OUR MISSION
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.

Dr Freed has published over 200 peer-reviewed articles on child health policy and health economics, immunizations, and preventive care services for children.

Dr Hallas will be a presenter at the National Association of Neonatal Nurses 32nd Annual Educational Conference in Palm Springs, CA, on October 27, 2016.
Eucerin Eczema Relief Body Creme relieves dry, itchy skin and provides hydration for patients with eczema-prone skin—in a light, fast-absorbing daily formula.

*Subjects applying daily Eucerin® Eczema Relief Body Creme demonstrated a statistically significant difference (P=0.006) in the prevention of eczema flares compared with control group subjects.*


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On ‘Dyslexia: What you need to know.’
“The author mentions convergence insufficiency. There is currently a multicenter randomized clinical trial sponsored by the National Institutes of Health/National Eye Institute for 9- to 14-year-old children with symptomatic convergence insufficiency. Reading and attention are tested before and after treatment. The study is in the last year of recruitment. This study may be of interest to medical professionals who have patients with convergence insufficiency. Clinical sites are at Bascom Palmer in Miami; Akron Children’s Hospital; Ohio State University in Columbus; Salus University in Philadelphia; University of Alabama in Birmingham; Nova Southeastern University in Fort Lauderdale; Marshall B. Ketchum University in Fullerton, CA; State College of New York in NYC; and the Advanced Vision Center in Chicago. Information can be found at cirit-art.com.”

On our e-news article ‘Gun safety: What can you do?’
“What about addressing the extreme amounts of gun use and killing in video games, on TV, and in the movies? Our kids are in a saturated environment of violence. How does this affect their perception when they are exposed to a real weapon? Limiting access to firearms is necessary, but what about limiting their access to violent media?”

—George Starr, MD
Emeritus Associate Professor of Pediatrics and Child Psychiatry, SUNY Upstate Medical University, Syracuse, NY

Dr Starr gets our e-news. Do you? Don’t miss an issue! ContemporaryPediatrics.com/enews-signup

October is Eczema Awareness Month
How do pediatric and adult AD differ? Check out our latest vid. ContemporaryPediatrics.com/microbiome-in-AD

Top articles
Here’s what your peers are reading.

Peeling rash in a 4-year-old boy
ContemporaryPediatrics.com/puzzler-0916

Thyroid testing: When to worry (not often) and when to reassure
ContemporaryPediatrics.com/thyroidtesting

Evaluating fontanels in the newborn skull
ContemporaryPediatrics.com/fontanels

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Contemporary Pediatrics invites submission of review articles for peer review on clinical issues and in therapeutic areas encountered by the practicing community and hospital-based pediatrician and nurse practitioner. Of particular interest are review articles that provide pragmatic distillation of current guidelines, standards of care, and anticipatory guidance at point-of-care. E-mail catherine.radwan@ubm.com for author submission guidelines.

Not able to attend AAP?
We’ve got you covered. Don’t miss our next issue for clinical news, analysis, and more!
The US Food and Drug Administration (FDA) recently furthered the discussion of the mind-numbing, myriad issues around the use of opioids in children.

In materials introducing a 2-day meeting of 3 FDA advisory committees in September, the agency said, “There are few analgesic products labeled for use in pediatric patients aside from the nonsteroidal anti-inflammatory drugs indicated for juvenile rheumatoid arthritis. As a result, there is an unmet need for pediatric-specific labeling of analgesics to assist clinicians in proper patient selection and in determining the appropriate dosing for their patients.”

The agency had asked for information on issues including selection of the type of patient for these drugs; the appropriate patient for study of immediate-release or extended/long-acting opioid analgesics; the extrapolation of efficacy from adults to children; and the safety concerns surrounding the use and study of opioids in children.

In background materials, the FDA said, “In the US outpatient retail setting, pediatric patients 16 years of age and younger accounted for approximately 4% (2.5 million patients) of the total 66.5 million patients of any age who received dispensed prescriptions for opioid analgesics in 2015. The majority of pediatric patients were ages 7 to 16 years. There was a 34% decrease in the number of pediatric patients from 2011 to 2015.”

**Risks vs benefits of opioids**

At the actual session, participants discussed the lack of data on the risks versus benefits more than anything else.

Connie Houck, MD, representing the American Academy of Pediatrics (AAP) surgical specialty panel, told the meeting, “We are increasingly concerned that there is inadequate information to inform our care of postoperative pain” in terms of both overtreatment and undertreatment of pain.

Houck noted that recent guidelines from the Centers for Disease Control and Prevention do not provide information on use in children aged younger than 18 years.

Chris Feudtner, MD, PhD, of the Children’s Hospital of Philadelphia, Pennsylvania, said he is keeping his eye on 2 groups: adolescents and young adults who take and more parents are asking surgical specialists not to treat their children with opioids for postoperative pain because of concerns about addiction, said Houck, a pediatric anesthesiologist for Boston Children’s Hospital, Massachusetts. In addition, she said, advances in repairing congenital defects have also increased the need for such understanding.

On the other hand, Houck said, “There is no evidence that providing appropriate labeling of opioids in children increases use.”

**New labeling is needed**

According to Houck, pediatric surgeons recommend “robust studies of all opioid analgesic agents in order to provide appropriate labeling of opioid medications for use in infants, children, and adolescents in the perioperative period.”

Houck also called for education of providers on acute pain in children, for all age groups and inpatient and outpatient surgery, including multimodal approaches for perioperative pain control. In addition, she said, surgical specialists and dentists need to know how to counsel parents about both use and disposal of unneeded meds.
opioids in a prohibited, harmful manner, and children at risk of having inadequately relieved severe pain. Nevertheless, he argued, labeling is not for the purpose of trying to strike this balance. Labeling, he said, “has a fiduciary interest of providing evidence-based guidance for individual-level decision making.”

Labeling, Feudtner said, “can provide both a confirmation of the best practice, the most evidence-based practice, as well as to constrain practices—to say that there are other ways of using this drug that are not to be employed.”

Feudtner, like Houck, noted that when the FDA expanded indication for OxyContin to some children aged 11 to 17 years, there was concern there might be a boost in its use, but that does not seem to be happening.

Labeling, he argued, is but one small piece of how the nation should respond to the opioid epidemic, and the nation needs to also look at more effective use, including prescription monitoring.

What must be done

The systems that have to be thought through to strike the balance in opioid concerns include the FDA, the health system, the payment system, and law enforcement, Feudtner said. He also warned that we lack information about the risk and benefit for an individual and have even less certainty about specific interventions on misuse or pain on a population level. He cautioned that despite the specific focus on pediatric opioid abuse, most pediatric patients who misuse don’t get their medications from a pediatric source.

During the final day of discussion, Sharon Hertz, MD, director of the FDA Division of Anesthesia, Analgesia, and Addiction Products, said, “We are here because we know that there is a real paucity of data.” The agency never thought it would be simple, she said, but, “I think we didn’t adequately provide space for the complexities and the questions.”

Among other things, Hertz noted, the session heard about data showing that adolescents may be more at risk, but the agency would want to hear if there is some aspect of the adolescent risk with opioids to consider. Another question, she said, is how long studies should follow these children to determine if there were problems.

“What we can do is require that data be collected, which could stimulate the interest of companies who have to fulfill these requirements to look for ways to do it,” Hertz said.

Tamar Lasky, PhD, of MIE Resources, Baltimore, Maryland, cited the estimate that there are hundreds of thousands of opioid prescriptions for children for dental pain and indicated that might be a patient pool for clinical trials to provide answers about labeling. Looking at those prescriptions might also be an opportunity, she said, to learn about dentists’ prescribing and whether it is contributing to the problems.

Another suggestion concerned studying clinical screening tools that would be given after patients have started opioid therapy to determine if they know how to use it safely, as well as what is the history of medication adherence or misuse.

In a submitted comment, several medical groups including the American Society of Anesthesiologists cited the AAP estimate that almost 50,000 children die in the United States each year and about a third of those deaths are attributed to conditions associated with substantial pain. In addition, there are many children with severe refractory pain from cancer, sickle cell anemia, musculoskeletal disorders, and other illnesses.

“To ensure that pediatric patients have access to opioid analgesics, we support reasonable regulatory approaches that incentivize prescribers to obtain the proper education and training to treat acute pain in children,” the society wrote.

They indicated the lack of pediatric pain specialists in many regions may require looking at alternatives, including web-based collaborations. The FDA had said that it would not make determinations on any of the issues until later. Materials from the meeting, which may eventually include a transcript and a webcast, are available at www.FDA.gov under advisory meetings for September 15-16, 2016.
Enterobius vermicularis in adults and children over 2 years of age for the treatment of EMVERM (mebendazole) 100 mg chewable tablet is indicated.

**INDICATION**

**duodenale**

Ascaris lumbricoides

An increase in plasma concentrations of mebendazole. cimetidine inhibits mebendazole metabolism and may result in

**Drug Interactions:**

**recommended;** and very rare cases of convulsions.

for prolonged periods and at dosages substantially above those recommended.

reports of neutropenia and agranulocytosis when mebendazole was taken for prolonged periods and at dosages substantially above those recommended.

**Precautions:**

Periodic assessment of organ system functions, including hematopoietic and hepatic, is advisable during prolonged therapy.

**Adverse reactions include:**

Transient symptoms of abdominal pain and diarrhea with expulsion of worms in cases of massive infection; liver function test elevations [AST (SGOT), ALT (SGPT), and GGT]; and on rare occasions hypersensitivity (rash, urticaria and angioedema); rare reports of neutropenia, agranulocytosis (see Warnings) and hepatitis when mebendazole was taken for prolonged periods and at dosages substantially above those recommended; and very rare cases of convulsions.

**Drug Interactions:**

Preliminary evidence suggests that cimetidine inhibits mebendazole metabolism and may result in an increase in plasma concentrations of mebendazole.

**INDICATION**

EMVERM (mebendazole) 100 mg chewable tablet is indicated in adults and children over 2 years of age for the treatment of Enterobius vermicularis (pinworm), Trichuris trichiura (whipworm), Ascaris lumbricoides (common roundworm), Ancylostoma duodenale (common hookworm), and Necator americanus (American hookworm) in single or mixed infections.

**IMPORTANT SAFETY INFORMATION**

Mebendazole is contraindicated in persons who have shown hypersensitivity to the drug.

**Warnings:**

There is no evidence that mebendazole, even at high doses, is effective for hydatid disease. There have been rare reports of neutropenia and agranulocytosis when mebendazole was used for highly contagious pinworm infections.

**Precautions:**

Periodic assessment of organ system functions, including hematopoietic and hepatic, is advisable during prolonged therapy.

**Adverse reactions include:**

Transient symptoms of abdominal pain and diarrhea with expulsion of worms in cases of massive infection; liver function test elevations [AST (SGOT), ALT (SGPT), and GGT]; and on rare occasions hypersensitivity (rash, urticaria and angioedema); rare reports of neutropenia, agranulocytosis (see Warnings) and hepatitis when mebendazole was taken for prolonged periods and at dosages substantially above those recommended; and very rare cases of convulsions.

**Drug Interactions:**

Preliminary evidence suggests that cimetidine inhibits mebendazole metabolism and may result in an increase in plasma concentrations of mebendazole.

**Pregnancy Category C:**

Mebendazole has shown embryotoxic and teratogenic activity in pregnant rats at single oral doses as low as 10 mg/kg (approximately equal to the human dose, based on mg/m²). In view of these findings the use of mebendazole is not recommended in pregnant women.

**Nursing Mothers:**

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

** Pediatric Use:**

EMVERM has not been extensively studied in children under two years; therefore, in the treatment of children under two years, the relative benefit/risk should be considered.

**Overdosage:**

In the event of accidental overdosage, gastrointestinal complaints lasting up to a few hours may occur. Vomiting and purging should be induced. Activated charcoal may be given.

**Information for Patients:**

- **Patients should be informed of the potential risk to the fetus in women taking mebendazole during pregnancy, especially during the first trimester (See Pregnancy Category C).**
- **Patients should also be informed that cleanliness is important to prevent reinfection and transmission of the infection.**

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. To report SUSPECTED ADVERSE REACTIONS contact Impax Laboratories, Inc. at 1-877-994-6729.

Please see full Prescribing Information at www.EMVERMHCP.com and Brief Summary on following page.

**References:**

1. EMVERM [prescribing information]. Horsham, PA: Amedra Pharmaceuticals LLC; 2015.
EMVERM™ (mebendazole) 100 mg Chewable Tablets

BRIEF SUMMARY: See Package Insert for full Prescribing Information

INDICATIONS AND USAGE
Mebendazole tablets are indicated for the treatment of Enterobius vermicularis (pinworm), Trichuris trichiura (whipworm), Ascaris lumbricoides (common roundworm), Ancylostoma duodenale (common hookworm), Necator americanus (American hookworm) in single or mixed infections. Efficacy varies as a function of such factors as preexisting diarrhea and gastrointestinal transit time, degree of infection, and helminth strains. Efficacy rates derived from various studies are shown in the table below.

<table>
<thead>
<tr>
<th></th>
<th>Pinworm (enterobiasis)</th>
<th>Whipworm (trichiuriasis)</th>
<th>Common Roundworm (ascarisis)</th>
<th>Hookworm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cure rates</td>
<td>95%</td>
<td>68%</td>
<td>98%</td>
<td>96%</td>
</tr>
<tr>
<td>Egg reduction</td>
<td>—</td>
<td>93%</td>
<td>99%</td>
<td>99%</td>
</tr>
</tbody>
</table>

CONTRAINDICATIONS
Mebendazole is contraindicated in persons who have shown hypersensitivity to the drug.

WARNINGS
There is no evidence that mebendazole, even at high doses, is effective for hydatid disease. There have been rare reports of neutropenia and agranulocytosis when mebendazole was taken for prolonged periods and at dosages substantially above those recommended.

PRECAUTIONS
General
Periodic assessment of organ system functions, including hematopoietic and hepatic, is advisable during prolonged therapy.

Information for Patients
Patients should be informed of the potential risk to the fetus in women taking mebendazole during pregnancy, especially during the first trimester (See Pregnancy Category C). Patients should also be informed that cleanliness is important to prevent reinfection and transmission of the infection.

Drug Interactions
Preliminary evidence suggests that cimetidine inhibits mebendazole metabolism and may result in an increase in plasma concentrations of mebendazole.

Carcinogenesis, Mutagenesis, Impairment of Fertility
In carcinogenicity tests of mebendazole in mice and rats, no carcinogenic effects were seen at doses as high as 40 mg/kg (one to two times the human dose, based on mg/m²) given daily over two years. Dominant lethal mutation tests in mice showed no mutagenicity at single doses as high as 640 mg/kg (18 times the human dose, based on mg/m²). Neither the spermatocyte test, the F₂ translocation test, nor the Ames test indicated mutagenic properties. Doses up to 40 mg/kg in mice (equal to the human dose, based on mg/m²), given to males for 60 days and to females for 14 days prior to gestation, had no effect upon fetuses and offspring, though there was slight maternal toxicity.

Pregnancy
Teratogenic Effects
Pregnancy Category C
Mebendazole has shown embryotoxic and teratogenic activity in pregnant rats at single oral doses as low as 10 mg/kg (approximately equal to the human dose, based on mg/m²). In view of these findings the use of mebendazole is not recommended in pregnant women. Although there are no adequate and well-controlled studies in pregnant women, a post-marketing survey has been done of a limited number of women who inadvertently had consumed mebendazole during the first trimester of pregnancy. The incidence of spontaneous abortion and malformation did not exceed that in the general population.

In 170 deliveries on term, no teratogenic risk of mebendazole was identified.

Nursing Mothers
It is not known whether mebendazole is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when mebendazole is administered to a nursing woman.

Pediatric Use
The drug has not been extensively studied in children under two years; therefore, in the treatment of children under two years the relative benefit/risk should be considered.

ADVERSE REACTIONS
Gastrointestinal
Transient symptoms of abdominal pain and diarrhea in cases of massive infection and expulsion of worms.

Hypersensitivity
Rash, urticaria and angioedema have been observed on rare occasions.

Central Nervous System
Very rare cases of convulsions have been reported.

Liver
There have been liver function test elevations [AST (SGOT), ALT (SGPT), and GGT] and rare reports of hepatitis when mebendazole was taken for prolonged periods and at dosages substantially above those recommended.

Hematologic
Neutropenia and agranulocytosis. (See WARNINGS).

OVERDOSAGE
In the event of accidental overdosage, gastrointestinal complaints lasting up to a few hours may occur. Vomiting and purging should be induced. Activated charcoal may be given.

DOSAGE AND ADMINISTRATION
The same dosage schedule applies to children and adults. The tablet may be chewed, swallowed, or crushed and mixed with food.

<table>
<thead>
<tr>
<th></th>
<th>Pinworm (enterobiasis)</th>
<th>Whipworm (trichiuriasis)</th>
<th>Common Roundworm (ascarisis)</th>
<th>Hookworm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>1 tablet, once</td>
<td>1 tablet morning and evening for 3 consecutive days</td>
<td>1 tablet morning and evening for 3 consecutive days</td>
<td>1 tablet morning and evening for 3 consecutive days</td>
</tr>
</tbody>
</table>

If the patient is not cured three weeks after treatment, a second course of treatment is advised. No special procedures, such as fasting or purging, are required.

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. To report SUSPECTED ADVERSE REACTIONS contact Impax Laboratories, Inc. at 1-877-994-6729.


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Antibiotics weaken breastfeeding’s benefits

The protective effects of breastfeeding against infections and overweight are reduced or eliminated by antibiotic use early in life, according to a retrospective study in 226 5-year-old Finnish children, almost all of whom had been breastfed for at least 1 month. The study also found that antibiotic use has a strong negative influence on microbiota composition.

Investigators divided participants into 2 groups based on antibiotic use before or immediately after weaning: children who did not receive antibiotics during breastfeeding through 4 months after weaning and those who did receive antibiotics during breastfeeding through 4 months after weaning. Each of these 2 groups represented half of the total participants—113 children.

In the no-antibiotics group, each month of breastfeeding decreased the number of postweaning antibiotic courses by 5% and body mass index (BMI) z score by 0.08 units at age 5 years. In the antibiotic-user group, each month of breastfeeding reduced postweaning antibiotic courses by an estimated 4% (only borderline significant) and had no impact on BMI z score.

An analysis of the fecal microbiota composition of 42 study participants showed that among children with no early life exposure to antibiotics, those who were breastfed for up to 6 months had significantly fewer beneficial Bifidobacterium and Akkermansia than those who were breastfed longer (8 to 16 months). However, this benefit of long duration breastfeeding disappeared in children with early exposure to antibiotics (Korpela K, et al. JAMA Pediatr. 2016;170[8]:750-757).

Algorithm accurately identifies babies at low risk of IBI

The so-called “Step-by-Step” algorithm, a sequential approach to identifying young febrile infants at low risk for invasive bacterial infection (IBI) on the basis of clinical and laboratory parameters, is more accurate than the classic Rochester criteria or the more recently developed “Lab-score,” a new study shows.

Investigators collected data for 2185 infants aged 90 days or younger with fever without a source brought to 11 European pediatric emergency departments. They then applied the Step-by-Step algorithm to the study sample to analyze its accuracy. This approach evaluates sequentially the general appearance of the infant, his or her age, results of the urinalysis, and results of tests for blood biomarkers, including procalcitonin, C-reactive protein (CRP), and absolute neutrophil count. Investigators also applied the Rochester criteria and the Lab-score to study participants’ data and compared the diagnostic performances of the 3 guidelines.

Of total participants, 87 (4%) were diagnosed with an IBI (meningitis, bacteremia, or septic arthritis), 80 of whom were identified as at high or intermediate risk using the Step-by-Step protocol. Sensitivity and negative predictive value for ruling out an IBI were 92.0% and 99.3%, respectively, for Step-by-Step; 81.6%
and 98.3% for the Rochester criteria; and 59.8% and 98.1% for the Lab-score. Step-by-Step misclassified 7 infants with an IBI compared with 16 by Rochester criteria and 35 by the Lab-score. Six of 7 missed patients had fever duration of less than 2 hours at presentation (Gomez B, et al. Pediatrics. 2016;138[2]:e20154381).

The age-old pediatric struggle continues: deciding which young babies with fever have serious bacterial infections while being judicious in use of invasive diagnostic studies, hospitalization, and treatment. This updated approach incorporates newer laboratory technology, but no screening protocol, even this improvement on past versions, is perfect. The youngest babies (in the Step-by-Step protocol, those aged 21 days or younger) and those who appear ill are still at high risk no matter what their screening labs show. Procalcitonin offers new information, but even this rapidly responsive measure offers little help in the first hours of a febrile illness. Nonetheless, if procalcitonin and CRP are quickly available where you work, adoption of the Step-by-Step protocol may offer an improved approach to the young infant with fever without a source. —Michael G Burke, MD

Young children with asthma who take acetaminophen to alleviate pain or fever are no more likely than those who take ibuprofen for this purpose to experience asthma complications, a randomized, double-blind trial showed. The trial was conducted in 300 children aged from 1 to 5 years with mild persistent asthma who were assigned to receive either acetaminophen or ibuprofen when needed during the course of 46 weeks. Children in both groups also received standardized asthma-controller therapies.

The 2 groups experienced about the same number of asthma exacerbations—a mean of 0.81 per participant with acetaminophen and 0.87 per participant with ibuprofen. In the acetaminophen group, 49% of participants had at least 1 asthma exacerbation during the study period, and 21% had at least 2, similar to the 47% and 24%, respectively, in the ibuprofen group. The proportion of asthma-control days was parallel in the 2 groups: 85.8% for those taking acetaminophen and 86.8% for those taking ibuprofen. Likewise, the groups did not differ significantly with regard to use of an albuterol rescue inhaler, making an unscheduled healthcare visit for asthma, or experiencing an adverse event (Sheehan WJ, et al. N Engl J Med. 2016;375[7]:619-630).

For years, practitioners have been concerned that acetaminophen causes or worsens asthma, and case-controlled studies and a plausible biologic mechanism offered support for the concern. This large, multicenter, prospective, randomized trial gets acetaminophen at least partially off the hook by showing that children with diagnosed asthma are no worse off with acetaminophen than they are with ibuprofen. We don’t know if asthmatic children would be best off with neither, nor do we know from this study whether early use of acetaminophen promotes the initial development of asthma. These are questions for another study, another day. —Michael G Burke, MD

Trial investigates if acetaminophen aggravates asthma symptoms

For years, practitioners have been concerned that acetaminophen causes or worsens asthma, and case-controlled studies and a plausible biologic mechanism offered support for the concern. This large, multicenter, prospective, randomized trial gets acetaminophen at least partially off the hook by showing that children with diagnosed asthma are no worse off with acetaminophen than they are with ibuprofen. We don’t know if asthmatic children would be best off with neither, nor do we know from this study whether early use of acetaminophen promotes the initial development of asthma. These are questions for another study, another day. —Michael G Burke, MD

Thumb-sucking and nail-biting may not be all bad. Children who suck their thumbs or bite their nails between ages 5 and 11 years are less likely than youngsters without these habits to have atopic sensitization at age 13 years and beyond, a study in more than 1000 New Zealanders found. Investigators noted that since thumb-sucking and nail-biting probably increase microbial exposure, these findings offer additional support for the hygiene hypothesis (Lynch SJ, et al. Pediatrics. 2016;138[2]:e20160443).
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Relief from dry skin associated with eczema

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Rich and long-lasting formula

FOR EVERYONE
FOR BABY
FOR EVERYONE
Treat plays trick on a 3-year-old boy

THUY TRANG J NGUYEN, BS, MS4; ARTHUR K CHO, MD

A 3-year-old boy presents to the emergency department (ED) with a 1-day history of irritability and listlessness. According to his parents, he was well until the night before when he began to behave abnormally, becoming excessively tired approximately 2 hours after eating dinner. During the night, the boy slept poorly, sporadically awakening with crying followed by brief periods of calmness. The morning of presentation, he was difficult to arouse with intermittent fussiness and reluctance to ambulate.

FOR MORE ON THIS CASE, TURN TO PAGE 47.
### Look how Children’s Claritin stacks up

<table>
<thead>
<tr>
<th>Non-Drowsy (based on label direction)</th>
<th>Children’s Claritin Grape Syrup</th>
<th>Children’s Allegra® Berry Syrup</th>
<th>Children’s ZYRTEC® Grape Syrup</th>
<th>Children’s Benadryl® Cherry Syrup</th>
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</thead>
<tbody>
<tr>
<td>24-Hour Once-Daily Dosing</td>
<td>☑️</td>
<td>☐️</td>
<td>☑️</td>
<td>☐️</td>
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<tr>
<td>Indicated for Kids Ages 2+</td>
<td>☑️</td>
<td>☑️</td>
<td>☐️</td>
<td>☐️</td>
</tr>
<tr>
<td>#1 Pediatrician-Recommended Non-Drowsy OTC Oral Allergy Brand¹</td>
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<td>☐️</td>
</tr>
</tbody>
</table>

Remind parents to always read the label

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24-hour **non-drowsy** allergy relief

Register at [www.claritin.com/healthcare-professionals](http://www.claritin.com/healthcare-professionals)¹ to receive samples

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**Children’s Claritin Syrup is:**
- Dye free
- Sugar free
- Alcohol free
- Gluten free
- Kosher certified

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Use as directed.


Bayer, the Bayer Cross, and Claritin are registered trademarks of Bayer.

Children’s Allegra, Children’s ZYRTEC, and Children’s Benadryl are registered trademarks of their respective owners.

Helping kids cope with skin diseases

Atopic dermatitis, psoriasis, and acne can significantly affect the psychosocial health and well-being of children and adolescents, especially identity and self-esteem.

MARY BETH NIERENGARTEN, MA.
REVIEWED BY BERNARD A COHEN, MD, AND KELLY CORDORO, MD.

Among the stressors that can have a significant negative impact on the quality of life of children are skin diseases, particularly those that affect physical appearance such as psoriasis, atopic dermatitis (AD), and acne. In 2002, the psychosocial effect of these 3 skin diseases was examined in a literature review that found that these skin diseases seriously affected patients’ lives by causing a host of psychological problems, including depression and anxiety. Based on the evidence at that time, the investigators concluded that the effect of skin disease on the psychological well-being of patients is underappreciated.

To date, this may still be true. Although certain pediatricians recognize the importance of skin-related psychosocial issues, Bernard A. Cohen, MD, professor of Dermatology and Pediatrics at Johns Hopkins University School of Medicine, Baltimore, Maryland, says that he doesn’t think it is universally accepted among pediatricians—and it should be. “It is important to involve the pediatrician in the management of an underlying skin problem because of the positive impact it has on developmental and behavioral issues in addition to making the skin better,” he says.

The need for pediatricians to be aware of the substantial negative effects of skin diseases on children is highlighted by the fact that many children under their care will have a skin condition that could contribute to emotional and behavioral problems if not identified and managed. Both AD and acne are among the most prevalent skin conditions in childhood, with AD associated with early childhood and acne associated with older children. Of the children who develop AD, 60% do so in the first year of life and another 30% before age 5 years. It is estimated that about 40% of children...
who develop AD will carry the skin disease into adulthood. Unlike AD, acne is most common in adolescents, particularly between ages 15 to 17 years, and is estimated to affect 85% of adolescents.2

In another very recent literature review published in 2016 that looked at the psychosocial effects of AD and acne on children’s self-esteem and identity, investigators found that the effect of AD on a child’s quality of life is comparable to the effect of other chronic diseases, such as diabetes and hypertension.2,3 The effect on mental health and social functioning can be even more severe, with data showing that AD has a more severe impact on mental health than diabetes and more severe impact on social functioning skills than hypertension.2,4 For older children, acne has been shown to have a more negative effect on mental health and social function than other chronic conditions such as asthma, arthritis, back pain, diabetes, and epilepsy.2,5

When examining the effect of AD and acne specifically on identity and self-esteem in children, the literature review showed that multiple factors contribute to difficulties in these areas.2 For children with AD, the investigators found little data on the direct impact of AD on identity and self-esteem but found that most studies focused on the development of behavioral problems associated with AD and the effect of AD on activities and relationships. Data on preschool children with AD show that these children have increased dependency, fearfulness, and nighttime sleep disturbances, and that the incidence of behavioral problems, family disruption, and stressed parenting are all significantly greater with these children. Many of these children can develop behavioral problems that affect their sense of identity (ie, some children may see themselves as “outcasts”).

Other important factors contributing to behavioral problems in children with AD include their relationship with authority figures and peers. Data show that parents and other authority figures of children with AD may unwittingly hinder their child’s ability to develop coping skills, and therefore reinforce behavioral problems and identity issues by not exerting sufficient discipline and giving in to their child’s demands.2 In addition, data show that children with AD often feel stigmatized and fear interacting with others, which results in social isolation and poor self-esteem;

### Table 1: Assessing Cutaneous Body Image (CBI)

<table>
<thead>
<tr>
<th>Considerations</th>
<th>Assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Consider the degree of dissatisfaction with appearance of skin by using clinical or prevalidated rating scales or both.</td>
<td>See Table 2.</td>
</tr>
<tr>
<td>2. Consider the potential for comorbid body image pathologies associated with a higher frequency of CBI concerns.</td>
<td>These pathologies include body dysmorphic disorder (BDD), eating disorders, and delusional disorders.</td>
</tr>
<tr>
<td>3. Consider the possible comorbid psychiatric disorders that can confound the clinical presentation of a CBI complaint.</td>
<td>These disorders include major depressive disorder, bipolar disorder, obsessive-compulsive disorder, social phobia (social anxiety) disorder, posttraumatic stress disorder, factitious disorder, dissociative disorders, psychotic disorders, and personality disorders.</td>
</tr>
</tbody>
</table>

From Gupta MA, et al.6

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Between 30%-50% of adolescents experience psychological difficulties associated with their acne.

INDICATION

DYANAVEL™ XR (amphetamine) extended-release oral suspension is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including DYANAVEL XR, other amphetamine-containing products, and methylphenidate, 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.

- DYANAVEL XR is contraindicated
  - In patients known to be hypersensitive to amphetamine, or other components of DYANAVEL XR. Hypersensitivity reactions, such as angioedema and anaphylactic reactions, have been reported
  - During treatment with monoamine oxidase inhibitors (MAOIs) and within 14 days following discontinuation of treatment with an MAOI because of the risk of hypertensive crisis

- Prior to and during treatment assess for the presence of cardiac disease. Sudden death, stroke and myocardial infarction have been reported in adults with CNS stimulant treatment at recommended doses. Sudden death has been reported in children and adolescents with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during DYANAVEL XR treatment.

- CNS stimulants can cause increases in blood pressure (mean increase about 2-4 mm Hg) and heart rate (mean increase about 3-6 bpm). Monitor all patients for tachycardia and hypertension.

- CNS stimulants may cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychiatric illness. Prior to treatment, assess for the presence of bipolar disorder.

- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients with ADHD. Monitor weight and height in children during treatment with DYANAVEL XR. Treatment may need to be interrupted in children not growing as expected.
Customize the **DYANAVEL XR** dose* to their responses and needs

*The starting dose is 2.5 or 5 mg, taken once-daily in the morning with or without food, may be titrated by 2.5 to 10 mg per day, every 4 to 7 days, up to a maximum dose of 20 mg per day. Periodically re-evaluate long-term use and adjust dosage as needed.

- Low starting dose options and the ability to titrate within one prescription
- Prior to treatment assess for cardiac disease and risk for abuse
- Optimize the dose to balance symptom control and side effects
- After prescribing, keep prescription records, educate about and monitor for abuse and overdose, and re-evaluate the need for DYANAVEL XR use

**If switching from other amphetamine products to DYANAVEL XR**

- To switch from another amphetamine product, discontinue treatment, then follow the titration schedule for DYANAVEL XR
- Do not substitute for other amphetamine products on a mg-per-mg basis because of different amphetamine base compositions and differing pharmacokinetic profiles

See Full Prescribing Information for complete Dosing and Administration.

- CNS stimulants, including DYANAVEL XR, are associated with peripheral vasculopathy, including Raynaud’s phenomenon. Signs and symptoms are usually intermittent and mild; very rare sequelae include digital ulceration and/or soft tissue breakdown. Careful observation for digital changes is necessary during treatment with ADHD stimulants.
- Most common adverse reactions observed with amphetamine products: dry mouth, anorexia, weight loss, abdominal pain, nausea, insomnia, restlessness, emotional lability, dizziness, and tachycardia. There is limited experience with DYANAVEL XR in controlled trials. Based on this limited experience, the adverse reaction profile of DYANAVEL XR appears similar to other amphetamine extended-release products. The most common (≥2% in the DYANAVEL XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 108 patients with ADHD (aged 6–12 years) were: epistaxis (DYANAVEL XR 4%, placebo 0%), allergic rhinitis (4%, 0%) and upper abdominal pain (4%, 2%).
- DYANAVEL XR use during pregnancy may cause fetal harm.
- Breastfeeding is not recommended during treatment with DYANAVEL XR.

Please see additional Important Safety Information, including Boxed Warning regarding potential for Abuse and Dependence, and Brief Summary of Full Prescribing Information on next page.

DYANAVEL is a trademark of Tris Pharma, Inc.

DYANAVEL™ XR (amphetamine ext) extended-release oral suspension, CII 2.5 mg/mL

BRIEF SUMMARY: See Full Prescribing Information for complete product information.

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including DYANAVEL XR, other amphetamine-containing products, and methylphenidate, 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.

INDICATIONS AND USAGE

DYANAVEL XR is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

CONTRAINDICATIONS

DYANAVEL XR is contraindicated: In patients known to be hypersensitive to amphetamine, or other components of DYANAVEL XR. Hypersensitivity reactions such as angioedema and anaphylactic reactions were reported in patients treated with other amphetamine products. During treatment with MAOIs, and also within 14 days of following discontinuation of treatment with a MAOI, because of risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS

Potential for Abuse and Dependence (See Boxed Warning above).

Serious Cardiovascular Reactions

Sudden death, stroke, myocardial infarction were reported in adults with CNS stimulant treatment at recommended doses. Sudden death reported in children and adolescents with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. Avoid use with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during DYANAVEL XR treatment.

Blood Pressure / Heart Rate Increases

CNS stimulants cause increase in blood pressure (mean increase ~2.4 mm Hg) and heart rate (mean increase ~3-6 bpm). Monitor for potential tachycardia and hypertension.

Psychiatric Adverse Reactions

Exacerbation of Preexisting Psychotic CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with preexisting psychotic disorder. Induction of a Manic Episode in Patients with Bipolar Illness CNS stimulants may induce mixed or manic episode in patients with bipolar disorder. Prior to initiating treatment, screen patients for risk for developing a manic episode. New Psychotic or Manic Symptoms CNS stimulants at recommended doses, may cause psychotic or manic symptoms in patients without prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing DYANAVEL XR. In pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in 0.1% of CNS stimulant-treated compared to 0% in placebo-treated patients.

Long-Term Suppression of Growth

CNS stimulants were associated with weight loss and slowing growth rate in pediatric patients. Closely monitor growth (weight, height) in pediatrics treated with CNS stimulants, including DYANAVEL XR.

Peripheral Vasculopathy, including Raynaud’s Phenomenon

Stimulants, including DYANAVEL XR are associated with peripheral vasculopathy, including Raynaud’s phenomenon. Signs, symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Effects were observed in post-marketing reports at different times, therapeutic doses in all age groups through treatment. Signs, symptoms generally improve after dose reduction or discontinuation of drug. Careful observation for digital changes is necessary during treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

ADVERSE REACTIONS

Clinical Trial Experience

Because clinical trials are conducted under varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect rates observed in clinical practice. With Other Amphetamine Products in Pediatric Patients and Adults with ADHD Cardiovascular: Palpitations, tachycardia, elevation of blood pressure, sudden death, myocardial infarction. There were isolated reports of cardiomyopathy associated with chronic amphetamine use. CNS: Psychotic episodes at recommended doses, overstimulation, restlessness, irritability, euphoria, dyskinesia, dysphoria, depression, tremor, tics, aggression, anger, lability, insomnia, emotional lability and dizziness. Eye Disorders: Vision blurred, mydriasis. Gastrointestinal: Dryness of mouth, unpleasant taste, diarrhea, constipation, nausea, other gastrointestinal disturbances. Anorexia, weight loss may occur as undesirable effects. Allergic: Urticaria, rash, hypersensitivity reactions including angioedema and anaphylaxis. Serious skin rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis were reported. Endocrine: Impotence, changes in libido. Skin: Alopecia. With DYANAVEL XR in Pediatric Patients with ADHD There is limited experience with DYANAVEL XR in controlled trials. Based on this, the adverse reaction profile of DYANAVEL XR appears similar to other amphetamine extended-release products. Most common (≥2% DYANAVEL XR group and greater than placebo) adverse reactions reported in Phase 3 controlled study conducted in n=108 with ADHD (aged 6–12 yrs) were: epistaxis, allergic rhinitis, upper abdominal pain.

Postmarketing Experience

Adverse reactions were identified during post approval of other amphetamine products. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate frequency or establish causal relationship to drug exposure. Endocrine: frequent or prolonged erections. Musculoskeletal: Connective Tissue, and Bone Disorders: rhabdomyolysis. Psychiatric Disorders: delirium.

DRUG INTERACTIONS

Drugs Having Clinically Important Interactions with Amphetamines MAO I, MAOII antidepressants slow amphetamine metabolism, increasing amphetamines effect on release of norepinephrine and other monoamines from adrenergic nerve endings causing headaches and other signs of hypertensive crisis. Toxic neurological effects and malignant hyperpyrexia may occur, sometimes with fatal results. Intervention: Do not administer DYANAVEL XR during or within 14 days following administration of MAOI. Alkalizing Agents: Increase blood levels and potentiate action of amphetamine. Intervention: Co-administration of DYANAVEL XR and gastrointestinal alkalizing agents should be avoided.

Acidifying Agents: Lower blood levels and efficacy of amphetamines. Intervention: Increase dose based on clinical response.

Tricyclic Antidepressants: May enhance activity of tricyclic or sympathomimetic agents causing striking and sustained increases in concentration of d-amphetamine in brain; cardiovascular effects can be potentiated. Intervention: Monitor frequently, adjust or use alternative therapy based on clinical response.

Proton Pump Inhibitors: Time to maximum concentration (Tmax) of amphetamine is increased compared to when administered alone. Intervention: Monitor patients for changes in clinical effect, adjust therapy based on clinical response.

Drug/Laboratory Interactions: Amphetamines can cause elevation in plasma corticosteroids. This is greatest in the evening. Amphetamines may interfere with urinary steroid determinations.

USE IN SPECIFIC POPULATIONS

Pregnancy Risk Summary: There are limited published data on amphetamines in pregnant women. Data are insufficient to determine drug-associated risk of major congenital malformations or miscarriage. Adverse pregnancy outcomes, including premature delivery, low birth weight, in infants born to mothers dependent on amphetamines. DYANAVEL XR may cause fetal harm.

Lactation Risk Summary: Breastfeeding is not recommended during treatment with DYANAVEL XR. Postmarketing Experience: Newborns - Based on limited case reports published in literature, amphetamine (d- or d,-l-) is present in human milk, at relative infant doses of 2%-13.8% of maternal weight-adjusted dosage and milk/plasma ratio ranging 1.9 to 7.5. Because of potential for serious adverse reactions in breastfed infant, advise patients breastfeeding is not recommended during treatment with DYANAVEL XR.

Pediatric Use Safety and effectiveness were established in patients with ADHD ages 6-17. Safety and efficacy in patients younger than 6 yrs with ADHD have not been established.

Geriatric Use DYANAVEL XR has not been studied in geriatrics.

DRUG ABUSE AND DEPENDENCE

Controlled Substance FYANAVEL XR contains amphetamine, which is a Schedule II controlled substance in the U.S. Controlled Substance Act.

OVERDOSAGE

Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice for treatment of overdose. Individual patient response varies widely. Toxic symptoms may occur idiosyncratically at low doses. Manifestations of overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, hypotension, hallucinations, panic states, hyperpyrexia, and rhabdomyolysis. Fatigue and depression usually follow CNS stimulation. Others include arrhythmias, hypotension or hypertension, circulatory collapse, nausea, vomiting, diarrhea, abdominal cramps. Fatal poisoning usually preceded by convulsions and coma.

Manufactured by: Tris Pharma, Inc., Monmouth Junction, NJ 08852 www.trispharma.com Based on LB 8417, Rev02

DYANAVEL XR contains amphetamine, which is a Schedule II controlled substance in the U.S. Controlled Substance Act.

Table 1. Common Adverse Reactions Occurring in ≥2% of Subjects on DYANAVEL XR or Greater than Placebo during double blind phase.

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>DYANAVEL XR (N=52)</th>
<th>Placebo (N=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Epistaxis</td>
<td>3.8%</td>
</tr>
<tr>
<td>Rhinitis allergic</td>
<td>3.8%</td>
<td>0%</td>
</tr>
<tr>
<td>Abdominal pain upper</td>
<td>3.8%</td>
<td>2.1%</td>
</tr>
</tbody>
</table>
bullying and teasing also negatively affect self-esteem and self-identity.

For children with acne, studies show a direct link between acne and identify and self-esteem issues. Many of these children feel embarrassed by their acne and have problems with low self-esteem, which is exacerbated by reported teasing and bullying from others. Children with severe acne experience these difficulties even more, which often leads to changes in areas that affect their lifestyle and identity (ie, choices they make in dress, activities, hobbies, and schoolwork).

Critical to helping children with the psychosocial issues potentially developing from skin diseases is first the recognition that skin diseases can and do cause much suffering in children, and this suffering can have negative consequences that carry into adulthood. Emphasizing that the appearance of the skin can have significant effects on the development of self-esteem, social interactions, relationships, school performance, extracurricular activities, and overall emotional and psychological health that can persist into adulthood, Kelly Cordoro, MD, associate professor of Clinical Dermatology and Pediatrics at the University of California, San Francisco, and senior author of the 2016 literature review, emphasized the need for pediatricians to take the concerns of children who are struggling with skin issues seriously.

“When we see severe skin disease it is obvious that it requires referral to dermatology for management, but even minor or limited skin problems may be interpreted as ‘flaws’ by patients and can result in disproportionate impact on the child’s body image and lead to body image pathology,” she says.

Armed with this recognition, pediatricians play an important role in helping to identify and address potential psychosocial problems in these children early to stem the negative effects that can become more difficult to address over time. Once identified, pediatricians can then also help children and their families develop coping skills.

This article summarizes some of the evidence cited in the 2016 review article on clinical tools used in dermatology practices to assess whether a child is experiencing psychosocial difficulties related to his or her skin disease, as well as coping strategies that can be used to help children and their families manage these potentially difficult psychosocial issues.

**Clinical assessment**

Assessing the potential psychosocial effect of a skin disease on a child can be difficult because it relies on the child’s mental perception of...
One way to assess the potential psychosocial effects of skin diseases is to measure what is called cutaneous body image (CBI), which refers to a person’s mental representation of his or her skin, hair, and nails. Assessment of CBI generally involves 3 major areas (Table 1).

To measure CBI specifically, a well-validated Cutaneous Body Image Scale (CBIS) can be used. Comprised of 7 items, the CBIS provides a composite score based on the mean ratings of the 7 items with a high score indicating greater satisfaction with CBI (Table 2).2

Cordoro emphasizes that the CBIS is very easy to use, is written in easy to understand language, and takes only minutes for patients to complete. An alternative to using the full test, she says, is to simply ask the child directly during the clinic visit how he or she feels about his/her skin disease. "This will allow assessment of body image and validate an adolescent’s concerns as medically relevant and not a sign of vanity," she says.

Assessment of CBI is seen as both a way to evaluate skin-related psychosocial effects as well as a way for clinicians to acknowledge the validity of such effects on their patients. As such, regular monitoring of CBI is recommended to take into account its subjectivity and changeability over time as well as a way to build a trusting relationship between the clinician and patient.2,6

According to Cordoro, the responses made on the assessment “can then be used to guide interventions such as counseling and/or the need for referrals to dermatology.”

### Interventions and coping skills

No studies to date provide specific data on strategies to intervene to help children and parents cope with skin-related psychosocial problems. In the absence of such data, Cordoro and colleagues culled data from a number of sources to offer clinicians a “stepwise” approach to promoting healthy body image and self-esteem in patients with skin-related psychosocial issues (Table 3).2

Cordoro emphasizes that the coping strategies adopted depend on various factors, including patient age, type of skin disease, and the patient and family’s reaction to the skin problem. Saying that some kids cope very well with their skin disease, she points out that even minor skin disease in some children can create an enormous social and psychological burden. “We try to individualize our discussions of coping strategies to the patient’s specific scenario because there really is no ‘one-size-fits-all’ approach,” she says, stressing the imperative to address cutaneous body image in the office given the evidence on the many

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**More teenagers with acne than those without (76% vs 53%) report they have been bullied—and almost 3 times as many of these teens with blemishes compared to those without believe this bullying has happened because of their skin.**

deleterious effects that skin diseases, such as acne, can have on patients.

Along with providing children with good coping tools, Cordoro and colleagues emphasize the critical role played by parents and caregivers to help their child develop good coping skills. To that end, parents and families also need coping strategies (Table 4).1

For children who may need more help than can be offered in the pediatrician’s office, referral to a psychologist or other counseling professional can be considered. Saying that he thinks pediatricians are good at assessing major distress in children or disruption of family dynamics, Cohen says that he also thinks most will be good judges at when the need for counseling goes beyond their capabilities. He says he routinely works with a psychologist who has a special interest in AD and who will even come to his clinic to see patients when they are evaluated in pediatric dermatology.

67% OF TEENS WITH ACNE HAVE NEVER SEEN A DOCTOR FOR IT. — Kelton Research Survey. Acne and Bullying. 2012.

All these proposed coping strategies are only suggestions and not based on any evidence. Evidence on specific interventional techniques for children with AD and acne who have poor CBI does not yet exist.2 Other suggestions for pediatricians to help children and their families cope with skin-related psychosocial issues are provided in “General tools and resources for managing skin-related psychosocial issues” at ContemporaryPediatrics.com/skin-diseases.

**Summary**

Skin diseases can and do have a significant impact on the psychosocial health of children and adolescents. Atopic dermatitis and acne are among the most common skin diseases in children that can have a negative impact on the quality of their lives. As described in a recent review, children with these diseases often have issues with identity and self-esteem.

For children with AD, problems with identity can be associated with behavioral problems that result from not developing healthy coping skills. Parents can unwittingly participate in this by not asserting the discipline a child needs to form good coping skills. For children with acne, self-esteem and identity are more directly connected to their skin disease. The embarrassment many of these children feel because of their acne leads to low self-esteem. For all these children, teasing and bullying by peers is a major contributor to the negative psychosocial affects of having a skin disease.

Pediatricians play an important role in helping to identify and address potential psychosocial problems in children with skin diseases. Clinical assessment is aimed at determining the effect of the skin disease based on a child’s mental representation of his or her skin. Once psychosocial difficulties are identified, pediatricians can then help children and their families develop coping skills.

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**COPING STRATEGIES FOR PARENTS AND FAMILIES**

<table>
<thead>
<tr>
<th>ACTIONS</th>
<th>STRATEGIES</th>
</tr>
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</table>
| Help parents and families adjust to a child coping with skin-related psychosocial issues. | - Teach principles of the “theory of cognitive adaptation” that espouses establishing a sense of mastery or control over an event to enhance one’s self-esteem.  
- Establishing a sense of control over a situation includes obtaining both information control (expanding one’s knowledge of the skin disease and situation) as well as behavioral control (taking direct action to change the situation). |
| Encourage motivated parents and families to engage in additional strategies to enhance their child’s control and self-esteem. | - Form productive therapeutic alliances with their child’s physician.  
- Engage in disease education and advocacy organizations.  
- Focus on the positive aspects or benefits of the situation (find the silver lining). |

From Nguyen CM, et al.2

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For resources and references, go to ContemporaryPediatrics.com/skin-diseases
Patch testing in atopic dermatitis

A new consensus statement provides the first guidance on when and how to perform patch testing for allergic contact dermatitis in patients with atopic dermatitis.

CRYSTAL MU R C I A, PHD.
REVIEWED BY JENNIFER K CHEN, MD, AND SUSAN T NEDOROST, MD

Atopic dermatitis (AD), colloquially referred to as eczema, typically presents in children as itchy, dry, scaly patches of skin that appear on the scalp, forehead, and/or face.1 Symptoms may begin developing in infants aged as young as 2 to 3 months. For most people, symptoms of AD present before the age of 5 years, although AD occasionally manifests in adolescence or adulthood. It is estimated that 10% to 20% of children worldwide suffer from AD.

Individuals who have AD also may experience allergic contact dermatitis (ACD), which arises from separate pathologic processes. Allergic contact dermatitis is a hypersensitivity reaction resulting from contact sensitization.2 Common sources of ACD include poison ivy, poison oak, poison sumac, nickel, fragrances, rubber, and various dyes and additives. Pediatric ACD has become increasingly common, affecting as many as 20% of children. Detecting ACD in patients with AD is important because its presence may serve to exacerbate AD.

Patch testing is a standard part of the diagnostic regimen for ACD. However, patch testing in patients with AD represents a conundrum for clinicians. As explained to Contemporary Pediatrics by Jennifer K. Chen, MD, Department of Dermatology, Stanford University, Redwood City, California, “In the patch testing community, we’ve noticed that AD patients represent a conundrum for clinicians. As explained to Contemporary Pediatrics by Jennifer K. Chen, MD, Department of Dermatology, Stanford University, Redwood City, California, “In the patch testing community, we’ve noticed that AD patients represent a conundrum for clinicians. As explained to Contemporary Pediatrics by Jennifer K. Chen, MD, Department of Dermatology, Stanford University, Redwood City, California, “In the patch testing community, we’ve noticed that AD patients represent a conundrum for clinicians.

New guidance for clinicians

To address this knowledge and practice gap, a working group of experts in AD and ACD created the first expert consensus recommendations on patch testing in patients with AD.3 This guidance, which was published this summer in the journal Dermatitis, grew from an interactive session held at the 2014 American Contact Dermatitis Society annual meeting in Denver, Colorado.

The expert consensus statement guides clinicians in determining when and how to perform patch testing in patients with AD, including identification of scenarios in which patch testing would be appropriate. The authors recommend that patch testing be considered in patients with AD who have:

- dermatitis that fails to improve with topical therapy;
- atypical/changing distribution of dermatitis, or a pattern suggestive of ACD;
- therapy-resistant hand eczema (among those in the working population);
- adult-onset or adolescent-onset AD; and
- severe or widespread dermatitis, in which case patch testing is recommended before initiating

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Eczema is not an allergy itself, but allergies can trigger it.

—Nemours Center for Children’s Health Media.
systemic immunosuppressant treatment.

Patch testing is not likely to be informative for patients with stable, well-controlled AD; those who are currently experiencing an AD flare; or those who have a recent or current exposure to immunosuppressive therapy or ultraviolet radiation. The experts also note that certain medications may lead to false-negative tests, whereas preexisting cutaneous inflammation may cause false-positive test results.

Allergen selection for patch testing should be individualized, taking into account allergens that the patient is likely to encounter based on local environment, avocation, use of personal care products or topical medications, and so on. These allergens may differ in patients with AD from that of the general population.

Susan T. Nedorost, MD, Department of Dermatology, University Hospitals Cleveland Medical Center, Cleveland, Ohio, an author on the consensus statement, notes that, “We often see allergy to less potent allergens such as vitamin E and propylene glycol in [patients with AD]. Most of these weaker sensitizers are not routinely patch tested; routine patch tests are composed mostly of potent sensitizers. Failure to patch test to the allergens most relevant for this population has perpetuated the myth that contact allergy does not occur in these patients.”

Modified patch testing for kids
In the pediatric population, patch testing requires some modification to account for differences in patient size and allergen exposure. Chen, first author of the consensus statement, relays her experience, stating that, “In children who are very young, we tend to do targeted testing given the small size of their backs and the often shorter list of potential exposures. We try to avoid patch testing with allergens that may have higher rates of active sensitization if there is no history of exposure to common culprit items that may contain these allergens. paraphenylenediamine and acrylates are great examples of this. Children 12 and older can be patched tested with a standard screening series the same as adults.”

Interpreting patch testing results in patients with AD can be challenging in that increasing reactivity over time may not occur and the overall response may be weaker. Delayed reading of test results may be beneficial and, for clinicians with limited patch testing experience, referral to an experienced practitioner should be considered. A searchable directory of practitioners who offer patch testing may be found at the American Contact Dermatitis Society website.

By sharing these recommendations, the authors of the consensus document hope to build awareness and improve the appropriate evaluation of ACD in patients with AD.

Dr Murcia is a medical writer in North Carolina. She has nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.

REFERENCES

New research from the United Kingdom examines the potential association between hard water in the home and incidences of atopic dermatitis in infancy. To read more about what the investigators found, see Study links hard water to eczema at ContemporaryPediatrics.com/eczema-hard-water
Common pediatric disorders in skin of color

Biological differences in skin disorders such as atopic dermatitis and acne affect presentation and severity among children of color.

Although pediatric atopic dermatitis (AD) and acne have some similarities among children with skin of color and lighter-skinned children, there are important differences when these common skin conditions affect darker skin types, according to Nanette Silverberg, MD, clinical professor of Dermatology and Pediatrics, Icahn School of Medicine at Mount Sinai, and chief, Pediatric Dermatology, Mount Sinai Health System, New York.

Starting with eczema

Atopic dermatitis is the most common skin condition of childhood and affects about 25% of children in the United States, according to Silverberg, who presented on the topic at the Skin of Color Seminar Series, held earlier this year in New York City.

“In particular, there have been studies that have shown AD is more common in children of African American descent or of Afro-Caribbean descent,” she says. “It certainly represents a very concerning issue in children of color.”

Differences in AD can occur in both the presentation and severity among children of color. “In somebody who is very light skinned, eczema is going to be red, but in children of color, we see much less erythema. Instead, we see much more in the way of lichenification, or thickening of the skin, and more follicular prominence,” Silverberg explains. “These are particularly vexing types of eczema in that the lichenification or lichenoid type of dermatitis is often very thick and very itchy. And the follicular type can be quite deceptive. You don’t see redness. You don’t necessarily see thick or oozing skin, but it is incredibly itchy and it significantly affects children psychologically.”

Many of the kids with AD will manifest in early childhood with a lot of hypopigmentation or lightness of the skin. These pigmentary alterations, which we see in kids of color, are temporary, but are sometimes very noticeable and can concern parents,” she continues. “But this generally resolves, and that’s something we can reassure parents about.”

Acne challenges

Acne is common in the pediatric population and comes with different concerns in children with skin of color. “Whereas many of
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Clinical Feature

Our Caucasian patients talk about the actual pimple lesions, most of our African American patients and many of our Hispanic and Asian patients will obsess over postinflammatory pigmented alterations after their acne clears,” Silverberg notes.

Hispanic pediatric patients tend to have the most severe acne types among children of skin of color, Silverberg states. “We don’t see as much in the way of cystic acne in African American patients, historically and in the literature,” she says. “So, the population that we tend to focus on for more severe treatment or treatment, like isotretinoin, are usually Hispanic teenagers. It’s an important consideration because they have some tendency to have the cystic component. Although you can see it in everybody, it seems to be the most concerning among that population in the teen-aged years.”

Physicians treating these children need to pay special attention to communicating the need for using good sun protection and to work with patients to develop a skin care regimen that’s effective both at clearing current lesions and preventing new lesions, so that pigmentation improves over time, according to Silverberg.

“There are some wonderful new acne guidelines that have come out recently from the American Academy of Dermatology . . . saying it’s clear that most patients of color will respond quite nicely to the products we have available, including topical retinoids . . . as well as azelaic acid, which has been demonstrated to be beneficial in improving both tone and skin lesions,” Silverberg says.

Additional pigmentation issues

Some pigmentation issues that arise in children of color can persist into adulthood. “The most vexing, of course, being vitiligo,” says Silverberg.

Vitiligo is an acquired pigmen-tary disorder of the skin and mucous membranes characterized by circumscribed, depigmented macules and patches, and, microscopically, by the total absence of melanocytes. The exact cause of the destruction of these cells is not known but one possible explanation might be that the body’s immune system destroys the cells, as in other autoimmune conditions. Although vitiligo affects all races equally, it is more noticeable in dark-skinned patients.

Children are more likely to develop AD if one or both parents have AD, asthma, or hay fever.

—American Academy of Dermatology.
"In [skin of color] patients, about .5% to 2% of the population has vitiligo and about half of those cases begin in childhood," Silverberg states.

Initial lesions occur most frequently around the eyes, the mouth, and the lips; on the chest and around underarms; in the crooks of the elbows and wrists; and around the toes and in joint spaces. “Sometimes, we’ll see loss of pigmentation around moles, which are called halo nevi,” Silverberg says.

Physicians should inquire about family history of vitiligo, because children who have family members with the skin disease are more likely to develop it at a young age.

Vitiligo symptoms include an often rapid pigment loss in several areas of the skin. The initial appearance of the white patches can be followed by a stable period without any progression of the condition. Later on, further cycles of pigment loss and stability may be observed. If not treated early in skin of color, it can affect children’s self-esteem and quality of life. “Younger kids may not be as bothered, but teenagers become very concerned with their appearance,” Silverberg says.

“We have a variety of different treatments,” notes Silverberg. “We know that patients of color may respond a little bit better than other patients to treatments that include topical calcineurin inhibitors, such as tacrolimus. We also have good data on the use of narrow band [ultraviolet B] and the excimer laser in both children and adults of color with good results. We have an expectation that if we intervene early, we may be able to help patients achieve good repigmentation.”

**Hair concerns start early**

Children of color have a spectrum of hair and scalp issues including seborrhic dermatitis, which generally doesn’t have a standard cradle top appearance in children with darker skin, according to Silverberg.

“[In infants with darker skin types] we’ll often see erythema, redness, flaking, and hypopigmentation, including hypopigmentation of the folds of the skin, which will sometimes overlie AD. That makes the hypopigmentation look worse,” she says.

As these children age, their hair styling choices also can cause hair thinning problems, Silverberg continues. "In African American kids, we see braiding and pony tails, multiple pony tails or the addition of hair extensions, and hair braiding or hair twisting. And many of these processes are used by both African American girls and boys. You’ll also see a lot of tight pony tail usage among Latino girls,” she says. “Those contribute to traction alopecia, which is a thinning along the marginal parts, from chronic pulling on the curved or straight hair follicle.”

The traction alopecia that results from hair styling practices can be exacerbated by use of gel pomades or oils to slick the hair back. These products can ultimately block the hair follicles and may result in folliculitis around the follicle and, eventually, scarring and hair loss. Physicians who observe acne along the forehead should suspect kids are using pomades to slick back their hair, according to Silverberg.

Other hair issues common in children and teenagers of color include hair breakage and bubble hair, an acquired hair shaft abnormality characterized by multiple air-filled spaces within the hair shaft that result from over-styling and thermal injury.

“I’ll also see hair infections on the scalp of kids of color—in particular, tinea capitis,” Silverberg says. “Tinea capitis, also called ringworm of the scalp, is a dermatophyte infection of the scalp and hair structure. It goes down inside to a certain point in the hair where keratin starts to be produced called Adamson’s fringe. In tinea capitis, dermatophytic infection of of hair extensions, and hair braiding or hair twisting. And many of these processes are used by both African American girls and boys. You’ll also see a lot of tight pony tail usage among Latino girls,” she says. “Those contribute to traction alopecia, which is a thinning along the marginal parts, from chronic pulling on the curved or straight hair follicle.”

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In the Rotavirus Efficacy and Safety Trial (REST)

**RotaTeq showed high-level efficacy against RGE caused by common serotypes G1, G2, G3, and G4 through the first rotavirus season postvaccination**¹,ᵃ:

- **98% efficacy against severe RGE** (N=5,673: 2,834, vaccine; 2,839, placebo)
- **74% efficacy against mild, moderate, and severe RGE** (N=5,673: 2,834, vaccine; 2,839, placebo)

**Selected Safety Information (continued)**

Infants with Severe Combined Immunodeficiency Disease (SCID) should not receive RotaTeq. Post-marketing reports of gastroenteritis, including severe diarrhea and prolonged shedding of vaccine virus, have been reported in infants who were administered RotaTeq and later identified as having SCID.

Infants with a history of intussusception should not receive RotaTeq.

No safety or efficacy data are available from clinical trials regarding the administration of RotaTeq to infants who are potentially immunocompromised.

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**RotaTeq** is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3, and G4 when administered as a 3-dose series to infants between the ages of 6 to 32 weeks.

The vaccination series consists of 3 ready-to-use liquid doses of RotaTeq administered orally starting at 6 to 12 weeks of age, with the subsequent doses administered at 4- to 10-week intervals. The third dose should not be given after 32 weeks of age.

**Selected Safety Information**

RotaTeq should not be administered to infants with a demonstrated history of hypersensitivity to the vaccine or any component of the vaccine.
Selected Safety Information

(continued)

In a post-marketing observational study in the US, cases of intussusception were observed in temporal association within 21 days following the first dose of RotaTeq, with a clustering of cases in the first 7 days.

No safety or efficacy data are available for administration of RotaTeq to infants with a history of gastrointestinal disorders.

Vaccine virus transmission from vaccine recipient to nonvaccinated contacts has been reported. Caution is advised when considering whether to administer RotaTeq to individuals with immunodeficient contacts.

In clinical trials, the most common adverse events included diarrhea, vomiting, irritability, otitis media, nasopharyngitis, and bronchospasm.

In post-marketing experience, intussusception (including death) and Kawasaki disease have been reported in infants who have received RotaTeq.

RotaTeq may not protect all vaccine recipients against rotavirus.

Please see the adjacent Brief Summary of the Prescribing Information.

RotaTeq®  
(Rotavirus Vaccine, Live, Oral, Pentavalent)  

BRIEF SUMMARY OF PRESCRIBING INFORMATION  

DOSE AND ADMINISTRATION  

FOR ORAL USE ONLY. NOT FOR INJECTION. The vaccination series consists of three ready-to-use liquid doses of RotaTeq administered orally starting at 6 to 12 weeks of age, with the subsequent doses administered at 4 to 10-week intervals. The third dose should not be given after 32 weeks of age.  

CONTRAINDICATIONS  

A demonstrated history of hypersensitivity to any component of the vaccine. Infants who develop a rash suggestive of hypersensitivity after receiving a dose of RotaTeq should not receive further doses of RotaTeq. Infants with Severe Combined Immunodeficiency Disease (SCID) should not receive RotaTeq. Post-marketing reports of gastroenteritis, including severe diarrhea and prolonged shedding of vaccine virus, have been reported in infants who were administered RotaTeq and later identified as having SCID. Infants with a history of intussusception should not receive RotaTeq.  

WARNINGS AND PRECAUTIONS  

Managing Allergic Reactions: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.  

Immunocompromised Populations: No safety or efficacy data are available from clinical trials regarding the administration of RotaTeq to infants who are potentially immunocompromised including: Infants with blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic system; Infants on immunosuppressive therapy (including high-dose systemic corticosteroids). RotaTeq may be administered to infants who are being treated with topical corticosteroids or inhaled steroids; Infants with primary and acquired immunodeficiency states, including HIV/AIDS or other clinical manifestations of infection with human immunodeficiency viruses; cellular immune deficiencies; and hypogammaglobulinemic and agammaglobulinemic states. There are insufficient data from the clinical trials to support administration of RotaTeq to infants with indeterminate HIV status who are born to mothers with HIV/AIDS; Infants who have received a blood transfusion or blood products, including immunoglobulins within 42 days. Vaccine virus transmission from vaccine recipient to non-vaccinated contacts has been reported.  

Intussusception: Following administration of a previously licensed live rhesus rotavirus reassortant vaccine, an increased risk of intussusception was observed. In a post-marketing observational study in the US cases of intussusception were observed in temporal association within 21 days following the first dose of RotaTeq, with a clustering of cases in the first 7 days. In worldwide passive post-marketing surveillance, cases of intussusception have been reported in temporal association with RotaTeq.  

Gastrointestinal Illness: No safety or efficacy data are available for administration of RotaTeq to infants with a history of gastrointestinal disorders including infants with active acute gastrointestinal illness, infants with chronic diarrhea and failure to thrive, and infants with a history of congenital abdominal disorders, and abdominal surgery. Caution is advised when considering administration of RotaTeq to these infants.  

Shedding and Transmission: Shedding of vaccine virus was evaluated among a subset of subjects in REST* 4 to 6 days after each dose and among all subjects who submitted a stool antigen rotavirus positive sample at any time. RotaTeq was shed in the stools of 32 of 360 (9.5%, 95% CI (6.2%, 12.3%)) vaccine recipients tested after dose 1; 0 of 249 (0.0%, 95% CI (0.0%, 1.5%)) vaccine recipients tested after dose 2; and in 1 of 385 (0.3%, 95% CI (<0.1%, 1.4%)) vaccine recipients after dose 3. In phase 3 studies, shedding was observed as early as 1 day and as late as 15 days after a dose. Transmission of vaccine virus was not evaluated in phase 3 studies. Transmission of vaccine virus strains from vaccinees to non-vaccinated contacts has been observed post-marketing. The potential risk of transmission of vaccine virus should be weighed against the risk of acquiring and transmitting natural rotavirus. Caution is advised when considering whether to administer RotaTeq to individuals with immunodeficient close contacts such as: individuals with malignancies or who are otherwise immunocompromised; individuals with primary immunodeficiency; or individuals receiving immunosuppressive therapy.  

Fibrile Illness: Fibrile illness may be reason for delaying use of RotaTeq except when, in the opinion of the physician, withholding the vaccine entails a greater risk. Low-grade fever (<100.5°F [38.1°C]) itself and mild upper respiratory infection do not preclude vaccination with RotaTeq.  

Incomplete Regimen. The clinical studies were not designed to assess the level of protection provided by only one or two doses of RotaTeq. Limitations of Vaccine Effectiveness: RotaTeq may not protect all vaccine recipients against rotavirus.  

POST-EXPOSURE PROPHYLAXIS  

No clinical data are available for RotaTeq when administered after exposure to rotavirus.  

ADVERSE REACTIONS  

Clinical Studies Experience: 71,725 infants were evaluated in 3 placebo-controlled clinical trials including 38,185 infants in the group that received RotaTeq and 35,580 infants in the group that received placebo. Parents/guardians were contacted on days 7, 14, and 42 after each dose regarding intussusception and any other serious adverse events. The racial distribution was as follows: White (89% in both groups); Hispanic-American (14% in both groups); Black (8% in both groups); Multiracial (5% in both groups); Asian (2% in both groups); Native American (RotaTeq 2%, placebo 1%); and Other (<1% in both groups). The gender distribution was 51% male and 49% female in both vaccination groups. Because clinical trials are conducted under conditions that may not be typical of those observed in clinical practice, the adverse reaction rates presented below may not be reflective of those observed in clinical practice.  

Serious Adverse Events: Serious adverse events occurred in 2.4% of recipients of RotaTeq when compared to 2.9% of placebo recipients within the 42-day period of a dose in the phase 3 clinical studies of RotaTeq. The most frequently reported serious adverse events for RotaTeq compared to placebo were: bronchiolitis (0.6% RotaTeq vs. 0.7% Placebo), gastroenteritis (0.2% RotaTeq vs. 0.3% Placebo), pneumonia (0.2% RotaTeq vs. 0.2% Placebo), fever (0.1% RotaTeq vs. 0.1% Placebo), and urinary tract infection (0.1% RotaTeq vs. 0.1% Placebo).  

Deaths: Across the clinical studies, 52 deaths were reported. There were 25 deaths in the RotaTeq recipients compared to 27 deaths in the placebo recipients. The most commonly reported cause of death was sudden infant death syndrome, which was observed in 8 recipients of RotaTeq and 9 placebo recipients.  

Intussusception: In REST, 34,837 vaccine recipients and 34,788 placebo recipients were monitored by active surveillance to identify potential cases of intussusception at 7, 14, and 42 days after each dose, and every 6 weeks thereafter for 1 year after the first dose. For the primary safety outcome, cases of intussusception occurring within 42 days of any dose, there were 6 cases among RotaTeq recipients and 5 cases among placebo recipients (see Table 1). The data did not suggest an increased risk of intussusception relative to placebo. Table 1: Confirmed cases of intussusception in recipients of RotaTeq as compared with placebo recipients during REST  

<table>
<thead>
<tr>
<th>RotaTeq (n=34,837)</th>
<th>Placebo (n=34,788)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirmed intussusception cases within 42 days of any dose</td>
<td>6</td>
</tr>
<tr>
<td>Relative risk (95% CI)†</td>
<td>1.6 (0.4, 6.4)</td>
</tr>
<tr>
<td>Confirmed intussusception cases within 365 days of dose 1</td>
<td>13</td>
</tr>
<tr>
<td>Relative risk (95% CI)</td>
<td>0.9 (0.4, 1.9)</td>
</tr>
</tbody>
</table>

†Relative risk and 95% confidence interval based upon group sequential design stopping criteria employed in REST.  

Among vaccine recipients, there were no confirmed cases of intussusception within the 42-day period after the first dose, which was the period of highest risk for the rhesus rotavirus-based product (see Table 2).  

Table 2: Intussusception cases by day range in relation to dose in REST  

<table>
<thead>
<tr>
<th>Day Range</th>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Dose 3</th>
<th>Any Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1-14</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1-21</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>1-42</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

All of the children who developed intussusception recovered without sequelae with the exception of a 9-month-old male who developed intussusception 98 days after dose 3 and died of post-operative sepsis. There was a single case of intussusception among 2,470 recipients of RotaTeq in a 7-month-old male in the phase 1 and 2 studies (716 placebo recipients). Hematocrit: Hematocrit was reported as an adverse event occurred in 0.6% (39/6,130) of vaccine and 0.6% (34/5,560) of placebo recipients within 42 days of any dose. Hematocrit was reported as a serious adverse event occurred in <0.1% (4/36,160) of vaccine and <0.1% (3/35,598) of placebo recipients within 42 days of any dose.  

*Rotavirus Efficacy and Safety Trial.
**RotaTeq® (Rotavirus Vaccine, Live, Oral, Pentavalent)**

Seizures: All seizures reported in the phase 3 trials of RotaTeq (by vaccination group and interval after dose) are shown in Table 3.

<table>
<thead>
<tr>
<th>Day range</th>
<th>1-7</th>
<th>1-14</th>
<th>1-42</th>
</tr>
</thead>
<tbody>
<tr>
<td>RotaTeq</td>
<td>10</td>
<td>15</td>
<td>33</td>
</tr>
<tr>
<td>Placebo</td>
<td>5</td>
<td>8</td>
<td>24</td>
</tr>
</tbody>
</table>

Seizures reported as serious adverse experiences occurred in <0.1% (27/36,150) of vaccine and <0.1% (18/35,538) of placebo recipients (not significant). Ten febrile seizures were reported as serious adverse experiences, 5 were observed in vaccine recipients and 5 in placebo recipients.

Kawasaki Disease: In the phase 3 clinical trials, infants were followed for up to 42 days of vaccine dose. Kawasaki disease was reported in 5 of 36,150 vaccine recipients and in 1 of 35,538 placebo recipients with unadjusted relative risk 4.9 (95% CI 0.6, 239.1).

Most Common Adverse Events

Solicited Adverse Events: Detailed safety information was collected from 11,711 infants (6,138 recipients of RotaTeq) which included a subset of subjects in REST and all subjects from Studies 007 and 009 (Detailed Safety Cohort). A Vaccination Report Card was used by parents/guardians to record the child's temperature and any episodes of diarrhea and vomiting on a daily basis during the first week following each vaccination. Table 4 summarizes the frequencies of these adverse events and irritability.

| Table 4: Solicited adverse experiences within the first week after doses 1, 2, and 3 (Detailed Safety Cohort) |
|---|---|---|---|---|---|
| Adverse event | RotaTeq | Placebo | RotaTeq | Placebo | RotaTeq | Placebo |
| N=5,616 | N=5,077 | n (%) | N=5,215 | n (%) | N=4,725 | n (%) | N=4,865 | n (%) | N=4,382 | n (%) |
| Elevated temperature | 17.1% | 16.2% | 20.0% | 19.4% | 18.2% | 17.6% |
| Vomiting | 6.7% | 5.4% | 5.0% | 4.4% | 3.6% | 3.2% |
| Diarrhea | 10.4% | 9.1% | 8.6% | 6.4% | 6.1% | 5.4% |
| Irritability | 7.1% | 7.1% | 6.0% | 6.5% | 4.3% | 4.5% |

Adverse events that occurred at a statistically higher incidence (i.e., 2-sided p-value <0.05) within the 42 days of each dose were shown in Table 5.

Post-Marketing Experience: The following adverse events have been identified during post-approval use of RotaTeq from reports to the Vaccine Adverse Event Reporting System (VAERS). Reporting of adverse events following immunization to VAERS is voluntary, and the number of doses of vaccine administered is not known; therefore, it is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to vaccine exposure using VAERS data. In post-marketing experience, the following adverse events have been reported following the use of RotaTeq: immune system disorders—Anaphylactic reaction. Gastrointestinal disorders—Intussusception (including death), Hematemesis, Gastroenteritis with viral viral shedding in infants with Severe Combined Immunodeficiency Disease (SCID). Skin and subcutaneous tissue disorders—Urticaria, Angioedema. Infections and infestations—Kawasaki disease, Transmission of vaccine virus strains from vaccine recipient to non-vaccinated contacts.

Other Adverse Events: Parents/guardians of the 11,711 infants were also asked to report the presence of other events on the Vaccination Report Card for 42 days after each dose. Fever was observed at similar rates in vaccine (N=6,138) and placebo (N=5,573) recipients (42.6% vs. 42.8%). Adverse events that occurred at a statistically higher incidence (i.e., 2-sided p-value <0.05) within the 42 days of any dose among recipients of RotaTeq as compared with placebo recipients are shown in Table 5.

Reporting of adverse events to their health care provider. Health care providers should report all adverse events to the US Department of Health and Human Services’ Vaccine Adverse Events Reporting System (VAERS). VAERS accepts all reports of suspected adverse events after the administration of any vaccine, including but not limited to the reporting of events required by the National Childhood Vaccine Injury Act of 1986. For information or a copy of the vaccine reporting form, call the VAERS toll-free number at 1-800-822-7967 or report online at www.vaers.hhs.gov.

**DRUG INTERACTIONS**

Immunosuppressive therapies including irradiation, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to vaccines. Concomitant Vaccine Administration: In clinical trials, RotaTeq was administered concomitantly with diphtheria and tetanus toxoids and acellular pertussis (DTaP), inactivated poliovirus vaccine (IPV), H. influenzae type b conjugate (Hib), hepatitis B vaccine, and pneumococcal conjugate vaccine. The safety data available are in the ADVERSE REACTIONS section. There was no evidence for reduced antibody responses to the vaccines that were concomitantly administered with RotaTeq.

**USE IN SPECIFIC POPULATIONS**

Pediatric Use: Safety and efficacy have not been established in infants less than 6 weeks of age or greater than 32 weeks of age. Data are available from clinical studies to support the use of RotaTeq in pre-term infants according to their age in weeks since birth in REST. All pre-term infants were followed for serious adverse experiences; a subset of 308 infants was monitored for all adverse experiences. There were 4 deaths throughout the study, 2 among vaccine recipients (1 SIDS and 1 motor vehicle accident) and 2 among placebo recipients (1 SIDS and 1 unknown cause). No cases of intussusception were reported. Serious adverse experiences occurred in 5.5% of vaccine and 5.8% of placebo recipients. The most common serious adverse experience was bronchiolitis, which occurred in 1.4% of vaccine and 2.0% of placebo recipients.

Parents/guardians were asked to record the child’s temperature and any episodes of vomiting and diarrhea daily during the first week following vaccination. The frequencies of these adverse experiences and irritability within the week after dose 1 are summarized in Table 6.

**Post-Marketing Experience:**

The following adverse events have been identified during post-approval use of RotaTeq from reports to the Vaccine Adverse Event Reporting System (VAERS). Reporting of adverse events following immunization to VAERS is voluntary, and the number of doses of vaccine administered is not known; therefore, it is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to vaccine exposure using VAERS data. In post-marketing experience, the following adverse events have been reported following the use of RotaTeq: immune system disorders—Anaphylactic reaction. Gastrointestinal disorders—Intussusception (including death), Hematemesis, Gastroenteritis with viral viral shedding in infants with Severe Combined Immunodeficiency Disease (SCID). Skin and subcutaneous tissue disorders—Urticaria, Angioedema. Infections and infestations—Kawasaki disease, Transmission of vaccine virus strains from vaccine recipient to non-vaccinated contacts.

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**USE IN SPECIFIC POPULATIONS**

Pediatric Use: Safety and efficacy have not been established in infants less than 6 weeks of age or greater than 32 weeks of age. Data are available from clinical studies to support the use of RotaTeq in pre-term infants according to their age in weeks since birth. Data are available from clinical studies to support the use of RotaTeq in infants with controlled gastroesophageal reflux disease.

**NONCLINICAL TOXICOLOGY**

Carcinogenesis, Mutagenesis, Impairment of Fertility: RotaTeq has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility.

**PATIENT COUNSELING INFORMATION**

Information for Parents/Guardians: Parents or guardians should be given a copy of the required vaccine information and be given the “Patient Information” appended to the Prescribing Information. Parents and/or guardians should be encouraged to read the patient information that describes the benefits and risks associated with the vaccine and ask any questions they may have during the visit.

For more detailed information, please read the Prescribing Information.

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RED STATE, BLUE STATE

What the election may mean for kids

The outcome of this year’s presidential election could significantly change the federal government’s role in addressing children’s health.

LAIRD HARRISON

One candidate favors reducing the government’s role in healthcare, the other increasing it. One candidate offers broad-brush proposals, the other detailed policy briefs. One candidate has spent years working on children’s welfare, the other has no public track record on it.

All in all, it’s hard to imagine a more polarizing choice than the one that Donald Trump and Hillary Rodham Clinton will offer voters interested in children’s health in this year’s presidential election.

“Elections, particularly presidential elections, are often characterized as historic and important,” says Irwin Redlener, MD, president and co-founder, Children’s Health Fund, New York. “This one transcends what normally happens.”

In combination with the results of the congressional elections, the outcome could significantly change the number of children with health insurance and the way pediatricians are reimbursed.

Contemporary Pediatrics reached out to children’s advocacy groups for their input for this article. The National Institute for Children’s Health Quality, the Heritage Foundation, and the Children’s Hospital Association declined to comment; the Anne E. Casey Foundation responded that it does not work in this area but offered a referral; and the Robert Wood Johnson Foundation did not respond by press time. Neither campaign responded to a request to discuss the candidates’ healthcare positions.

Mr Harrison is a writer based in Oakland, California. He has nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.

editors’ note

Contemporary Pediatrics reached out to children’s advocacy groups for their input for this article. The National Institute for Children’s Health Quality, the Heritage Foundation, and the Children’s Hospital Association declined to comment; the Anne E. Casey Foundation responded that it does not work in this area but offered a referral; and the Robert Wood Johnson Foundation did not respond by press time. Neither campaign responded to a request to discuss the candidates’ healthcare positions.

>1/5 of US children live in a family that experiences food insecurity.


The candidates differ sharply on matters of insurance. The percentage of children without healthcare coverage has steadily declined in recent decades, reaching a historic low of 4.8% in the most recent census, down from 13.9% in 1997.

Most of the gain in coverage results
from the expansion of Medicaid and the Children’s Health Insurance Program (CHIP), which together cover more than a third of US children aged 0 to 18 years. Depending on what voters decide in November, these programs could continue expanding or begin to contract.

Both programs pay for health-care costs for children whose families are in poverty, and together they have improved children’s health, says Joan Alker, MPhil, executive director of the Georgetown University Health Policy Institute, Washington, DC. “There’s a lot of research coming out showing the health benefits for kids,” she says, “and the benefits continue to accrue even when they’re adults.” She cites lower blood pressure, less use of emergency departments, better high school graduation rates, and better economic outcomes.

Medicaid
Medicaid covers about 36.8 million children. The Affordable Care Act (ACA) of 2010 expanded eligibility for Medicaid to 138% of the federal poverty level in states that choose to participate. That level is $20,160 for a family of 3.

Prior to the passage of the ACA, states set their own eligibility cutoff levels, and eligibility still varies in the 19 states that have declined to participate in the expansion.

Clinton says on her website that she would work to expand Medicaid in these states by making the federal government pick up 100% of the program’s costs. That won’t affect children directly, says Alker, because CHIP already picks up where Medicaid leaves off, insuring children up to at least 200% of the federal poverty line.

However, the expansion of Medicaid has indirectly brought healthcare coverage to some children because not all of those eligible for CHIP are enrolled. Sometimes, when parents gain coverage they sign up their children as well, Alker says.

Trump, on the other hand, proposes to fund Medicaid through block grants. “The state governments know their people best and can manage the administration of Medicaid far better without federal overhead,” his website says. “States will have the incentives to seek out and eliminate fraud, waste, and abuse to preserve our precious resources.”

In practice, Alker and other analysts interpret this to mean that overall Medicaid funding would be reduced. “[Trump’s] proposal doesn’t have a lot of detail, but there really has never been a block grant proposal that doesn’t include substantial cuts,” she says “and reimbursement for providers would probably be one of the first things on the chopping blocks for states.”

In an analysis by the nonpartisan Rand Corporation, switching to block grants for Medicaid and repealing the ACA would reduce the number of people with health insurance by 25.1 million. Rand arrived at this figure by assuming that federal funding for the program would drop back to levels from before the ACA passed into law. The Rand report does not say
how many of those losing coverage would be children.

CHIP
The Children’s Health Insurance Program covers 8.4 million children. Clinton has been a staunch supporter of the program. Although her exact role in its genesis is somewhat in dispute, Clinton has energetically worked to reauthorize it. She has shown a keen interest in children’s issues in general, beginning early in her career when she served as a staff attorney at the Children’s Defense Fund.

The CHIP’s current funding expires September 30, 2017, and given her record on the program, Clinton could be expected to make reauthorization a priority if she were president.

Trump has said little on the topic, nor does he have a track record of showing interest in public policy specifically related to children. However, on his website he implies that Medicaid and CHIP would become less necessary if he were elected.

“To reduce the number of individuals needing access to programs like Medicaid and Children’s Health Insurance Program we will need to install programs that grow the economy and bring capital and jobs back to America,” his website says. “The best social program has always been a job—and taking care of our economy will go a long way toward reducing our dependence on public health programs.”

Affordable Care Act
The 2 candidates have taken opposite positions on the ACA, with Trump promising to repeal it and Clinton promising to defend it.

Simply repealing the ACA would reduce the number of insured Americans by 19.7 million, according to the Rand Corporation analysis. The analysis did not break down the effects by age group, but Alker estimates that about 1 million chil-

23% OF HOMELESS INDIVIDUALS ARE KIDS.
— US Dept of Housing and Urban Development

dren are currently insured through the insurance exchanges set up by the ACA. Children are underrepresented in the exchanges compared with the general population because so many are covered by Medicaid and CHIP, she says.

Repealing the ACA could also affect children by eliminating a couple of provisions aimed specifically at children:

- It requires states to maintain their current eligibility levels of children’s coverage in Medicaid and CHIP through September 2019.
- It requires states to keep children aged 6 to 18 years with family incomes between 100% and 138% of the federal poverty level in Medicaid rather than CHIP.

This eliminates insurance premiums for these families. Charging premiums reduces enrollment by low-income families, Alker says.

Other proposals
Trump has proposed to “replace” the ACA with a set of other initiatives. Apart from the broad package of economic reforms that he says would reduce the number of people needing government assistance, he would expand tax deductions for healthcare costs, allow insurance companies to offer plans across state lines, allow the import of drugs from overseas, broaden the use of tax-deductible health savings accounts, and require more transparency in healthcare costs.

Would these policies compensate for the loss of coverage through ACA and Medicaid? According to the Rand analysis, the combined effects of repealing the ACA, expanding tax deductions, paying for Medicaid through block grants, and allowing insurers to sell across state lines would result in a net reduction of 20.3 million persons (adults and children) losing

Childcare accounts for ~25% of the budget for a family with 2 children.
healthcare coverage.

Rand does not attempt to analyze Trump’s other proposals. A 2005 analysis by a researcher at Columbia University, New York, found that health savings accounts were unlikely to expand health insurance coverage because most uninsured people are not paying high enough taxes to benefit from the deductions.

Clinton, meanwhile, offers programs aimed at expanding government healthcare coverage. The one that might most directly affect children is elimination of the so-called “family glitch.” Currently, the ACA provides tax credits for employees with low incomes if their employer charges them a health insurance premium exceeding 9.66% of their income. However, the ACA considers only the cost of the premium for insurance provided to the employee. Clinton would amend the law to include the cost of premiums for insurance provided to the employee’s family. This would extend insurance to 1.1 million persons, according to Rand, and, presumably, many of them would be children.

Clinton also proposes to institute a new “public-option” insurance plan, a new tax credit of $5000 per family to offset the cost of out-of-pocket spending above 5% of income, and a reduction in the maximum premium individuals must pay in the ACA’s insurance marketplace.

Whereas Rand estimates that these policies could extend coverage to millions more adults and children, it doesn’t offer a combined total and notes that Clinton also has put out multiple other proposals. Among these proposals are new negotiation strategies with drug companies, limits on out-of-pocket costs for drugs, and increased funding for community health centers.

**Divided government**

Clinton’s proposals fit much more closely than Trump’s with the policy agenda of the American Academy of Pediatrics (AAP), the nation’s largest organization of pediatricians. In its *Blueprint for Children*, released in September 2016, the organization supports CHIP reauthorization and repair of the family glitch. It lays out a wish list for children’s provisions it would like to add to the ACA. In addition, it opposes block grants for Medicaid.

The document goes far beyond such programs aimed directly at children’s health insurance to call for changes in policies around childcare, immigration, emergency preparedness, juvenile justice, food security, and a host of other issues.

Although the organization refrains from endorsing candidates, this document and the AAP’s other public statements come down on one side in the philosophical debate that divides most Republicans from most Democrats: whether the federal government should do more or less.

“Right now, if we look out across the landscape, children have very different experiences based on their zip codes,” explains the AAP’s chief public affairs officer Mark Del Monte, JD. “And we don’t believe that’s just. It’s a national priority to have healthy children and to have children that are growing up well and developing as they should. That’s a collective priority for all of us across the country. So it’s the role of the federal government to ensure there is a basic minimum for all kids.”

The presidential election won’t necessarily tip the balance of power either for or against the expansion of the federal government, however. Most projections show the Republicans retaining a majority in the House of Representatives, where they could block many of Clinton’s initiatives. Prognostications about the Senate have oscillated, but no one expects either party to gain the two-thirds majority necessary to pass sweeping reforms.

If Trump is elected but Republicans don’t have the necessary numbers to rescind the ACA, Redlener says, Trump could still undermine the program, perhaps by pushing through legislation to eliminate a crucial provision such as...
A Bioethicist’s Perspective
Why consent for newborn screening matters

NORMAN FOST, MD, MPH

Imagine you are leaving your local hospital or clinic, having just completed a routine visit for a nonserious problem. As you approach the main exit you are tackled and held down by 4 strong men in white coats. One of them grabs your arm, and another sticks your finger with a lancet and guides a few drops onto a small paper card. He applies a small Band-Aid and then they let you go.

“What the hell was that all about!” you sputter.

“Well,” says the apparent leader, “We think there’s a 1:10,000 chance you have a really bad disease that could cause your brain to rot, and if you do have it, and if you go on this unpleasant diet for the next 5 years, you will probably be OK.”

What’s wrong with this picture? Let me count the ways. First, it seems to be a simple case of battery, with witnesses, and you should be able to get a substantial settlement from the hospital that employs these guys, assuming they have enough sense not to go to trial.

Second, there are laws in every state that generally require health-care providers to ask you if you would be interested in getting medical care. There are exceptions, but not for situations like this. The laws are based, among other things, on the foundational ethical principle of liberty: the notion that a competent adult should be free to live his or her life the way he/she wants, unless he or she is causing harm to someone else.1 Because you’ve never heard of the disease they’re talking about, you might have a lot of questions. That is, before deciding whether you wanted to have this test and before consenting to have the test, you would need to be informed of some basic facts.

You might want to know, for example, whether or not this test is accurate, particularly whether there are false positives that could scare the bejeezus out of you and lead you to start on this nasty diet for no good reason. Also, you might want to know what the evidence is that the diet really worked, or worse, whether it might be harmful.

“Time out!” you might say at this point. Why is the absurd story appearing in a respected medical publication? Everyone knows these principles. Adults don’t get assaulted like this in trusted healthcare facilities.

Precisely, but children do—the persons least able to defend themselves, run away, or hire lawyers. Not big children so much, but the smallest, most vulnerable ones—newborn infants.

Treat or die?
Theoretically, the same rules are supposed to apply. Children are not supposed to be attacked like this without consent, and because they are incapable of providing meaningful consent (although they are pretty good at expressing their dissent!) someone has to do it for them, presumably their parents. That’s what the laws and innumerable professional guidelines say.2,3

However, since the early 1960s, virtually all children have been restrained, stuck, tested, and referred for treatment with very little involvement by their parents until after a test result comes back positive, when the parent is presented with a Hobson-like choice: “Treat or die!” or suffer profound brain damage or some other serious disability.

The usual rationale for this is that some rare but horrible preventable disease will befall the child; parents and doctors can’t be trusted to test for or treat these diseases; hence, the usual requirements for consent need to be suspended to protect children from harm.

Of course, the same argument could be made about adults—that they, and their doctors, commonly fail to get needed tests or treatments and suffer great harm as a result—but no one has suggested that assaulting them, without their consent, is justified to protect them from harm. Let’s skip that pesky inconsistency and get back to the infants.

The claim that it’s OK to invade a child’s body, without the

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FAST FACT

Each year over 5000 babies are identified with a newborn screening condition.

—BABY’S FIRST TEST, GENETIC ALLIANCE.
parent’s consent, falls apart if the invasion involves a test of uncertain or unknown validity, and treatment of uncertain benefit and risks. Suspending the basic principle of consent, one would think, is a really big deal, and the invader should be really sure that the alleged harms and benefits are based on good science, not just a hunch that the test and treatment plan are good ideas. In fact, there is a federal law that prohibits newborn screening for research purposes without explicit consent.4

**How newborn screening began**

Newborn screening without consent got off to a bad start when phenylketonuria (PKU) was mandated by state statutes in the 1960s. The idea was promulgated by a passionate group of well-meaning advocates, including Robert Guthrie, who developed the ingenious screening test, and President John Kennedy, whose family was devoted to improving the well-being of people with retardation because of their experience with the president’s sister, Rosemary.

However, passion is not a substitute for science, and the PKU mandatory screening program went from idea to implementation without reliable information about the characteristics of the screening test or the safety and efficacy of the diet. The test, it turned out years later, had a false-positive rate of around 20:1, so that many children labeled as having PKU were, in fact, destined to be normal.3 It also slowly came to light that phenylalanine restriction could be more harmful than phenylalanine excess, so that excessive restriction could cause not only severe brain damage, but also death attributed to protein malnutrition.

No one knows how often this happened because the screening program was not thought of as a research project, so there was not a systematic study of its benefits and risks. The American Academy of Pediatrics (AAP) thought it was a serious enough problem that it recommended shutting down the program, after most states had passed laws requiring screening, until experts could figure out the problems with the test and the diet. This was eventually accomplished, but it was a big enough problem that a congressional investigation was held, which recommended that the National Academy of Sciences (NAS) convene an expert committee to look into the problem and make recommendations in anticipation of other proposals for newborn screening.

One of the key recommendations of the NAS committee was that informed consent should be an essential prerequisite for newborn screening. That recommendation has been endorsed by innumerable committees and organizations, most recently the AAP and the American College of Medical Genetics (ACMG),2,3 but it is honored more in the breach.

**What happened next**

Some might say that the PKU story was long ago and far away, and we have learned our lessons. Would that it were so. In the 2000s, spurred by the development of tandem mass spectroscopy, it became easy to screen for dozens of abnormalities on the same drop of blood obtained for PKU screening. An expert committee of the ACMG, using criteria that were widely criticized,6 recommended a dramatic expansion of newborn screening, without the benefit of scientific studies of the tests or requirements for meaningful consent.7

One outcome of these recommendations was the labeling of dozens of children with 2-methylbutyryl-CoA dehydrogenase deficiency (MBADD), previously thought to be so rare that only 5 cases had ever been identified. Parents of the “affected” children identified in the new screening program were told their children would die, or suffer profound damage, if they were not maintained on a strict diet. Because virtually all of the affected children were from Hmong parents, with limited understanding of what the doctors were saying and little confidence in Western ideas of health and disease, compliance with the recommendations was close to zero, but years later the children seemed to be developing normally.8 It gradually came to light that the children

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**The children caught up in the MBADD program had 100% false-positive results and no true positives—possibly the worst medical test in history.**

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**Norman Fost, MD, MPH**

The children caught up in the MBADD program had 100% false-positive results and no true positives—possibly the worst medical test in history.

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did not have the dreaded disease MBADD, but a different mutation that led to an abnormal test and no apparent risk for serious disease. Unlike the PKU program that had a 20:1 false-positive rate, the children caught up in the MBADD program had 100% false-positive results and no true positives—possibly the worst test in medical history, but supported and recommended by experts.

Newborn screening and treatment with unproven remedies is not confined to state-mandated screening. In the 1970s, thousands of premature infants were screened for acidosis, for a decade or more, in virtually every neonatal intensive care unit in North America, and treated with concentrated bicarbonate solutions, often resulting in severe intracranial bleeding with no evidence of improved outcomes.9,10 A larger number of otherwise healthy newborns were screened for hyperbilirubinemia, and for decades treated with exchange transfusions using blood with unknown levels of hepatitis virus, with no evidence that the magic threshold of 20 mg/dL had any association with neurologic damage in this population.11 An even larger number of premature infants were screened for low oxygen levels for more than a century and treated with indiscriminate amounts of oxygen, causing blindness and lung damage, until studies showed that oxygen, like all drugs, had a dose-response curve, some doses being too high, some too low.12

Where we are today
Newborn screening has had many successes. Hundreds of thousands of children have been able to enjoy long healthy lives, free of disability, because of tests and treatments that turned out to have good benefit/risk profiles. However, there is still no “tollgate” for new ideas in newborn screening, no equivalent entity such as the US Food and Drug Administration with the authority to require that new ideas be tested before being unleashed on the population with no requirement for meaningful scientific studies or informed consent. Some committees have done better than others in using rigorous methods to sort out good from bad ideas.13

Taking consent seriously doesn’t necessarily mean reading an incomprehensible long document. For some tests an “opt-out” process might be appropriate, although you need to know some basic facts before deciding whether to opt out. Imagine that the guy who was tackled and tested was told, “We think you might have a disease that affects 1:10,000 persons, but we’re not really sure, and we don’t really know whether the diet will help you or hurt you.” Faced with those facts, at least a few persons, given the choice, might pass on the test, whether for themselves or for their apparently healthy children.

Dr Fest is Professor Emeritus, Departments of Pediatrics and Medical History and Bioethics, University of Wisconsin School of Medicine and Public Health, Madison, and the author of “Informed consent should be a required element for newborn screening, even for disorders with high benefit-risk ratios” (J Law Med Ethics. 2016;42(2):241-255), from which this article is derived. He discloses that he served as a nonvoting member of the National Academy of Sciences expert committee for newborn screening as referenced in this article.

REFERENCES

For additional references, go to ContemporaryPediatrics.com/ethics-newborn-screening
**Clinical Feature**

CONTINUED FROM PAGE 33

the hair shaft is restricted to this zone and the fungi do not penetrate further down the infected hair in the bulb of the follicle.

“When we see an infection, we’re not able to treat it with topical agents. It’s very contagious in the classroom setting and households, particularly when kids are sharing products, like combs or brushes,” Silverberg notes. Parents and children should be counseled to avoid sharing hats, combs, brushes, and pillow cases.

Silverberg says physicians will typically encounter pediatric tinea capitis between ages 3 to 11 years. “When you see it clinically, it appears initially almost like a little dandruff—fine flaking and redness. But as it progresses, we’ll see hair loss where the hairs break. Those are called black dot hairs. Or we’ll see something called kerion, which is an inflammatory form of tinea capitis,” she says.

**Females are slightly more likely than males to get AD.**

—American Academy of Dermatology.

Physicians should intervene right away to avoid scarring and hair loss. Often, the first step is to use antifungal shampoos.

“Then, we put them on an oral antifungal, to address the fungus from inside out because topical medications only reach the hair follicle,” Silverberg says. “It’s very important that when we see hair loss accompanied by flaking and glands in the neck, it is more than 80% likely that the child has tinea capitis. We start treatment even before we get the diagnosis. If we don’t, the child can get an inflammatory form of tinea capitis,” she says.

Ms Hilton is a medical writer who has covered health and medicine for 25 years. She resides in Boca Raton, Florida. She has nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.

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I certify that the statements made by me above are correct and complete.
The patient’s medical and developmental history are unremarkable. A review of systems is negative for headaches, seizures, rash, nausea, vomiting, and abnormal bowel movements. He did not have any new or unusual foods for dinner aside from individually wrapped Halloween candy he had collected while trick-or-treating a week earlier. There are no other unusual ingestions reported, and his parents deny access to any chemicals or medications in the home.

On physical exam, the patient is a well-developed, well-nourished but listless boy with intermittent irritability that is consolable by his mother. The patient appears to be agitated by loud noises, lights, and touch. His temperature is 98.0°F; heart rate is 130 beats per minute; blood pressure is 106/70 mm Hg; and respiratory rate is 30 breaths per minute. Pupil diameter is 3 mm, equal and reactive to light. Head is normocephalic and atraumatic, and his neck is supple without lymphadenopathy. Cardiac and pulmonary auscultation is unremarkable.

Abdominal exam reveals normoactive bowel sounds and a soft, nondistended abdomen with diffuse tenderness and voluntary guarding but no rebound tenderness. Neurologic exam is limited by participation, but there are no obvious focal neurologic deficits and the patient is able to track across midline without nystagmus. Fundoscopic exam is normal with clearly defined optic discs without papilledema. He has normal muscle bulk, tone, and strength throughout but is unwilling to stand or walk without support. Sensation is intact. The patient is unwilling to cooperate with performing a cerebellar examination.

Complete blood count (CBC), basic metabolic panel, urinalysis, hepatic function panel, and serum acetaminophen and salicylate levels are all normal. A chest x-ray and kidneys/ureters/bladder x-ray series are also normal.

**Differential diagnosis**

Altered mental status (AMS) in children is characterized by the inability to respond to stimulation at a level appropriate to the child’s developmental stage. Children who present with AMS should be assessed for impairment of airway, breathing, and circulation, and stabilized before etiology is formally evaluated. Given the extremely broad differential diagnosis, the workup of acute-onset AMS in children is particularly challenging and the vast array of etiologies can be remembered utilizing the Table.2

Detailed and thorough history taking can significantly narrow the differential diagnosis and should encompass medical history; developmental history; medications for the child or others in the home; family history of similar events; recent trauma or illnesses; and prodromal events prior to change in mental status. Review of systems should be expansive and include screening for headaches, seizures, fatigue, rash, nausea, vomiting, abdominal pain, and abnormal bowel movements. A thorough physical exam will help focus the diagnostic evaluation. Vital signs can suggest underlying pathologies such as infection, toxic ingestion, or increased intracranial pressure. A detailed neurologic exam is essential.

Focusing on broad categories such as infection, further diagnostic evaluation should include a CBC with differential. Altered mental status with fever suggests central nervous system (CNS) infection such as meningitis or encephalitis, or systemic infection such as sepsis caused by bacteremia or toxin production. Blood and urine cultures should be collected, and lumbar puncture should be performed, particularly in patients demonstrating meningismus or toxicity. The absence of fever and normal CBC in our patient makes an infectious etiology less likely.

Altered mental status caused by intoxication can be accompanied by toxidromes such as bradycardia/bradypnea (eg, from opioids) or tachycardia/tachypnea (eg, from sympathomimetics), and physical
exam findings such as abnormal pupil size, nystagmus, and skin changes (flushed, pale, cyanotic). If toxic ingestion is suspected, one should obtain urine toxicology screenings and serum levels of suspected intoxicants.

It is important to evaluate for painful etiologies that can cause abnormal behavior, particularly in young children who do not localize their pain well. This is particularly true for intussusception. Intussusception is characterized by episodic, colicky abdominal pain with associated irritability that can often cycle through periods of calm reflecting the reduction of the intussusception. This can progress to lethargy and bloody stools when it is no longer irreducible. If clinical suspicion is high for intussusception, consider targeted imaging and surgical consultation.

Metabolic abnormalities such as electrolyte abnormalities or hepatic and renal disorders should also be considered in the evaluation of AMS. A rapid glucose should be performed on any child with AMS. Hypoglycemia can present with palpitations, diaphoresis, irritability, confusion, seizures, or coma. Large abnormalities in serum sodium may present with headache, weakness, irritability, disorientation, and seizures. Obtain serum electrolyte levels and renal and hepatic function tests to evaluate for signs of renal or hepatic failure, and serum ammonia if metabolic disorder is suspected.

Other etiologies to consider include nonaccidental trauma, brain tumor, cerebrovascular disorders, and generalized seizures that can cause prolonged AMS or unresponsiveness in children. Trauma may lead to insufficient cerebral perfusion, diffuse cerebral swelling, increased intracranial pressure, or direct compression of the reticular activating system causing AMS, for which a head computed tomography (CT) scan is warranted. Evaluate for signs of abuse on history and physical exam. Cerebrovascular abnormalities causing AMS are uncommon in otherwise healthy young children, but should be considered in patients with underlying comorbidities such as sickle cell anemia or prothrombotic disorders.

**Diagnosis**

The patient is evaluated for intussusception given his episodic irritability and listlessness and tenderness on abdominal exam. An abdominal ultrasound is ordered, which shows no evidence suggesting intussusception. A head CT scan also is ordered to evaluate for intracranial pathology.

On further questioning of unusual ingestions, the parents reveal that after their son ate the Halloween candy he had collected from trick-or-treating, his eyes “flickered left and right.” When directed to retrieve the candy, the patient’s uncle later arrives to the ED with the candy wrapper, revealing a chocolate bar that contains 90 mg THC (delta-9-tetrahydrocannabinol)—the active ingredient of marijuana (cannabis).
A urine toxicology screen is performed and the diagnosis of cannabis intoxication is confirmed. Evaluation for intussusception is subsequently aborted, and the head CT scan is cancelled.

**Cannabis ingestion**

A study by Wang et al (2013) found that unintentional cannabis exposure in young children is increasing in the United States and that most pediatric cannabis exposures are from ingestion of medical marijuana in food products.³ This may be because of the increased presence of cannabis in the household as well as improved palatability of THC-containing foods, including edible candy and baked goods that are appealing to young children. Unintentional poisonings are common in young children, therefore education of caregivers on primary prevention of potential toxic exposures in the household and reference to poison control centers locally or nationally (800-222-1222) are important.

Many patients who ingest cannabis may experience CNS alterations such as irritability, depressed mental status, or ataxia.⁴⁻⁵ Other symptoms include jerking, conjunctival hyperemia, emesis, tachycardia, and tremor.⁶ If severe, respiratory insufficiency and coma may result.⁷ Although most cases of cannabis ingestion do not have serious sequelae, young patients may be exposed to a myriad of unnecessary tests, procedures, and imaging during evaluation if the diagnosis is unclear or exposure to cannabis is not known.⁸ Knowing about cannabis exposure up front is associated with fewer ancillary tests; however, even when cannabis exposure is accidental, families may be reluctant to report it to healthcare facilities because they fear legal ramifications.⁹

Treatment of cannabis intoxication is primarily supportive, including monitoring and managing respiratory and hydration status until recovery. There is no specific antidote for cannabis intoxication currently available. Unnecessary stimulation of an affected patient should be avoided. In some cases, benzodiazepines may be given as an anxiolytic.

**Patient outcome**

The patient is further observed in the ED after the diagnosis of cannabis intoxication. Given the potential for child neglect, child protective services is consulted. The patient is admitted overnight for monitoring on intravenous fluids and he recovers completely by the next morning.

**Conclusion**

The differential diagnosis of AMS in children should be approached with a detailed and comprehensive history and physical exam once the patient is stabilized. Narrowing the differential diagnosis with a thorough history and physical exam will allow the avoidance of unnecessary and possibly invasive tests and help guide diagnostic evaluation. Healthcare providers should specifically inquire about potential toxic exposures and ingestions, and should be aware of the presenting symptoms.

Given increased pediatric exposure to cannabis in US households, providers should consider cannabis intoxication in a child with AMS and become familiar with its presentation and management, which is primarily supportive. A diagnosis of cannabis ingestion, even if unintentional, should be reported to child protective services.

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For references, go to ContemporaryPediatrics.com/puzzler-1016
Improve your practice: Medical practice websites

Creating and implementing a website for your practice can be a valuable service for your patients and staff.

Most medical practices that are thriving nowadays have learned the nuances of attracting patients and keeping those in their practices content with the services they provide.

Practice websites are a valuable tool to attract new parents to your practice, and they can offer a wide variety of indispensable information that can reduce your staff’s workload. Let’s explore ways to improve your practice website and integrate important features that will elevate your practice to Peds v2.0 status.

Basics
Everyone knows that building and maintaining a practice website is relatively easy to do. One can employ a local website firm, negotiate a price, and decide on the features to include. Alternatively, creative individuals, with little effort, can build their own robust site, including the many bells and whistles I’ll detail shortly. Gone are the days when one had to learn HTML coding or master a complicated program such as Adobe’s Dreamweaver to become proficient at website design.

Today, web creation involves using software called web content management systems (WCMS), including WordPress or Joomla, to accomplish wonders. It is not hard to do and can be a fun hobby for one of the practice partners. Best of all, if the pediatrician webmaster ever gets bored, the chore can be handed off to another physician in the practice or to a website firm for maintenance and upgrades.

No matter which path you choose, the basics of getting a website up and running involve simply obtaining a website address as well as a hosting service, in addition to a website developer. In general, pricing depends on the amount of traffic anticipated, the number of features supported, and the frequency of changes. There are a number of services that specialize in medical website creation such as Officite, MedToWeb, and iHealthSpot. These no doubt have more experience in catering to the unique needs of a medical office, such as Health Insurance Portability and Accountability Act (HIPAA) compliance, but they may be more expensive than neighborhood website developers.

Level 1 websites
Starter websites identify the location of your practice and provide necessary information such as office hours and phone and fax numbers, and introduce prospective patients to the staff. They list insurance companies your practice accepts, as well as office policies. To attract patients to the practice, your site must include photos of lots of “shiny happy people” (apologies to rock band REM)—happy parents, happy children, happy staff. This means motivating your grumpy
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Eeyore-like partner (most practices have at least one) to break with tradition and smile!

Be sure to list all the practice partners as well as associate providers, along with their education and areas of interests and hobbies. Kidding aside, exclude potentially controversial hobbies such as hunting and taxonomy (fishing is OK, as an acceptable euphemism). Sporting hobbies including skiing, tennis, and golf are usually popular and patient-attracting hobbies. The purpose of all this is to humanize the staff and make anyone who views your site want to join your practice. If you happen to employ zombie-like, “dehumanized” medical providers—a consequence of Medical Documentation Stress Disorder (see Peds v2.0, Contemporary Pediatrics, July 2016)—don’t include them in the listing of staff, unless, of course, you can get them to smile!

For most practices, basic websites are often sufficient, but there is much more that you can do with your website rather than utilizing it as an elaborate Yellow Pages advertisement.

**Level 2 websites**

In my opinion, websites should be functional and provide not only demographic information but useful medical and administrative information as well. By incorporating medical advice into the website, you can avoid unnecessary phone calls to the office for common questions. It is also prudent to provide a repository of frequently requested practice forms.

To avoid providing free services to nonpatients, the “good stuff” should require registration and a login to access this information. This may involve using a patient portal, but there are plug-ins that you can use in conjunction with WCMS to limit access to only registered users, requiring a patient to log in to the practice content pages.

In your library of documents, provide a fillable PDF registration form, your standard HIPAA form, and one that indicates that patients have reviewed your office policies. Having this latter form ensures that patients have read and acknowledged your policies regarding no-show visits, the need for payment of copays and deductibles at the time of service, and your policies regarding requests for forms and renewal of prescriptions.

In addition to documents, you can also integrate a frequently asked questions (FAQ) section that lists answers to popular questions about dosages of antipyretics, management of gastroenteritis, treating diaper rash, or when to call the doctor. Helpful links to dependable web-based information is useful as well. These would include the Centers for Disease Control and Prevention website (www.cdc.gov) and the American Academy of Pediatrics (AAP) HealthyChildren.org. You can save yourself considerable effort and link directly to HealthyChildren.org web pages regarding advice for fever management, including tables for acetaminophen and ibuprofen dosing; the importance of immunizations and schedules; and recommendations for AAP-sponsored mobile applications (see “Helpful resources for pediatricians,” page 53). The information is great and it’s free!

**Level 3 websites: Patient portals**

Your electronic health record (EHR) software may include optional access to an integrated online patient portal. Features will vary according to your vendor and may necessitate added costs and a supplementary contract. If you choose to provide a patient portal—and you should—your website should provide a link to the front page of the patient portal. These require patient registration and an activation code to access. The capabilities of the portal are determined by your vendor, but you can decide which ones to include or exclude.

If you are lucky, the portal will include features such as secure messaging, bill payment, and request for prescription refills. Secure messaging allows patients and physicians to communicate utilizing HIPAA-compliant software that encrypts data. Communicating with your practice this way enables patients to reduce their time on hold with your office, in situations when they

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**Websites should be functional and provide not only demographic information but useful medical and administrative information as well.**
do not require an “immediate” response. Likewise, from the practice’s perspective, secure messaging also reduces the amount of time spent answering phone calls and limits wait times for those patients with dilemmas that need urgent attention. Messages can be screened by your staff who may be able to provide answers themselves, book appointments, call patients back to resolve issues, and so on, limiting the number of messages that providers need to address.

With the best portals, patients also can access their lab and x-ray results, and obtain copies of health forms and back-to-work forms with minimal hassle.

If you are not pleased with the portal provided by your EHR vendor, you can use independent patient portal services such as Bridge Patient Portal (www.bridgepatientportal.com/) or Solutionreach (www.solutionreach.com) that can be customized to your liking. Costs will vary with the services provided. Of note is that one of the features advertised by Bridge Patient Portal is videoconferencing for those wishing to begin integrating telehealth into their practices.

Portals are a great business decision because they provide an easy means for patients to pay bills and to request appointments. Many portals enable you to send patients reminders of missed appointments, announcements of flu vaccine availability, or reminders regarding need for follow-up visits in the office. Thus, patient portals have the potential for cementing the relationship between physician and patient, and expanding access to the patient medical home.

Other things to consider
To keep your website interesting, consider adding a quarterly newsletter (or link to the HealthyChildren.org seasonal newsletter), and provide news regarding staff members or even local pediatrics-related news and information regarding services for children in your community. You may want to be creative and record videos regarding certain medical conditions, involving your providers on a rotating basis. To engage patients, you may want to consider linking to a Facebook page and even enable text messaging to remind patients of upcoming appointments or to acknowledge receipt of payment. In this day and age, e-mail and text messaging are much more efficient than reminder calls, and are appreciated by patients.

To keep your practice vibrant and unique, consider using your website and/or portal to make your practice family friendly. Sponsor a quarterly party or cookout that you announce via the website. Have contests with prizes, with enrollment via the website. Include congratulations for patients’ academic or sports achievements (after obtaining parental permission, of course). Most importantly, ask parents to give you their opinions regarding your site and take these conversations to heart, so you can add new features on a regular basis.

In summary
The sky’s the limit when it comes to your practice website. It can be functional and basic, or a resource for staff and patients. No matter what you decide, it’s now time to assess your situation and make things happen! ■
Given the possibility of divided government, it may be enlightening to look at recent bipartisan healthcare legislation. Without much fanfare last year, for example, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) by a vote of 92 to 8 in the Senate and 392 to 37 in the House of Representatives.

Besides reauthorizing CHIP, the legislation moved Medicare in the direction of new payment models in which physicians are reimbursed less through fees for their services and more for achieving measurements of “value” such as reducing hospitalizations or infections.

Pediatricians don’t get paid through Medicare, but the agency wields huge influence that is likely to shape the way private insurers set up payment models, Antos says, so more and more pediatricians may be asked to accept value-based payments. That won’t happen overnight because what constitutes value in the context of pediatric care is likely to be the subject of protracted debate, he points out.

Meanwhile, Antos envisions pressure on pediatricians to group together in larger practices that might be asked to accept lump-sum payments per patient or per “episode of care.”

“The idea of encouraging physicians to get together in some business arrangement so that there could be some bundled payment in something other than fee-for-service is where we’re headed,” he says.

Might new cost-cutting initiatives work in the favor of primary care physicians such as pediatricians, who labor so hard to prevent their patients from getting sick?

“Primary care, for all of the lip service that Congress gives to it, has always been reimbursed at lower rates by Medicare and Medicaid and private insurance,” says Antos. “There is no light at the end of the tunnel.”

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Juvenile dermatomyositis (JDM) is a rare, systemic, inflammatory myopathy that affects children aged 18 years and younger. Skin manifestations typically precede muscle weakness, and include Gottron papules (erythematous-violaceous scaly papules over the metacarpophalangeal or interphalangeal joints, elbows, and knees); shawl sign (poikiloderma over the back of the neck, upper back, and scalp); and a heliotrope rash (violaceous edematous periorbital patches). Children also present with symmetric proximal muscle weakness that may progress over a few days to weeks, often in conjunction with myalgia. Other organs such as the gastrointestinal tract, heart, and lungs also may be affected.

Epidemiology
Dermatomyositis can occur at any age, but usually displays a bimodal distribution, peaking in 5- to 14-year-olds and 45- to 65-year-olds. Females are twice as likely as males to be affected. The median age of onset for JDM is 7.3 years in boys and 6.8 years in girls.

Pathophysiology
Juvenile dermatomyositis occurs when the humoral immune system attacks muscle capillaries and arterioles. Antibodies activate C3, leading to the deposition of membrane attack complexes (C5b-9) in endomysial vasculature. The disease eventually destroys capillaries and causes muscle microinfarction.

The currently held belief is that JDM occurs in a genetically susceptible child that experiences an environmental trigger such as a viral or bacterial infection, possibly in conjunction with intense exposure to ultraviolet light.

Differential diagnosis
The differential diagnosis for JDM includes other inflammatory myopathies such as polymyositis, noninflammatory myopathies, and other disorders of denervation or neuropathy. The skin findings may mimic atopic dermatitis, psoriasis, drug reactions, and viral exanthema.

Clinical diagnosis of JDM can be made by the presence of proximal muscle weakness and the characteristic skin rash. Elevated muscle enzymes such as creatine kinase and aldolase are useful in confirming a diagnosis. Myositis can be definitively diagnosed by biopsy, magnetic resonance imaging, or electromyography. However, biopsy is not always performed in the presence of classic skin and laboratory findings.

Histology shows perimysial and perivascular infiltrates of macrophages, B lymphocytes, and plasmacytoid dendritic cells, as well as myofiber necrosis and regeneration. Histologic findings more specific to JDM include endomysial microangiopathy with deposits of membrane attack complexes in capillaries. Certain antibodies are associated with different prognoses. The most common antibodies seen in JDM are anti-NXP-2 (associated with calcinosis), anti-Mi2, anti-TIF1γ, and anti-MDA-5.

Treatment/Outcome
According to the Childhood Arthritis and Rheumatology Research Alliance, the initial treatment for JDM should include a combination of high-dose oral prednisone (2 mg/kg per day) and subcutaneous methotrexate (15 mg/m²). Dietary modifications can be made to minimize prednisone toxicity. Folic acid supplementation is recommended while the patient is on methotrexate. With the use of corticosteroids, mortality is less than 2%. However, joint and muscle function can be permanently affected, and dystrophic calcification even after resolution of skin and muscle disease can be a cause of serious morbidity.

Within a few days of starting oral prednisone and applying topical steroids to her extremities, the patient noted significant resolution of her cutaneous manifestations and improvement of muscle weakness. She has been more active, and is now able to ride her bicycle.
Girl with rash and muscle weakness

EMILY BOOZALIS, BA, MS2

THE CASE

The mother of a healthy 10-year-old girl brings her daughter to the office for evaluation of new onset “eczema.” The rash is asymptomatic and began on her upper eyelids, later spreading to her chest and extremities over several weeks. The child complains of difficulty riding her bicycle.

FOR MORE ON THIS CASE, TURN TO PAGE 55.
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