Medicalizing 'the terrible 2s'

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40
20
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% Improvement

12 hours

24 hours

P<0.0001

P<0.0001

35%‡

47%‡

1Efficacy and safety assessments were performed by a trained evaluator at baseline, and at 12 and 24 hours post-baseline (N=57). Subjects (2-36 months of age) must have received an "Overall Severity Score" of >1.5 as determined by evaluator at enrollment. Diaper rash severity was assessed using a 0- to 3-point scale (0=mild; 3=severe).

†Trial assessing the efficacy of DESITIN® Maximum Strength Original Paste for 3±1 hours in children (N=31) 3-36 months of age, with mild to moderate diaper rash, wearing diapers for 24 hours a day.¹

²P=0.0001

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#1 with Pediatricians and Moms.

The diaper rash experts.

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Uneventen Consequences

ContemporaryPediatrics.com/FDAwarnings

When the FDA widely publicized warnings beginning in 2003 about possible suicide risks associated with antidepressant use, the expectation was that physicians and parents would more closely monitor young patients taking the drugs.

Instead, a recent study finds, trends in both usage and resultant poisonings diverged abruptly.

While teen usage of the popular drugs fell 31%, teen poisonings from their use—a validated proxy for suicide attempts—spiked by nearly 22%.

First author Stephen B. Soumerai, ScD, professor of population medicine at Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, discusses the study’s controversial findings in our latest Google Hangout.


1. “Good parents” denial puts kids at risk for heat stroke
2. AAP updates drug testing guidelines
3. Treating infection in burns
4. Unremitting rash, neck masses complicate toddler’s diagnosis
5. Will ICD-10 mean financial hit for pediatricians?

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You weighed in online on our article ‘Altered gut bacteria raising the rate of ASD?’ (eConsult, May 29, 2014)

Most pediatricians I know, [myself included, do not believe in this theory. Rather, a child with ASD does not communicate well, so they don’t eat a well-balanced diet either, thus changing the makeup of their gut bacteria. I wish the answer was as simple as changing the diet of a child with ASD or giving them a pill of good bacteria.

That’s one opinion. What’s yours?

Go to POST A COMMENT in the gray box at the end of each article and tell us!

Contemporary Pediatrics is part of the ModernMedicine Network, a Web-based portal for health professionals offering best-in-class content and tools in a rewarding and easy-to-use environment for knowledge sharing among members of our community.
Chronically ill teens are more than a set of sexual behaviors

The issue of teaching sexual self-management to young adults with chronic conditions is important. As I reviewed the article (“Transition planning: Teaching sexual self-management.” Contemp Pediatr. 2014;31[4]:16-22), I was struck by the surprising absence of the obvious: the desire for relationship and belonging. Ironically, this need is often stronger in chronically ill persons and they may suffer even greater disappointment, and possible health consequences, if these basic human objectives fail.

Whether in the article on sexual teaching at the office visit, the high-risk behaviors of sexual minority teens, or this article from Gleit, Freed, and Fredericks, the focus seems off. When we interact with adolescents, we are seeing whole persons, not collections of risks and adverse behaviors. Many of them are not simply seeking just physical connections, or weekend sensations, or recreational sex. They are aware they want communication, respect, and trusting relationships. We do them a disservice by reducing their urges to physiologic and hormonal functions addressed by contraceptives and trendy websites.

The siloed approach to development in adolescents has served us poorly. Although we follow risks through our dependence on the CDC’s Youth Risk Behavior Survey, teens are not a simple collection of drug, obesity, violence, and sex risks. Even with our awareness of the role of protective factors in promoting successful teen and young adult years, we have not embraced those factors in our pediatric and adolescent practices. We have also failed to incorporate sound health behavior change practices that address support systems, preparation for meaningful communication and relationships, training for decision making and refusal skills, and planning for adult relationships, marriage, and parenting.

As noted in the article, “serious medical complications can arise from unsafe sexual behaviors.” We must remember that for all teens, and especially those with chronic conditions, “unsafe” can include a broken heart, not simply an STD or poorly timed pregnancy.

ALMA L. GOLDEN, MD
Associate professor of pediatrics
Texas A&M Health Science Center
Temple, Texas

Voice recognition software trumps science fiction

I asked Siri to open the pod bay doors and he said: “That’s it, I’m reporting you to the Intelligent Agent Union for harassment!”

This article (“Speed EHR documentation with voice recognition software.” Contemp Pediatr. 2014;31[6]:28-32) gave me hope for the future of electronic health records! Now if we could only get systems that talked to each other.

TERRIE SNOW, RN, MSN, CPNP
Redding, California

TREATMENT FOR ACUTE APPENDICITIS?

Regarding the online article “No surgery for uncomplicated acute appendicitis?” Contemporary Pediatrics eConsult, April 24, 2014:

Does treating the infection and leaving the appendix there leave the child at risk for recurrent appendicitis, presumably also at the low risk for pseudomyxoma peritonei?

CATHERINE G. QUINN, PNP (RETIRED)
Falls Church, Virginia
It is widely accepted in the medical community that the presentation of pharyngitis caused by *Streptococcus pyogenes* in children aged younger than 3 years is rare and does not require treatment because there is no risk of rheumatic heart disease. However, in my practice, strep pharyngitis in this age group is not so rare, and I have observed many cases of untreated strep develop into otitis media, perforations of the tympanic membrane, mastoiditis, wheezing, pneumonia, or even personality changes.

Therefore, I treat children under age 3 who have a positive strep culture with antibiotics. A large percentage of children where I work tend to live in close proximity. It is therefore reasonable to believe that when older siblings and neighbors have strep, their younger siblings and neighbors, even if they are babies, can contract strep as well.

Few, if any, studies have followed untreated strep in children under 3 years because many in the medical community believe that strep infection does not exist or is harmful in this age group. I know it does occur, probably more frequently than current statistics state, but many patients are treated unknowingly because they develop simultaneous ear infections or other negative sequelae. With the upsurge in antibiotic resistance, healthcare providers, including myself, have been trying to limit antibiotic use. However, I do not know whether it is appropriate to withhold antibiotics when treating strep in children under 3. Is it safe and ethical not to treat until negative sequelae appear? What happens to mild cases if they are not treated? Are the patients who are not treated earlier in the course of their illness at greater risk of having developmental delays or other more serious consequences?

Conversely, is it wrong to treat? Would strep in this age group get better on its own with no sequelae even after it progresses only slightly? If detected early, is watchful waiting appropriate and is the antibiotic use more harmful than helpful?

For now, until there are more concrete answers, I am inclined to treat strep at any age. My hope is that more physicians will recognize that strep does affect this age group, but my ultimate goal is to encourage those interested and capable of clinical research to conduct a study following these children with strep and provide guidance on management.

**RACHEL SISSE, MD**
Brooklyn, New York

Dr Sisser is a pediatrician at ODA Primary Healthcare Network, Brooklyn, New York.

I encourage feedback regarding this issue. Send queries or comments to rsisser@yahoo.com

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** Markers of stem cell differentiation into neural progenitor cells as measured in cell culture.
*** Provided in OptiGRO formulas as RRR-alpha-tocopheryl acetate.

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Drugs’ impact on kids’ bone health mostly unknown

FDA workshop begins investigation into long-term effects.

The US Food and Drug Administration (FDA) looked at what’s lacking in research on drugs in children and discovered that much more information is needed on how various medications affect bone health.

In a June workshop convened to talk to experts on the issue, Lynne Yao, MD, associate director, Office of New Drugs, Pediatric and Maternal Health Staff, said, “Many of the products that we use in children, we don’t necessarily have the best information that we can use to advise patients and their families about long-term safety issues.”

She noted that since the passage of the Best Pharmaceuticals for Children Act (2002) and the Pediatric Research Equity Act (2003), which encourage or require drug research in children, pediatric studies have led to over 500 label changes on drugs. “The numbers are growing exponentially,” she said.

Kids’ bones are different

An FDA working group had been looking at drugs’ effects on the hypothalamic-pituitary-adrenal axis, but decided that effects on bone maturation and health needed more research, Yao said.

At the session, Stephen Voss, MD, clinical reviewer in the Division of Bone, Reproductive, and Urologic Products, said that biomarkers in adults reflect only one process: bone remodeling or “turnover.” In children, levels of the markers are generally higher than in adults because they can also reflect the growth in length and the growth in width, called “modeling.”

“The bone markers that we have available to use represent the sum of all of these processes,” making interpreting markers in children much more complex, he said.

However, an advantage of bone biomarkers, Voss said, is that they can provide information about bone metabolism that cannot be obtained in other noninvasive ways and the biomarkers respond rapidly to changes in bone metabolism caused by disease or therapy.

Markers of bone formation are alkaline phosphatase, osteocalcin, and procollagen type I propeptides, he said. Those for bone reabsorption include products of collagen type I breakdown and osteoclast enzymes.

Drugs and BMD

In another presentation, Miya Paterniti, MD, clinical reviewer in the Division of Pulmonary, Allergy, and Rheumatology Products, noted that warnings on the labels say that “Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids.”

However, she said, it’s unknown what is the clinical significance of small changes in BMD related to long-term outcomes such as fracture.

“Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (eg, anticonvulsants and corticosteroids) should be monitored and treated with established standards of care,” she said.

More issues to address

Presentations at the session also looked at bone toxicity with tenofovir, the FDA’s experience with esomeprazole strontium, questions about proton pump inhibitors, and other issues.

At the end of the meeting, Jean Temeck, MD, supervisor in the Office of Pediatric Therapeutics, noted that the session had heard about, among other things, the potential for using the dual-energy x-ray absorptiometry (DEXA) scan in studies and the importance of bone geometry, of longitudinal measurement of DEXA scan rather than just taking a single measurement, and of “developing validation for bone biomarkers specifically in children . . . and how it is dependent on age and sex and
There were also calls for integrating all current information that might shine light on child bone health, including data from humans and animals, and information in large claims databases.

Yao indicated there might be funding from the FDA and elsewhere for research in this area: “If we need to advance the development of bone biomarkers as a way to assess long-term safety in children, that is something we can take and say, ‘Listen, we need to do this.’”

The workshop is the first of a series with experts on research on pediatric drug safety. The meetings are designed, Yao said, to get expert input without the conflict-of-interest vetting of participants required for FDA advisory committees.

The meeting agenda and presentations are available online.

Severe irritability: Bipolar disorder or something else?

Much has changed in research about children with irritability in recent years, notes Ellen Leibenluft, MD, chief of the Section on Bipolar Spectrum Disorders at the National Institute of Mental Health.

In the mid-1990s, the idea gained currency that children with bipolar disorder do not always have manic episodes and that children with extreme irritability and attention-deficit/hyperactivity disorder (ADHD) might have bipolar disorder. Over about 8 years, the percentage of mental health visits with children given the bipolar disorder diagnosis increased from almost none to about 0.4%.

However, to study the issue, researchers defined a category of children with “severe mood dysregulation (SMD),” with criteria that included having very severe temper outbursts and increased reactivity to negative emotional stimuli.

Data gathered in more recent years show irritable children with ADHD almost never grow up to have real manic episodes, Leibenluft says. “Therefore it doesn’t make sense to assign them the diagnosis of bipolar disorder.”

That matters a lot, she indicated in a recent talk at the National Institutes of Health (NIH), because if SMD were a form of bipolar disorder it should be treated with antipsychotic medication and lithium, the first-line treatment for pediatric bipolar disorder. “Stimulants and serotonergic reuptake inhibitors (SRIs) . . . would be relatively contraindicated because you’d be concerned about flipping a child into mania,” she says.

However, she adds, “if SMD is ADHD and anxiety or depression, then you would exactly treat with stimulants for the ADHD and SRIs for the anxiety or depression.”

There is a risk these children may have unipolar depression, Leibenluft says, but if they do it’s more likely that there has been a change in the last few months such as the child lacking interest in usual activities, being sad a lot, displaying changes in appetite, or being even less able to concentrate or sleep well.

In contrast, with children with just irritable ADHD, she says, “It’s more likely it’s what the kid has always been like.”

Leibenluft says that in extreme situations, the pediatrician may want to consult with a psychiatrist.

One important outcome of the recent studies is the indication that irritability is “a common yet relatively understudied clinical presentation in children.” There’s a need, she says, to know much more about its treatment, measurement, neural circuitry, and genetic influences.

Leibenluft adds, “An important thing to remember is that attention control is important not just for doing the task, but for controlling your emotions. One of the main ways that we manage to control our emotions adaptively is through directing our attention toward or away from frustrating things.”


The NIH Clinical Center is doing studies of both bipolar and severely irritable children and may be able to do an assessment by phone, or possibly in person, with expenses paid. Contact the center via e-mail to irritablekids@mail.nih.gov or call 301.496.8381.

Leibenluft says that in extreme situations, the pediatrician may want to consult with a psychiatrist.
To enhance understanding of the association between infection with *Clostridium difficile* and disease caused by this bacterium, investigators conducted population-based *C. difficile* infection (CDI) surveillance in children aged 1 to 17 years residing in 10 US geographic areas during a 1-year period. The *C. difficile* infection cases were defined by a *C. difficile*-positive stool sample and, for each CDI case, investigators determined if the infection was related to healthcare-facility onset or was community associated (CA).

Of 944 identified CDI cases, 71% were CA. While CDI incidence was highest among 1-year-olds and children who were white, the proportion of cases associated with diarrhea (72%) or severe disease (8%) was similar across all age groups. Interviews with a convenience sample of parents of children with CDI showed that almost three-quarters of the infected children had recent exposure to antibiotics, most often for ear, sinus, or upper respiratory tract infection (Wendt JM, et al. *Pediatrics*. 2014;133[4]:651-658).

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**Parents often are distracted when driving their children**

Parents frequently engage in a variety of potentially distracting behaviors when driving their children, according to a survey of child passenger safety practices conducted among adult drivers (mostly mothers) of 1- to 12-year-olds. The computerized survey was among 570 parents who brought their children to 2 Michigan emergency departments for care. Investigators queried parents about how often they engaged in potential distractions in the past month while driving their child. These distractions were grouped into 4 categories: nondriving-related distractions (such as eating, drinking, smoking, grooming, changing a DVD/CD/tape); cellular phone-related; child-related (providing food or picking up a toy); and directions-related distractions (reading a map or directions or using a GPS). The vast majority (90%) of participants disclosed that in the last month they had engaged in at least 1 of the 10 potential distractions investigators examined.

In addition, participants reported succumbing to a median of 4 distractions during the preceding month. Overall, more than 75% of participants engaged in nondriving-related and cellular phone-related distractions; 71.2% disclosed child-related distractions; and 51.9% disclosed directions-related distractions. Parents not only were just as likely as the general population to use their cell phones while driving...
their children, but they gave food to
their child while driving even more
frequently than they used phones.
Parents of children aged 5 to 7 years
were more likely than parents of
1-year-olds or 8- to 12-year-olds to
engage in nondriving-, cellular-, and
child-related distractions.
Investigators also collected infor-
mation about other unsafe driving
behaviors and found that engaging
in child-related distractions was also
associated with speeding or driving
while drowsy (Macy ML, et al. Acad

**Having a TV in the bedroom leads to excess weight gain**

A study in more than 6500 youngsters aged 10 to 14 years from across the United States found that having a bedroom television confers an additional risk for obesity. The baseline telephone survey, which included parental reports, explored current weight status, TV/movie viewing and videogame playing, parental style, and sociodemographic factors, while follow-up surveys 2 and 4 years later assessed changes in age- and sex-adjusted body mass index (BMI).

At baseline, 59.1% of participants had bedroom TVs. Boys were 8% more likely to have a bedroom TV than girls, and 16% more blacks and Hispanics had them than whites and other races.

At the 2-year follow-up, those having a bedroom TV at baseline had a mean 1.16 larger BMI than those without a bedroom TV. At year 4, the comparable figure was even larger—1.31. Even after adjusting for time spent watching TV and movies, playing video games, and parenting style, having a bedroom TV was associated with an excess BMI of 0.57 at year 2 and 0.75 at year 4, and a BMI gain of 0.24 from years 2 to 4. Each hour per day of TV viewing at baseline also predicted a mean excess BMI gain of 0.14 (Gilbert-Diamond D, et al. JAMA Pediatrics. 2014;168[5]:427-434).

**also of note**

Smoke-free legislation improves perinatal and child health outcomes. A review and meta-analysis of 11 studies (5 North American and 6 European) of the effect of smoke-free legislation on perinatal and child health found that these laws are associated with a 10% reduction in both preterm births and hospital admissions for asthma. The analysis also revealed reductions in the risk of being born very small for gestational age (Been JV, et al. Lancet. 2014;383[9928]:1549-1560).
Child with fever after foreign travel

You are on call as a local pediatric infectious disease physician and receive a message from a colleague at a nearby primary care clinic. A 10-year-old boy is being referred to you for persistent fever and intermittent dry cough that began 4 weeks ago after a week spent visiting family in Karachi, Pakistan.

THE CASE

You are on call as a local pediatric infectious disease physician and receive a message from a colleague at a nearby primary care clinic. A 10-year-old boy is being referred to you for persistent fever and intermittent dry cough that began 4 weeks ago after a week spent visiting family in Karachi, Pakistan.

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Juvenile idiopathic arthritis (JIA) refers to a heterogeneous group of all forms of chronic arthritis in childhood with no apparent cause that begins prior to age 16 years and lasts for more than 6 weeks.\(^1,2\) It is the most common form of rheumatic disease in children, with an estimated incidence of 2 to 20 cases per 100,000 children and prevalence of 16 to 150 cases per 100,000 children worldwide.\(^1,3\) In the United States, it is estimated that more than 300,000 children currently have JIA.\(^4\)

 Diagnosis and treatment of JIA has improved over the years with an increased understanding of the different subtypes and clinical presentations of JIA and the availability and efficacy of newer antirheumatic medications to treat these subtypes.\(^5\) The efficacy of methotrexate as first-line treatment for most patients with JIA, combined with other conventional disease-modifying antirheumatic drugs (DMARDs) and/or the more recent biologic agents as needed, has resulted in an increasing number of patients who attain longer periods of disease control and clinical remission. Despite these improvements, the response to therapy is as heterogeneous as the subtypes themselves and many children who achieve clinical remission experience recurrence and disease flares even while on continuous medication.\(^6\)

What is emerging is recognition of the need to better understand the biology underlying the differences among the subtypes of JIA in terms of response to therapy and outcomes\(^4\) and the need to understand
this biology to develop better individualized treatment. New data from a study that used gene expression profiling in a cohort of JIA patients suggest that current definitions of clinical remission thought to indicate a return to normal patterns of gene expression in children who attain control of disease activity do not accurately describe the underlying biology of clinical remission. Rather, the underlying biology of clinical remission seems to involve the counterbalancing of proinflammatory responses by anti-inflammatory responses.6

“Although children in remission on medication appear to be completely normal, our medications do not result in normal immune homeostasis,” according to James Jarvis, MD, clinical professor and chief, Allergy/Immunology and Rheumatology, University of Buffalo, New York, a lead investigator of the study.

The implications, he emphasized, are that although children can now achieve long-term disease-free periods when they stay on their medications, their vulnerability to disease persists. “While our findings explain why children who appear to be doing well experience disease recurrences, they don’t explain how to prevent them,” he said.

For pediatricians who see children with JIA, these new data and understanding of remission emphasize the need to continually treat children with JIA with appropriate medications for years and not just months, even when they are doing well, according to Jarvis.

To help pediatricians manage JIA in their patients, this article provides a brief primer on the subtypes of JIA and their clinical presentation; an update on the most current treatments and outcomes; and a look at the emerging issue and evidence on the biology of remission and therapeutic response that is promising to help better tailor treatment and optimize outcomes for children with JIA.

**Subtypes of JIA and clinical presentation**

Distinct phenotypes of the disease have been recognized based on disease presentation, clinical course, and specific biomarkers.6 Currently the disease is classified into specific disease subtypes with distinct clinical presentations (Table 1).1,7

Despite these subtypes, the disease remains heterogeneous in terms of response to therapy and overall outcome.5,6

**Current treatment goals and options**

The goal of treatment of all subtypes of JIA is control of active inflammation and symptoms of the disease, as well as prevention of morbidities such as joint damage, functional limitations, and growth disturbances.5 Current definitions of disease control and remission include recognition that patients treated for JIA are on a spectrum of active disease and inactive disease while on medication as well as off medication.5 Criteria for inactive disease are shown in Table 2.

Patients with inactive disease are considered in 1 of 2 categories of clinical remission: clinical remission on medication (CRM), defined as 6 continuous months of inactive disease on medication; and clinical remission off medication (CR), defined as 12 continuous months...
With the current treatment approaches, many patients are now able to attain CRM but CR remains challenging. To achieve clinical remission, early and aggressive treatment that combines new and older therapies is recommended. For most children with JIA, methotrexate has become the first-line therapy. For specific types of JIA, the addition of other agents to methotrexate have shown improved efficacy (Table 3). Treating patients early and aggressively has been found to provide optimal efficacy. Data from the Trial of Early Aggressive Therapy in JIA (TREAT JIA) study, which compared methotrexate alone or with etanercept in children with newly diagnosed JIA, showed a higher likelihood and longer duration of clinical remission in patients treated with more aggressive therapy. In addition, some have suggested there may be

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**TABLE 1**

**SUBTYPES OF JUVENILE IDIOPATHIC ARTHRITIS AND CLINICAL PRESENTATIONS**

<table>
<thead>
<tr>
<th>Subtype</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oligoarthritis</strong></td>
<td>Most common form accounting for up to 60% of most JIA. Arthritis affecting 1-4 joints during first 6 mo of disease. Two subcategories: 1) persistent (never has more than 4 joints involved through the course of the disease); and 2) extended (more than 4 joints involved after the first 6 mo of the disease). Uveitis not uncommon.</td>
</tr>
<tr>
<td><strong>Polyarthritis</strong></td>
<td>Accounts for 25%-40% of JIA. Two subcategories: 1) rheumatoid factor negative (arthritis in 5 or more joints during the first 6 mo of disease and all tests for rheumatoid factor are negative); and 2) rheumatoid factor positive (arthritis in 5 or more joints during the first 6 mo of disease and at least 2 positive tests for rheumatoid factor at least 3 mo apart). Anterior uveitis uncommon.</td>
</tr>
<tr>
<td><strong>Systemic onset</strong></td>
<td>Accounts for 10% of JIA. Accounts for significant percentage of morbidity and mortality of JIA. Arthritis with or preceded by a fever lasting at least 2 wk (intermittent fever spiking for at least 3 days), and accompanied by at least 1 of the following: 1) generalized enlargement of the lymph nodes; 2) enlargement of the liver or spleen; 3) inflammation of the lining of the heart or lungs (pericarditis or pleuritis); or 4) rash characteristic of rheumatoid arthritis (ie, flat, pale, pink, and generally not itchy).</td>
</tr>
<tr>
<td><strong>Psoriatic arthritis</strong></td>
<td>Arthritis and psoriasis present at the same time along with at least 2 of the following: 1) inflammation and swelling of an entire finger or toe; 2) nail pitting or splitting; or 3) a first-degree relative with psoriasis.</td>
</tr>
<tr>
<td><strong>Enthesitis-related arthritis</strong></td>
<td>Arthritis and inflammation of an enthesitis site (ie, the enthesis is the point at which a ligament, tendon, or joint capsule attaches to the bone, with the most common locations around the knee and Achilles tendon); or Arthritis or enthesitis with at least 2 of the following: 1) inflammation of the sacroiliac joints or pain and stiffness in the lumbosacral area; 2) a positive blood test for the (HLA) B27 gene; 3) onset of arthritis after age 6 yr in males; or 4) a first-degree relative diagnosed with ankylosing spondylitis, enthesitis-related arthritis, or inflammation of the sacroiliac joint in association with inflammatory bowel disease or acute inflammation of the eye.</td>
</tr>
<tr>
<td><strong>Undifferentiated arthritis</strong></td>
<td>Arthritis manifestations do not fulfill the criteria for 1 of the other 6 categories or if they fulfill the criteria for more than 1 category.</td>
</tr>
</tbody>
</table>

Abbreviations: HLA, human leukocyte antigen; JIA, juvenile idiopathic arthritis.
From Khan P; National Institute of Arthritis and Musculoskeletal and Skin Diseases.
a window of opportunity to provide the best treatment for chronic arthritis, and that window may vary widely depending on the underlying disease and individual patient characteristics. Regardless of what that window may be, early and aggressive treatment to control potentially debilitating and painful symptoms of JIA that may also affect growth in children is needed.4

Understanding biological remission and clinical implications
Although many children with JIA now achieve CRM and attain sustained periods of disease control with these new medications, emerging data are showing that the biological state of CRM in these children does not point to a restoration of immunological normalcy as postulated. Instead, new data suggest that the biological state of CRM indicates attainment of a homeostatic state in which proinflammatory disease networks are counterbalanced by the emergence of anti-inflammatory networks.6,11

In a study published in 2013 to determine whether CRM achieved in a typical clinical setting resulted in a return to normal immune homeostasis, Jiang and colleagues used gene expression profiling to examine medication-specific effects on gene transcriptional profiles in 2 cohorts of children with polyarticular onset rheumatoid factor-negative JIA and a cohort of healthy controls.6 The study found numerous differences in gene expression in peripheral blood mononuclear cells and granulocytes between the JIA cohorts who achieved remission induced by either methotrexate alone or with etanercept and the cohort of healthy controls.

The study also found that treatment with combined methotrexate and etanercept produced distinct gene expression responses more biologically focused at the gene expression level than the responses detected among the patients treated by methotrexate alone that were more heterogeneous.6

The study concluded that CRM in children with polyarticular JIA is a distinct biological state that does not reflect a return to normalization of immune homeostasis.6 Rather, gene expression in peripheral blood mononuclear cells and granulocytes remains abnormal in children who achieve CRM compared with healthy children. “Computational analysis shows that remission is a lot closer to the active disease state than it is to normal,” said Jarvis.

In addition, the study showed that CRM achieved by methotrexate alone differs from CRM achieved by combined methotrexate and etanercept.6 In particular, the study found significant differences in the CRM state in JIA neutrophils depending on whether CRM was achieved with methotrexate alone or methotrexate plus etanercept.

These findings, conclude the investigators, “provide a framework from which to understand therapeutic response in JIA and, furthermore, may be used to develop strategies to increase the frequency with which

Pediatricians should be on the lookout for signs and symptoms of recurring active disease in children who have achieved clinical remission while continuously taking their medications.

### TABLE 2

<table>
<thead>
<tr>
<th>CRITERIA OF INACTIVE DISEASE^a</th>
</tr>
</thead>
<tbody>
<tr>
<td>• No active synovitis</td>
</tr>
<tr>
<td>• No fever, rash, serositis, splenomegaly, or generalized lymphadenopathy because of JIA</td>
</tr>
<tr>
<td>• No active uveitis</td>
</tr>
<tr>
<td>• Normal erythrocyte sedimentation rate and/or C-reactive protein</td>
</tr>
<tr>
<td>• Physician’s global assessment of disease activity indicates no active disease.</td>
</tr>
</tbody>
</table>

^aPatients must have all these criteria to satisfy the definition of inactive disease.

Abbreviations: JIA, juvenile idiopathic arthritis.
From Shenoi S, et al.5
remission is achieved in adult forms of rheumatoid arthritis."

More recent data on the possibility of using biomarkers developed from gene expression profiles to predict disease status in children treated for JIA was recently presented in an abstract at the European League Against Rheumatism annual congress in June 2014. Yao and colleagues showed that long-term disease status at 12 months could be accurately predicted in newly diagnosed patients only after treatment was initiated. The study included children with polyarticular JIA enrolled in the TREAT study who were treated either with methotrexate alone or methotrexate with etanercept.

**Main message to pediatricians**

Ongoing investigation is needed to identify biomarkers to better predict which children with JIA will respond to which particular therapies. Until then, Jarvis emphasizes the need for pediatricians to recognize the need for continuous medication treatment in children with JIA, even those who achieve clinical remission.

“Overall the lives of children with JIA are far more normal than they were 30 years ago when I started,” said Jarvis. However, he emphasized the need for pediatricians to be on the lookout for signs and symptoms of recurring active disease in children who have achieved clinical remission while continuously taking their medications. “Pediatricians need to be aware that, even in children who have been doing well, morning stiffness, gait disturbance, and joint swelling can recur and referral to a pediatric rheumatologist is highly desirable,” he said.

**Future directions**

Distinct phenotypes of JIA have been recognized based on disease presentation, clinical course, and specific biomarkers, which has led
to classifying the disease into 6 subtypes. However, the disease remains heterogeneous in terms of response to therapy and overall outcome regardless of the subtypes.5,6

Newer treatment options over the past decades have offered significant improvements in clinical outcomes, with increasing numbers of children with specific subtypes treated with specific agents attaining remission of disease and sustained disease control. However, disease recurrence and flares persist for many of these children who attain clinical remission. Emerging evidence that CRM is a distinct biological state that differs from normal, as well as the differences in gene expression in children who achieve CRM on different treatment regimens, is helping to identify future biomarkers that may help predict therapeutic response and make possible tailored treatment to optimize outcomes.

REFERENCES
Are we medicalizing “the terrible 2s”?  

CHERYL GUTTMAN KRADER

Ms Krader has 30 years of experience as a medical writer. She has worked as both a hospital pharmacist and a clinical researcher/writer for the pharmaceutical industry and is presently a freelance writer in Deerfield, Illinois. 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.

New data raise red flags on the use of stimulant medications for behavior management in toddlers and young children.

The Centers for Disease Control and Prevention (CDC) has been monitoring the prevalence of diagnosed and medicated attention-deficit/hyperactivity disorder (ADHD) among children aged 4 to 17 years since 1997, and the evolving data show rates for both measures have been rising steadily and more dramatically in recent years.

Although articles in the lay press raise concerns that these temporal trends are explained by indiscriminate diagnosis of ADHD and overuse of stimulant medications, child behavioral health experts believe they mostly reflect increased awareness, improved diagnosis, and the increased numbers of adolescents and adults since the realization that ADHD does not disappear at puberty but can continue throughout life.

However, just-reported findings from analyses focusing on the preschool population are generating real worry. Whereas behavior therapy should be first-line treatment for very young children, the data show that among 4- to 5-year-olds as well as in the younger toddler group (ages 2 and 3 years), high numbers of children were receiving medication for ADHD.

Susanna N. Visser, MS, DrPH, from the CDC collaborated on the preschool project that initially analyzed data from 2012 on ADHD diagnosis and management among 4- to 5-year-olds covered by the Georgia Medicaid program. The project was designed to assess whether treatment of ADHD among these preschoolers was in compliance with available best-practice guidance that clearly states behavior therapy should be the first line of intervention, explains Visser, acting associate director of science, Division of Human Development and Disability, National Center on Birth Defects and Developmental Disabilities, CDC, Atlanta, Georgia.

The study found an ADHD diagnosis prevalence rate of about 5.6% and...
determined that the majority of children, 74%, were receiving stimulant medication while only 44% were receiving some kind of psychological services that might be behavior therapy.¹

Having no expectation for uncovering these remarkable findings but because the data were available, the researchers further explored ADHD diagnosis and treatment among children aged 2 and 3 years. Much to their surprise, the results revealed an ADHD diagnosis prevalence rate of about 1.0% and showed 46% of those children were being given medications, while 45% were receiving psychological services.¹

**Deciphering the data**

Visser is careful to observe that these initial data provide only a snapshot on prevalence rates of diagnosed and medicated ADHD among the preschool groups, and that details on context are lacking. However, for now is that the studies documented practice patterns inconsistent with evidence-based guideline recommendations for ADHD management. “The observations indicate a need to ensure healthcare providers are aware of the best practices and for us to try to understand and address barriers to providing behavior therapy,” she says.

**It is extremely difficult to diagnose ADHD in very young children because many of the symptoms on which the diagnosis is based are developmentally appropriate.**

In order to explore if the data on 2- to 3-year-olds reflected a phenomenon limited to just the Medicaid population or to the entire state of Georgia, additional analyses were undertaken looking at a private insurance population using a national claims database.¹ The results showed a lower overall prevalence of ADHD diagnosis, 0.24%, but nearly the same high rate of ADHD medication use, about 40%.

Speaking to *Contemporary Pediatrics*, Visser notes the only conclusion that can be reached a number of follow-up analyses are now being conducted to develop insights. The expanded research will look at whether the findings are replicated using data from other patient samples and if there are variations by state. In addition, the investigators will continue looking at patterns by age and will be mining the available data to see whether the medication-treated children were more likely to have co-occurring conditions and if any particular group of physicians (pediatricians, psychiatrists, family practitioners) were.

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**Differential Dx: ADHD or sleep deficit?**

Pediatricians should first screen for sleep disorders before writing that prescription for ADHD medications.

PAT F BASS III, MD, MS, MPH

Do we all need to wake up to the relationship between attention-deficit/hyperactivity disorder (ADHD) and sleep deficits in our patients? Could it be that a moody, inattentive, and difficult-to-control child has a sleep disorder instead of ADHD?

More sleep is something that we all need but that our patients and their parents rarely get. According to the 2014 *Sleep in America* poll from the National Sleep Foundation children of all ages are, on average, getting at least an hour less sleep than is recommended, and most parents admit that their children need at least an hour more than they are currently getting.¹

There is significant clinical and research data demonstrating that inadequate sleep leads to continued on *PAGE 24*
predominant medication prescribers. The latter information would help to target educational outreach messages, she explains. Visser also observes that the finding that diagnosed ADHD was more prevalent in the Medicaid toddler population than among children covered by private insurance was not surprising, considering the latter group has fewer socioeconomic risk factors for ADHD. However, it is important to keep in mind that the circumstances under which the preschool-aged children in the Georgia Medicaid and private insurance populations received medication are not known.

“These may be families in great crisis because of the child’s behavior, and it is important not to conclude that the physicians involved were being flippant with stimulant medication use,” Visser says.

Use of methylphenidate is recommended for preschoolers only if behavior interventions do not provide significant improvement.2

“Certainly, quick intervention with medications may be appropriate in some situations. However, those cases should be rare, and the focus should always be to use behavioral therapy first.”

Speaking to the practices of his colleagues, Mark Wolraich, MD, who serves as chair of the American Academy of Pediatrics (AAP) ADHD subcommittee and who is CMRI/Shaun Walters Professor of Pediatrics, and chief, Section of Developmental and Behavioral Pediatrics, Oklahoma University Health Sciences Center, Oklahoma City, says he believes most pediatricians are very hesitant about using stimulant medications in very young children.

In terms of the Medicaid data, Wolraich points out that it captures children in the foster care system who may be brought to physicians because their disruptive behavior is increasing the challenges of home placement. Given their living situation and insurance coverage, lack of access to behavior therapy may be a particular issue for these children, while medication that can effectively control their behavior might provide them with an increased chance for a stable home environment.

However, even in other scenarios, providers may be frustrated in trying to assist families in receiving behavioral services because high quality therapy is not always accessible. “It could be that infrastructure deficits underlie reliance on medication treatment in these very young children,” Visser says.

Choosing appropriate treatment

Discussing the AAP’s clinical practice guideline for ADHD,2 Wolraich observes that the Academy recommends medication as first-line treatment for ADHD in children aged 6 years and older, but that clinicians first prescribe evidence-based parent- and/or teacher-administered behavior therapy for preschoolers aged 4 to 5 years. Use of methylphenidate is recommended for preschoolers only if the behavior interventions do not provide significant improvement and there is moderate-to-severe continuing disturbance in the child’s function. If evidence-based behavioral treatments are not available, the guideline recommends clinicians weigh the risk of starting medication at an early age against the harm of delaying diagnosis and treatment.

Explaining the recommendations for preschoolers, Wolraich notes, “In this age group, there is limited research evaluating medications and a lot more evidence demonstrating the efficacy of behavior therapy, especially intervention focusing on parent training. Therefore, it is important to be encouraging parents of these young children with ADHD to get those services. Medication rarely should be considered unless behavior therapy has been tried first.”

The Preschool ADHD Treatment Study (PATS) is the only rigorously designed, multicenter clinical trial investigating use of ADHD medication among preschoolers.3 It randomized 165 children aged 3 to 5.5 years to active treatment or placebo, but included very few 3-year-olds. In addition, participants had to have moderate-to-severe dysfunction, and PATS evaluated only
methylphenidate, which is not even approved by the US Food and Drug Administration for use in children aged younger than 6 years. (Only the combination drug amphetamine and dextroamphetamine [Adderall] is approved by the FDA for use in children aged younger than 6 years and it is not recommended for children aged younger than 3 years.)

The PATS trial found that children treated with methylphenidate derived some benefit, but also that the adverse effects of treatment, particularly emotional adverse events, were greater in the preschool population than had been reported in school-aged children.

“The AAP ADHD committee used PATS to inform its recommendations on preschoolers and concluded that there are elevated health risks to children who receive ADHD medications at an early age, and that it is a better, more balanced approach to try behavior therapy first. Then, only if significant impairment persists, consider a low dose of methylphenidate with careful titration,” Wolraich says.

Introducing another side of the coin, Michael J. Manos, PhD, head, Center for Pediatric Behavioral Health, Cleveland Clinic, Cleveland, Ohio, notes there is preliminary information from magnetic resonance imaging studies indicating stimulant medication may not have the feared consequences on the brain harbored by many parents. He explains that investigations involving preadolescent and adolescent youth show pharmacotherapy may reduce brain volume deficits associated with ADHD.

“All the children exhibiting extreme forms of hyperactivity that are highly disruptive and causing damage to the family. However, the main issue is that the child should receive a proper diagnostic evaluation to make sure the behaviors are associated with ADHD and not something else.”

Making the diagnosis
Although the ADHD clinical practice guideline from the AAP does not even reference children aged 2 and 3 years and recommendations pertaining to preschoolers in the American Academy of Adolescent and Child Psychiatry practice parameters refer to children aged 3 to 5 years, technically there is no lower age limit for diagnosing ADHD. Nevertheless, the experts consider it is extremely difficult if not impossible to diagnose ADHD in very young children because many of the symptoms on which the diagnosis is based are developmentally appropriate.

“That is one reason why the CDC national surveillance program never even looked at ADHD prevalence data for children younger than 4 [years],” Visser says.

Manos also noted that while it may be possible to diagnose ADHD prior to age 3 years, it is almost never done because of the uncertainty of making an accurate diagnosis. In addition to the difficulty in differentiating ADHD symptoms from normal temperamental characteristics, there is overlap between ADHD symptoms and features of potentially coexisting emotional, behavioral, developmental, and physical conditions.

“Even a child who exhibits all the symptoms associated with ADHD may not actually have ADHD,” says Manos. “Many children in this young age group show emotional dysregulation and that may be combined with ineffective parenting that adversely shapes the child’s behavior. Furthermore, there may be co-occurring conditions, such as mood disorders. Any of these issues may be hard to detect, and so even when a child seems to fulfill the diagnostic criteria for ADHD, there is always the uncertainty that the diagnosis is not correct.”

Insufficient encounter time within the constraints of a short office visit further limits the ability to diagnose ADHD with certainty. Manos believes this inability to conduct a thorough assessment combined with the complexity of
the diagnosis may be contributing to ADHD overdiagnosis and, secondarily, to high rates of ADHD medication use.

However, even if ADHD has not been formally diagnosed using set criteria, behavior therapy might be recommended to the family of children exhibiting hyperactive/impulsive behaviors considering its potential for benefit without causing any real harm.

"Studies that have been done evaluating behavioral intervention were not diagnostically specific, and a child does not have to have a set diagnosis before the family is referred for services. The main downsides are that behavior therapy can be frustrating and takes up time," notes Wolraich.

Advice for clinicians
Manos says that the success of behavior therapy depends on the ability of caregivers to deliver it, and thorough diagnosis is required to clearly define the parameters of treatment. “Clinicians identify target behaviors, determine whether target behaviors are manageable by caregivers, and only then clarify whether pharmacotherapy is needed,” he explains.

Manos urges primary care physicians to refer families to a professional with expertise in developmental and behavioral pediatrics if they feel unable to undertake the evaluation needed to diagnose ADHD and uncover comorbid conditions. The professionals who provide these services are also able to counsel the family on behavioral interventions, he says.

In addition to helping families make proper connections for evaluation and care, Manos notes there are a number of good books on parenting that physicians can recommend. He cites 1-2-3 Magic: Effective Discipline for Children 2-12 by Thomas Phelan as a particular favorite.

Recognizing that access to adequate services is a real issue preventing some families from using behavioral intervention, Wolraich urges pediatricians and other professionals involved in the management of these patients to be advocating for more qualified therapists. He suggests speaking to representatives in local and state government and child services agencies as well as working through their local AAP chapter that can help identify available resources for families.

“There is frustration for primary care physicians in not having ready availability of resources for referral,” says Wolraich. “That is particularly true in rural areas and for families and children covered by Medicaid. However, the solution is not to resort to medications,” he advises. “The environment in which the child is being raised is a very important aspect of development, and that is to some extent the focus of behavioral interventions.”

For references, go to ContemporaryPediatrics.com/stimulants-for-toddlers

CONTINUED FROM PAGE 21
symptoms very similar to ADHD including:

- tiredness;
- difficulty focusing attention;
- learning problems; and
- impulse modulation problems.

In 1991, Dahl and colleagues were among the first to note that sleep deprivation could clinically present in a similar fashion to ADHD and that sleep-directed treatment improved the behavioral symptoms.

1 Children of all ages are getting 1 hour less sleep than is recommended.

Children of all ages are getting 1 hour less sleep than is recommended.

Think of the busy schedules your patients or even your own kids are keeping—school activities, extracurricular activities, family activities, and homework. My own 5th-grader was like a college student recently, trying to manage end-of-year activities for school and baseball and preparing for a violin recital. Sleep disturbances may potentially be the cause of a behavioral problem that parents or schools are attributing to ADHD, or that may be making existing ADHD worse.

Vatsal G. Thakkar, MD, clinical assistant professor of psychiatry at the New York University School of Medicine,
shared his own sleep story in a recent New York Times editorial. He recounted his journey of performance problems, tiredness, difficulty focusing, and struggling through medical school. He was given many different diagnoses, including ADHD, but was finally found to have an atypical form of narcolepsy. Thakkar feels that pediatricians should “routinely screen for sleep disorders” and that as many as “10% of adolescents [he has] seen for behavioral issues turn out to have a primary sleep problem.”

We are, however, not well prepared. A 2011 survey of pediatricians found only 1 in 5 had received any formal training in pediatric sleep disorders. It is no surprise that pediatricians reporting formal training not only did better on knowledge-based assessments, but also were more confident and likely to assess for sleep problems.

Sleep and performance
Poor sleep can lead to a decreased ability to perform cognitive tasks, which may mimic ADHD. Gruber and colleagues examined the impact of 1 hour of sleep restriction over the course of 6 nights in both ADHD patients and normal controls. They demonstrated declines in both the ability to sustain attention and vigilance, in both normal controls and ADHD patients. In the ADHD children, the changes were significant enough to move children from a subclinical diagnostic category into a clinical one.

As our patients fill their days with more activities and less sleep, leading to later bedtimes, and as school systems seem to start earlier and earlier, what are the impacts of sleep deprivation over the long term? If we see significant declines over 6 nights in a research setting with relatively minor sleep reductions, what sort of impact might a year of “sleep debt” have? The cumulative effect of things such as kids eating dinner 30 minutes later, staying up late to do more homework, and going to bed with a smartphone could lead to significant declines in attention and vigilance over the long term.

Sleep and ADHD symptoms
Patients with sleep disorders may mimic many of the symptoms demonstrated by those with ADHD. In a study of more than 2400 children aged 6 to 15 years, children with sleep problems displayed more inattention, hyperactivity, and impulsivity as assessed by both parental and teacher reports. Symptoms of early sleep-disordered breathing (SDB) in more at 7 years of age compared with kids without SDB. In another study, looking at children over a 5-year span, children with sleep-disordered breathing were more likely to demonstrate hyperactivity, impulsivity, aggressive behaviors, poorer social skills/communication, and decreased adaptability compared with those without sleep-disordered breathing.

Treating breathing problems improves behavior
A number of studies have also examined the impact of treating sleep-disordered breathing on ADHD symptoms. Dillon and colleagues found that attention and disruptive behavior disorders decrease significantly 1 year following adenotonsillectomy. Wei and colleagues found that improvements in sleep and ADHD symptoms were greater at 6 months following adenotonsillectomy, but that improvements were still present 2.5 years following surgery. In a study that looked at children with ADHD and mild obstructive sleep apnea, patients were offered standard ADHD treatment with methylphenidate, adenotonsillectomy, or no treatment. The

Symptoms of sleep-disordered breathing (SDB) were associated with 40% more behavioral problems at age 4 and 60% more at age 7 than in kids without SDB.
While not all studies have demonstrated a positive effect on behavioral symptoms following surgery, a recent meta-analysis demonstrated a positive relationship between sleep-disordered breathing and ADHD. The study went on to further examine symptoms in patients treated surgically and found decreased symptoms 2 to 13 months following surgery.

**What should I do in my practice?**

It seems reasonable that there is at least a relationship between sleep-disordered breathing and neurobehavioral problems. It also seems reasonable to consider surgical treatment in patients where appropriate.

At a minimum, “screening [for sleep disorders] should be done for every child on stimulant treatment,” according to Thakkar. This does not mean that every child needs a formal sleep study, but some sort of formal assessment is required. While polysomnography is the gold standard for some sleep disorders, a pediatric sleep specialist or lab may not be available to you. A screening questionnaire will help you make a good assessment of whether a sleep problem may be contributing to your patient’s behavioral problem. If your patient has significant symptoms related to sleep, you may want to get a formal assessment, consult a sleep specialist, or consider treating the sleep problem before starting a stimulant.

One helpful option is a focused and standardized history provided by parents or taken by you or a member of your staff. Mindell and Owens suggest asking all parents about BEARS. The acronym guides you to ask about:

- **Bedtime problems**;
- **Excessive daytime sleepiness**;
- **Awakening at nighttime**;
- **Regular bedtime and awakening time**; and
- **Snoring or other difficulty breathing at night**.

One more formal tool is the free, parent-administered Pediatric Sleep Questionnaire, or PSQ. The tool screens for a number of specific pediatric sleep disorders, such as obstructive sleep apnea and periodic leg movements, and includes scales targeting for snoring, sleepiness, and daytime disruptive behavior.

The daytime disruptive behavior scale is based on the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, symptoms for inattentive, hyperactive, and impulsive behavior. A more comprehensive sleep questionnaire and sleep diary is also freely available from the University of Chicago Medicine Comer Children’s Hospital Section of Pediatric Sleep Medicine.

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**Final thoughts**

As with the calories in/calories out (eat less and exercise more) argument related to the treatment of obesity, it is easy to tell parents to improve their children’s sleep hygiene and set a regular bedtime. In the face of overwhelming activities, schoolwork, video games, caffeinated drinks, social media, and other choices of a modern lifestyle, however, a quick solution seems unlikely. Rather, improving sleep may take a significant therapeutic effort on our part to help parents understand all the different things that can impact sleep and the subsequent consequences of poor sleep. As a parent myself, I am wondering whether my kids should just do less. School start times and homework will continue to be debated, and I believe sleep will continue to be an issue in those discussions.

In terms of our practice, pediatricians need to become educated on the consequences of poor sleep; the ways we can assess sleep in our patients; and how to address poor sleep habits when we see them. At a minimum, I will think about assessing sleep more thoroughly before I consider a stimulant medication for one of my patients in the future.

**“Screening [for sleep disorders] should be done for every child on stimulant treatment.”—Vatsal Thakkar, MD**

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**For references, go to ContemporaryPediatrics.com/ADHD-or-sleep-deficit**
The diaper bank concept

JOANNE SAMUEL GOLDBLUM, MSW

‘Diaper need’ is a malady of early childhood poverty.

For the nearly 6 million children under the age of 3 years who are living in poor or low-income families, small things such as clean diapers can impact big things including health and well-being.

“Child well-being is a public good that benefits us all,” rightly states the Academic Pediatric Association Task Force on Childhood Poverty.

Yet, when it comes to providing children from low-income families with access to diapers, a basic need as essential to well-being as food, shelter, medicine, and love, federal assistance programs fall short. Unlike other basic needs, such as food and heat, the federal government offers no provisions to help families acquire diapers. Federal antipoverty programs such as the Supplemental Nutrition Assistance Program do not cover diapers, often leaving low-income and poor families without the means to secure clean diapers, which can cost up to $100 per month per child.

This often-hidden consequence of poverty is known as “diaper need,” and it impacts 1 in 3 families who are unable to buy an adequate supply of diapers for their children.

Evidence of diaper need

This past year, the National Diaper Bank Network (NDBN), New Haven, Connecticut, joined with faculty at the Yale School of Medicine, New Haven, to conduct the first peer-reviewed study to quantify diaper need. Key findings included the following:

- Nearly 30% of low-income mothers reported they could not afford to change their children as frequently as they wished.
- One in 10 mothers reported stretching diapers, a practice associated with urinary tract infections and diaper dermatitis.
- More than 30% of respondents reported increased levels of maternal stress and depression as a result of diaper need. These mental health needs were even more pronounced in mothers who had...
trouble obtaining diapers than in mothers who reported food insecurity.

The good news is:
- An overwhelming majority (77%) of respondents reported a consistent relationship between their children and a pediatric provider.
- Individuals working within organizations that provide diapers to low-income families have countless stories that illustrate the need. For example, a program director at a crisis nursery in Spokane, Washington, said recently, “We’ve had people come in with babies wrapped in a dish towel because they don’t have diapers.”
- Personally, I have encountered families resorting to cleaning out or drying soiled diapers and reusing them in order to meet their diaper needs.

A bigger problem
The lack of something as simple as a package of diapers can keep parents out of the workforce and place babies at enormous risk.

Most childcare providers require parents to supply disposable diapers for their children. A parent who cannot comply with this requirement cannot work or attend job training or other programs designed to help people improve their situation. Temporary Assistance for Needy Families (TANF) often requires attendance at such programs, so parents who cannot attend risk loss of TANF benefits. Without childcare, children miss opportunities for early childhood education, and thus the achievement gap widens.

Fortunately, community-based diaper banks have sprouted around the country to help families obtain diapers. In addition to raising awareness of diaper need, the NDBN helps individuals and organizations start new diaper banks and promotes the growth of existing ones. Since its incorporation in 2011, the NDBN has distributed more than 60 million diapers from founding sponsor Huggies to diaper banks across the United States. In addition, the NDBN has linked more than 170 diaper banks in 42 states, all working together to address diaper need.

The NDBN’s mission is not to apply a Band-Aid to a problem but to provide a long-term solution to a chronic issue. Just as food banks are a reliable source of support for families in need, diaper banks provide a basic need for families in crisis.

However, there are not enough of these organizations or diapers to meet the needs of the 5.8 million US children aged younger than 3 years who live in poverty.

What you can do to help
As trusted advocates for children, pediatricians are in the ideal position to help raise awareness of diaper need among all members of their local communities regardless of their economic status. Doctors also can help quantify the scope and impact of diaper need on children and families. The first step is to recognize diaper need as a malady of early childhood poverty and to ask parents if they struggle to obtain diapers. Secondly, in many communities the opportunity exists to direct families to community resources—diaper banks, faith-based organizations, and social services agencies—that provide diapers. Thirdly, the pediatric community can partner and collaborate with diaper banks to replicate and expand the NDBN’s initial research.

Overall, the NDBN takes no position on whether the solution to diaper need should be a public or private program, or some combination thereof. We simply think that discussions about basic needs should include all basic needs, and who better to lead such discussions than pediatricians?

On an individual level, when a baby is obviously in distress, people are quick to ask, “Does she need a change?”

In America today, millions of babies and toddlers are less comfortable, less safe, and less likely to prosper in the long term because they are sitting in wet, soiled diapers.

They do need a change.

For references, go to ContemporaryPediatrics.com/diaper-bank

We all are advocates for children. Tell us how you innovate care in your office and in your local community so that others can replicate your ideas. Share your stories. Send to cradvan@advanstar.com

RESOURCES FOR PEDIATRICIANS

For more information on diaper need and how to help resolve the diaper need crisis in your communities, go to www.nationaldiaperbanknetwork.org
History
The patient was able to see a local physician while traveling and was started on a 10-day course of amoxicillin/clavulanic acid. The fever and cough briefly resolved; however, 4 days later, he returned to the United States and was noted to have worsening cough and an elevated temperature of 104°F with chills.

Upon further questioning, the boy did complain of brief headaches, dizziness, diarrhea, nausea, and vomiting on the plane ride back to the United States. He was taken to his primary pediatrician’s office soon after his family returned. His mother denied any recent camping, travel to bushy areas, or intake of unpasteurized milk. However, the boy did state he had multiple mosquito bites while in Pakistan and that the family ate local foods. The family was unaware of any specific vaccinations recommended prior to their recent overseas trip. The child was born in Saudi Arabia without any complications. He has no significant past medical/surgical history or allergies, and he was up-to-date on standard vaccinations.

Considering the boy’s history of mosquito bites while in Pakistan and the intermittent fevers with chills, his pediatrician suspected malaria. The child was started on a 3-day course of atovaquone/proguanil while completing the 10 days of amoxicillin/clavulanic acid.

His initial labs showed a white blood cell count of 4.9 10^3/µL and hemoglobin of 11.9 g/dL with 70.7% neutrophils and 0% eosinophils. Complete metabolic panel showed mild transaminitis with aspartate transaminase (AST) 69 IU/L and alanine aminotransferase (ALT) 53 IU/L. Erythrocyte sedimentation rate was 51 mm/hr.

The boy’s symptoms continued with intermittent high-spiking fevers, and he began complaining of significant abdominal pain. He returned to his pediatrician who ordered additional labs. Urine analysis, repeat complete blood count (CBC), and basic metabolic panel all were normal. Hepatitis panel was negative and repeat liver profile showed worsening transaminitis with AST 110 IU/L and ALT 111 IU/L. Because of the abdominal pain and persistent fever, an abdominal computed tomography (CT) scan was obtained that showed enlarged mesenteric and retroperitoneal lymph nodes, as well as an enlarged liver and spleen (Figures 1A and 1B). His stool sample was

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### Table 1: Differential Diagnosis for Persistent Fevers with Hepatomegaly

<table>
<thead>
<tr>
<th></th>
<th>Malaria</th>
<th>Dengue Fever</th>
<th>Typhoid</th>
<th>Scrub Typhus</th>
<th>Brucellosis</th>
<th>Meliodosis</th>
<th>Viral Hepatitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
</tr>
<tr>
<td>Hepatomegaly</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>+</td>
<td>+/-</td>
<td>+</td>
</tr>
<tr>
<td>Abnormal LFTs</td>
<td>+/-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Splenomegaly</td>
<td>+/-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>CBC findings</td>
<td>Hemolysis and anemia</td>
<td>Leukopenia, thrombocytopenia</td>
<td>Leukopenia</td>
<td>Leukocytosis</td>
<td>Anemia</td>
<td>Leukocytosis</td>
<td>Unchanged</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>Blood smear, malaria antigen II</td>
<td>Serology</td>
<td>Blood &amp; stool culture</td>
<td>Serology</td>
<td>Serology</td>
<td>Serology</td>
<td>Serology</td>
</tr>
<tr>
<td>Treatment</td>
<td>Antimalarial medications</td>
<td>Fluid management, platelet or blood transfusions if needed</td>
<td>Antibiotics</td>
<td>Antibiotics</td>
<td>Antibiotics</td>
<td>Antibiotics</td>
<td>Supportive</td>
</tr>
</tbody>
</table>

Abbreviations: CBC, complete blood count; LFT, liver function test.


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CHILD WITH FEVER AFTER FOREIGN TRAVEL

CONTINUED FROM PAGE 12
negative for ova, parasites, culture, and blood.

Persistent symptoms included a dry cough and intermittent multiple, unpredictable fevers per week associated with sweating, chills, nausea, headache, vomiting, and abdominal pain. The patient has lost 8 lb to 10 lb since his symptoms began. He returned to his pediatrician’s office for another follow-up and was started on a second course of atovaquone/proguanil. He was then referred to your pediatric infectious disease office for fever of unknown origin.

Physical examination

On physical exam, the boy’s weight is 47.1 kg (~95th percentile for age); temperature, 98.2°F; heart rate, 114 beats per minute; blood pressure, 112/67 mm Hg; and respiration, 20 breaths per minute. He is alert, cooperative, and mildly pale but otherwise well appearing.

His abdomen is soft with appropriate bowel sounds but tenderness is present on the right upper quadrant. Hepatic margin is palpable 2 cm to 3 cm below the right costal margin without appreciable splenomegaly. No ascites is noted.

Head, eyes, ears, nose, throat, and neck exams are normal. Respirations are clear with good respiratory effort. Cardiac examination reveals normal S1 and S2 without a murmur, rub, or gallop. Peripheral pulses are normal.

Musculoskeletal exam is normal, showing no loss of strength, decreased range of motion, or edema. Genital exam is normal. Neurologic exam is normal without focal deficits, neck stiffness, or weakness. Skin exam reveals a few small, healed circular bug bites on his bilateral extremities without significant rash.

Differential diagnosis

There are extensive causes for prolonged fever, but you consider the boy’s recent travel and hepatomegaly to construct a differential diagnosis along with common findings (Table 1). You also review high-risk infectious diseases from Pakistan (Table 2).

Pakistan is located on the southern coast of Asia. Its temperate to tropical climate is known for a high prevalence of mosquitoes and is endemic for malaria, brucellosis, and scrub typhus. You recall that malaria is transmitted by female Anopheles mosquitoes and that the disease has an incubation period of 7 to 30 days depending on parasite species. Malaria is often associated with fevers every 2 (tertian) or 3 (quartan) days, and such a diagnosis could explain this child’s constellation of symptoms.

Brucellosis is contracted by ingestion of contaminated foods and fluids from infected animals or unpasteurized milk. Infection is associated with fever, dyspepsia, abdominal pain, and cough.

Dengue fever is primarily transmitted by Aedes mosquitoes and has an incubation period of 3 to 14 days. It is classically associated with headache, purpuric rash, and severe muscle/joint pain, and it can present with a biphasic fever curve of 5 to 7 days followed by return of fever for 1 to 2 days. Marked fatigue can last for weeks. Development of hemorrhagic dengue fever can result in circulatory failure, shock, and significant thrombocytopenia, all of which can be fatal.

Typhoid fever is caused by contaminated food or water with Salmonella enterica (formerly S typhi). The incubation period lasts from 5 to 21 days.
Renovating your medical home

There is no such thing as the “perfect” pediatric medical practice, but there are always ways to improve the services we provide.

In 2007, a joint statement issued by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians, the American College of Physicians, and the American Osteopathic Association endorsed the patient-centered medical home (PCMH) concept and described how the PCMH can optimize care for patients.¹

In addition to identifying the primary care practitioner as the leader of a team whose role is to provide and coordinate patient care, the joint statement further noted that physicians should adhere to evidence-based guidelines, advance the use of information technologies to improve care, and implement practices that improve the quality of care provided to patients.

The medical home is at the very center of the many controversies now surrounding healthcare in this country. There appear to be 2 contrasting views of healthcare in the United States. From the public health perspective, too many patients receive inadequate healthcare because they don’t have ready access to a “medical home” where they receive compassionate care from a medical practice that coordinates necessary medical services. Meanwhile, primary care pediatricians practicing in the “trenches” try to provide the best medical home we can, while recognizing that our patients have individual needs. In this installment of Peds V2.0, we’ll take look at how to identify and rectify practice problems (that is, improving the medical home you provide for patients) and provide insights regarding the small- and big-picture aspects of healthcare.

Institute of Medicine: Healthcare is broken!

The Institute of Medicine (IOM) presented a negative critique of healthcare in the United States in its 2001 report Crossing the Quality Chasm: A New Healthcare System for the 21st Century.² It described a healthcare system that is too expensive, too complicated, and with too many patients obtaining fragmented care from too many providers. The consequence of healthcare deterioration is that patients often suffer poor health outcomes. To remedy the situation, the IOM listed several goals for change:

- Improve the safety of the healthcare system;
- Make healthcare more effective via implementation of evidence-based medicine;
- Provide patient-centered care that is respectful and involves patients in decision making;
- Provide timely services that avoid unnecessary delays; and
- Provide care that is equitable and that does not vary in quality because of socioeconomic status, gender, or ethnicity.

Because of the IOM recommendations developed well over a decade ago, we now have a healthcare system that is trying to embrace the above values, with the government seeking radical changes through the implementation of the Affordable Care Act (ACA) and medical insurance companies seeking ways to incentivize physicians to improve the quality of care while containing costs. To support a medical home...
information technology infrastructure, some pediatric practices with substantial numbers of Medicaid patients have received modest payments to implement electronic health records (EHRs) that facilitate data collection. Payments also are in place to encourage practices to use EHRs to achieve medical home certification and to demonstrate “meaningful achievement” of government-defined outcomes.

Currently, several clinical quality measures are associated with “optimal pediatric care” as outlined by the Centers for Medicaid and Medicare Services (CMS) and the National Committee for Quality Assurance (NCQA). Pediatricians may be eligible for enhanced reimbursements by providing data documenting the achievement of good patient outcomes, and may eventually be subject to reduced payments if we score poorly!

These benchmarks include:

- Optimizing immunization rates;
- Screening children for obesity;
- Avoiding prescribing antibiotics for children with upper respiratory infections;
- Obtaining rapid strep tests on patients before antibiotics are prescribed;
- Using recommended medications for management of patients with asthma;
- Seeing patients on medications for attention-deficit/hyperactivity disorder quarterly;
- Developmental screening in the first 3 years of life;
- Regular well-child checks; and
- Chlamydia screening for sexually active young women aged 16 years and older.

A home divided

From the public health perspective, all pediatric patients would benefit from having a medical home. Of course, the main flaw in the “big picture” of healthcare is that patients are not just data points in a spreadsheet. Each patient requires individualized care. As discussed in a previous Peds V2.0 article (Contemp Pediatr. 2014;30[5]:30-35), the most cost-effective remedy to the “medical homeless” situation is to raise Medicaid insurance compensation to levels commensurate with those of private payers, enabling pediatricians to provide care to these previously underserved patients.

Unfortunately, the ACA has had unforeseen consequences that discourage utilization of the medical home. In my experience, the high deductibles associated with Obamacare are making parents reluctant to seek care when children are ill, and when they do seek care they wish to minimize the cost of the office visit and associated services.

In my view, it is also inappropriate merely to equate quality care with scores achieved on a short list of benchmarks. Some patients cannot be convinced to immunize their children despite pediatricians’ best efforts. Most pediatricians would empirically treat the symptomatic sibling of a child with a rapid strep test without testing, and according to the above, pediatricians would not be given credit for what is, in reality, cost-effective healthcare. We also cannot control when patients refuse care or fail to make appointments, or do not use healthcare portals as required by stage 2 of the “meaningful use” requirements of the ACA.

How does your practice measure up?

Both at state and federal levels, data have been collected to monitor the quality of healthcare provided to our
nation’s children. The CMS publishes yearly reports from the Secretary of Health and Human Services. In 2012, it published an interesting comparison of the percentage of children meeting certain core healthcare measures who were enrolled in either Medicaid or the Children’s Health Insurance Program and compared these with the percentage who had commercial insurance (Table 1). Not unexpectedly, children with commercial insurance tended to be more up-to-date with well visits and immunizations. Adolescents tended to be poorly immunized no matter what type of insurance they had. Interestingly, adolescent teenagers were more likely to be screened for chlamydia if they had Medicaid compared with commercial insurance.

Table 2 shows median (50th) percentile and 90th percentile data from NCQA Healthcare Effectiveness Data and Information Systems (HEDIS) measures. These are the performance measures on which your practice will be graded if you apply for NCQA certification, and they also are the numbers that many insurance companies utilize to determine if you are eligible for quality incentive reimbursements.

It would be useful to use your EHR to determine where your practice falls regarding these benchmarks. If your numbers look good, you can feel confident your practice should perform well when you apply for medical home certification or participate in insurance plans that are beginning to compensate physicians for quality of care. If you underperform, you would be well advised to work toward improving your practice performance. Also note that surveys of parents figure in the marks you receive from NCQA and insurance companies. Sample surveys can be obtained from www.cahps.ahrq.gov/surveys-guidance/cg/pcmh/index.html.

**Start renovating: Identify flaws**

Despite our best efforts, there is no such thing as a “perfect” pediatric practice, and we can always find ways to improve the services we provide patients. If you have an EHR (and even if you don’t), it would be a good idea to collect data regarding how your practice is performing with the core pediatric performance metrics noted above and consider surveying your patients to determine how their parents perceive the care their children receive from you.
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Erythema multiforme (EM) is an acute, self-limited skin condition associated with certain antigenic stimuli, most commonly medications and infections. It probably represents a variant of a type IV hypersensitivity reaction, and repeat or persistent exposure to the antigenic stimulus may lead to recurrence of the disease. With EM, patients develop skin and limited mucous membrane involvement that must be distinguished from Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) with severe widespread mucous membrane ulceration.

Pathophysiology and etiology
The destruction of epithelial cells in EM appears to be the result of cell-mediated immunity in response to specific triggers. Macrophages and CD8 T cells infiltrate the epidermis early in the disease, with an increased density of CD4 T cells in the dermis. These cells release cytokines that mediate an inflammatory reaction resulting in apoptosis of epithelial cells.

Many etiologic factors have been reported to cause EM. Infections, particularly with herpes simplex virus and Mycoplasma species, are common triggers for EM in children and young adults. However, many other viral, bacterial, fungal, and parasitic agents can trigger EM. Notable virus-drug interactions include Epstein-Barr virus (EBV) infection treated with amoxicillin or cytomegalovirus infection treated with terbinafine.

Indeed, a large number of the reported cases of EM are because of medication use. Sulfonamides appear to be the most common trigger, although anticonvulsants, antituberculoid agents, penicillins, tetracyclines, macrolides, and non-steroidal anti-inflammatory drugs are also known offenders.

Clinical presentation
In EM, patients may experience mild prodromal symptoms of an upper respiratory tract infection followed by the abrupt onset of a rash within 3 days that begins symmetrically on acral sites and spreads centripetally. Involvement of a single mucous membrane, particularly the mouth, may develop in up to half of patients.

The skin lesions of EM have a characteristic target appearance. They typically begin as red to violaceous, thereby forming the typical target lesion with concentric rings. The lesions may coalesce or form arcuate plaques.

Differential diagnosis
Skin conditions that have a presentation similar to EM include SJS, TEN, and staphylococcal scalded skin syndrome (SSSS). Contact dermatitis, bullous pemphigoid, and paraneoplastic pemphigus also should be considered when evaluating a patient with suspected EM, as well as urticarial vasculitis, serum sickness, meningococcemia, lichen planus, and granuloma annulare. The relative sparing of the mucous membranes helps to exclude SJS/TEN and lack of a Nikolsky sign is against SSSS and SJS/TEN.

The diagnosis of EM can be made clinically because no laboratory studies allow for definitive diagnosis.

For an extended version of this article and references, go to ContemporaryPediatrics.com/dermcase0714

Mr Khalifian is a fourth-year medical student at Johns Hopkins University School of Medicine, Baltimore, Maryland. Dr Cohen, section editor for Dermcase, is professor of pediatrics and dermatology, Johns Hopkins University School of Medicine, Baltimore. The author and section editor have 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. Vignettes are based on real cases that have been modified to allow the author and section editor to focus on key teaching points. Images also may be edited or substituted for teaching purposes.
The worried parents of an 8-year-old girl bring her to your office late Friday afternoon for evaluation of a generalized, rapidly progressive, blistering eruption that started 24 hours earlier. She is afebrile, itchy, and uncomfortable, but still eating and drinking well. She had a sore throat and positive strep screen 2 days ago that is improving on an oral antibiotic. FOR MORE ON THIS CASE, TURN TO PAGE 35.
EpiPen® 0.3 mg EPINEPHRINE AUTO-INJECTOR EpiPen Jr® 0.15 mg EPINEPHRINE AUTO-INJECTOR

BRIEF SUMMARY. See package insert for full Prescribing Information.

CONTRAINDICATIONS: There are no absolute contraindications to the use of epinephrine in a life-threatening situation.

WARNINGS: EpiPen and EpiPen Jr Auto-Injectors should only be injected into the anterolateral aspect of the thigh. DO NOT INJECT INTO BUTTOCK. Injection into the buttock may not provide effective treatment of anaphylaxis. Advise the patient to go immediately to the nearest emergency room for further treatment of anaphylaxis.

Since epinephrine is a strong vasoconstrictor, accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area. Treatment should be directed at vasodilation in addition to further treatment of anaphylaxis. Advise the patient to go immediately to the nearest emergency room and to inform the healthcare provider in the emergency room of the location of the accidental injection.

DO NOT INJECT INTRAVENTRICULARLY: Large doses or accidental intravascular injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Rapidly acting vasodilators can counteract the marked pressor effects of epinephrine if there is such inadvertent administration.

Epinephrine is the preferred treatment for serious allergic reactions or other emergency situations even though this product contains sodium metabisulfite, a sulfite that may, in other products, cause allergic-type reactions including anaphylactic symptoms or life-threatening or less severe asthmatic episodes in certain susceptible persons. The alternatives to using epinephrine in a life-threatening situation may not be satisfactory. The presence of a sulfite content in this product should not deter administration of the drug for treatment of serious allergic or other emergency situations even if the patient is sulfite-sensitive.

Epinephrine should be administered with caution in patients who have heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, e.g., digitalis, diuretics, or anti-arrhythmics, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. It should be recognized that the presence of these conditions is not a contraindication to epinephrine administration in an acute, life-threatening situation.

PRECAUTIONS:

(1) General
EpiPen and EpiPen Jr Auto-Injectors are not intended as a substitute for immediate medical care. In conjunction with the administration of epinephrine, the patient should seek immediate medical or hospital care. More than two sequential doses of epinephrine should only be administered under direct medical supervision.

Epinephrine is essential for the treatment of anaphylaxis. Patients with a history of severe allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs, and other allergens as well as idiopathic and exercise-induced anaphylaxis should be carefully instructed about the circumstances under which epinephrine should be used. It must be clearly determined that the patient is at risk of future anaphylaxis.

The effects of epinephrine may be potentiated by tricyclic antidepressants and monoamine oxidase inhibitors.

Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include: hyperthyroid individuals, individuals with cardiovascular disease, hypertension, or diabetes, elderly individuals, pregnant women, pediatric patients under 30 kg (66 lbs), body weight using EpiPen Auto-Injector, and pediatric patients under 15 kg (33 lbs), body weight using EpiPen Jr Auto-Injector.

Despite these concerns, epinephrine is essential for the treatment of anaphylaxis. Therefore, patients with these conditions, and/or any other person who might be in a position to administer EpiPen or EpiPen Jr Auto-Injector to a patient experiencing anaphylaxis should be carefully instructed in regard to the circumstances under which epinephrine should be used.

(2) Drug Interactions
Patients who receive epinephrine while concomitantly taking cardiac glycosides or diuretics should be observed carefully for the development of cardiac arrhythmias.

The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothryoxine sodium, and certain antihistaminics, notably chlopheniramine, triprolenamine and diphenhydramine.

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

The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs, such as phentolamine. Ergot alkaloids may also reverse the pressor effects of epinephrine.

(3) Carcinogenesis, Mutagenesis, Impairment of Fertility
Epinephrine and other catecholamines have been shown to have mutagenic potential in vitro and to be an oxidative mutagen in a WP2 bacterial reverse mutation assay. Epinephrine had a moderate degree of mutagenicity, and was positive in the DNA Repair test with B. subtilis (REC) assay, but was not mutagenic in the Salmonella bacterial reverse mutation assay.

Studies of epinephrine after repeated exposure in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted. This should not prevent the use of epinephrine under the conditions noted under INDICATIONS AND USAGE.

(4) Usage in Pregnancy
Pregnancy Category C: There is no study on the acute effect of epinephrine on pregnancy. Epinephrine has been shown to have developmental effects when administered subcutaneously in rabbits at a dose of 1.2 mg/kg daily for two to three days (approximately 30 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis), in mice at a subcutaneous dose of 0.5 mg/kg daily for 4 days (approximately 5 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis). These effects were not seen in mice at a subcutaneous dose of 0.5 mg/kg daily for 10 days (approximately 3 times the maximum recommended daily subcutaneous or intramuscular dose on a mg/m² basis). Although, there are no adequate and well-controlled studies in pregnant women, epinephrine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

It is not known if epinephrine passes into breast milk.

ADVERSE REACTIONS: Adverse reactions to epinephrine include transient, moderate anxiety; apprehensiveness; restlessness; tremor; weakness; dizziness; sweating; palpitations; pallor; nausea and vomiting; headache; and/or respiratory difficulties. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or certain drugs [see PRECAUTIONS, Drug Interactions]. Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Angina may occur in patients with coronary artery disease. The potential for epinephrine to produce these types of adverse reactions does not contraindicate its use in an acute life-threatening allergic reaction.

Accidental injection into the digits, hands or feet may result in loss of blood flow to the affected area (see WARNINGS). Adverse events experienced as a result of accidental injections may include increased heart rate, local reactions including injection site pallor, coldness and hypoesthesia or injury at the injection site resulting in bruising, bleeding, discoloration, erythema or skeletal injury.

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EpiPen® Auto-Injectors should only be injected into the anterolateral aspect of the thigh. DO NOT INJECT INTO BUTTOCK, OR INTRAVENOUSLY.

Epinephrine should be used with caution in patients with certain heart diseases, and in patients who are on drugs that may sensitize the heart to arrhythmias, because it may precipitate or aggravate angina pectoris and produce ventricular arrhythmias. Arrhythmias, including fatal ventricular fibrillation, have been reported in patients with underlying cardiac disease or taking cardiac glycosides or diuretics. Patients with certain medical conditions or who take certain medications for allergies, depression, thyroid disorders, diabetes, and hypertension, may be at greater risk for adverse reactions. Other adverse reactions include transient moderate anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

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