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 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.

See accompanying brief summary on next page.

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OR HEARD.
Ausi-Q™
(epinephrine injection, USP) 0.3 mg, 0.15 mg Auto-Injector

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE
Ausi-Q™ is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g., Hymenoptera, which include bees, wasps, hornets, yellow jackets and fire ants) and biting insects (e.g., tritoma, mosquitoes), allergen immunotherapy, food allergies and allergic reactions to radiocautery media and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Ausi-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, tachyarrhythmias, anaphylactic shock (progressive vascular collapse), bronchospasm, pulmonary edema because of peripheral vascular constriction together with cardiac stimulation, and is not a substitute for immediate medical care.

2 CONTRAINDICATIONS

No known contraindications.

3 WARNINGS AND PRECAUTIONS

5.1 EMERGENCY TREATMENT

Ausi-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. If an adequate dose of epinephrine is 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), patients should be observed in a hospital setting until the patient is clinically stable.

5.2 INCORRECT LOCATIONS OF INJECTION

Ausi-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). Injection sites should be rotated to avoid tissue atrophy.

• 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 vasoconstrictors may 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 vasodilatation, 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 severe asthmatic episodes in certain susceptible persons.

The presenters of this sulfite in the 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 Ausi-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 epinephrine, 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; apprehension; 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), Amphythiasms, 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 reactions experienced as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypotension 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, levodopa, or certain anesthetic agents, notably chlorpromazine, trihexyphenidyl, and diphenhydramine.

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

The vasoconstricting and hypotensive 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

Tetrahydrofolic Acid: 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 avoided 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 at doses of 0.3 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 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 AUSI-Q™ is administered to a nursing woman.

8.4 PEDIATRIC USE

AUSI-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 AUSI-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

Overdose 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 overdose 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 (pre fibrillation rhythm). Subsidence of the ventricular effects may be delayed for several hours. If evidence of cardiac failure is present, appropriate measures must be taken in such situations.

Revised September 2012
Manufactured for:
AUSI-Q™
Rx Only

EPI-RLR-SA-SEP12
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Office- and hospital-based pediatricians and nurse practitioners use Contemporary Pediatrics' timely, trusted, and practical information to enhance their day-to-day care of children. We advance pediatric providers' professional development through in-depth, peer-reviewed clinical and practice management articles, case studies, and news and trends coverage.

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Babies born by cesarean delivery more likely to become overweight
Children born via cesarean delivery are slightly more likely than babies delivered vaginally to become heavy or obese.

ContemporaryPediatrics.com/overweight

Jury out on diagnostic value of GERD tests
In children with suspected gastroesophageal reflux disease (GERD), the accuracy of common diagnostic tests remains unclear.

ContemporaryPediatrics.com/GERD

Doctors should counsel kids about not smoking
Doctors should talk to children about the consequences of smoking and how to avoid peer pressure to smoke.

ContemporaryPediatrics.com/antismoking

Children who overeat more likely to take up drugs
Kids and teenagers who reported overeating or binge eating were more likely to start using marijuana and other drugs.

ContemporaryPediatrics.com/overeating

Disability to rise as more premature babies survive
With preterm births on the rise across Europe, rates of serious disability are likely to increase, doctors say.

ContemporaryPediatrics.com/disabilities

Many kids self-injure after parent’s cancer death
After losing a parent to cancer, 1 in 5 teenagers self-injure by cutting or burning compared with 1 in 10 with 2 living parents.

ContemporaryPediatrics.com/selfinjury

Identifying the etiology of Kawasaki disease has been a vexing problem, but researchers all agree on the urgent need for early diagnosis and improved treatment therapies.

Kawasaki Disease
ContemporaryPediatrics.com/KD

Have you seen the December issue?
Tell the Editorial Board which articles and departments you liked and help shape the content of future issues.

- Kawasaki disease: Genetics, pathology, and a need for earlier diagnosis and treatment
- When to get anxious about social anxiety disorder
- Year-end review: Best new tech products
- Dermatology: What’s your DX?
- Puzzler
- Editorial: Kawasaki disease: Looking back
- Journal Club

Answer this survey
Head over to http://ow.ly/gfUal to answer this survey and get more news from Contemporary Pediatrics.

Join us on Twitter
We want to know your thoughts on the latest issue, current events, and more. Engage with us on Twitter by mentioning @ContemPeds

Contemporary Pediatrics is part of the ModernMedicine Network, a Web-based portal for health professionals offering best-in-class content and tools in a rewarding and easy-to-use environment for knowledge sharing among members of our community.
We are entering a long-term period after this tragedy that will be relevant to primary care pediatricians, including the reactions of parents and children, the stigma of mental illness, and the management of guns.

I will not focus on the families and children in Newtown who were directly exposed to the violence and horrible sights. There will need to be a thoughtful community-wide mental health plan for all these survivors, the parents and spouses who suffered the death of a loved one, and the first responders so stressed by the intensity of what they had to do and see.

It will take a long time for the community to recover. There will need to be years of memorials, and for many parents, siblings, and spouses, any recovery will be partial.

Most of the millions of children and parents indirectly exposed to the Sandy Hook murders will be resilient. Their parents’ explanation, reassurance, foundation of love, and resumption of normal activities will be sufficient.

However, for a small minority in your practice, this particular tragedy will persist. Some may have a genetic and/or temperamental vulnerability to anxiety or depression, and others may have had previous experiences in their lives, usually losses of loved ones through divorce or death. Some will be vulnerable because of not feeling valued earlier in their own lives secondary to poverty, abuse, or neglect.

For all these vulnerable children, Sandy Hook will be a nodal event. Parents may have become totally absorbed in the acute phase of the story and could not follow advice, especially for their children, to limit access to the media.

Children may develop anxiety about being safe in school, become clingy to parents (regressing to a younger age), or have posttraumatic stress disorder symptoms from what they have seen on television (nightmares, flashback images, etc). Parents may also become very anxious about school safety and overall too restrictive concerning their children’s activities.

Primary care pediatricians will try to reassure the child and parent and will be alerted that this is a more serious concern if parents cannot hear or respond to the pediatrician’s guidance. They will be more rigid than expected and feel that the pediatrician does not understand.

These patients will ignore facts about odds of such an event affecting their child or undervalue the cost of
limiting their child’s autonomy in the face of an anxiety-driven sense of danger.

For these families, pediatricians should be empathic. These anxieties are a way of coping with past and current events, a “solution,” despite being dysfunctional, to their anxiety.

Pediatricians should take a family history for anxiety, depression, previous losses, or very disturbing events. A useful question that may serve as a guide is: “Have you ever felt this anxious before? What were those circumstances?” Hopefully, this history and discussion will help the family accept a mental health referral.

Another issue that all of us face is an increase in stigma associated with mental health issues, and in this case, the alleged diagnosis of Asperger syndrome. I have concerns that experts are either pressured or willing to comment on this shooter’s mental health diagnosis before we have information from clinicians who actually evaluated him and the appropriate records.

Although the wish to find some path through the uncertainty of this evil deed is very powerful, speculation by professionals will do more harm than good.

Associating this level of violence and behavior with Asperger syndrome is presumptuous, a disservice, and a leap into the unknown. Primary care pediatricians will probably face and have to minimize the stigma.

Last, pediatricians will have to redouble their efforts at gun safety. No matter what the political perspective, guns that do exist in the home have to be safely stored, not available for impulsive actions, and explicitly discussed when risk factors such as alcohol use, violence, or instability are evident in the family’s behavior.

Pediatricians, despite their commitment to the safety of children, have to live with the anxiety of inevitable risks, uncertainty, and accepting that there are moments of human behavior we cannot understand, only grieve.

“‘There will need to be years of memorials, and for many parents, siblings, and spouses, any recovery will be partial.’

A call for meaningful action after Newtown

From the Survivor Pediatrics blog, December 16, 2012

JENNIFER SHAER, MD

obody would argue that there should be meaningful action after such a massacre. However, I would argue that the focus on gun control as that meaningful action is misguided.

Someone disturbed enough to walk into an elementary school and start shooting is going to find a way to inflict tragedy in one way or another. There will always be access to guns or bombs or whatever the device of destruction for those motivated to find them.

I am not saying that there should not be a meaningful discussion about gun control but the crux of the issue here is prevention.

You stop a tragedy like this by recognizing signs and intervening in the potential shooter before he becomes a shooter. What possesses a 20-year-old young adult to walk into an elementary school and start shooting? An act like this does not come out of nowhere.

In the field of pediatrics, we are experts in prevention. We use vaccines to prevent life-threatening illness. We support things like breastfeeding, exercise, and helmets to promote wellness and safety.

However, when it comes to supporting mental health, we are ill prepared. In our busy pediatric offices, we do not have the time or the advanced training to help our patients who need mental health support.

When we look to refer them to psychiatrists, psychologists, or social workers, all too often the patient cannot find one who takes their insurance.

Gun control or not, tragic incidents like this murder of so many innocents will not stop unless we figure out how to provide affordable and accessible mental health wellness to our children and young adults.

That is the meaningful action that needs to take place in the wake of this tragedy.

DR SHAER is a pediatrician at Allied Pediatrics of New York, a board-certified lactation consultant, and a member of the Academy of Breastfeeding Medicine. She is a contributor to the Survivor Pediatrics blog at http://survivorpediatrics.wordpress.com/.

There will need to be years of memorials, and for many parents, siblings, and spouses, any recovery will be partial.”
Circumcision reduces lifetime risk for UTIs

Baby boys who are not circumcised face a 10-fold higher risk for urinary tract infection (UTI) in their first year compared to boys who are circumcised and a 23% increased risk of UTI throughout their lifetimes. Researchers determined the prevalence and relative risk of UTI for boys aged younger than 1 year, 1 to 16 years, and older than 16 years and from this data calculated lifetime prevalence.

They found the likelihood of UTI between birth and 1 year to be 9.91 times higher in uncircumcised boys compared with those who were circumcised; 6.56 higher for uncircumcised boys aged 1 to 16 years; and 3.41 higher for uncircumcised boys aged 16 and older compared with circumcised men.

Urinary tract infections include infections of the kidneys, bladder, ureter, and urethra and are more common in the first year of life. Adverse effects can include kidney scarring, fever, pain, and septicemia.

The American Academy of Pediatrics (AAP) has stated that circumcision can reduce the risks for UTI, HIV and other sexually transmitted infections, and penile cancer, and that the health benefits outweigh the risk of complications from the procedure. However, AAP leaves the decision whether to circumcise up to the parents of the child.


IRON SUPPLEMENTS REDUCE IMPAIRED NEURODEVELOPMENT IN LBW BABIES

Researchers in Sweden have found that giving iron supplements to infants of low birth weight (LBW) during the first 6 months of life appears to significantly reduce the risk of behavior problems by the time the children are preschoolers.

In a randomized, controlled trial, 285 marginally LBW infants (<2,500 g) were given placebo or either 1 mg/kg or 2 mg/kg of ferrous succinate per day from age 6 weeks to 6 months.

Infants taking placebo or iron were assessed at 6, 12, and 19 weeks; 6 months; and 3.5 years. Ninety-five controls were seen only at 3.5 years.

At the 3.5-year follow-up, all infants were given a psychometric test to determine verbal, performance, and full-scale IQ. Parents completed a checklist questionnaire for behavioral and emotional problems.

Researchers found no significant differences in cognitive scores among the 3 groups of LBW infants compared with controls. Infants who received the 1 mg/kg and 2 mg/kg iron supplements were significantly less likely (2.9% and 2.7%, respectively) to score above the subclinical cutoff for behavior problems than infants given placebo (12.7%). The rates for LBW infants given supplements were similar to the rate for babies of normal birth weight (3.2%).

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ULTRASOUND BEST FOR DIAGNOSING PNEUMONIA

A study that compared traditional auscultation by stethoscope with ultrasonography for diagnosing pneumonia in children and young adults has found that ultrasound is more accurate.

Researchers looked at 200 patients aged between birth and 21 years (median age, 3 years) who were given chest x-rays for suspected community-acquired pneumonia at the emergency departments of 2 urban hospitals. After clinical diagnosis of pneumonia, patients underwent ultrasonography.

Chest radiography confirmed prevalence of pneumonia among 18% of patients. Ultrasound showed high specificity (97%) and sensitivity (86%) for diagnosing pneumonia lung consolidation. In contrast, specificity for auscultation by stethoscope was 77% to 83%, with 24% sensitivity. Ultrasound also detected pneumonias as small as 1 cm or less, which a chest x-ray might miss.

The researchers say that diagnosing pneumonia by stethoscope can be difficult when the patient is coughing or wheezing, whereas ultrasound is not affected.

The Centers for Disease Control and Prevention (CDC) has released what it calls the first report to document state by state the contribution of assisted reproductive technology (ART) to multiple births, low birth weight, and preterm birth.

Some differences among states are eye opening. Using data from 2009, the report says that 33.4% of infants conceived through ART were born preterm, ranging from 21.3% in Vermont to 47.1% in Wyoming. Rates were 40.7% in Texas, but were only 30.9% in New York and 31.9% in California.

Similarly, 32.3% of these infants were low birth weight, ranging from 19.7% in Alaska to 47.8% in Puerto Rico.

Denise Jamieson, MD, of the CDC’s Division of Reproductive Health, points out, however, that low birth weight and preterm births are determined by many factors, including maternal age, and those factors also vary by state. So even with babies conceived through ART, it’s not possible to know how much ART contributed to the difference among states in low birth weight and preterm births.

Overall, ART contributed to 1.4% of US births, but according to the report: “Nationally, infants conceived with ART contributed approximately 3.9%, 4.5%, and 3.8%, respectively, to all preterm, very preterm, and moderate preterm births. The contribution of ART to preterm births ranged from 0.5% in Puerto Rico to 11.1% in Massachusetts.”

One major factor is that 47% of infants conceived through ART are born in multiples, according to the CDC.

The CDC urges that clinicians and state policymakers should continue to support fewer numbers of embryos transferred and, when possible, promote the transfer of single embryos as recommended by the Society for Assisted Reproductive Technologies and the American Society for Reproductive Medicine.

The number of embryos transferred has decreased over time, says Jamieson. “I think the guidance is helping people to transfer fewer embryos, depending on the clinical characteristics of the woman, such as age.”

But the elective single-embryo transfers are still very much in the minority, accounting for 7% in women aged younger than 35 years, 3% in women aged 35 to 40 years, and .5% in women older than 40 years.

Jamieson says, “To many women, a healthy twin pregnancy, even if the babies are smaller or born earlier, seems like a great outcome.” Many women don’t understand the increased risk to the mother in pregnancies with multiples, and they are particularly not motivated to have a single egg transferred when they have paid for the expensive cycle themselves, she notes.

The CDC report points out that some research shows that in states that mandate insurance coverage for in vitro fertilization treatments, there are large increases in access to ART services, but there are also fewer embryos transferred per procedure.

When the patient does not have insurance for the procedure, the report indicates, physicians may be transferring multiple embryos in hopes that the expensive procedure will not have to be repeated. However, the report says, “Even singleton infants conceived with ART have a higher risk of low birth weight.”

The reports mentions a 2006 Institute of Medicine report on preterm births that noted that ovulation promotion is just as important in producing multiple gestations as ART. The risks of multiple gestations resulting from those treatments are not as well studied.
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**Single ivermectin application is effective against head lice**

One 10-minute at-home application of topical ivermectin eliminates lice—without combing—in most patients within 1 day, a recent investigation showed.

Two parallel studies were conducted simultaneously in 765 patients at 16 sites in 12 states during a 5-month period. Eligible patients were aged at least 6 months and had a minimum of 3 live lice on their hair or scalp.

Once investigators identified an index patient in a family, they also enrolled into the study any other household members with at least 1 live louse. Families at each site were divided into 2 groups: 1 group received a tube of lotion containing 0.5% ivermectin and the other group an identically formulated lotion without ivermectin (control group). Participants were instructed to apply the lotion to their hair and scalp and leave it on for 10 minutes before rinsing the hair with water.

One day after application of the lotions (day 2 of the study), 94.9% of patients who received lotion with ivermectin were louse free compared with 31.3% of those whose lotion contained no ivermectin. Similarly, significantly more patients in the ivermectin group than in the control group were free of live lice at subsequent observations: 85.2% versus 20.8% at day 8 and 73.8% versus 17.6% at day 15. In addition, topical ivermectin was not associated with increased frequency or severity of adverse events (Pariser DM, et al. *N Engl J Med*. 2012;367[18]:1687-1693).

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**Recurrent Lyme disease usually caused by reinfection**

A study in 17 adult patients with culture-confirmed episodes of erythema migrans—whose first bout of Lyme disease was treated appropriately with standard courses of antibiotics—found that additional consecutive episodes of erythema migrans were due to reinfection, not relapse.

In making this determination, investigators examined the genotype of the gene encoding outer-surface protein C (*ospC*) of *Borrelia burgdorferi* strains detected in cultures of skin or blood specimens from patients who had experienced several episodes of erythema migrans. (Paired consecutive occurrences in the 17 patients totaled 22 because although most of the participants had 2 episodes, a few patients had 3 or 4.)

None of the paired occurrences of erythema migrans...
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Is procalcitonin readily available in the hospital or emergency room where you see patients? If so, I suggest a trial inclusion of this test in your evaluation of certain patients. Procalcitonin is not a perfect test, but after 10 years of studies, it seems to be the best we have for now. It may have a role in how we answer the age-old question in pediatrics: Is this febrile child “sick” or “not sick”? — Michael Burke, MD

**Commentary**

This study should offer reassurance to those who are concerned that a second bout of erythema migrans represents failure of a first round of treatment for Lyme disease. Rather than focusing on chronic, relapsing infection, our patients and their parents can be told to work on tick avoidance and early tick removal. — Michael Burke, MD

**Also of Note**

Dispensing asthma meds in the emergency department (ED) reduces future visits and costs. Using a decision-analysis model and data from the literature, investigators compared outcomes of usual care (recommending outpatient follow-up), uniform prescribing of inhaled corticosteroids (ICS) at the time of the visit, and uniform dispensing of ICS for a hypothetical group of 100 children with asthma being discharged from the ED.

They found that the rate of return to the ED per 100 patients within 1 month of the initial ED visit was 8.4 visits for medication dispensing and 9.4 for medication prescribing compared with 10.6 visits for usual care. Dispensing and prescribing ICS also reduced hospital admissions. Similarly, direct costs per 100 patients for each of the 3 groups were estimated to be $19,100; $20,800; and $23,400, respectively (Andrews AL, et al. *J Pediatr*. 2012;161[5]:903-907).

**Commentary**

From initial and subsequent consecutive episodes shared the same *ospC* genotype. Furthermore, using a separate genotyping method, investigators confirmed infection with a different genotype of *B burgdorferi* in all 22 of the paired episodes. In total, 12 different *ospC* genotypes caused infection (Nadelman RB, et al. *N Engl J Med*. 2012;367[20]:1883-1890).

**Commentary**

Is procalcitonin readily available in the hospital or emergency room where you see patients? If so, I suggest a trial inclusion of this test in your evaluation of certain patients. Procalcitonin is not a perfect test, but after 10 years of studies, it seems to be the best we have for now. It may have a role in how we answer the age-old question in pediatrics: Is this febrile child “sick” or “not sick”? — Michael Burke, MD

**PROCALCITONIN LEVEL ACCURATE BIOMARKER FOR INVASIVE BACTERIAL INFECTION**

A retrospective study in more than 1,000 well-appearing infants aged younger than 3 months with fever without a source (FWS) found that procalcitonin (PCT) performs better than C-reactive protein (CRP) in identifying patients with invasive bacterial infections (IBIs), which are positive bacterial cultures of cerebral spinal fluid (CSF) or blood, and seems to be the best marker for ruling out IBIs.

The study was conducted in infants admitted to 7 Spanish and Italian pediatric emergency departments in which standard protocol for such infants included urine dipstick (UD) testing, measurement of CRP and PCT levels, white blood count (WBC), and obtaining blood and urine cultures.

A total of 289 infants (26%) were diagnosed with a definite serious bacterial infection (positive bacterial culture of CSF, blood, urine, or stool) and 23 (2.1%) with an IBI. Previously identified risk factors were compared in patients with and without IBI, including specified levels of PCT and CRP, WBC, and absolute neutrophil count. Only PCT 0.5 ng/mL or higher was found to be an independent risk factor for IBI. Investigators also conducted a separate analysis in infants with fever of recent onset and a normal UD, which showed that PCT level was the best marker for identifying IBIs in these patients (Gomez B, et al. *Pediatrics*. 2012;130[5]:815-822).
Food allergy is extremely common and affects approximately 8% of US children.\(^1\) Prevalence rates for the most common food allergies are estimated to be 2.5% for milk, 1.3% for egg, 1% for peanut, and 0.5% for tree nuts. The overall prevalence of food allergy appears to be rising in all developed countries.\(^2\)

Because food allergies appear to be such a common problem, pediatricians are likely to regularly encounter children with true allergy and to entertain questions about allergies from families on a daily basis.

Because most reported adverse food reactions are in fact not true food allergy, and the diagnostic tests for food allergy are not terribly accurate, answers may be ambiguous.

**What are real food allergies?**

To begin, it is important to recognize that not all adverse food reactions are really food allergies but rather food intolerances or other more benign conditions. It is therefore very important that we work with a common definition for food allergy, which is, *a specific immune response that occurs reproducibly on exposure to a given food, almost always the protein component of the food*.\(^3\)

Although more than 170 foods have been recognized as food allergens, for day-to-day practice, it
is important to remember that just 8 foods (or food groups) account for more than 90% of all food reactions. The most important allergens are milk, egg, and peanut, followed by tree nuts, wheat, soy, fish, and shellfish.

The immune mechanisms leading to food allergy most often involve production of immunoglobulin E (IgE) antibodies, but the mechanisms can also be non-IgE mediated (cell mediated) or mixed (with both IgE and non-IgE elements).

The antibody class that causes type 1 hypersensitivity reactions, IgE can be detected by the skin and blood tests commonly used in the diagnosis of food allergy. It is important to remember that IgE cannot be detected or used to diagnose non-IgE-mediated food allergies such as food protein-induced enterocolitis syndrome or allergic proctocolitis.

**Diagnosis of food allergy**

Diagnosis of food allergy should be guided by a comprehensive medical history and physical exam. Although food allergy should of course be considered in all patients who report symptoms of an acute allergic reaction or anaphylaxis, it is important to consider food allergy in certain chronic conditions without obvious relationship to food ingestion. These include infants and children with moderate to severe atopic dermatitis and patients with eosinophilic esophagitis, gastroenteropathy, or proctocolitis.

For example, a prospective study of children with moderate to severe atopic dermatitis found that 37% had IgE-mediated food allergy. Another study of children with eosinophilic esophagitis found that 14.8% had confirmed IgE-mediated food allergy, most commonly to peanut, egg, and milk.

A thorough medical history, including questions regarding the foods that were ingested, the amount, and in what form (cooked, raw, etc) can help focus subsequent testing. IgE-mediated reactions typically occur within a few minutes to hours after ingestion of the culprit food, so details of the reaction experienced, including timing of onset, resolution, treatment, and reproducibility, should be assessed (Table). Factors surrounding the event, including exercise, alcohol consumption, and aspirin or nonsteroidal anti-inflammatory use, should also be identified because these can provoke or exacerbate a food allergy-associated reaction. Outside of acute reactions, physical exam findings are typically not helpful in diagnosing food allergy.

**History**

In acute reactions, the history may be virtually diagnostic (eg, hives immediately after the first egg ingestion). Unfortunately, however, the food allergy history is not very accurate. Most people reporting food allergy do not turn out to have true food allergy on further testing.

For example, a 2007 meta-analysis found that 12% of children and 13% of adults had self-reported food allergy, but the prevalence fell to only 3% when skin testing, IgE testing, and food-challenge results were taken into consideration. Findings from the medical history should therefore be confirmed with objective measures, although it is important to recognize that many of these are far from perfect.
Testing
Skin prick testing and serologic testing for allergen-specific IgE are most commonly used to help identify causative foods. However, the presence of a positive reaction or a specific IgE found via either method only signifies sensitization and does not necessarily predict clinical reactivity. So although negative tests rule out an allergy at least 90% of the time, a positive test only indicates a true allergy about 50% of the time.

The positive predictive value of these tests falls even lower if they are used indiscriminately, because it is common to find positive tests to foods that a child is eating without difficulty. As an example of how peanut allergy might be erroneously diagnosed, although 8% of people test positive to peanut, we know that only about 1% are truly allergic. Therefore, testing should only be done when it is clinically indicated, and results should always be interpreted in the context of a carefully acquired history.

Serologic testing is currently under development to analyze allergen-specific IgE binding to food allergen components instead of whole allergen extracts. These assays may provide better specificity in diagnosis and identify tests that may be positive because of cross-reactivity with other allergens. It is reasonable to either refer patients with suspected food allergy to an allergy specialist or for the primary care provider to obtain screening serologic tests and then refer patients with positive results for further evaluation.

Food challenge
The gold standard for the diagnosis of food allergy continues to be an oral food challenge. In a food challenge, the patient is given gradually increasing doses of the food in question under close medical supervision. Challenges are also used to determine whether a known allergy has been outgrown. When indicated, the medical history and serum specific-IgE testing can guide the timing of a challenge. Although it is the most definitive means of diagnosis, food challenges may not be practical in a busy office setting given their time commitment, expense, and inherent risk.

Non-IgE-mediated food allergies
The diagnosis of a non-IgE-mediated food allergy can be especially difficult given the lack of available objective measures. As with IgE-mediated food allergy, a thorough medical history should be the first step in diagnosis.

For some conditions that involve acute symptoms, such as food protein-induced enterocolitis syndrome (FPIES), the history may be very helpful. For conditions with more chronic manifestations, such as eosinophilic gastroenteritis, the history is less likely to be informative.

The next step in the evaluation most often includes an elimination diet, which may vary depending on the history, the age of the patient, and the specific condition that is suspected. For example, in FPIES, only 1 or 2 foods that were associated with reactions may need to be avoided, whereas in eosinophilic gastroenteritis, multiple foods may need to be avoided, and some sicker patients may even need to be placed on an elemental diet. In some instances, such as in patients with eosinophilic esophagitis, the success or failure of an avoidance diet can only
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be determined through follow-up endoscopy with biopsy.

**Management of food allergy**

Once the diagnosis of food allergy is made and the culprit food has been identified, strict avoidance of those food allergens is recommended for both IgE-mediated and non-IgE-mediated disease. Families must be educated on reading food labels and ingredient lists to help recognize food allergens.

The Food Allergen Labeling and Consumer Protection Act (FALCPA), passed in 2004, requires manufacturers to identify any product containing milk, egg, soy, wheat, peanut, tree nut, fish, and shellfish on the package ingredient label. This does not include precautionary labels that are used at the discretion of the manufacturer and include wording such as “may contain,” “processed on shared equipment,” or “processed in a facility.” Foods with these warning labels also should be avoided for most patients.

Food avoidance, especially for young patients on extensive elimination diets, could have effects on their nutritional status. The guidelines recommend that children with food allergy should have nutritional counseling and ongoing growth evaluations. Particular attention should be given to following total daily calorie, protein, calcium, and vitamin D intake.

**Natural history of food allergy**

Studies on the natural history of food allergy have shown that approximately 70% to 80% of patients outgrow milk and egg, 60% to 70% outgrow soy and wheat, and 10% to 20% outgrow peanut and tree nut allergy. Therefore, follow-up reassessment is indicated to update reaction history, and repeat serum-specific-IgE testing is necessary. Serum-specific-IgE testing may provide additional information regarding the likelihood of clinical reactivity based on predictive values for passing oral food challenges. For milk, egg, and peanut, a specific IgE level of less than 2 kUA/L predicts a 50% likelihood of passing an oral food challenge. Reliable levels for wheat and soy have not been identified. Yearly reevaluation is recommended for patients with milk, egg, wheat, and soy allergy, but less frequent testing is usually sufficient for those with peanut, tree nut, fish, and shellfish allergy, especially in those who clearly have persistent disease.

**Management of reactions**

Despite food avoidance, reactions to accidental exposures are common. For example, in a study of children with peanut allergy, the rate of yearly peanut ingestion was 4.7%, with 1.6% of exposures causing severe reactions; epinephrine was used at a rate of 1.1% per year.

For children, food allergy is the leading cause of anaphylaxis requiring medical attention. Ingestion of peanut and tree nuts, age (adolescents and young adults), asthma, and delay of epinephrine treatment are all risk factors for mortality from food-induced anaphylaxis.

For acute IgE-mediated food allergy, intramuscular epinephrine is the recommended treatment for anaphylaxis, and self-injectable epinephrine should be available to the patient at all times. Dosing of the epinephrine auto-injector is based on weight, with patients weighing 10 kg to 25 kg receiving 0.15 mg, and patients weighing more than 25 kg requiring a 0.3 mg dose.

If symptoms do not improve after the initial dose, epinephrine injections should be administered every 5 to 15 minutes. A recent study found that 19% of food-induced anaphylactic reactions required more than 1 dose of epinephrine. All patients should be observed for at least 4 to 6 hours in a medical facility after a severe allergic reaction.

In addition to epinephrine, other interventions and medications can be used as adjunctive treatment of anaphylactic reactions. Bronchodilators are indicated for bronchospasm that has not responded to epinephrine treatment. First- and second-generation H1 antihistamines can be used to treat pruritis...
and urticaria for minor reactions and anaphylaxis. Although there are very few studies to support their use, H₂ antihistamines are often also prescribed.

Other therapeutic interventions include placing the patient in the recumbent position with feet elevated or administering intravenous fluids, oxygen, vasopressors, glucagon (for patients taking β-adrenergic receptor-blocking medications), and atropine.

After the initial anaphylactic reaction, some patients will experience a biphasic reaction, and a few will have protracted reactions. Most biphasic reactions will occur within 4 hours but can occur up to 72 hours after the initial reaction and are experienced in up to 20% of episodes. Although evidence is actually limited to support their use, corticosteroids are typically administered to prevent biphasic reactions and treat protracted symptoms. However, in most instances, only a single dose of corticosteroid needs to be administered.

**Future directions**

Although strict avoidance is still the mainstay of therapy for most food allergy, there are exciting new studies documenting that many children with milk and egg allergy may tolerate these foods in an extensively heated (eg, baked) form, even though they are still allergic to the uncooked forms of the food. In addition to improving quality of life by allowing these children to eat many of their favorite foods (eg, birthday cake), studies have shown that this exposure may help to build tolerance and potentially help to outgrow the allergy more quickly.

Immunotherapy for treatment of IgE-mediated food allergy is currently under investigation. The goal of immunotherapy is to effectively induce long-term tolerance to the culprit food with the least amount of systemic adverse effects. Many different modalities of delivery have been or are currently being studied, including subcutaneous injection, oral ingestion, sublingual absorption, epicutaneous, and rectal.

The optimum route of administration, product formulation, dosing protocol, length of treatment, and safety profile are yet to be determined. Therefore, immunotherapy is not currently US Food and Drug Administration approved and is not recommended for the treatment of food allergy, pending further study.

For non-IgE-mediated food allergy, avoidance of the culprit food is indicated. In cases of eosinophilic esophagitis unrelated to food allergy, topical corticosteroid treatment with budesonide or fluticasone propionate can help improve symptoms and histologic findings. Patients with food protein-induced enterocolitis and allergic proctocolitis usually outgrow the allergy within a few years of diagnosis, so oral food challenges are indicated at appropriate intervals.

Another common issue in pediatric practice relates to immunizations in children with egg allergy. Current guidelines say that the measles, mumps, and rubella vaccine contains negligible levels of egg allergen and is safe for all children with egg allergy to receive. Influenza vaccines do contain measurable levels of egg protein, and although levels may vary among manufacturers, they have become more consistently low in recent years.

Numerous studies have also documented that reactions to influenza vaccines are very uncommon, even in children with significant egg allergy. It is therefore recommended that patients with a history of mild allergic reactions to egg, including hives, may receive the inactivated (not intranasal) vaccine in their primary care physician’s office with a 30-minute observation, and those with a history of more severe reactions should be referred to an allergist for management. Older measures such as skin testing with the vaccine and dividing doses are no longer recommended.
FOOD ALLERGY

Facing the challenges

The diagnosis and management of the food allergic patient can be challenging given the paucity of evidence-based data, together with diagnostic tests that leave much to be desired. Optimal care of patients with food allergy can be best provided as a partnership between the pediatrician, the allergist, and the family, all working to keep the child or adolescent safe and yet maximize their quality of life in spite of the dietary restrictions and constant fear of a reaction. New studies provide hope that food allergy will someday be a treatable condition, and all pediatricians anxiously wait for that day to come.

REFERENCES

The parents of a 15-day-old boy who returned for his 2-week checkup are worried about a firm, glistening papule on his abdomen that has been present since birth. The patient is otherwise healthy, but the parents are seeking reassurance. A pediatric dermatology referral was quickly placed.

TELL US ON FACEBOOK

Have you ever had any experience with foregut cysts in your practice? Ever seen anything as unusual as this? Tell us on Facebook. facebook.com/ContemporaryPediatrics

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Cutaneous foregut cyst

CLINICAL AND HISTOLOGIC FINDINGS
On exam, a healthy, vigorous newborn with a nontender, bluish papule measuring approximately 1.0 cm in diameter located in the midline of his epigastric region was noted. There was no apparent sinus opening or tract around this lesion. Abdominal ultrasound identified a superficial and subcutaneous cyst measuring up to 8 mm with no definite communication with underlying abdominal structures.

Histopathology showed the cyst to be lined by pseudodified ciliated columnar epithelium. Most of the lining was directly in apposition with fibrous connective tissue, with very few areas of associated smooth muscle noted. No inflammation or cartilage was noted, and the cyst appeared to be localized to the dermal space superficial to the subcutis.

FOREGUT CYSTS
Foregut cysts are formed by abnormal budding during the process of embryonic foregut division to respiratory and intestinal elements at about the fifth week of intrauterine life. Most foregut cysts are located in the mediastinum; however, if complete separation and migration occur, they can appear in remote locations such as the skin. These cysts are further broken down into bronchial, esophageal, gastric, and enteric cysts on the basis of microscopic features.

Controversy exists between the labeling of these cysts as foregut versus bronchogenic. However, the absence of cartilage and bronchial glands and the presence of smooth muscle excludes the diagnosis of a bronchogenic cyst. The ciliated epithelium should not be used to classify these cysts, because this lining may persist postnatally and is variably present in both esophageal and bronchogenic cysts.

There have been more than 50 reported cases of cutaneous bronchogenic cysts; most do not include the presence of cartilage as a diagnostic requirement. The most common location of the cutaneous bronchogenic cysts is the suprasternal notch followed by the presternal area, neck, and scapula.

The primary difference between foregut cysts and bronchogenic cysts appears to be the time at which abnormal budding occurs. During embryonic development, the primitive foregut arises in the third week of gestation and divides into the dorsal portion, which forms the esophagus, and the ventral portion, which forms the tracheobronchial tree.

The cutaneous location of bronchogenic cysts may result from migration of pinched-off tissue from the thorax to the abdomen, continuing through the midline, before closure of the sternal mesenchymal bars during the seventh week.

This theory may make cutaneous, nonbronchogenic foregut cysts even more of a rarity because the pinching off in foregut cysts occurs at a later time in prenatal development.

Although rare, cutaneous foregut cysts should be included in the differential diagnosis of congenital cysts and papules/nodules on the anterior abdominal wall. This case may be the first reported foregut cyst to be located completely in the dermis of the abdominal wall.

EVALUATION AND TREATMENT
With most midline cystic lesions, imaging is recommended to exclude any communication with underlying structures. An ultrasound was sufficient to exclude this finding in our patient; however, further imaging such as magnetic resonance imaging may be indicated if ultrasound is inconclusive.

Bronchogenic cysts have associated complications such as infections, hemorrhage, and rarely malignant transformation. Therefore, in most instances, complete surgical excision is the recommended treatment.

Our patient underwent surgical excision of the cyst at 4 weeks and has had no complications or recurrences. He was recently seen in the office for a different reason and is doing well.

REFERENCES
Each year more than 7 million patients seek emergency department (ED) care for traumatic lacerations, and more than 2 million lacerations occur in patients aged younger than 18 years.¹

Not only are pediatric patients disproportionately affected, but they pose a specific set of challenges to physicians charged with caring for their wounds. Younger patients may have increased anxiety about needles and painful procedures and are typically less likely than their older counterparts to remain still during evaluation and repair.

Regardless of the patient’s age, proper wound care is essential for reducing infections and promoting healing. Although copious “higher”-pressure irrigation is the best means to remove foreign matter and reduce bacterial load, good skin apposition and closure are also required to prevent further bacterial contamination and infection as well as produce the best cosmetic outcome.

In selecting a method of wound closure, today’s provider has an armamentarium of choices including sutures, staples, adhesive strips, and adhesive glues.

Laceration repairs in pediatric patients ideally should be quick and painless, be strong and resistant to infection, promote healing, and yield good cosmetic outcomes. Tissue adhesives offer these advantages and are a wise choice for children who present with minor, low-tension wounds, especially on the head and face.
These methods not only differ in their intrinsic properties but also in their application, required skill, amount of pain caused, and duration of the procedure.

Because of the added challenges associated with treating the pediatric patient, the ideal method of closure in this population would be easy, quick, and painless and would not require a second visit for removal. Of course the closure must also produce sufficient tensile strength, have a low risk of infection, and result in a good cosmetic outcome.

As a method of laceration repair, skin adhesives offer many of these advantages, including minimal pain, intrinsic antibacterial activity, and good cosmetic results.

Despite these beneficial properties, skin adhesives are still limited from comprehensive use by their lesser tensile strength. However, they remain a good choice for pediatric patients, whose wounds are more likely to be short and linear and in areas of low tension, such as on the head or face.2

### History of tissue adhesives

Most tissue adhesive glues used today are from a family of molecules known as cyanoacrylates. A German chemist synthesized the first cyanoacrylate in 1949.1

Initially, cyanoacrylates were marketed for commercial (nonpharmaceutical) purposes (eg, Krazy Glue). It was not until the 1970s that cyanoacrylates became available for clinical use in Canada, Europe, Israel, and the Far East.4

The US Food and Drug Administration (FDA) first approved 2-octyl cyanoacrylate (DermaBond) for use in 1998.5 Over the following years, other cyanoacrylates (Indermil and Histoacryl, both n-butyl-2 cyanoacrylates) garnered FDA approval for humans.6,7 Tissue adhesives are now widely used in both operative surgical closures as well as ED laceration repairs.

### Polymerization

The family of cyanoacrylates is formed from the endothermic reaction of an alkyl cyanoacetate and formaldehyde to form an alkyl cyanoacrylate monomer. When the monomer comes into contact with water on the skin surface, it polymerizes into long chains, forming a film. Over time, the cyanoacrylate polymer degrades via hydrolysis back into an alkyl cyanoacetate and formaldehyde, both of which can be histotoxic.4

Like many organic compounds, the physical properties of the alkyl cyanoacrylate monomers and resulting polymers largely depend on the nature of their alkyl side chains. A short side chain (ie, methyl or ethyl) results in a very reactive monomer that quickly polymerizes into a film. Unfortunately, these bonds are subject to rapid hydrolysis and degrade quickly, releasing toxic products.8

A longer side chain (ie, butyl or octyl) produces a more stable monomer. Although these monomers may be slower to polymerize, polymerization results in a bond that degrades more slowly.9 When used as a skin adhesive, the longer chain cyanoacrylates typically undergo little in situ degradation and instead slough off with the outer layer of skin over time, minimizing the release of histotoxic byproducts.3

### Application

Early studies using cyanoacrylates for wound repair involved administering the adhesive directly into the wound.3 This technique produced good tensile strength during the initial days after administration. As time progressed, however, the presence of adhesive glue within the wound acted as a foreign body that prevented apposition of tissue and appropriate healing. A significant inflammatory reaction occurred, resulting in frequent wound dehiscence.

Current technique stresses the importance of avoiding application of the glue directly into the wound. Instead, the wound edges should be manually approximated first and the adhesive then applied as a film over the top. This method

CONTINUED ON PAGE 29
INDICATION AND USAGE
Desonate Gel is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

IMPORTANT SAFETY INFORMATION
Desonate is contraindicated in those with a history of hypersensitivity to any of the components of the preparation. Topical corticosteroids can produce reversible hypothalamic pituitary adrenal (HPA) axis suppression, Cushing’s syndrome and unmask latent diabetes. Systemic absorption may require evaluation for HPA axis suppression. Modify use should HPA axis suppression develop.

Potential patients may be more susceptible to systemic toxicity when treated with topical corticosteroids due to their larger skin surface-to-body mass ratios. Unless directed by a physician, do not use on the underarm or groin area of children. Do not use to treat diaper dermatitis. Use in children less than 3 months of age is not recommended.

Local adverse reactions may include atrophy, striae, irritation, acneiform eruptions, hypopigmentation and allergic contact dermatitis and may be more likely with occlusive use or more potent corticosteroids. The most common adverse reactions (incidence ≥ 1%) are headache, application site burning and rash.

To report SUSPECTED ADVERSE REACTIONS, contact Bayer HealthCare at 1-866-463-3634 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

2. Desonate Gel 0.05% [package insert]. Morristown, NJ: Intendis Inc; 2010.

Models used for illustrative purposes only.

Systemic absorption of topical corticosteroids can lead to irreversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for clinical glucocorticoid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid. The effect of Desonate on HPA axis function was investigated in pediatric subjects, 6 months to 6 years old, with atopic dermatitis covering at least 35% of their body surface. Of 37 subjects (3%) treated with Desonate twice daily for 4 weeks, one of 37 subjects (3%) developed adrenal suppression after 4 weeks of use, based on the cosyntrin stimulation test. As follow-up evaluation of the subject’s adrenal axis was not performed, it is unknown whether the suppression was reversible [see Use In Specific Populations (8.4) and Clinical Pharmacology (12.2)]. Pediatric patients may be more susceptible to systemic toxicity from equivalent doses of Desonate due to their larger skin surface-to-body mass ratios [see Use In Specific Populations (8.4)].

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent steroids, use over large surface areas, use over prolonged periods, use under occlusion, use on an altered skin barrier, and use in patients with liver failure. An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression. If HPA axis suppression is documented, a new corticosteroid agent should be used. If a favorable response does not occur promptly, the use of another corticosteroid should be discontinued until the infection is adequately controlled.

Concomitant Skin Infections

If concomitant skin infections are present or develop during treatment, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of Desonate should be discontinued until the infection is adequately controlled.

Skin Irritation

If irritation develops, Desonate should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

ADVERSE REACTIONS

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 practice. In controlled clinical studies of 425 Desonate-treated subjects and 157 Vehicle-treated subjects, adverse events occurred at the application site in 3% of subjects treated with Desonate and the incidence rate was not higher compared with vehicle-treated subjects. The most common local adverse events in Desonate treated subjects were application site burning in 1% (4/425) and rash in 1% (3/425) followed by application site pruritus in <1% (2/425).

Adverse events that resulted in premature discontinuation of study drug in Desonate treated subjects were telangiectasia and worsening of atopic dermatitis in one subject each. Additional adverse events observed during clinical trials for patients treated with Desonate included headache in 2% (8/425) compared with 1% (2/157) in those treated with vehicle.

The following additional local adverse reactions have been reported infrequently with topical corticosteroids. They may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, secondary infection, skin atrophy, striae, and miliaria.
allows the adhesive to act as an outer bridge, holding the layers of skin together as wound healing occurs beneath.

Cosmetic outcome

Since the first cyanoacrylates were used clinically, there have been several randomized, controlled trials in the pediatric population comparing the cosmetic outcome of wounds closed with Histoacryl to wounds closed with sutures. For example, as early as 1993, Quinn and colleagues enrolled 81 children and adolescents (aged 0-18 years) with facial lacerations that were less than 4 cm in length and less than 0.5 cm in width, not requiring deep layer closure.10

Later similar studies continued to evaluate skin adhesive as a method of pediatric laceration repair.11-13 There were no significant differences in cosmetic outcome between Histoacryl and sutures when scars were compared at 2 to 3 months and again at 12 months. In addition, secondary end-point analyses showed skin adhesives to be significantly faster in application than standard suture wound closure and significantly less painful than sutures, despite the use of an anesthetic (injected lidocaine or topical tetracaine-epinephrine-cocaine) when necessary. There were no significant differences in rates of infection or dehiscence.

In a study of DermaBond versus sutures, Quinn and associates enrolled 130 adults with face, torso, or extremity lacerations, regardless of the laceration’s length or need for deep sutures.14 Again, there was no significant difference in cosmetic outcome at 3 months. As with Histoacryl, application of DermaBond was faster and less painful than the standard suture alternative.

Subsequently, Osmond and colleagues reported an interadhesive comparison between Histoacryl and DermaBond in 94 children and adolescents with simple facial lacerations.15 Despite differences in butyl versus octyl side chain and method of application, there were no significant differences between groups for time of repair, ease of procedure, pain score, infection rate, dehiscence rate, or cosmetic outcome at 3 months.

Finally, Zempsky and associates compared DermaBond to reinforced Steri Strip skin closures in 97 children and adolescents with short, low-tension facial lacerations and found no significant differences in procedural pain or cosmetic outcome at 2 months.16 However, there was a trend (P=.06) toward fewer short-term complications, specifically infection and dehiscence, in the Steri Strip group.

Tensile strength

Despite the many advantages of skin adhesives, they remain restricted in use because of their limited tensile strength. The aforementioned studies, which claim equal rates of wound dehiscence, must be interpreted with caution, because entry criterion generally precluded inclusion of large, high-tension wounds.

Using guinea pigs to compare Histoacryl to percutaneous sutures, Noordzij and associates found a drastic difference in wound strength between groups immediately after repair: sutures proved 12 times stronger than adhesive.17 However, after 7 days of healing and after suture removal, there was no significant difference in breaking strength.

Also in a guinea pig model, Bresnahan and colleagues compared wound strength in 4 groups: Nexaband liquid (n-butylcyanoacrylate) alone, Nexaband liquid with a single subcutaneous suture, percutaneous sutures alone, or percutaneous sutures with a subcutaneous suture.18

Ninety-six hours after closure, wounds repaired with adhesive glue alone had significantly lower tensile strength than those closed with any of the other 3 methods. Although the addition of a subcutaneous suture increased the tensile strength of the adhesive, the insertion of stitches begins to eliminate the many benefits of using adhesive glues.

Shapiro and associates used fresh porcine skin to compare, in vitro, the tensile strength just after

Point Taken

- Studies have shown no significant differences in cosmetic outcome between Histoacryl and sutures.
- Despite their advantages, skin adhesives are restricted in use because of their limited tensile strength.
placement of 4 common wound closure methods: DermaBond, surgical staples, Steri Strips, or interrupted, subcuticular 4-0 sutures. Staples proved significantly stronger than sutures or DermaBond, and sutures or DermaBond proved significantly stronger than Steri Strips. However, the increased strength of the sutures versus DermaBond did not reach significance in this study.

It has been suggested that DermaBond (which also contains plasticizers) is stronger and more pliable in vivo than Histoacryl. However, a published report of a direct tensile strength comparison in an animal model could not be located. Furthermore, Osmond and colleagues’ interadhesive comparison of Histoacryl and DermaBond in pediatric patients showed no differences in dehiscence rates.

**Antibacterial activity**

Although copious irrigation remains paramount for preventing wound infection, there are also data to suggest that at least some of the cyanoacrylate products exhibit intrinsic bacteriostatic activity (beyond their sealant effect), which may help keep infection rates low.

For example, using an in vitro agar-plating technique, Chen and associates demonstrated that both Histoacryl and a methoxypropyl cyanoacrylate created zones of growth inhibition against *Staphylococcus aureus*, *Streptococcus pneumoniae*, and *Mycobacterium chelonae*. However, these adhesives had no such inhibitory effect on *Escherichia coli* or *Pseudomonas aeruginosa*.

Noordzij and colleagues inoculated guinea pig incisions with *S. aureus* before closure and found decreased bacterial counts in wounds closed with Histoacryl compared with sutures on day 4.

In a 2-part experimental design (in vivo in guinea pigs and in vitro in soy broth), Howell and associates investigated cyanoacrylate liquid and obtained similar antibacterial results against *S. aureus*.

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**How to use**

**Wound selection**

Only certain lacerations are appropriate for skin adhesive repair. The cyanoacrylates are best used on short, linear, low-tension wounds that can be manually approximated easily. Lacerations in areas of high tension, such as over joints or on the hands or feet, should be avoided. Similarly, moist areas, such as the mucous membranes, perineum, and axillae, prevent adequate adhesion. Crush injuries and stellate lesions can be difficult to approximate.

**Anesthetic administration**

After initial evaluation of the wound, a topical anesthetic formulation such as lidocaine, ephinephrine, and tetracaine solution should be applied as soon as possible. In most studies, topical anesthetics have proven to be at least as effective for pain control as lidocaine infiltration. Topical anesthetics have the added benefit of needleless, nearly pain-free application, which is especially good for children. Administering the anesthetic early in the patient’s care relieves pain sooner and provides analgesia before irrigation.

**Direct irrigation**

General wound care is unchanged. Copious high-pressure irrigation is key to removing foreign matter and preventing infection. Using a syringe with a splashguard helps optimize this procedure. Traumatic lacerations should be irrigated with approximately 100 cc per 1 cm length of laceration or an even larger volume when significant contamination is likely. The patient’s tetanus immunization status should be addressed.

**Skin adhesive application**

After hemostasis, irrigation, and patting dry, the wound edges are manually apposed. The adhesive should be applied to the outer surface of the skin, forming a bridge-like film across the defect. Care must be taken to avoid administering the adhesive directly into the wound, which actually prevents skin edge contact and healing.

*CONTINUED ON PAGE 33*
The first and only extended-release methylphenidate oral suspension for ADHD treatment

Now FDA Approved | Now available in pharmacies

INDICATION
Quillivant XR is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The efficacy of Quillivant XR was established in a 2-week, placebo-controlled trial in children aged 6 to 12 years with a diagnosis of ADHD. Accumulated efficacy data from other methylphenidate products were also considered.

IMPORTANT SAFETY 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.

• 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.
  – During treatment with monoamine oxidase inhibitors (MAOIs), and also within 14 days following discontinuation of treatment with an MAOI because of the risk of hypertensive crisis.

• 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.

• Use of stimulants may cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychiatric illness. Evaluate for bipolar disorder prior to Quillivant XR use.

• CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Growth should be monitored during treatment with stimulants, including Quillivant XR. Patients who are not growing or gaining weight as expected may need to have their treatment interrupted.

• 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.

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

For more information, visit www.QuillivantXRPro.com

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NEW Quillivant XR™
methylphenidate HCl
for extended-release oral suspension
25 mg/5 mL
Quillivant XR® (methylphenidate HCl) for extended-release oral suspension, CI 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). 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 mm Hg) 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 or worsen manic episodes in patients with bipolar disorder.

**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, and ophthalmic complications, eclampsia, pulmonary edema, and renal failure.

**USAGE 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 rats at 40 times the maximum recommended human dose (MRHD), on a mg/m² 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 vasodilation 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: 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/m² basis. The no-effect level for embryo-fetal development in rabbits was 70 mg/kg/day (11 times the MRHD on a mg/m² 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/m² 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/m² 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/m² basis), but no other effects on postnatal...
Glue adhesives for wound repair

Continued from page 30

DermaBond is applied via a porous applicator tip (supplied by the manufacturer) across the skin edges, which are held in place for another 30 seconds to allow for drying. This process is repeated with 2 to 3 additional layers, holding for 30 seconds between each; Histoacryl is applied as drops of glue across the skin edges and held in place for 30 seconds.

Avoiding pitfalls

A common complication of skin adhesive application is leakage of glue into nearby, unintended areas. With use of adhesive for facial lacerations, leakage into the eye is of particular concern. To help prevent inadvertent lid margin and ocular involvement, position the patient so that any seeping of product will occur away from the eye. A ridge of petroleum jelly can also be applied between the laceration and eyelid to act as a barrier.

In the event glue does affect the eye, avoid using water to wipe the glue away because the glue adheres to water. Use the following technique:

1. Use a clean, dry cloth and pull the eye open to allow the glue to fall out of the eye.
2. If the glue is stubborn, use airdrie pressure to blow the glue out. Glue adhesives for wound repair

Important to remember

- Early application of a topical anesthetic provides analgesia during irrigation as well as repair.
- Cyanoacrylates exhibit antibacterial activity, but copious irrigation remains paramount for infection prevention.
- Use of adhesive glue over areas of high tension, such as joints, should be avoided.
- Adhesive glue should not be installed directly into a wound but instead applied as a bridge-like film overtop manually apposed skin edges.
- Skin adhesives can be used for epidermal closure in conjunction with deep sutures (if deep sutures are needed for added tensile strength) to speed time of total repair.
- Skin adhesives produce equivalent cosmetic outcomes as sutures for small lacerations, including wounds up to 5 cm in length.

Glue adhesives for wound repair

Quillivant XR® (methylphenidate HCl) Brief Summary continued...

development were observed. The no effect level for pre- and postnatal development in rats was 15 mg/kg/day (equal to the MRHD on a mg/m² basis). Nursing Mothers Methylphenidate is present in human milk. Long-term neurodevelopmental effects on infants from stimulant exposure are unknown. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Pediatric Use The safety and effectiveness of Quillivant XR have been established in pediatric patients 6 to 17 years. Use of Quillivant XR in pediatric patients 6 to 12 years of age is supported by adequate and well-controlled studies. Use in 12 to 17 year olds is supported by the adequate and well-controlled studies of Quillivant XR in younger pediatric patients and additional pharmacokinetic data in adolescents, along with safety information from other methylphenidate-containing products. The long-term efficacy of methylphenidate in pediatric patients has not been established. Safety and efficacy in pediatric patients below the age of 6 years have not been established. Long-Term Suppression of Growth Growth should be monitored during treatment with stimulants, including Quillivant XR. Children who are not growing or gaining weight as expected may need to have their treatment interrupted (see Warnings and Precautions). Juvenile Animal Data Rats treated with methylphenidate early in the postnatal period through sexual maturity demonstrated a decrease in spontaneous locomotor activity in adulthood. A deficit in acquisition of a specific learning task was observed in females exposed to the no effect level for juvenile neurobehavioral development in rats was 5 mg/kg/day (half the MRHD on a mg/m² basis). The clinical significance of the long-term behavioral effects observed in rats is unknown. Geriatric Use Quillivant XR has not been studied in patients over the age of 65 years.

Drug Abuse and Dependence

Controlled Substance Quillivant XR contains methylphenidate, a Schedule II controlled substance.

Abuse CNS stimulants including Quillivant XR, other methylphenidate-containing products, and amphetamines have a high potential for abuse. Abuse is characterized by impaired control over drug use, compulsive use, continued use despite harm, and craving. Signs and symptoms of CNS stimulant abuse include increased heart rate, respiratory rate, blood pressure, and/or sweating, dilated pupils, hyperactivity, restlessness, insomnia, decreased appetite, loss of coordination, tremors, flushed skin, vomiting, and/or abdominal pain. Anxiety, psychosis, hostility, aggression, suicidal or homicidal ideation have also been observed. Abusers of CNS stimulants may chew, snort, inject, or use other unapproved routes of administration which can result in overdose and death (see Overdosage).

To reduce the abuse of CNS stimulants including Quillivant XR, assess the risk of abuse prior to prescribing. Keep careful prescription records, educate patients and their families about abuse and on proper storage and disposal of CNS stimulants, monitor for signs of abuse while on therapy, and re-evaluate the need for Quillivant XR use.

Dependence Tolerance Tolerance (a state of adaptation in which exposure to a drug results in a reduction of the drug’s desired and/or undesired effects over time) can occur during chronic therapy with CNS stimulants including Quillivant XR. Dependence Physical dependence (a state of adaptation manifested by a withdrawal syndrome produced by abrupt cessation, rapid dose reduction, or administration of an antagonist) can occur in patients treated with CNS stimulants including Quillivant XR. Withdrawal symptoms after abrupt cessation following prolonged high-dosage administration of CNS stimulants include extreme fatigue and depression.

Overdosage

Signs and Symptoms Signs and symptoms of acute methylphenidate overdose, resulting primarily from overdosage of the CNS and from excessive sympathomimetic effects, may include the following: nausea, vomiting, diarrhea, restlessness, anxiety, agitation, tremors, hypertension, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperventilation, tachycardia, palpitations, cardiac arrhythmias, hyperpnea, hypertension, tachypnea, mydriasis, and dryness of mucous membranes.

Management of Overdose Consult with a Certified Poison Control Center for up-to-date guidance and advice on the management of overdosage with methylphenidate (1-800-222-1222). Provide supportive care, including close medical supervision and monitoring. Treatment should consist of those general measures employed in the management of overdosage with any drug. Consider the possibility of multiple drug overdosage. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Use supportive and symptomatic measures.
polymerization of glue may be accelerated by water. Copious application of antibacterial ophthalmic ointment (ie, erythromycin ophthalmic ointment) may help break down the adhesive. An ophthalmologist should be consulted as necessary.

**Dressing**
There is no need for antibacterial ointment because the adhesive has antibacterial properties and because the emollient ointment can cause premature loosening of the glue and wound dehiscence. Generally, there is no need for a dressing. If cotton gauze is requested, it is imperative that the polymerization reaction has completed and that the glue is completely dry. There is a case report of contact between cyanoacrylate household glue and cotton pajamas causing a severe exothermic reaction and full thickness burn injury.²⁴

**Discharge instructions**
Patients should be instructed to keep their wounds clean and dry for the first 24 hours, after which they can shower, taking care not to overly soak the wound. Obviously, picking at the adhesive should be avoided to reduce the risk of dehiscence.

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**References**

Fever and failure to thrive in toddler

KALINDI DHEKNEY, MD; SAHAR FAGHIH, DO; ELIZABETH SECORD, MD

THE CASE

It’s been a busy day in the emergency department (ED). You pick up the next chart and prepare to see a 14-month-old Arab American boy with a 10-day history of rhinorrhea, cough, fever, and tugging of his ear. The boy’s mother explains that his pediatrician evaluated her son about 1 week ago and that the pediatrician prescribed amoxicillin for otitis media.

When his fever rose that night to 41.1°C, despite the antibiotics, she took her son the next day to a community hospital ED, where a blood culture and complete blood count (CBC) with differential were drawn. Fortunately, the mother has brought a copy of the records from that ED visit.

The CBC showed a white blood count (WBC) of 25,000 cells/mm³, with a differential of 57% neutrophils, 31% lymphocytes, 11% monocytes, and no bands. Hemoglobin (Hb) was 8 g/dL; platelet count was 553,000 cells/mm³; and the urinalysis was normal. Nasal washes for respiratory syncytial virus (RSV) and influenza were negative.

The boy was given 1 dose of intramuscular ceftriaxone and then sent home but was called back to the pediatrician’s office because of growth in the blood culture obtained in the ED. The mother tells you that the pediatrician repeated the CBC and blood culture and said that the WBC had come down. She says the pediatrician thought the blood culture result was just a contaminant.

You note that the ED paperwork shows that the blood-culture isolate was identified as *Staphylococcus warneri*, a coagulase-negative organism that commonly colonizes the skin, so this seems consistent. The mother tells you that the repeat blood culture drawn in the pediatrician’s office was negative. The patient, however, continued to have intermittent fevers that were treated with acetaminophen and ibuprofen for approximately 3 weeks. Frustrated and concerned, the mother decided to bring her son to the children’s hospital ED for further evaluation.

History

You ask about past medical history and elicit that the boy was born full term, weighing 3.422 kg (25th-50th percentile) via spontaneous vaginal delivery to a healthy 21-year-old woman who had no pregnancy complications and reports unremarkable prenatal laboratory results. The mother tells you that she tested negative for human immunodeficiency virus (HIV),...
hepatitis B, and syphilis during the first trimester of pregnancy, and you verify this by reviewing the mother’s prenatal records.

The child was breastfed for 2 weeks after delivery then was switched to cow’s milk formula because the mother felt she did not have an adequate milk supply. His length and head circumference at birth were measured in the 25th percentile, and his mother has been concerned for some time about his eating and his growth; however, he has had no developmental delay or loss of milestones. The child was born in the United States and has received all age-appropriate immunizations. He lives with his parents, both of whom were born outside the United States. The child has no siblings. He has had no previous hospitalizations.

**Physical findings**

The child is alert and crying but consolable. His temperature is 39.1°C (rectal); weight is 8.8 kg (<3rd percentile); height is 73 cm (<5th percentile); head circumference is 45.1 cm (5th percentile); heart rate is 120 beats per minute; respiratory rate is 26 breaths per minute; and blood pressure is 100/54 mm Hg.

The otoscopic exam reveals an erythematous and bulging right tympanic membrane. His oropharynx is noninjected, and there is no thrush. There are a few scattered crackles heard bilaterally. Heart exam reveals a regular rate and rhythm without murmurs, abdomen is soft without hepatosplenomegaly, and capillary refill time is 2 seconds. No rashes or lesions are noted on skin examination.

The musculoskeletal exam reveals full range of motion, adequate strength, and no erythema or effusions. Neurologically, his deep tendon reflexes are 2/4 bilaterally, and cranial nerves II to XII are symmetric without any focal deficits. The positive blood culture from the outside hospital admission, it returned 1 week after he was discharged. Today, the CBC with differential shows an elevated WBC of 18,600 cells/mm³, with a differential of 9% bands, 36% neutrophils, and 44% lymphocytes; Hb of 8.8 g/dL; and platelet count of 232,000 cells/mm³. The Hb remains low at 8.1 g/dL. The reticulocyte count is 5.6%. The child remains afebrile during his hospital stay. Iron studies return and are not consistent with a diagnosis of iron-deficiency anemia. The mean corpuscular volume is 81.8 fl (normocytic), and the red blood cells are normochromic on smear.

You note that his mother is thin in build. The boy’s diet consists of milk and cereal with no meat or other sustainable form of protein. As you look through his records, you note that even though at birth his weight was between the 25th and 50th percentile, he has steadily been crossing percentiles to less than the 3rd percentile during this admission. His height was following the 10th percentile but has now fallen in the last year to the 3rd percentile.

You are concerned that the boy’s failure to thrive (FTT) is not fully explained by poor nutrition and obtain further lab studies. Electrolyte levels along with blood urea nitrogen, creatinine, calcium, magnesium, phosphorus, and bilirubin levels are normal. Alanine and aspartate aminotransferases are elevated at 260 units/L and 450 units/L, respectively. Alkaline phosphatase, lactate dehydrogenase (LDH), uric acid, and soluble transferrin receptor levels are normal. You think of the differential for FTT again (Table 1) and consider the transaminitis, history of persistent fevers, otitis media resistant to oral therapy, and the normocytic anemia. The FTT does not appear to be purely nutritional. The child is afebrile at discharge and given a follow-up appointment to continue the FTT evaluation.

**Back into the hospital**

Before his appointment, he returns to the ED with fever, diarrhea, and decreased oral intake. You are informed that although the child’s fever had resolved during his previous hospital admission, it returned 1 week after he was discharged. Today, the CBC with differential shows an elevated WBC of 18,600 cells/mm³ with 3% bands, 44% neutrophils, and 44% lymphocytes. A repeat blood culture is also sent. Alanine and aspartate aminotransferases have risen even further to 524 units/L and 526 units/L, respectively. On physical exam he does not appear toxic. There are no abnormal findings on exam, and the otitis media infiltration or pleural effusion. The chest x-ray reading indicates small airway disease. Because of the persistent acute otitis despite oral antibiotics and concern for bacteremia, you continue the ceftriaxone.

Blood and urine cultures are sterile after 2 days. The CBC shows a decline in the WBC count to 17,900 cells/mm³. The Hb remains low at 8.1 g/dL. The reticulocyte count is 5.6%. The child remains afebrile during his hospital stay. Iron studies return and are not consistent with a diagnosis of iron-deficiency anemia. The mean corpuscular volume is 81.8 fl (normocytic), and the red blood cells are normochromic on smear.
has resolved. The child is febrile with a temperature of 39.7°C. You decide to readmit the patient.

During this admission, you delve further into the social history and past medical history of this child. You ask about past or family history of metabolic abnormalities, celiac disease, autoimmune diseases, consanguinity, or history of transfusions for either the child or mother during pregnancy. The history for each is negative. Alpha-1-antitrypsin, alpha-1-phenotype, hepatitis B surface antigen and antibody, and hepatitis C antibody screen are all negative. An abdominal ultrasound shows mild hepatomegaly. In the past month, the patient has gained only 100 g, from 8.8 kg to 8.9 kg.

On exam, the liver is palpable at 5 cm below the right costal margin. The hepatitis screen is negative. In order to determine whether there is an underlying immune deficiency to explain the FTT, repeated febrile illnesses, and infections, you send for tests for immunoglobulins (IgG, IgA, IgM, IgE), lymphocyte subsets, and antibody titers to pneumococcus, diphtheria, and tetanus. You review the case with the hematologist, who recommends testing for glucose-6 phosphate deficiency (G6PD) as a cause of the anemia. He is again given intravenous antibiotics, the fever and diarrhea resolve, and the child is discharged home with a follow-up appointment in clinic.

The follow-up
The child returns for follow-up at your clinic. His laboratory results reveal G6PD deficiency that appears to confirm the etiology of his anemia. The IgG is elevated to 2,810 mg/dL (normal range, 345-1,213 mg/dL), but the IgM and IgA are within normal parameters. You attribute the elevated IgG to recent infection. You are concerned because of the child’s insufficient weight gain since his hospital discharge.

You once again ask about the home situation and state of health of other members of the family. The mother reports that her primary care doctor is evaluating her for lymphadenopathy. Considering this new information, you realize that in this child’s previous evaluation for FTT, an HIV screen was never performed. You recall that his mother had a negative HIV enzyme-linked immunosorbent assay (ELISA) during the first trimester of her pregnancy, but you decide to order the HIV DNA polymerase chain reaction (PCR) test as well as an HIV ELISA on this child.

The HIV ELISA and subsequent Western blot for HIV come back positive, which confirms perinatal exposure to HIV. The HIV DNA PCR returns 3 days later, confirming the child’s HIV infection. You refer the patient to immunology for further care and evaluation.

Table 1

<table>
<thead>
<tr>
<th>Differential diagnosis of failure to thrive</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Neurologic</strong></td>
</tr>
<tr>
<td>- Cerebral palsy</td>
</tr>
<tr>
<td>- CNS tumors</td>
</tr>
<tr>
<td>- Neuromuscular and neurodegenerative disorders</td>
</tr>
<tr>
<td><strong>Renal</strong></td>
</tr>
<tr>
<td>- Recurrent urinary tract infections</td>
</tr>
<tr>
<td>- Renal tubular acidosis</td>
</tr>
<tr>
<td>- Chronic renal failure</td>
</tr>
<tr>
<td><strong>Endocrine</strong></td>
</tr>
<tr>
<td>- Diabetes mellitus and insipidus</td>
</tr>
<tr>
<td>- Hypothyroidism/Hyperthyroidism</td>
</tr>
<tr>
<td>- Growth hormone deficiency</td>
</tr>
<tr>
<td>- Adrenal insufficiency</td>
</tr>
<tr>
<td><strong>Genetic/Metabolic/Congenital</strong></td>
</tr>
<tr>
<td>- Sickle cell disease</td>
</tr>
<tr>
<td>- Inborn errors of metabolism (organic acidosis, hyperammonemia, storage disease)</td>
</tr>
<tr>
<td>- Fetal alcohol syndrome</td>
</tr>
<tr>
<td>- Skeletal dysplasias</td>
</tr>
<tr>
<td>- Chromosome disorders</td>
</tr>
<tr>
<td><strong>Gastrointestinal</strong></td>
</tr>
<tr>
<td>- Pyloric stenosis</td>
</tr>
<tr>
<td>- Gastroesophageal reflux</td>
</tr>
<tr>
<td>- Malrotation</td>
</tr>
<tr>
<td>- Malabsorption syndromes and celiac disease</td>
</tr>
<tr>
<td>- Pancreatic insufficiency syndromes (cystic fibrosis)</td>
</tr>
<tr>
<td>- Chronic cholestasis</td>
</tr>
<tr>
<td>- Inflammatory bowel disease</td>
</tr>
<tr>
<td>- Hirschsprung disease</td>
</tr>
<tr>
<td>- Short bowel syndrome</td>
</tr>
<tr>
<td>- Eosinophilic esophagitis</td>
</tr>
<tr>
<td><strong>Cardiac</strong></td>
</tr>
<tr>
<td>- Cyanotic heart disease</td>
</tr>
<tr>
<td>- Congestive heart failure</td>
</tr>
<tr>
<td>- Vascular rings</td>
</tr>
<tr>
<td><strong>Pulmonary/Respiratory</strong></td>
</tr>
<tr>
<td>- Severe asthma</td>
</tr>
<tr>
<td>- Cystic fibrosis; bronchiectasis</td>
</tr>
<tr>
<td>- Bronchopulmonary dysplasia</td>
</tr>
<tr>
<td>- Obstructive sleep apnea</td>
</tr>
<tr>
<td><strong>Infections</strong></td>
</tr>
<tr>
<td>- Perinatal infections</td>
</tr>
<tr>
<td>- Parasitic infections</td>
</tr>
<tr>
<td>- Tuberculosis</td>
</tr>
<tr>
<td>- HIV</td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
</tr>
<tr>
<td>- Collagen-vascular disease</td>
</tr>
<tr>
<td>- Primary immune deficiencies</td>
</tr>
<tr>
<td>- Malignancy</td>
</tr>
</tbody>
</table>

Abbreviations: CNS, central nervous system; HIV, human immunodeficiency virus. Adapted from McLean HS, et al.
Failure to thrive

Failure to thrive is better described as a failure to gain weight.¹ Most commonly, this is because of inadequate nutritional intake. However, other causes include inadequate calorie intake, inadequate caloric absorption, and excessive caloric expenditure, which can be because of conditions such as congenital heart disease, pulmonary disease, hyperthyroidism, metabolic disease, chronic immunodeficiency, recurrent infection, or malignancy.² The proportion of children seen in the primary care setting with FTT has been found to be as high as 10%. Failure to thrive can be the presenting finding in children with perinatal HIV infection.³

Pediatric HIV

Many clinical problems, including FTT, warrant HIV testing in their workup (Table 2).⁴ HIV in infants became uncommon with the implementation of treatment guidelines established after the landmark 076 study of the AIDS Clinical Trial Group in 1994, whereby all women are offered HIV testing during pregnancy, all infected women receive antiretroviral drugs during pregnancy and during labor and delivery, and known infants exposed to HIV receive oral zidovudine for the first 6 weeks after birth.⁵ With use of combination antiretroviral drugs during pregnancy now routine, the incidence of pediatric HIV infection has plummeted.

The primary mode of infant HIV acquisition is mother-to-child transmission (MTCT) via transplacental, intrapartum, or breastfeeding routes of exposure. Perinatally acquired HIV-1 infection shows 2 distinct patterns if untreated. During the first few weeks of life, 10% to 15% of infected infants have a profound immune deficiency leading to opportunistic infections, usually pneumocystis pneumonia.³ The other pattern is characterized by more gradually progressive immune deficiency over a period of several years and manifesting as lymphadenopathy, poor growth, and repeated bacterial infections.

Studies on timing of MTCT of HIV suggest that most transmissions in nonbreastfeeding populations occur at the time of delivery.⁷ The risk of transmission is particularly high for women with a primary HIV-1 infection during the last trimester of pregnancy. These women are more likely to have higher viral loads and less likely to have their HIV infection identified through usual HIV antibody testing.

The method of diagnosis for HIV varies by age group (Table 3).⁴ In children aged 18 months and older and in all adolescents and adults, HIV antibody is the confirmatory test. Most commonly, a blood sample is used, and testing is done via ELISA testing with confirmation using a Western blot. Plasma HIV RNA concentration (by PCR), or viral load, is used to determine the need for treatment and for monitoring response to treatment.

In infants aged through 18 months and for anyone who cannot make antibody (eg, a patient with common variable immune deficiency), HIV DNA (or RNA) by PCR is used to diagnose HIV.⁴ Antibody testing in infants younger than 18 months is not useful, because a positive test indicates the presence of passively acquired maternal antibody in the infant’s serum and does not distinguish HIV-infected from HIV-exposed, uninfected infants.

HIV testing

Current CDC guidelines recommend early HIV testing for all pregnant women, with repeat testing in the third trimester in women who meet at least 1 of the following criteria: 1) Receive health care in jurisdictions with elevated incidence of HIV or AIDS among women aged 15 to 45 years; 2) Receive health care in facilities in which prenatal screening identifies at least 1 HIV-infected pregnant woman per 1,000 women screened; 3) Known to be at high risk for acquiring HIV (eg, injection-drug users and their sex partners; exchange sex for money or drugs; are sex partners of HIV-infected persons; have had a new or more than 1 sex partner during this pregnancy); and 4) Have signs or symptoms consistent with acute HIV infection.⁸

This patient’s mother was not identified through the usual
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Measurement of the production of IL-1 and TNFα inflammation mediators and skin thickness (œdema).

(2) 2007 Multicentric, open, randomised comparative study conducted by 12 dermatologists on 80 children aged 4 months to 4 years presenting with slight to moderate atopic dermatitis. Group 1: application of corticosteroid twice a day on affected areas (n=40, average age: 2.3 years). Group 2: application of an emollient twice a day on lesions and on entire body (n=40, average age: 2.4 years). Evaluation of Scorad at baseline, day 0, day 7 and day 21. Evaluation of quality of life using the IDQOL-GFQ questionnaire and severity of eczema at day 7 and day 21.
perinatal screening (a missed opportunity to prevent transmission), and the child’s diagnosis was delayed because of several factors. Such presentations of pediatric HIV infection now are uncommon in the United States because of widespread HIV testing of pregnant women and implementation of effective strategies to prevent MTCT for women known to have HIV infection. She was tested for HIV during pregnancy and was negative in the first trimester but did not meet the high-risk criteria for repeat testing. She may have been in the window period when initially tested for HIV or may have acquired HIV infection during her second or third trimester. This woman was not considered to be a high-risk patient for contracting HIV because she reported only 1 lifetime partner and her ethnic background (Arab American) is not considered to be in the high endemic group of her state. She was not living in an area that was known to have HIV infection. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. Red Book: 2009 Report of the Committee on Infectious Diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009:380-400.

Several states, including Michigan (where this infant was born) are reporting cases of infants and toddlers with HIV born (or RNA PCR) Antibody

<table>
<thead>
<tr>
<th>Patient</th>
<th>Timing</th>
<th>Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant women</td>
<td>Prenatal: first trimester; repeat in third trimester.*</td>
<td>Antibody</td>
</tr>
<tr>
<td></td>
<td>Perform at delivery on high-risk mothers or those who missed third-trimester screening.</td>
<td></td>
</tr>
<tr>
<td>HIV-exposed newborns</td>
<td>Optional first test at birth. Testing recommended at 2-3 wk, 1-2 mo, and at or after 4 mo.</td>
<td>DNA PCR (or RNA PCR)</td>
</tr>
<tr>
<td></td>
<td>After 12-18 mo to confirm seronegativity.</td>
<td></td>
</tr>
<tr>
<td>Children of HIV+ mother</td>
<td>No maximum age.</td>
<td>Antibodya</td>
</tr>
<tr>
<td>Adolescents</td>
<td>Single screen at/after 13 yr; repeat annually if sexually active or injecting drugs</td>
<td>Antibodyc</td>
</tr>
</tbody>
</table>

Abbreviations: DNA, deoxyribonucleic acid; HIV, human immunodeficiency virus; PCR, polymerase chain reaction; RNA, ribonucleic acid.

a. In high-risk populations per Centers for Disease Control and Prevention guidelines.
b. Use infant testing algorithm if younger than 18 mo.
c. Use additional HIV RNA testing if clinical presentation is suggestive of acute retroviral syndrome. Adapted from Simpkins ES et al.4

HIV testing of pregnant women and implementation now are uncommon in the United States because of widespread HIV testing of pregnant women and implementation of effective strategies to prevent MTCT for women known to have HIV infection. She was tested for HIV during pregnancy and was negative in the first trimester but did not meet the high-risk criteria for repeat testing. She may have been in the window period when initially tested for HIV or may have acquired HIV infection during her second or third trimester. This woman was not considered to be a high-risk patient for contracting HIV because she reported only 1 lifetime partner and her ethnic background (Arab American) is not considered to be in the high endemic group of her state. She was not living in an area that was considered high enough prevalence for repeat testing during third trimester or at delivery.

Several states, including Michigan (where this infant was born) are reporting cases of infants and toddlers with HIV who were missed at birth because of first-trimester negative HIV ELISA without repeat testing in the third trimester or at delivery.4 Because of this case and others, the policy in Michigan has been changed to include a recommendation for third-trimester testing or rapid testing during delivery.4

Initial laboratory testing in an HIV-infected patient should include CD4 percentage and absolute cell counts, plasma HIV RNA concentration (viral load), and the HIV genotype to assess for baseline resistance mutations.4 In children aged younger than 5 years, the CD4 percentage is the preferred test for monitoring immune status because the absolute CD4 cell count (number of CD4 cells/mm3) in this age group varies with age-related changes in the absolute lymphocyte count.

**Our patient**

The patient was seen in the pediatric HIV clinic. The CD4+ T-cell count was 2,432 (38%), which was normal for age (2,307-2,864), and the HIV viral load was found to be 134,000 copies/mL. The genotyping of the virus did not reveal any resistance to antiretroviral drugs, and he was started on antiretroviral therapy because the viral load was above 100,000 copies/mL. The drug regimen consisted of zidovudine, lamivudine, and nevirapine. Both parents were confirmed to be HIV positive. On the return visit 2 months later, the patient had a CD4+ T-cell count of 2,500 and an HIV viral load of 115 copies/mL. Approximately 7 months into treatment, the patient’s viral load was less than 48 copies/mL (undetectable).5

**REFERENCES**

Vision screening in children
The role of automated vision screening technology

As we strive to see more patients while continuing to provide quality care, pediatricians are learning new ways to improve and invigorate their practices. Innovation can provide more accurate office diagnostics and new treatment alternatives while promoting staff efficiency and patient satisfaction. As a start to this ongoing series looking at ways to move pediatric practice to the “next level” (Pediatrics v2.0), we’ll review new recommendations that encourage pediatricians to use automated screening technologies (ie, photoscreeners) to detect vision problems in young children.

The importance of vision screening
Amblyopia is one of the most common visual problems of childhood, occurring in as many as 1% to 4% of children. It is defined as poor vision caused by abnormal development of visual areas of the brain; if undetected and untreated it can lead to permanent vision impairment.

Unfortunately, less than 21% of children are screened for this condition. Causes of amblyopia include strabismus (misalignment of eyes), anisometropia (inequality of vision of both eyes because of refractive errors or astigmatism), cataracts, ptosis, or other factors. Because children do not complain of problems with visual acuity, and affected eyes often appear normal, amblyopia can easily go undetected unless a child has vision screening done routinely at health maintenance examinations.

Vision screening in children aged younger than 3 years in a medical office can be challenging because few children this age can be screened with a vision chart. From age 3 to 5 years, screening is possible with Snellen charts, Tumbling E charts, or picture tests such as Allen Visual Acuity Cards, but this is time consuming and can lead to inconsistent or erroneous results.

Because vision screening is so important in young children, late last year the Section on Ophthalmology and Committee on Practice and Ambulatory Medicine of the American Academy of Pediatrics (AAP) issued a policy statement endorsing instrument-based vision screening (ie, photoscreeners) routinely in childhood.

This policy was endorsed by the American Academy of Ophthalmology, the American Association for Pediatric Ophthalmology and Strabismus, and the American Association of Certified Orthoptists. The policy recommends that photoscreening may be electively performed in children aged 6 months to 3 years to facilitate...
detection of conditions that may lead to amblyopia and that this technology be used as an alternative to visual acuity screening with vision charts for children aged from 3 to 5 years.

**Not always so**

Ten years earlier in 2002, the AAP issued a lukewarm endorsement of photoscreening, describing these devices as “an innovative tool that can facilitate vision screening in children” and “one option to increase the screening rate in preschool-aged children.” As a consequence, most insurance companies considered photoscreeners as experimental and refused to pay for vision screening using this technology.

In 2004 and again in 2011, the US Preventive Services Task Force, an independent group of national experts, also endorsed the use of photoscreeners to detect vision problems in children aged 3 years and older. Insurance companies also ignored this endorsement when pediatricians challenged rejected claims. Without insurance reimbursement, few pediatricians adopted these expensive devices, and parents were often reluctant to pay for screening out of pocket.

In the decade interval between the first and second AAP policy statements, photoscreening technologies have evolved and have been scrutinized in many well-designed studies. Now there is compelling evidence that supports their routine use in pediatric practice.

In the Vision in Preschoolers Study, published in 2004, it was found that visual acuity testing (using eye charts) in more than 2,500 preschool children had a 77% sensitivity for detecting conditions associated with amblyopia, and photoscreener devices had a sensitivity of 81% to 88%. Note that the use of photoscreeners not only improves detection of eye pathology but also does so in a fraction of the time required to perform testing with eye charts. The AAP points out that the referral criteria integrated into these devices balances detection of vision problems against overreferrals.

Additional studies have looked at the effect of early detection and treatment of amblyopia on visual acuity. With mild disease, treatment with patching or glasses has been shown to improve visual acuity significantly after 2 to 12 months of treatment. For those with more severe disease, treatment has been shown to improve visual acuity as much as 1 to 2 lines on the Snellen eye chart.

**Photoscreening devices**

Pediatricians interested in incorporating photoscreening technology into routine practice have a number of devices from which to choose. To start your program, you need to purchase a photoscreener, train support staff and providers to use the device, and become familiar with the reports that the devices generate.

Perhaps the most important component of an office-based vision screening program is establishing a relationship with your local pediatric ophthalmologist, who can help program the device with the assistance of the manufacturer to optimize referral rates (avoiding overreferrals while maximizing detection of treatable problems).

The German company PlusoptiX is introducing its fourth-generation vision screener this year, the portable **PlusoptiX model S12**. The child sits comfortably in his or her parent’s lap, and the device is positioned 1 meter away. Patient information is input with a touch screen interface, and pulling a trigger button then activates the camera. The device produces a warbling sound to attract the child’s attention and gaze toward the smiling face displayed on the patient side of the PlusoptiX device. The operator’s side of the device displays a video image of the patient. The
eyes are positioned in a white rectangle on the viewing screen, and the device performs its measurements automatically, in less than a second.

In this time interval, 36 pictures of both eyes are recorded, and measurements regarding pupil sizes, corneal reflexes, and refraction are displayed on the screen, as well as an indication of whether the child passed the screening. The device records the patient data on a secure digital card that can be transferred to a computer to print the result for incorporation into the patient record. According to PlusoptiX, the device can detect amblyopia with a sensitivity as high as 92% and specificity as high as 88%. The PlusoptiX S12 is expected to sell for $5,875. Reimbursement (when insurers do reimburse) is approximately $25 to $35 per screen.

PediaVision was once an American distributor of the PlusoptiX device, but a few years ago the company developed a photoscreener called the Spot Vision Screener. Physicians familiar with digital cameras find the screener easy to use. After inputting identifying information, one aims the device toward the child, and the child’s face is positioned on a display. The device indicates whether you are too close or too far from the patient and then initiates the screening sequence, which is completed in less than a second. The screen displays the pupillary size, distance, alignment, and complete refraction information for both eyes and indicates whether the child needs to be referred to a pediatric ophthalmologist. Additionally, the device can connect to a wireless network to facilitate printing a complete report for inclusion in the record. The Spot Vision Screener sells for $7,490.

The iScreen Vision Screener is yet another photoscreener that takes pictures of the pupillary and red reflex to screen for amblyopia. In contrast to the automatic computer analysis of the photos of the red reflex performed by the PlusoptiX and PediaVision devices, the iScreen Vision Screener is connected by a network cable to your office network and transfers each patient screening test to a “professional” who interprets the test (with computer assistance) and provides information regarding whether the patient is at risk for amblyopia and should be seen by a pediatric ophthalmologist. Additionally, the device can be used to transmit data to other professionals for interpretation.

The iScreen device sells for $4,000, and each test costs $8. The manufacturer states that having an experienced professional interpreting its photoscreening results improves the accuracy of the test. Because reports are transmitted to the patient’s provider the day after the test, parents must be informed via phone or letter with results.

**Coming soon: Retinal birefringence scanning**

The photoscreeners described above use analysis of the pupillary and red reflex to screen for amblyopia. As noted, screening is faster and often more accurate with photoscreeners compared with traditional screening using vision charts, particularly with children aged younger than 5 years. If there were a limitation to photoscreeners, it is that there is an overreferral rate on the order of 10% associated with these devices. Hence, it is important that screening is performed yearly at well-child checks, and when a child is referred to an ophthalmologist, parents should be reminded that there is a possibility that no pathology will be discovered.

David Hunter, MD, chief of ophthalmology at Boston Children’s Hospital, has a new technique of screening young children for amblyopia using a device he developed and refined over the past 20 years. The device, called the Pediatric Vision Scanner (PVS), uses polarized laser light to test eye orientation at the retinal level.

The PVS laser light scans the fovea at the center of the retina, which has the highest concentration of cone receptors. The polarized light passes through the nerve fibers surrounding the fovea and is reflected back toward the device sensors. This causes the strength of the returning light to change during a scan, indicating whether the eyes are in perfect alignment. The technology is called retinal birefringence scanning, and Hunter has formed a company called REBIScan to...
commercialize its use. The US Food and Drug Administration is currently evaluating the PVS and if given approval for distribution the device may be available for use by pediatricians as early as the second quarter of this year.

Data from several well-designed studies indicate that the PVS has a superior detection rate for amblyopia (96% sensitivity) and minimizes overreferrals because the specificity is very close to 100%. Therefore, when the device identifies a child as needing referral, it is likely that the pediatric ophthalmologist who examines the child will discover a condition requiring treatment rather than monitoring or yearly rescreening.

The PVS device looks somewhat like a projector used to give PowerPoint presentations. While the child sits comfortably in the parent’s lap, the PVS is aimed at the bridge of the nose, which is the target for the laser light emitted by the device. Once targeted, the device is activated, and seconds later, 2 lights atop the unit indicate a pass or refer result, while a small liquid crystal display indicates details of the test. As of this writing the cost of the device has not yet been determined.

The battle begins

As noted earlier, insurance companies have traditionally not reimbursed for photoscreening tests, stating that the technology is “investigational,” and consequently most pediatricians have not invested in this expensive technology. Photoscreening companies have encouraged pediatricians to have parents sign an insurance waiver permitting practices to perform the screen—and parents are charged a fee of $25 for the test. The new statement from the AAP endorsing photoscreeners gives pediatricians the leverage they need to confront insurance companies and to encourage reimbursement for the testing. The policy states: “Vision screening is a separately identifiable service and should not be bundled into the global code of well-child care. Adequate payment for photoscreening and handheld autorefraction must be ensured if there is to be widespread adoption of this recommendation.”

The Affordable Care Act assures that vision screening for children is a preventive care measure that will be implemented across the country by 2014, although it does not currently provide details regarding methods of screening. Pediatricians wishing to implement photoscreening must be willing to confront insurance companies with the assistance of the local AAP chapter, the state insurance commission, and even state government.

To advance pediatric practice to v2.0, we must be willing to aggressively advocate for the families we serve. Only by implementing vision screening in our younger patients can we hope to identify children with amblyopia that would benefit from early treatment.

REFERENCES

IN MEMORIAM

CAROLINE BREESE HALL

JULIA A MCMILLAN, MD

“Dr Hall’s colleagues in pediatric infectious diseases best know her accomplishments; they have affected pediatrics and children in very profound ways.”

In 1984 when Frank Oski, founding editor-in-chief of Contemporary Pediatrics, was assembling the members of his original Editorial Board, one of the first people he invited was Caroline (Caren) Breese Hall from the Department of Pediatrics at the University of Rochester.

Since the very first edition of this publication in January 1985, Dr Hall has appeared on the masthead. Her death on December 10, 2012, is a great loss for Contemporary Pediatrics and for the entire pediatric community.

Dr Hall’s colleagues in pediatric infectious diseases best know her accomplishments; they have affected pediatrics and children in very profound ways.

It was Dr Hall whose research clarified the importance of respiratory syncytial virus (RSV) as a cause of significant morbidity and mortality in infants.

She went on to elucidate the patterns of transmission of RSV and to provide us with a practical and rapid means of identifying it.

She never strayed far from the study of respiratory viruses, but when human herpesvirus 6 (HHV-6) was identified as the cause of roseola, she began studies of the epidemiology and pathogenesis of HHV-6 in infants. Her interest in HHV-6 was perhaps prompted by her father’s study of roseola while working as a community pediatrician in Rochester.

Dr Hall was a member of the Institute of Medicine and the Royal College of Physicians. She was a founding member and fifth president of the Pediatric Infectious Diseases Society and was honored with that Society’s Distinguished Service Award. She served as chair of the Committee on Infectious Diseases (the Red Book Committee) of the American Academy of Pediatrics and was a member of the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices.

Dr Hall was an honored scientist and pediatrician, but she was also a kind and generous friend. I visited Rochester many years ago to give grand rounds for the Department of Pediatrics. When I checked in to my hotel room, I found a basket of muffins and fruit that Caren had provided—the muffins were handmade by her, and the fruit came from trees on her property.

Caren Hall was an active and engaged member of the Editorial Board of Contemporary Pediatrics for all of the past 27 years. We will miss her kindness, her good humor, and her dedication to providing pediatricians with important information that will enhance their ability to provide excellent care for their patients.
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CONTACT: Association of Maternal and Child Health Programs, www.amchp.org/Calendar/Conferences/amchp-conference/Pages/default.aspx
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CONTACT: Pediatric Medical Group, www.neocomference.com
22-23: 2013 St Jude/Pediatric Infectious Diseases Research Conference. Memphis, Tennessee.

MARCH
2-3: Society for Pediatric Pathology Spring Meeting. Baltimore, Maryland.
CONTACT: Society for Pediatric Pathology, www.spponline.org/meetings.aspx
8-10: 7th Annual SPAP CME Conference. Atlanta, Georgia.

APRIL
CONTACT: National Foundation for Infectious Diseases (NFID), www.cvent.com/events/16th-annual-conference-on-vaccine-research/event-summary-db97bed5ee041eeb09d971650f76be0.aspx

MAY
1-5: 22nd Annual PPAG Meeting and 2013 Pediatric Pharmacy Conference. Indianapolis, Indiana.
4-7: PAS Annual Meeting 2013. Washington, DC.
CONTACT: Pediatric Academic Societies, www.pas-meeting.org/2013DC/default.asp
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