of the most commonly used IPV screening questions, "Do you feel safe at home?" is remarkably vague and has a sensitivity of just 8.8%.

Direct verbal screening for IPV in the presence of children aged 3 years or older is not recommended because the child may report your conversation to the perpetrator.[35] In these situations, you may choose to be more subtle in your approach (Table 4), or you may use self-administered screening modalities.

DOCUMENT

Documentation of IPV screening in the medical record has several benefits.[35] Most importantly, it can assist the IPV victim in taking legal action against the perpetrator. It is necessary to ask permission from

CONTINUED ON **PAGE 23**

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- Stroke and myocardial infarction have occurred in adults treated with CNS stimulants at recommended doses. Sudden death has occurred in children and adolescents with structural cardiac abnormalities and other serious cardiac problems, and in adults taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during treatment with Quillivant XR.
- CNS stimulants cause an increase in blood pressure (mean increase approximately 2-4 mm Hg) and heart rate (mean increase approximately 3-6 bpm). Some individuals may have larger increases. Monitor all patients for hypertension and tachycardia.
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IMPORTANT SAFETY INFORMATION (cont'd)

- Based on accumulated data from other methylphenidate products, the most common (≥5% and twice the rate of placebo) expected adverse reactions are appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased. There is limited experience with Quillivant XR in controlled trials. Based on this limited experience, the adverse reaction profile of Quillivant XR appears similar to other methylphenidate extended-release products. The most common (≥2% in the Quillivant XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 45 ADHD patients (aged 6-12 years) were affect lability (9%), excoriation (4%), initial insomnia (2%), tic (2%), decreased appetite (2%), vomiting (2%), motion sickness (2%), eye pain (2%), and rash (2%).
- Based on animal data, use of Quillivant XR during pregnancy may cause fetal harm. Quillivant XR should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing mothers should be advised to discontinue drug or discontinue nursing, taking into consideration the importance of the drug to the mother.

For more information, please visit www.QuillivantXRPro.com

Quillivant XR™ methylphenidate HCl for extended-release oral suspension | 25 mg/5 mL

*Please see Brief Summary of Prescribing Information, including **BOXED WARNING** regarding Abuse and Dependence, on the following page.*

Quillivant XR™ (methylphenidate HCl) for extended-release oral suspension, CII Rx only
BRIEF SUMMARY: Consult Full Prescribing Information for Complete Product Information.

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including Quillivant XR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy *[see Warnings and Precautions, Drug Abuse and Dependence].*

INDICATIONS AND USAGE

Quillivant XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The efficacy of Quillivant XR was established in a 2-week, placebo-controlled, laboratory classroom, crossover study in children aged 6-12 years with a diagnosis of ADHD. Patients in the trial met DSM-IV-TR® criteria for ADHD. Accumulated efficacy data from other methylphenidate products were also considered.

CONTRAINDICATIONS

Hypersensitivity to Methylphenidate or other Components of Quillivant XR. Quillivant XR is contraindicated in patients known to be hypersensitive to methylphenidate, or other components of Quillivant XR. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other methylphenidate products.

Monoamine Oxidase Inhibitors Quillivant XR is contraindicated during treatment with monoamine oxidase inhibitors, and also within 14 days following discontinuation of treatment with a monoamine oxidase inhibitor (MAOI), because of the risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS

Potential for Abuse and Dependence CNS stimulants, including Quillivant XR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy [*see Drug Abuse and Dependence*].

Serious Cardiovascular Reactions Stroke and myocardial infarction have occurred in adults treated with CNS stimulants at recommended doses. Sudden death has occurred in children and adolescents with structural cardiac abnormalities and other serious cardiac problems, and in adults taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during treatment with Quillivant XR.

Blood Pressure and Heart Rate Increases CNS stimulants cause an increase in blood pressure (mean increase approximately 2 to 4 mmHg) and heart rate (mean increase approximately 3 to 6 bpm). Individuals may have larger increases. Monitor all patients for hypertension and tachycardia.

Psychiatric Adverse Reactions Exacerbation of Pre-Existing Psychosis CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder.

Induction of a Manic Episode in Patients with Bipolar Disorder CNS stimulants may induce a manic or mixed episode in patients. Prior to initiating treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression).

New Psychotic or Manic Symptoms CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing Quillivant XR. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients, compared to 0 in placebo-treated patients.

Long-Term Suppression of Growth CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants, including Quillivant XR. Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or nonmedication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and nonmedication-treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth; however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

ADVERSE REACTIONS

Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. *Clinical Trials Experience with Other Methylphenidate Products in Children, Adolescents, and Adults with ADHD* Commonly reported (≥2% of the methylphenidate group and at least twice the rate of the placebo group) adverse reactions from placebo-controlled trials of methylphenidate products include: appetite decreased, weight decreased, nausea, abdominal pain, dyspepsia, dry mouth, vomiting, insomnia, anxiety, nervousness, restlessness, affect lability, agitation, irritability, dizziness, vertigo, tremor, blurred vision, blood pressure increased, heart rate increased, tachycardia, palpitations, hyperhidrosis, and pyrexia. *Clinical Trials Experience with Quillivant XR in Children and Adolescents with ADHD*. There is limited experience with Quillivant XR in controlled trials. Based on this limited experience, the adverse reaction profile of Quillivant XR appears similar to other methylphenidate extended-release products. The most common (≥2% in the Quillivant XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 45 ADHD patients (ages 6-12 years) were affect lability, excoriation, initial insomnia, tic, decreased appetite, vomiting, motion sickness, eye pain, and rash.

Table 2. Common Adverse Reactions occurring in ≥2% of subjects on Quillivant XR and greater than placebo during the controlled cross-over phase

Adverse reaction	Quillivant XR (N=45)	Placebo (N=45)
Affect lability	9%	2%
Excoriation	4%	0%
Initial Insomnia	2%	0%
Tic	2%	0%
Decreased appetite	2%	0%
Vomiting	2%	0%
Motion sickness	2%	0%
Eye pain	2%	0%
Rash	2%	0%

Postmarketing Experience The following adverse reactions have been identified during post approval use of methylphenidate products. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These adverse reactions are as follows:

Blood and Lymphatic System Disorders: Pancytopenia, Thrombocytopenia, Thrombocytopenic purpura
Cardiac Disorders: Angina pectoris, Bradycardia, Extrasystole, Supraventricular tachycardia, Ventricular extrasystole
*Eye Disorder*s: Diplopia, Mydriasis, Visual impairment
General Disorders: Chest pain, Chest discomfort, Hyperpyrexia
Immune System Disorders: Hypersensitivity reactions such as Angioedema, Anaphylactic reactions, Auricular swelling, Bullous conditions, Exfoliative conditions, Urticarias, Pruritus NEC, Rashes, Eruptions, and Exanthemas NEC
Investigations: Alkaline phosphatase increased, Bilirubin increased, Hepatic enzyme increased, Platelet count decreased, White blood cell count abnormal
Musculoskeletal, Connective Tissue and Bone Disorders: Arthralgia, Myalgia, Muscle twitching
Nervous System Disorders: Convulsion, Grand mal convulsion, Dyskinesia
Psychiatric Disorders: Disorientation, Hallucination, Hallucination auditory, Hallucination visual, Mania
Urogenital System: Priapism
Skin and Subcutaneous Tissue Disorders: Alopecia, Erythema
Vascular Disorders: Raynaud's phenomenon

DRUG INTERACTIONS

MAO Inhibitors Do not administer Quillivant XR concomitantly with monoamine oxidase inhibitors or within 14 days after discontinuing MAOI treatment. Concomitant use of MAOIs and CNS stimulants can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure.

USE IN SPECIFIC POPULATIONS

Pregnancy Pregnancy Category C Risk Summary There are no adequate or well-controlled studies with Quillivant XR in pregnant women. Adverse pregnancy outcomes, including premature delivery and low birth weight, have been seen in mothers dependent on other stimulant products such as amphetamines. Methylphenidate showed some potential for teratogenicity when pregnant animals were treated during organogenesis: an increased incidence of fetal spina bifida in rabbits at 40 times the maximum recommended human dose (MRHD), on a mg/m^2 basis, and an increased incidence of fetal skeletal variations in rats at 7 times the MRHD. A decrease in body weight gain was seen in the offspring of rats treated with methylphenidate throughout pregnancy and lactation at 4 times the MRHD. Quillivant XR should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Clinical Considerations Stimulant medications, such as Quillivant XR, cause vasoconstriction and thereby decrease placental perfusion. Infants born to amphetamine dependent mothers have an increased risk of premature delivery and low birth weight. Monitor infants for symptoms of withdrawal such as feeding difficulties, irritability, agitation, and excessive drowsiness. Animal Data In studies conducted in rats and rabbits, methylphenidate was administered orally at doses of up to 75 and 200 mg/kg/day, respectively, during the period of organogenesis. Teratogenic effects (increased incidence of fetal spina bifida) were observed in rabbits at the highest dose, which is approximately 40 times the maximum recommended human dose (MRHD) on a mg/m^2 basis. The no effect level for embryo-fetal development in rabbits was 60 mg/kg/day (11 times the MRHD on a mg/m^2 basis). There was no evidence of specific teratogenic activity in rats, although increased incidences of fetal skeletal variations were seen at the highest dose level (7 times the MRHD on a mg/m^2 basis), which was also maternally toxic. The no effect level for embryo-fetal development in rats was 25 mg/kg/day (2 times the MRHD on a mg/m^2 basis). When methylphenidate was administered to rats throughout pregnancy and lactation at doses of up to 45 mg/kg/day, offspring body weight gain was decreased at the highest dose (4 times the MRHD on a mg/m^2 basis), but no other effects on postnatal

CONTINUED FROM **PAGE 19**

the person experiencing IPV before documenting it in the chart because the perpetrator, if he is the father of the child, has access to the medical record and may inadvertently discover the content of your conversation. Direct quotes should be used whenever possible in the documentation. Many institutions have used cryptic acronyms ("MIPV + / - / ?" for maternal IPV positive/negative/unknown) to document IPV status. "Unknown" status can indicate that IPV screening was not performed or that the provider suspected abuse but was unable to screen for confidentiality reasons. Other institutions have created "shadow charts" to document IPV and other social problems when confidentiality is of great importance. These charts are separate from the official medical record.

ASSESS SAFETY AND WILLINGNESS TO LEAVE

After obtaining a positive IPV screen, the best response is to pause and allow the parent an opportunity to speak in more detail (Table 4). A statement such as "Tell me more about this . . ." is appropriate. In addition, let the parent know that she does not deserve to be treated that way and that help is available. The next best step is to assess the parent's willingness to change her situation by asking, "Have you thought about what you might want to do about this situation?" or "Would you like to speak to a counselor about this?" Alternatively, tell the parent that "there is a menu of options for you to consider in terms of next steps," thereby allowing her to make empowered decisions.

An assessment of safety is also critically important and may include the following questions:

- "Is it safe for you to go home today?"
- "What have you been doing to keep yourself and your children safe?"
- "Do you think the abuse is getting worse?"
- "Are drugs or alcohol influencing the abuse?"
- "Does your partner have access to weapons?"

IPV counselors are especially skilled in assessing safety and developing safety plans.[35] Given that the risk of mortality from IPV increases when a person

attempts to leave, collaboration with an IPV counselor can be extremely valuable. Physicians should never advise a caregiver experiencing IPV to "just leave" without ensuring that a well-designed safety plan is in place.

An assessment for child abuse must take place if a parent discloses IPV. Ask the parent how she believes that the IPV has affected her child and whether the child has been physically or emotionally abused by the perpetrator. If child abuse is present, it must be reported to Child Protective Services. In a few states, clinicians are mandated to report childhood IPV exposure or IPV; thus, it is imperative to know your state's reporting law and to make caregivers aware of these requirements before you screen.[35] Your local IPV agency should be able to provide this information for you.

REFER AND PROVIDE RESOURCES

If a parent discloses IPV to you, offer to contact your local IPV hotline from an office telephone. IPV counselors have a unique set of skills and resources that may not be available to health care professionals or traditional social workers. First and foremost, they have the time to devote exclusively to this issue. They can develop individualized plans for physical, sexual, emotional, financial, and technological safety. Furthermore, IPV counselors are familiar with IPV-related legal issues, such as child custody, restraining orders, and divorce.

IPV programs provide far more than shelter; most of them also offer personal IPV advocates, counselors, and legal aid. If you do not have a local IPV counselor, you may find one locally through the national IPV hotline (1-800-799-SAFE[7233]) or online at www.thehotline.org. Children exposed to IPV should also be referred to mental health services, preferably those that use a trauma-informed approach.[35]

Summary

IPV is a toxic stressor that is associated with a wide range of adverse physical and mental health outcomes. Physicians who routinely screen for IPV can connect patients and their parents to services that have been shown to improve the safety and well-being of IPV-affected families. Screening for IPV requires effective training and a clear office protocol, both of which can be developed through collaboration with a local IPV agency. CP

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COMMENTARY BY MICHAEL G BURKE, MD

Exercise has positive effects on children with ADHD

Engaging in moderately intense aerobic exercise for just 20 minutes leads to improved neurocognitive function and inhibitory control in children with attention-deficit/hyperactivity disorder (ADHD), a recent study shows. For this trial, investigators recruited 20 children aged 8 to 10 years who had diagnosed or suspected ADHD and no comorbid conditions. Participants completed brief intelligence tests and were evaluated for disruptive behaviors and other measures of ADHD.

After baseline testing, all participants, including healthy matched controls, visited a laboratory on 2 separate days and spent 20 minutes either sitting and reading or working out on a treadmill. They were then assessed for the inhibitory aspects of cognitive control with a screen-based task. At the same time, investigators performed neuroelectric assessments of brain responses to this task and conducted assessments of reading comprehension, spelling, and arithmetic.

Children in both the ADHD group and the control group performed better on tests of reading comprehension and arithmetic after exercising than after sitting or reading, although children with ADHD performed less well than those in the control group on the cognitive control task. Both groups also exhibited greater response accuracy and stimulus-related processing. In addition, after the single 20-minute session of exercise, children with ADHD also showed selective enhancements in regulatory processes, compared with their performance after sitting (Pontifex MB, et al. *J Pediatr.* 2013;162[3]:543-551).

COMMENTARY

I am reminded of an experienced teacher who regularly sent a fidgety second grader on an errand to deliver a note to the gym teacher. The note requested that the gym teacher allow the courier to run 5 laps around the gym while waiting for the gym teacher to send a fictional response. The improved performance after exercise in both children with ADHD and controls offers another argument for retaining active recess and physical education classes in elementary school curricula.

—Michael Burke, MD

LESS EXPOSURE TO SCREEN VIOLENCE IMPROVES PRESCHOOLERS' BEHAVIOR

Substituting educational programming for aggression-filled TV and video viewing can significantly enhance the overall social and emotional competence of preschool-aged children, a group of Seattle investigators has shown.

In a trial involving more than 500 3- to 5-year-old children recruited from area pediatric practices, investigators provided the treatment group with a "media diet" that focused on the content of what the preschoolers watched, not how much time they spent in front of a screen (daily average of 74 minutes). Case managers made an initial home visit to discuss the child's current media use, provide intervention handouts, and help the parents set goals, emphasizing replacing exposure to violent television with educational/prosocial programming.

The initial visit was followed by monthly newsletters and phone calls, as well as program guides tailored to participating families' television service. The control group received a nutrition intervention with analogous monthly newsletters promoting healthy food choices and monthly check-in calls.

Although time spent exposed to media violence was the same for the intervention and control groups at baseline, at 6 months the intervention group had

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significantly less exposure both in terms of minutes per day (22.4 vs 29.7 minutes) and as a proportion of total daily screen time (22.9% vs 30%).

Using the Social Competence and Behavior Evaluation parent version scale (the higher the score, the better), investigators compared the intervention and control groups at 6 months, finding that the intervention group had a 2.11-point better score than the control group. Compared with the control group, the intervention group also showed less externalizing (angry, aggressive, oppositional) behavior and more social competence. The intervention also had a positive effect on internalizing (anxious, depressive, withdrawn) behavior, although that difference was not statistically significant. Boys from low-income families seemed to benefit the most from the intervention (Christakis DA, et al. *Pediatrics*. 2013;131[3]:431-438).

COMMENTARY

The authors suggest that rather than fighting a losing battle trying to get parents to limit screen time, perhaps we should change tactics by helping parents to choose wisely from the dozens of viewing options available all day and night. But first we'll need to see more evidence that this approach has a positive impact—not only on childhood behaviors but on language development; time spent in unstructured, outdoor play; and obesity. I don't think I am ready to throw in the towel just yet.

—Michael Burke, MD

IS EARLY OTITIS MEDIA ASSOCIATED WITH IBD?

An analysis of 2 decades of data from a Canadian population-based database indicates that the answer to this question is "yes." The large sample size—2,671 children—included 294 with an inflammatory bowel disease (IBD) diagnosis, made at a mean age of 13.1 years. At 1 year of age, 50% of children later found to have IBD had at least 1 diagnosis of otitis media, compared with 48% of controls. By age 2, 72% of children with IBD and 68% of controls had an otitis media diagnosis, with the percentages rising to 89% and 82%, respectively, by age 5.

Investigators determined that the relationship between otitis and IBD was significant whether the type of IBD was ulcerative colitis (UC) or Crohn disease (CD), although the association was stronger for UC. Whereas having a diagnosis of otitis media by age 1 year was associated with a more than 2-fold greater likelihood of being diagnosed with CD, it was 3-fold greater for developing UC. When both types of IBD were considered, those with an otitis media diagnosis by age 1 year were 2.8-fold more likely to develop IBD than children who never received an otitis media diagnosis. The odds were similar at 5 years of age (Shaw SY, et al. *J Pediatr.* 2013;162[3]:510-514).

COMMENTARY

Is the diagnosis of otitis media simply a proxy for exposure to antibiotics in these children? The authors think so. In 1 of 4 hypotheses to explain the increased odds of IBD in this population, the authors suggest that antibiotics alter intestinal microflora with long-lasting effects on gut homeostasis and later risk of IBD. This theory serves as a reminder that whatever we do to treat our patients today has the potential for both intended and unintended consequences, sometimes years later.

—Michael Burke, MD

Also of Note

Recruiting young women for HIV screening via a social network is an effective strategy. Investigators enlisted more than 150 young women, primarily black and Hispanic/Latina, to recruit members of female friendship networks to undergo HIV screening. The 150 enlisters recruited a total of 381 network members, 90% of whom agreed to be screened for HIV (Boyer CB, et al. *JAMA Pediatr.* 2013;167[3]:289-296).

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ACNE AND THE ADOLESCENT
A PRACTICAL APPROACH TO MANAGEMENT

MIRIAM WEINSTEIN, MD

Acne flare-ups in adolescents respond best to treatment when patients and parents understand what acne is, follow their therapy guidelines, and have reasonable expectations about what therapy can achieve.

Acne is common and often prompts the patient to seek medical advice. It classically starts in the pubertal years, although individuals with an early adrenarche may develop acne in the prepubertal years. When these changes occur markedly before puberty or are accompanied by evidence of true precocious puberty or androgen excess, a workup should be considered. This review focuses on care for the typical adolescent with acne.

Pathophysiology

Four key pathophysiologic processes, involving the pilosebaceous unit, lead to the development of acne: 1) abnormal keratinization of the follicle, 2) sebum accumulation in the follicle, 3) active role of *Propionibacterium acnes*, and 4) inflammation. The pilosebaceous unit consists of a sebaceous gland attached at its opening to a hair follicle. The hair follicle opens to the surface of the skin (with or without a visible hair); follicular ostia on the face are commonly referred to as "pores."

Comedones, the initial lesions in acne, are hair follicles obstructed by keratinocytes and sebum, which is an oily, lipid-containing substance. When the follicular ostia are open, we refer to open comedones or "blackheads;" when the ostia are

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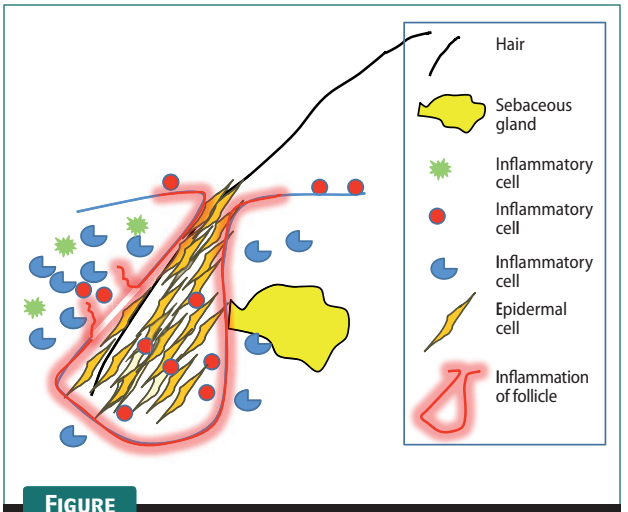
closed, the lesions are called closed comedones or "whiteheads."

Early development of "microcomedones" begins with disrupted shedding of keratinocytes into the follicular lumen.[1] These cells are produced more rapidly than normal and are more adherent to one another, thereby blocking the follicular orifice rather than being extruded through that orifice. An increase in androgen levels, typical during adrenarche, stimulates the sebaceous glands to produce sebum, which is secreted into the hair follicle. This secretion enables trapping of shed skin cells. When pressure builds up, the now larger comedo can rupture, allowing keratin and sebum to leak out, stimulating an inflammatory response with clinically evident papules, pustules, and nodules.

Even before rupture of the comedo, inflammation plays a role as increased inflammatory cells and cytokines are evident before the disruption of epithelial turnover (Figure). Finally, *P acnes*, a gram-positive rod, inhabits the sebaceous gland and stimulates inflammation and comedo rupture through a variety of pathways.

Many patients, parents, and physicians believe that dirt, sweat, and surface oils are the cause of acne and therefore that cleansing plays a key role in acne management. As noted above, acne is not a result of poor hygiene, and minimal evidence exists to support cleansing routines as a major intervention.[2] Some cleansers have medicinal additives (eg, salicylic acid or benzoyl peroxide [BPO]), and any benefit from these cleansers is likely due to their medicinal properties and not their cleansing role. Given that many acne medications are drying or irritating, it is reasonable to direct patients to mild cleansing products.

There is often a concern that diet plays a role in acne development. Although a large body of strong evidence is not yet available to substantiate this, some emerging data do indicate that diet may play a role. The dietary culprits include dairy products and foods with a high glycemic index, and several theories as to pathogenesis have been suggested.[3-7] However, there are not enough data yet to suggest specific dietary changes as therapeutic interventions for acne. A well-balanced diet based on national food-selection guides (eg, My Plate, US Department of Agriculture) is the best recommendation at this time.



FIGURE

Illustration of acne pathogenesis.

Morphology and distribution

Early acne develops at the center of the face (nose, chin, and forehead) in what is commonly known as the T-zone. It may spread from there to involve the cheeks and continue to spread to involve the chest and back. Not everyone develops acne in all areas. Patients also have a varying number of open or closed comedones and inflammatory lesions. Closed comedones can sometimes be difficult to identify, appearing as tiny flesh-colored papules.

It is important to recognize healing lesions. These can present as fading red papules or macules or hyperpigmented macules (post inflammatory hyperpigmentation). Patients often believe that treatments have failed because they still see marks on their faces. They may in fact have had substantial improvement in their active acne and need to recognize that full healing takes time.

It is also important to recognize scars, or lesions with the potential to scar, because these indicate the need for more aggressive management options. Scars can be papular, atrophic, or keloidal. Sometimes it is very challenging to

TABLE 1 Topical therapies for acne

Therapeutic class	Possible combinations
Topical retinoids	
• Tretinoin • Creams (0.025%, 0.05%, 0.1%) • Gels (0.01%, 0.025%) • Micro gels (0.04%, 0.1%)	Clindamycin–tretinoin; erythromycin–tretinoin
• Adapalene • Cream (0.1%) • Gels (0.1%, 0.3%)	Adapalene–BPO
Topical antibiotics	
• Clindamycin	Clindamycin–BPO; clindamycin–tretinoin
• Erythromycin	Erythromycin–BPO; erythromycin–tretinoin
• Dapsone	
• Sodium sulfacetamide	

Abbreviation: BPO, benzoyl peroxide.

Points Taken

Acne is not a result of poor hygiene and minimal evidence exists to support cleansing routines as a major intervention.

differentiate true scarring (a permanent alteration in the skin) from lesions with the potential to scar but that may still resolve. Accurate differentiation may require a referral to a dermatologist.

Excoriations often suggest that the patient has been "picking." Excoriating acne lesions is often a bad habit or stress-related activity; it can increase the risk of scarring and delay lesion healing. In addition, the acne will look worse and the excoriations will not necessarily respond to traditional treatments as primary lesions do. This is particularly important to point out to patients who think that they are not healing fast enough or that treatment is failing. When excoriations are extensive, there may be underlying psychological issues that need to be addressed.

Management

The best management plan starts with patient education. Successful therapy is much more likely when patients and parents understand what contributes to acne development, the natural history of acne, and how to properly use their medications. They also must have reasonable expectations about what therapy can achieve.

General education should include an explanation that the degree of acne varies not only between people, but also within a patient over time. It is a chronic condition that can wax and wane, often unpredictably. Patients should understand that the goal of therapy is control of acne, not a "cure," and that even with excellent control, some lesions are likely to appear from time to time. Therapeutic goals include reducing active lesions, preventing new lesions, and limiting scar formation.

Educating about sun protection is important in acne patients because the retinoids and several of the oral antibiotics prescribed can make patients more sensitive to the effects of ultraviolet radiation. Many people believe that the sun makes their acne better; however, there is no good evidence that sunlight plays a role as a management strategy.[5] Furthermore, the risks of such exposure outweigh the benefits.

Several classes of medications are used for acne treatment, each with many products. The following discussion summarizes the features and roles of the different classes and selection of the correct treatment for different acne presentations.

RETINOIDS

Retinoids are comedolytic agents (ie, they debride the plugged follicle); they can have some anti-inflammatory effects and can prevent new comedones from forming. Thus, they play an important role in treating comedonal acne and inflammatory acne, and have a maintenance role in helping to prevent new lesions. Retinoids normalize the process of keratinization and turnover of the epithelium. The 2 main topical retinoids are adapalene and tretinoin, which come in different strengths and vehicles and are available as single agents or as combination products with antibiotics or BPO (Table 1).

Tazarotene is a potent topical retinoid for more significant acne, and isotretinoin is an oral retinoid indicated for severe or scarring acne. Isotretinoin

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requires referral to a dermatologist, and its use is not discussed here. Pediatricians should become comfortable using topical retinoids because they form a major part of the therapy for acne. Yentzer and colleagues found that dermatologists prescribed topical retinoids considerably more frequently than pediatricians.[8]

Topical retinoids are useful for removing comedones and helping to prevent new flare-ups and also have some anti-inflammatory properties. Because acne is a chronic and recurrent condition, it is reasonable to consider keeping patients on retinoids for longer-term maintenance between flares.[9] Retinoids can cause xerosis, irritation of the skin, and even irritant dermatitis. They also make patients more sensitive to the effects of ultraviolet radiation. Patients with dry or atopic skin or those poorly tolerant to the irritating effects would do better with a milder strength or cream rather than a gel-based product.

Another strategy to improve tolerance is to use retinoids every second or third night, with an increase to nightly use if tolerated. Patients should be advised to refrain from laser therapy, waxing for hair removal, and exfoliating in treated areas because this can increase the risk of irritation or tissue injury. Because retinoids are teratogenic, their use (even topical) should be avoided during pregnancy. Tretinoin can be unstable with ultraviolet radiation exposure and thus should be applied at bedtime. Often a retinoid will cause acne lesions to become more prominent after initiation of therapy, and patients must be advised of this.

ANTI-INFLAMMATORY AGENTS

These agents include topical BPO and topical and oral antibiotics. All these products reduce *P acnes* and also directly reduce inflammation. BPO has an advantage because it does not seem to induce bacterial resistance in the way the antibiotics can. Therefore, even if BPO would not be enough as a single therapy for substantial acne, it should be considered as an adjunct when antibiotics are used. Several products on the market combine a topical antibiotic and BPO. BPO is also available as over-the-counter washes and leave-on products that can be incorporated into a management routine. Rarely, patients can develop an allergic contact dermatitis to BPO and therefore should not use it. Patients should be warned that BPO can bleach fabrics.

TABLE 2 Oral antibiotics and typical doses for acne

Antibiotic	Typical oral dose for acne
Doxycycline	50-100 mg BID
Erythromycin	250-500 mg BID
Minocycline	50-100 mg BID
Tetracycline	250-500 mg BID

Points Taken

- **There are not enough data yet to suggest specific dietary changes as therapeutic interventions for acne.**

Topical antibiotics typically include erythromycin, clindamycin, sodium sulfacetamide, and the newer topical dapsone. These are good treatments for mild-to-moderate inflammatory acne and, as mentioned above, clinicians should strongly consider adding BPO to the regimen either as a combination product or a separate product. Clindamycin and erythromycin are available in combination products with BPO (Table 1). Topical dapsone, used twice daily, is well tolerated and has good clinical efficacy.[10] It does not appear to be a problem for patients with G6PD deficiency. Topical dapsone should be applied at a separate time from BPO (and after all BPO is removed) because the 2 products together may lead to a benign but undesirable discoloration of the skin.[11]

Oral antibiotics are usually reserved for moderate acne, often after a trial of topical therapy has failed (Table 2). The tetracycline-based antibiotics are the classic treatments for acne. Tetracycline works well for acne, but because it cannot be taken with food, this often leads to compliance problems or poor absorption.

Minocycline is widely used and sometimes considered superior to other acne treatments; however, this belief is not supported by a recent Cochrane

review.[12] In addition to showing the same types of adverse effects as are possible with all tetracyclines, such as pseudotumor cerebri, gastrointestinal upset, and photosensitivity, minocycline has been associated with dyspigmentation of the skin and lupus-like reactions in rare cases.[13]

Doxycycline is also used for acne. Because tetracyclines can stain the teeth, they are usually avoided in children aged younger than 9 years. For younger children requiring oral therapy, the macrolide antibiotics such as erythromycin have been used. A variety of other antibiotics (eg, trimethoprim, azithromycin) have been used to treat the inflammatory components of acne.

Antibiotic resistance of *P acnes* is a concern because antibiotics are often used chronically or repeatedly, and resistance may manifest as treatment failures.[14] Of more ominous concern are data suggesting that antibiotics can change the resistance patterns in *Staphylococcus aureus* and *Streptococcus pyogenes* when they are used to treat acne.[15,16] Because the tetracyclines and trimethoprim, both used for acne, are also used for methicillin-resistant *S aureus*, it is important to avoid creating antibiotic resistance to pathogenic organisms while chronically treating acne. Treatment strategies to help prevent this include limiting monotherapy with antibiotics, considering retinoids instead for maintenance therapy, using BPO in therapeutic routines, and avoiding prolonged courses of oral antibiotics.[17]

Points Taken

- **Acne is a chronic condition that can wax and wane, often unpredictably.**
- **The best management plan starts with patient education.**

HORMONAL THERAPY

Oral contraceptives (OCs) have been used for acne and may be a good choice for females who experience perimenstrual flares or those with features of polycystic ovary syndrome. Estrogen may act by inhibiting androgen production at the gonadal level or by blocking the effects of androgens at the sebaceous glands.[1] There is no clear superiority of 1 OC over another, and treatment trials are often needed to assess relative benefits and adverse effects. Therapy must be continued for several months before assessing therapeutic effect.

Some OCs are labeled with an indication for acne, but even those not marketed for acne may have some off-label benefit. Patients should receive the standard counseling about the risks and benefits of OC use. Antiandrogen therapies are sometimes used, but are outside the scope of this review and are not typical of adolescent acne management.

AZELAIC ACID

Azelaic acid helps regulate the disordered keratinization of the follicular unit, aiding in comedonal control, and also inhibits *P acnes*, thereby reducing some of the inflammation. It is typically applied twice daily.

SALICYLIC ACID

Salicylic acid is available in over-the-counter preparations. This agent is comedolytic, can be mildly anti-inflammatory, and acts to "dry up" active lesions. Because it is drying and can cause irritation, caution should be used if retinoids are also prescribed.

Developing a therapeutic plan

Pediatricians can play an important role in managing mild-to-moderate acne. (Table 3) describes the appropriate first-line therapies.

MILD ACNE

Mild acne is usually treated with topical therapy. Topical products are available in various vehicles. Gels and solutions are less likely to have a greasy feeling on the skin but may be too drying or irritating for patients with dry or atopic skin. Creams are more moisturizing and may be good choices for patients with dry skin or those easily irritated, but may feel too greasy for some patients, especially those with very oily skin.

Patients with primarily comedonal acne benefit from starting with a topical retinoid, although adding an anti-inflammatory product helps reduce the inflammation that may occur during

initial retinoid therapy. Patients with mostly inflammatory acne should use topical antibiotics and topical BPO to treat active lesions, but would also benefit from adding a retinoid to this regimen to help with longer-term control of new comedones.

Combination products allow expansion of therapy while using only 1 or 2 topical products; however, there is no product that contains all 3 agents: BPO, a retinoid, and an antibiotic. Many patients will be compliant with use of only 1 product per day, and selecting the product that best fits the morphology of their acne would be a good starting place.

It is important to educate patients on how to apply topical therapy. The medication must be applied to the area or "field" where acne is occurring, and not just on the individual lesions. A thin layer applied to this area is usually sufficient. Patients often need 6 to 12 weeks of continuous therapy before assessing the benefit. This is longer than many patients will continue treatment unless they have physician guidance.

If a patient's acne fails to respond to first-line therapy, it is important to ensure that the patient complied with the use of the medication as intended. If the patient was compliant, then a switch to a different product or a different class of medication is warranted.

MODERATE ACNE

Patients with moderate acne may still benefit from topical therapy and can be offered this choice. However, oral therapy is often needed. Oral antibiotics are a good choice, but it is still useful to add a topical retinoid to address any comedones and help prevent new lesions, and it is suggested to use topical BPO (as a wash or a leave-on product) to reduce bacterial resistance from the oral therapy.

Some patients resist using topical therapy while they are also taking oral therapy. Physicians should highlight why multimodal therapy is preferred. Usually 4 to 12 weeks of treatment for moderate acne are needed to assess success. Ideally, the patient would be maintained on topical therapy, and an oral antibiotic would be reinstituted when flare-ups are no longer controlled by topical therapy. This strategy is preferable to chronic, long-term antibiotic use.

Some patients may experience flare-ups shortly after discontinuing oral antibiotics and may need them frequently; it might be reasonable to refer these cases to a dermatologist to consider isotretinoin.

Females with premenstrual flares, those who have failed oral antibiotics, or those who desire OCs for other reasons can consider hormonal therapy. Hormonal therapy can be used in conjunction with topical retinoids, BPO, or even with oral antibiotics. Often a longer course (at least 3 months) is needed to assess the benefits from OCs.

Patients with unyielding acne or scars, scarring potential, or deep nodulocystic acne should be referred to a dermatologist.

TABLE 3 Selection of first-line therapies for acne

State of acne	Comedonal acne	Inflammatory acne (papules, pustules)
Mild	Topical retinoid	Topical retinoid AND topical BPO or antibiotic–BPO combination
Moderate	Topical retinoid	Topical retinoid AND topical BPO or antibiotic–BPO combination OR Topical retinoid AND topical BPO and oral antibiotic +/– hormonal therapy
Severe	Refer to dermatologist to consider isotretinoin	
Maintenance	Consider topical retinoid for prevention and reduction of flares	

Abbreviation: BPO, benzoyl peroxide.

Points Taken

- **Some OCs are labeled with an indication for acne but even those not marketed for acne may have some off-label benefit.**
- **A variety of techniques are available to improve scars caused by acne.**

Patients should understand that the goal of therapy is control of acne, not a "cure," and that even with excellent control, some lesions are likely to appear from time to time.

Adjunctive therapy

Chemical peels and intralesional steroids applied to deep lesions are examples of adjunctive therapies sometimes used by dermatologists. A variety of techniques are available to improve scars caused by acne, such as laser treatments, filler injections, and small surgical procedures. Referral to a cosmetic dermatologist or plastic surgeon is suggested.

Summary

Most acne can be well controlled. Patient education is key because success is more likely when patients have a good understanding of why their acne occurs, the natural history of acne, the proper use of medications, and reasonable expectations of therapy. Selecting the correct treatment is an art that must address lesion morphology, extent of acne, patient preference regarding product choice and application, adverse-effect profile, and motivation of the patient to engage in therapy.

A wide variety of topical and oral therapies exist, so pediatricians can tailor the treatment regimen to the principles of acne therapy and the individual needs of the patient. Reevaluation and reeducation over time, and modifying the treatment if necessary, will ensure the most successful outcomes. CP

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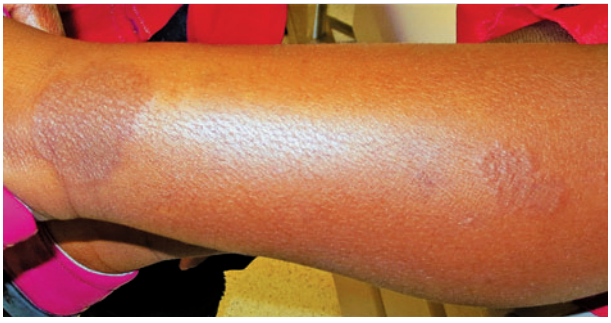

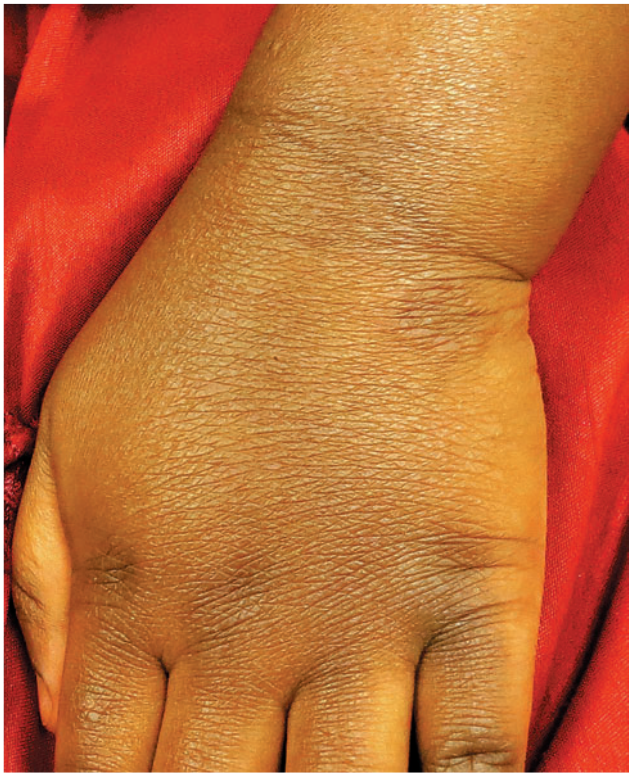

An urgent call for a puzzling ring!

MEGAN RYBARCZYK, MS4

THE CASE

You are called to the emergency room to examine a 3.5-year-old girl from Cameroon with several well-demarcated, indurated, and hyperpigmented plaques on the dorsum of her left hand and left lower leg and foot that have been slowly progressive for 4 weeks. The mother is quite anxious and seeks your input. She thinks it might be ringworm, but she is worried because there are so many lesions. The child's history and the remainder of the physical examination are unremarkable.

FOR DISCUSSION SEE PAGE 38

TELL US ON FACEBOOK

Have you ever seen a case like this in your practice? How did you resolve it? Share your story with us on Facebook.
facebook.com/ContemporaryPediatrics

PHOTOS COURTESY OF ANNIE GROSSBERG

MS RYBARCZYK is a fourth-year medical student at the Johns Hopkins School of Medicine, Baltimore, Maryland. DR COHEN, the section editor for Dermatology: What's Your Dx?, is director, Pediatric Dermatology and Cutaneous Laser Center, and associate professor of pediatrics and dermatology, Johns Hopkins University School of Medicine, Baltimore. The author and section editor have nothing to disclose regarding affiliation with or financial interest in any organization that may have an interest in any part of this article. Vignettes are based on real cases that have been modified to allow the author and editor to focus on key teaching points. Images may also be edited or substituted for teaching purposes.

DIAGNOSIS:

Granuloma annulare, localized type

CLINICAL FINDINGS

Granuloma annulare (GA) is a benign, self-limited, usually asymptomatic eruption most commonly occurring in children.[1,2] The primary skin lesions are usually round, annular, or serpiginous 1-cm to 5-cm nonscaling violaceous plaques with moderately indurated borders and central clearing or hyperpigmentation. Additionally, 1-mm to 2-mm papules may form an interrupted border and, rarely, may be present centrally.[2,3] The plaques are typically in a symmetrical distribution with a predilection for the distal extremities.[3]

GA presents in several subtypes: localized, generalized, subcutaneous, perforating, or patch. In localized GA—the subtype present in our patient—the dorsa of the hands and feet are the most commonly affected areas, but the ankles, legs, wrists, elbows, and even palms may also be involved.[3,4]

EPIDEMIOLOGY

The epidemiology of GA has not been well studied. For localized GA, the onset is usually under 30 years of age.[2] It is thought that GA affects mostly women, with the sex ratio most commonly reported as 2:1 or 2.5:1,[2,3] although some controversy does exist.[4] There are also reports of multiple family members with GA, suggesting a possible genetic component.[4]

Associations between GA and the future development of diabetes mellitus, autoimmune thyroid disease, malignancies, drug allergies, hypertension, arthritis, and HIV/AIDS have been suggested or investigated.[1] However, none have been consistently or definitively proven.

HISTOLOGY

Although a biopsy is not usually required for diagnosis, if the decision to perform a biopsy is made, the most common pattern seen in localized GA is characteristic palisading lymphohistiocytic inflammation surrounding a central core of necrobiosis in the superficial and mid-dermis.[5]

TREATMENT

There are no randomized trials involving the treatment of GA.[2] Only case reports describing varying success with the use of topical or intralesional corticosteroids, interferon, vitamin E, retinoids, dapsone, chlorambucil, chloroquine, niacinamide, fumaric acid esters, pimecrolimus, tacrolimus, injection of sterile water, CO_2 laser, cryotherapy, radiotherapy, ultraviolet light, cryosurgery, and surgical excision have been reported in the literature.[2,4]

Despite the paucity of evidence, treatment—particularly in children— is largely unnecessary because GA is usually asymptomatic and self-resolves in a few months to a few years.[2] Moreover, many of the treatments described may be painful and lead to scarring or atrophy.

DIFFERENTIAL DIAGNOSIS

GA is most commonly confused with tinea corporis,[2] as it was in our case. The most important differences to keep in mind are the presence of pruritus, scaling, and peripheral pustules in tinea corporis. If additional data is needed, a potassium hydroxide preparation and a fungal culture may be obtained and would only be positive in the case of tinea corporis. Contact dermatitis and nummular eczema as well as psoriasis and pityriasis rosea may also produce annular lesions, but like tinea corporis clinical findings include epidermal changes (eg, scale, lichenification, crusting); and psoriasis, contact dermatitis, and nummular eczema are associated with pruritus.

OUR PATIENT

We reassured the patient's mother of the innocent course of granuloma annulare and scheduled her daughter for a follow-up visit in 5 to 6 months.

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Winning the pediatric office paper chase

While many pediatricians still rely on paper, a nearly paperless system is not far off.

Most resourceful pediatric practices have discovered ways to avoid becoming overwhelmed with the volumes of paper-based information that we collect and distribute every day. More than just a way to preserve our rainforests, optimizing paper utilization is another way to improve a practice's workflow (see "Pediatrics V2.0," *Contemporary Pediatrics*, March 2013). In this installment of Pediatrics V2.0, we'll discuss improving forms and information handout use and detail ways to reduce the amount of paper you use each day.

Paper in perspective

An American Academy of Pediatrics (AAP) survey from 2009 showed pediatricians have lagged behind other specialties in adopting electronic health records (EHRs), with only 6% of pediatricians at the time using a comprehensive EHR system and only 25% using a basic EHR system.[1] Despite incentives to go electronic, many pediatricians continue to use a paper-based charting system. A chart for a high school-aged child can contain dozens and sometimes hundreds of sheets of paper depending on the number of ill visits, lab tests, x-rays, and consultations the child has accumulated. Not uncommonly, our more complicated patients have their medical charts overflow to 2 or 3 volumes in a matter of months.

There are many problems with this conspicuous consumption of paper; it can be difficult to locate important information quickly in a medical chart, many sheets of paper need to be copied when a patient transfers from one practice to another, and large amounts of space are needed to store both active and inactive medical charts.

Courageous pediatricians who have implemented EHRs are still heavily dependent on paper-based documentation. The reason? The universal "currency" of information exchange continues to be paper-based information. EHR-equipped practices continue to receive notes from consultants via mail, and school forms arrive by mail or are hand carried by parents. EHRs themselves generate paper-based information handouts, immunization records, and health forms. Despite the Internet, electronic communication, and EHRs, our dependence on paper will not diminish anytime in the near future. We are now so dependent on paper that even a temporary shortage of "sticky notes" could devastate some medical practices.

DR SCHUMAN is adjunct associate professor of pediatrics at the Geisel School of Medicine at Dartmouth, Lebanon, New Hampshire, and an editorial board member for *Contemporary Pediatrics*. He has nothing to disclose in regard to affiliations with or financial interests in any organization that may have an interest in any part of this article.

Practice paper efficiencies

Most pediatric practices are extremely efficient at using paper charts. Pediatricians save on paper and ink by using customized forms for physical and ill visits that can be filled out by checking boxes and writing sparingly. Practices have also discovered ways to "fit" documentation notes for several well and ill visits on a single sheet of paper. Likewise, many practices also keep a current version of a completed health form/immunization record in the patient's chart where it can be easily located for copying. Usually registration, HIPAA (Health Information Portability and Accountability Act) forms, as well as demographic information, problem, immunization, and medication lists, are kept in the front of a chart for quick access. Visit documentation notes, lab and imaging study reports, and consultant reports are usually kept in separate tabbed sections of the chart to facilitate access.

Resourceful offices also have a convenient storage system (file drawer or tabletop hanging file folder system) in every exam room to expedite distribution of vaccine information sheets (VIS), school absenteeism forms, physical forms, medication administration forms, and frequently used information handouts.

Not a "paperless" office, but perhaps a "less-paper" office

While many practices believe that they have done all they can to streamline paper usage, there are some additional paper-saving techniques that are underutilized. Paper consumption can be drastically reduced merely by using both sides of a sheet of paper in medical charts! This is very awkward if not impossible with traditional metal chart fasteners, but if you upgrade to plastic "space clip" chart fasteners, also called "U-clips" or "Medi-Clips," it is very easy to use both sides of a sheet of paper.

These fasteners (Figure 1) allow folders to open like a ring binder, enabling easy insertion or removal of papers. The clips also bend to facilitate copying, reading, and writing notes. When used in conjunction with a Tyvek strip, pages can even lie flat. Although twice as expensive compared with metal chart fasteners, these plastic fasteners (about $50 per box of 100) are well worth the investment.

Another trick that reduces your practice's "paper footprint" is using fax machines with duplex capability; ie, incoming faxes will print on both sides of a piece of paper. Alternatively, practices can direct incoming faxes to a computer with installed fax software such as VentaFax (Venta; St. Petersburg, Russian Federation; $99 for business version). Such software allows sorting and deletion of faxes before they print, eliminating unnecessary paper wastage. Used in conjunction with duplex printers, faxes can be printed on 2 sides of a sheet of paper.

Modern high-end copying machines are very sophisticated multifunction devices that can provide duplex faxing, copying, and scanning capabilities and even serve as "document" servers. In their capacity as document servers they electronically store your most frequently used forms and educational handouts for printing (2-sided, of course) when your room supplies run low. Such multifunction copying machines can quickly transform 1-sided documents into 2-sided documents. If you ever feel the need, on a slow day, you can use duplex copying to turn the lab, x-ray reports, and consultant notes in your existing medical charts from 1-sided to 2-sided, shrinking paper charts quickly and freeing up much needed storage space.

Improving usage of parental questionnaires

Practices often have parents complete questionnaires prior to well visits to identify parental concerns that need to be addressed. While official screening

FIGURE 1

Space clips are plastic chart fasteners that allow medical charts to open like a ring binder. Both sides of a sheet of paper can be used for charting.

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References:

1. Sulfacetamide Sodium Ophthalmic Ointment USP, 10% [package insert]. Locust Valley, NY; Fera Pharmaceuticals, LLC, 2011

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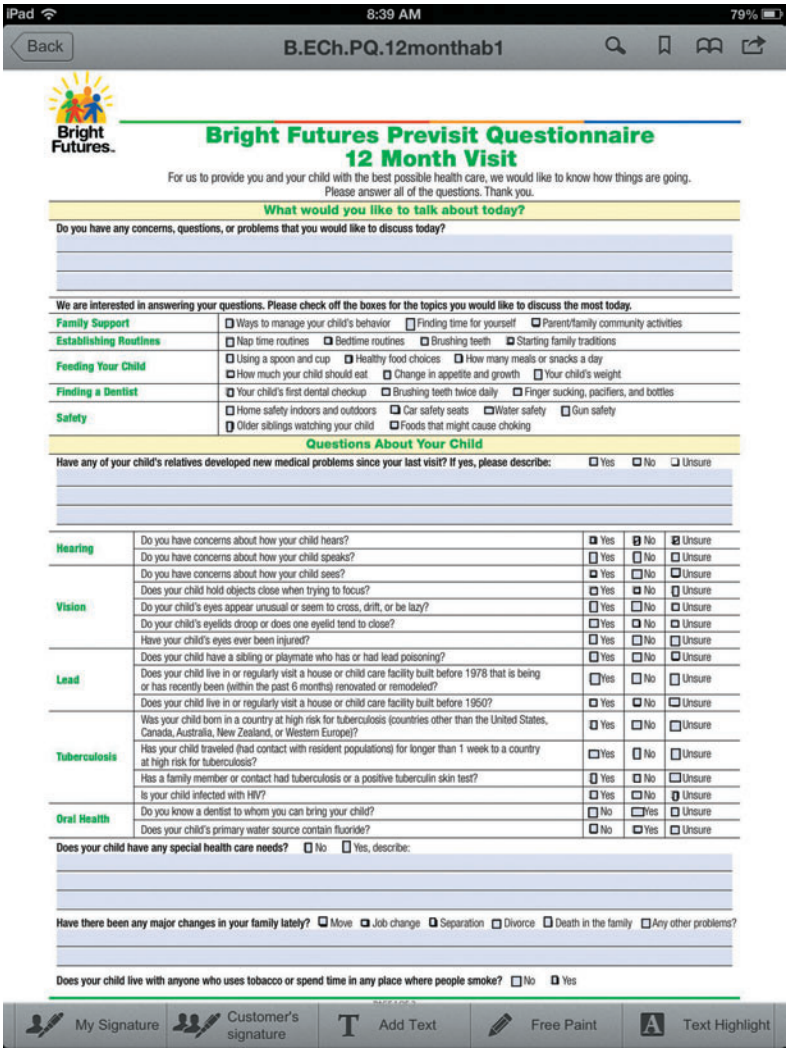

FIGURE 2

Special portable document format (pdf) files can be filled out on a tablet or computer. These can be generated with programs such as Adobe Acrobat, Nuance's Paperport 14, or Omnipage Professional 18.

documents such as the Modified Checklist for Autism in Toddlers (M-CHAT) and Vanderbilt forms are incorporated into the medical record, other paper questionnaires are placed in the trash after they are reviewed and discussed.

It is a relatively simple matter to convert your age-based questionnaires to portable document format (pdf) files. The pdf file format was developed by Adobe Systems (San Jose, California) and can be read by using a free Adobe reader software program. Excellent programs such as Adobe Acrobat ($450), Nuance PaperPort 14 (Nuance; Burlington, Massachusetts; $200), and OmniPage Professional 18 (Nuance; $500) can convert any

scanned or computer-based form file into a special pdf form file that can be easily filled out on computer or tablet (Figure 2).

I have had excellent results using OmniPage Professional 18 for converting regular pdf files into pdf forms. These can be loaded onto a mobile tablet running either the PDF Expert ($9.99) or the PDF Form ($8.99) application that enables parents to fill out questionnaires quickly. Once reviewed these forms can be deleted, saved, or printed if you'd like to incorporate forms into a patient's paper medical record.

Another approach to questionnaire completion is investing in the CHADIS (Total Child Health; Baltimore, Maryland) parental questionnaire service (Figure 3). Child Health and Development Interactive System (CHADIS) is an online screening tool for pediatricians and their patients that revolutionizes how we integrate behavioral screening into daily practice. The AAP recommends that all children be screened at the 18-month visit for autism, and older children be screened for developmental delays and parental concerns beginning at age 2 using standardized screening tools.

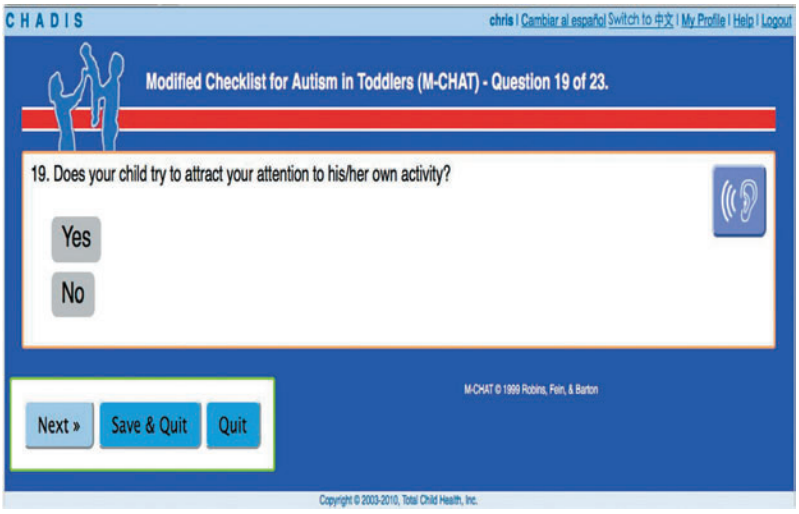

FIGURE 3

Child Health and Development Interactive System (CHADIS) is an online screening tool that can reduce a pediatric office's paper footprint. Screening questionnaires can be completed at home with a computer or while sitting in the waiting area using a tablet.

It has been demonstrated that educational handouts are effective tools that can facilitate parental compliance with treatment recommendations.

Unfortunately, there is little time at a routine well-child visit to address all the concerns parents may have. CHADIS allows pediatricians to invite parents to fill out online age-appropriate screening tools in advance of well-child visits. The online system will evaluate the forms filled out by parents, perform scoring when indicated, and alert pediatricians of issues that need to be discussed with parents at well-child or behavior-related visits.

Many pediatricians speak favorably of the CHADIS system in that it allows them to identify parental concerns and behavior issues that would have gone unidentified in the past. A CHADIS subscription costs about $1,000 per provider per year, with discounts available for volume licenses, and incorporates the majority of screening tools pediatricians utilize frequently such as Ages and Stages, Parents' Evaluation of Developmental Status (PEDS), and Vanderbilt forms.

Vanderbilt forms can be sent to parents and teachers before and after treatment, with results scored automatically. CHADIS doesn't stop at screening; it also provides a full library of resources for pediatricians and parents to assist in management once a condition is diagnosed.

Educational handouts

Pediatricians often provide educational handouts to parents at the conclusion of our office visits. These may include instructions for managing fever or dehydration, discuss the diagnosis made at a visit, or provide guidance regarding feeding and development at well-child visits. It has been demonstrated that educational handouts are effective tools that can facilitate parental compliance with treatment recommendations.[2]

We need affordable and efficient EHRs that can communicate with one another as well as directly with insurance companies, consultants, ancillary health providers (physical therapists, psychologists), and most importantly with patients.

Traditionally pediatricians keep a ready supply of frequently used handouts (Bright Futures handouts or instructions for treating otitis media, sore throats, fever, gastroenteritis, and more) available in every exam room. However parents may be frazzled at the time of their office visits, and many of the handouts we hope parents will read and review may never make it inside their front doors or just go unread. There are, perhaps, better ways to provide parents with educational materials.

Firstly, HIPAA regulations permit pediatricians to communicate with parents of our patients via email. In addition to addresses and phone numbers, sophisticated practices will also record parents' email addresses and document permission to communicate with parents this way. At the conclusion of a visit, pediatricians or their staffs can send email messages to parents of children and include educational attachments appropriate to the visit. These are impossible for parents to lose, and your concern and attention to detail is usually well appreciated. Your usage of paper handouts will also be reduced considerably.

Most high-end EHR programs also provide access to a "patient portal." These portals provide an alternative way to message patients who have had recent visits. Parents usually are alerted via an email that new information is waiting for them via the portal. Even if you don't have an EHR, there are services such as Intuit Health Patient Portal (http://healthcare.intuit.com/portal) that can develop a practice Web site with an integrated patient portal at a reasonable fee. With such a patient portal, you can schedule patients, collect payments or copays, and direct patients to questionnaires or educational materials on the portal/Web site. You can also have patients sign documents (transfer of records forms, HIPAA forms) sent by email with services such as RightSignature (Santa Barbara, California; $50 per month) or HelloSign (JN Projects; San Francisco, California; free).

Will there ever be a paperless pediatric practice?

Hopefully within a decade's time we can look forward to a true, nearly paperless office. Advances in the banking industry and in mobile technology associated with our willingness to trust the security measures of cash transactions, including payroll deposits and purchases, have shown us that a nearly paperless system should be possible in the health care industry.

To accomplish this, we need affordable and efficient EHRs that can communicate with one another as well as directly with insurance companies, consultants, ancillary health providers (physical therapists, psychologists), and most importantly with patients. Once this has been accomplished, questionnaires will be filled out at home via a patient portal or in the office on a tablet; all prescriptions (even controlled prescriptions) will be electronic; and educational materials, including handouts and instructional videos, will be available online. By conserving paper we can be friendlier to our natural resources and ensure that our supply of precious sticky notes won't vanish any time soon. CP

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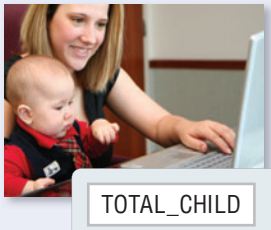

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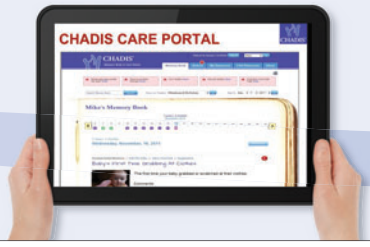

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CALENDAR

MAY

10-11: Pediatric Oncology Hematology Education Day. Vancouver, British Columbia.
CONTACT: Northern Continuing Medical Education, www.ncme.ca/calendar/events/index.php?com=detail&eID=2035

14-18: Society for Pediatric Radiology 56th Annual Meeting and Postgraduate Course. San Antonio, Texas.
CONTACT: Society for Pediatric Radiology, www.pedrad.org/

20-21: Society for Pediatric Sedation Conference 2013. Houston, Texas.
CONTACT: Society for Pediatric Sedation, www.pedsedation.org/sections/meetings/

31-1: Maternal and Child Global Health: What You Need to Know Before You Go. Boston, Massachusetts.
CONTACT: Massachusetts General Hospital for Children, cme.med.harvard.edu/index.asp?SECTION=CLASSES&ID=03324553&SO=N

JUNE

1-7: 6th Annual Pediatric Pain Master Class. Minneapolis, Minnesota.
CONTACT: Children's Institute for Pain and Palliative Care, www.cvent.com/events/6th-annual-master-class-for-pediatric-pain-management/event-summary-ea03b80818844ef1a9ce416207878e78.aspx

18-20: 7th Biennial Childhood Obesity Conference. Long Beach, California.
CONTACT: California Department of Public Health, www.childhoodobesity2013.com

22-25: 6th International Conference on Children's Bone Health. Rotterdam, Netherlands.
CONTACT: ICCBH, www.iccbh.org

27-28: 4th International Conference on Pediatric Abusive Head Trauma. Burlington, Vermont.
CONTACT: Penn State Hershey College of Medicine, www.pennstatehershey.org/web/aht/home

JULY

10-13: 15th Annual Summer Conference on Pediatrics. Napa, California.
CONTACT: Symposia Medicus, www.symposiamedicus.org/Assets/Conference/1261/1261.html

22-24: Pediatric and Adult Infectious Diseases: An Evidence-Based Approach to Common Problems (CME). Anaheim, California.
CONTACT: MCE Conferences, www.mceconferences.com/conference-detail.php?conf_id=PN939-6-5-19-32

28-2: 31st Annual Conference on Pediatric Infectious Diseases. Vail, Colorado.
CONTACT: Children's Hospital Colorado, www1.childrenscolorado.org/Events/calendar-detail/?eventId=c52e487c-7571-e211-8f54-2c768a4e1b84

AUGUST

1-4: Pediatric Hospital Medicine Conference. New Orleans, Louisiana.
CONTACT: American Academy of Pediatrics, www.aap.org/en-us/about-the-aap/Committees-Councils-Sections/Section-on-Hospital-Medicine/Pages/Pediatric-Hospital-Medicine-2012.aspx

24-29: International Congress of Pediatrics. Melbourne, Australia.
CONTACT: International Pediatric Association, www2.kenes.com/IPA/Pages/home.aspx

26-30: 19th Annual Pediatric Board Review Symposium. Cleveland, Ohio.
CONTACT: Cleveland Clinic, www.clevelandclinicmeded.com/live/courses/pediatric/overview.asp

SEPTEMBER

19-22: Pediatric Urology Fall Congress. Las Vegas, Nevada.
CONTACT: Society for Pediatric Urology, http://fallcongress.spuonline.org/

27-30: SDBP 2013 Annual Meeting. Baltimore, Maryland.
CONTACT: Society for Developmental and Behavioral Pediatrics, www.sdbp.org/annual_meeting.cfm

OCTOBER

26-29: AAP National Conference and Exhibition. Orlando, Florida.
CONTACT: American Academy of Pediatrics, www.aapexperience.org

NOVEMBER

8-10: Southwest Regional NAPNAP Conference. Palm Springs, California.
CONTACT: National Association of Pediatric Nurse Practitioners, http://southwestregionalnapnapconference.com/

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Do not use EPIDUO gel for a condition for which it was not prescribed. Do not give EPIDUO gel to other people, even if they have the same symptoms you have. It may harm them.

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- are pregnant or planning to become pregnant. It is not known if EPIDUO gel can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if EPIDUO gel passes into your breast milk and if it can harm your baby. Talk to your doctor about the best way to feed your baby if you use EPIDUO gel.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

- Especially tell your doctor if you use any other medicine for acne. Using EPIDUO gel with topical medicines that contain sulfur, resorcinol or salicylic acid may cause skin irritation.
- Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

WHAT SHOULD I AVOID WHILE USING EPIDUO GEL?

- You should avoid spending time in sunlight or artificial sunlight, such as tanning beds or sunlamps. EPIDUO gel can make your skin sensitive to sun and the light from tanning beds and sunlamps. You should wear sunscreen and wear a hat and clothes that cover the areas treated with EPIDUO gel if you have to be in the sunlight.
- You should avoid weather extremes such as wind and cold as this may cause irritation to your skin.
- You should avoid applying EPIDUO gel to cuts, abrasions and sunburned skin.
- You should avoid skin products that may dry or irritate your skin such as harsh soaps, astringents, cosmetics that have strong skin drying effects and products containing high levels of alcohol.
- You should avoid the use of "waxing" as a hair removal method on skin treated with EPIDUO gel.
- EPIDUO gel may bleach your clothes or hair. Allow EPIDUO gel to dry completely before dressing to prevent bleaching of your clothes.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF EPIDUO GEL?

The most commonly reported side effects when using EPIDUO gel include erythema, scaling, dryness, application site irritation, stinging and burning.

Depending upon the severity of these side effects, patients should be instructed to use a moisturizer, reduce the frequency of the application of EPIDUO gel, or discontinue use.

Tell your doctor right away if these side effects continue for longer than 4 weeks or get worse, you may have to stop using EPIDUO gel. Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of EPIDUO gel. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch* or call 1-800-FDA-1088. You may also contact GALDERMA LABORATORIES, L.P. at 1-866-735-4137.

HOW SHOULD I USE EPIDUO GEL?

- Use EPIDUO gel exactly as your doctor tells you to use it. EPIDUO gel is for skin use only. Do not use EPIDUO gel in or on your mouth, eyes, or vagina.
- Apply EPIDUO gel 1 time a day.
- Do not use more EPIDUO gel than you need to cover the treatment area. Using too much EPIDUO gel or using it more than 1 time a day may increase your chance of skin irritation.

APPLYING EPIDUO GEL:

- Wash the area where the gel will be applied with a mild cleanser and pat dry.
- EPIDUO gel comes in a tube and a pump. If you have been prescribed the:
  - Tube: Squeeze a small amount (about the size of a pea) of EPIDUO gel onto your fingertips and spread a thin layer over the affected area.
  - Pump: Depress the pump to dispense a small amount (about the size of a pea) of EPIDUO gel and spread a thin layer over the affected area.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT EPIDUO GEL?

- Talk to your doctor or pharmacist
- Go to **www.epiduo.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA
Revised: February 2013

Reference: 1. IMS Health - Monthly Midas Database, all countries selected - Topical Anti Acne Market - November 2012 MAT, retail RX market - at sales manufacturer local currency dollar value - Copyright IMS Health or its affiliates. All rights reserved.

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14501 N. Freeway
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EPI-984R Printed in USA 02/13

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The #1 PRESCRIBED,
BRANDED TOPICAL ACNE AGENT IN THE WORLD IS…[1]

NOW THE **ONLY** TOPICAL ACNE AGENT APPROVED FOR PATIENTS AS YOUNG AS 9 YEARS OF AGE!

Important Safety Information

Indication: EPIDUO® Gel is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.
Adverse Events: In controlled clinical studies, the most commonly reported adverse events (≥1%) in patients treated with EPIDUO® Gel were dry skin, contact dermatitis, application site burning, application site irritation and skin irritation.
Warnings/Precautions: Patients taking EPIDUO® Gel should avoid exposure to sunlight and sunlamps and wear sunscreen when sun exposure cannot be avoided. Erythema, scaling, dryness, stinging/burning, irritant and allergic contact dermatitis may occur with use of EPIDUO® Gel and may necessitate discontinuation.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of full Prescribing Information on next page.

www.epiduo.com/hcp