CONTEMPORARY PEDIATRICS DECEMBER 2013, VOL. 30 NO. 12 2013 ISSUES & ATTITUDES SURVEY ■ OBAMACARE FOR KIDS ■ EE VS GERD ■ YEAR'S TOP TECH

CONTEMPORARY Pediatrics®

DECEMBER 2013
VOL. 30 | NO. 12

THE YEAR'S TOP TECH

Expert Clinical Advice for Today's Pediatrician

ContemporaryPediatrics.com

OUR 1ST ISSUES & ATTITUDES SURVEY

5 WAYS YOUR PRACTICE WILL CHANGE

& THE ONE WAY IT WON'T

Obamacare
What's in it for kids?

+ EE vs GERD Differential Dx

ADVANSTAR
MEDICAL COMMUNICATIONS GROUP

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Vyvanse® (lisdexamfetamine dimesylate) capsules may be taken whole or opened and mixed in water[1]

Vyvanse is a prodrug* that is converted into active *d*-amphetamine in the body[1]

Exposure to active *d*-amphetamine is bioequivalent† when Vyvanse is taken as a whole capsule or mixed in water[2]

Capsules not shown at actual size.

Recommended Dosing[1]:

- Take once daily in the morning with or without food
  - — Avoid afternoon doses because of the potential for insomnia
- Swallow whole **OR**
- Open the capsule and mix contents in glass of water until completely dispersed
  - — Stir with a spoon to break apart any compacted powder
  - — Consume immediately (do not store)
  - — Take full contents of capsule (do not divide)
  - — Active ingredient dissolves completely once dispersed
  - — Inactive ingredient may leave film on glass. This is normal
- Titrate at approximately weekly intervals in 10- or 20-mg increments as needed up to a maximum dose of 70 mg

Prior to prescribing, assess for cardiac disease and risk of abuse. Monitor for signs of abuse and dependence while on therapy.

*Lisdexamfetamine is hydrolyzed to *d*-amphetamine and *l*-lysine primarily in the blood

†The bioavailability of oral lisdexamfetamine dimesylate was assessed in a pharmacokinetic study in 18 healthy adults. Single-dose administration after fasting of 70 mg of Vyvanse as an intact capsule or in solution resulted in equivalent AUCs for dextroamphetamine

INDICATION

Vyvanse is indicated for the treatment of ADHD in patients ages 6 and above. Efficacy was established in short-term controlled studies in children aged 6 to 17 and in adults. Vyvanse is also approved as a maintenance treatment for patients ages 6 and above with ADHD based on one maintenance study in patients aged 6 to 17 and one maintenance study in adults.[1]

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE

- **CNS stimulants (amphetamines and methylphenidate-containing products) have a high potential for abuse and dependence.**
- **Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.**

- Contraindications:
  - Known hypersensitivity to amphetamines or other ingredients in Vyvanse. Anaphylactic reactions, Stevens-Johnson syndrome, angioedema, and urticaria have been observed in postmarketing reports.
  - Concurrent administration of monoamine oxidase inhibitors (MAOI) or administration of Vyvanse within 14 days of the last MAOI dose. Hypertensive crisis can occur.
- Educate patients about abuse and periodically re-evaluate the need for Vyvanse.
- Sudden death, stroke and myocardial infarction have been reported in adults with CNS stimulant treatment at recommended doses. Sudden death has been reported in children and adolescents with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. Prior to treatment assess for the presence of cardiac disease. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during Vyvanse treatment.
- CNS stimulants cause an increase in blood pressure (mean increase about 2-4 mm Hg) and heart rate (mean increase about 3-6 bpm). Monitor all patients for tachycardia and hypertension.

How Vyvanse is converted[1]

Administration[1]

SWALLOW WHOLE

Capsule can be swallowed whole

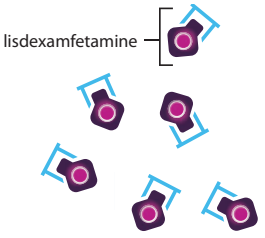
OR

MIX IN WATER

Open the capsule and mix contents in glass of water until completely dispersed

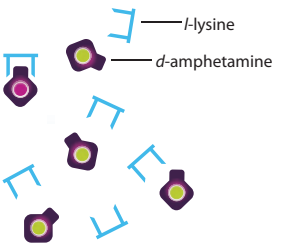
Metabolism[1,2]

PHARMACOLOGICALLY INACTIVE MOLECULES



Lisdexamfetamine is a therapeutically inactive molecule composed of *d*-amphetamine bonded to *l*-lysine

ACTIVATION IN BLOOD



Lisdexamfetamine is rapidly absorbed from the gastrointestinal tract and converted to *d*-amphetamine and *l*-lysine primarily in the blood due to the hydrolytic activity of red blood cells

Go to www.VisitVyvansePro.com for ADHD resources and information about a Vyvanse prescription savings offer*

*Restrictions may apply

IMPORTANT SAFETY INFORMATION (CONTINUED)

- Use of stimulants may cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with preexisting psychosis. Clinical evaluation for bipolar disorder is recommended prior to stimulant use.
- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Monitor weight and height in children during treatment with Vyvanse. Treatment may need to be interrupted in children not growing as expected.
- Stimulants used to treat ADHD, including Vyvanse, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Careful observation for digital changes (e.g., numbness, pain, skin color change, or sensitivity to temperature, and rarely ulcerations and/or soft tissue breakdown) is necessary during treatment and may require further evaluation (e.g., referral).
- The most common adverse reactions (≥5% and at least twice the rate of placebo) reported in clinical trials were:
  - *Children aged 6 to 12*: decreased appetite, insomnia, upper abdominal pain, irritability, vomiting, decreased weight, nausea, dry mouth and dizziness;
  - *Adolescents aged 13 to 17*: decreased appetite, insomnia, and decreased weight;
  - *Adults*: decreased appetite, insomnia, dry mouth, diarrhea, nausea, anxiety and anorexia.
- Vyvanse is in Pregnancy Category C. Vyvanse should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Amphetamines are excreted into human milk and there is the potential for serious adverse reactions in nursing infants.

Please see Brief Summary of Full Prescribing Information, including Boxed WARNING regarding Potential for Abuse and Dependence, on the following pages.

References: 1. Vyvanse (lisdexamfetamine dimesylate) [package insert]. Wayne, PA: Shire US Inc; June 2013. **2.** Krishnan S, Zhang Y. Relative bioavailability of lisdexamfetamine 70-mg capsules in fasted and fed healthy adult volunteers and in solution: a single-dose, crossover pharmacokinetic study. *J Clin Pharmacol*. 2008;48:293-302.

This information is brought to you by
Shire US Inc.

S00589 09/13

Shire

Vyvanse™ II
(lisdexamfetamine dimesylate)
20 • 30 • 40 • 50 • 60 • 70 mg capsules

Vyvanse® (lisdexamfetamine dimesylate) Capsules CII Rx Only

BRIEF SUMMARY: Consult the Full Prescribing Information for complete product information.

WARNING: ABUSE AND DEPENDENCE

CNS stimulants (amphetamines and methylphenidate-containing products) have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

INDICATIONS AND USAGE

Vyvanse® is indicated for treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Efficacy of Vyvanse in the treatment of ADHD was established on the basis of three short-term controlled trials in children ages 6 to 12 years, one short-term controlled trial in adolescents ages 13 to 17 years, one short-term trial in children and adolescents ages 6-17 years, one maintenance trial in children and adolescents ages 6-17 years, two short-term controlled trials in adults, and one maintenance trial in adults.

DOSAGE AND ADMINISTRATION

- Recommended starting dose: 30 mg once daily in the morning in patients ages 6 and above
- Increase in increments of 10 or 20 mg at approximately weekly intervals if needed
- Maximum dose: 70 mg per day
- Prior to treatment, assess for presence of cardiac disease

CONTRAINDICATIONS

Vyvanse is contraindicated in patients with:

- Known hypersensitivity to amphetamine products or other ingredients of Vyvanse. Anaphylactic reactions, Stevens-Johnson Syndrome, angioedema, and urticaria have been observed in postmarketing reports.
- Concurrent administration of monoamine oxidase inhibitors (MAOI) or administration of Vyvanse within 14 days of the last MAOI dose. Hypertensive crisis can occur.

WARNINGS AND PRECAUTIONS

Potential for Abuse and Dependence *(See Boxed Warning Above)*

Serious Cardiovascular Reactions

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

Blood Pressure and Heart Rate Increases

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

Psychiatric Adverse Reactions

Exacerbation of Pre-existing Psychosis

CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a preexisting psychotic disorder.

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a mixed/manic episode in patients with bipolar disorder. Prior to initiating treatment, screen patients for risk factors for developing a manic episode.

New Psychotic or Manic Symptoms

CNS stimulants, at recommended doses, may cause psychotic or manic symptoms, e.g. hallucinations, delusional thinking, or mania in children and adolescents without a prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing the CNS stimulant. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in 0.1% of CNS stimulant-treated patients compared to 0% in placebo-treated patients.

Suppression of Growth

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants, including Vyvanse. In a 4-week, placebo-controlled trial of Vyvanse in patients ages 6 to 12 years old, there was a dose-related decrease in weight in the Vyvanse groups compared to weight gain in the placebo group. Additionally, in studies of another stimulant, there was slowing of the increase in height.

Peripheral Vasculopathy, including Raynaud's Phenomenon

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

ADVERSE REACTIONS

Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect rates observed in clinical practice.

The safety data in this section is based on data from 4-week parallel-group controlled clinical studies of Vyvanse in pediatric and adult patients with ADHD.

Adverse Reactions Associated with Discontinuation of Treatment in Clinical Trials

In the controlled trial in patients ages 6 to 12 years, 9% (20/218) of Vyvanse-treated patients discontinued due to adverse reactions compared to 1% (1/72) of placebo-treated patients. Most frequent adverse reactions leading to discontinuation (i.e. leading to discontinuation in at least 1% of Vyvanse-treated patients and at a rate at least twice that of placebo) were ECG voltage criteria for ventricular hypertrophy, tic, vomiting, psychomotor hyperactivity, insomnia, and rash [2 instances for each adverse reaction, i.e., 2/218 (1%)].

In the controlled trial in patients ages 13 to 17 years, 4% (10/233) of Vyvanse-treated patients discontinued due to adverse reactions compared to 1% (1/77) of placebo-treated patients. Most frequent adverse reactions leading to discontinuation were irritability (3/233; 1%), decreased appetite (2/233; 1%), and insomnia (2/233; 1%).

In the controlled adult trial, 6% (21/358) of Vyvanse-treated patients discontinued due to adverse reactions compared to 2% (1/62) of placebo-treated patients. Most frequent adverse reactions leading to discontinuation (i.e. leading to discontinuation in at least 1% of Vyvanse-treated patients and at a rate at least twice that of placebo) were insomnia (8/358; 2%), tachycardia (3/358; 1%), irritability (2/358; 1%), hypertension (4/358; 1%), headache (2/358; 1%), anxiety (2/358; 1%), and dyspnea (3/358; 1%).

Most common adverse reactions (incidence ≥5% and at a rate at least twice placebo) reported in children, adolescents, and/or adults were anorexia, anxiety, decreased appetite, decreased weight, diarrhea, dizziness, dry mouth, irritability, insomnia, nausea, upper abdominal pain, and vomiting.

Adverse Reactions Occurring at an Incidence of 2% or More Among Vyvanse-Treated Patients in Clinical Trials

Adverse reactions reported in the controlled trials in pediatric patients ages 6 to 12 years, adolescent patients ages 13 to 17 years, and adult patients treated with Vyvanse or placebo are presented in Tables 1, 2, and 3 below.

Table 1 Adverse Reactions Reported by 2% or More of Children (Ages 6 to 12 Years) Taking Vyvanse and at least Twice the Incidence in Patients Taking Placebo in a 4-Week Clinical Trial

	Vyvanse (n=218)	Placebo (n=72)
Decreased Appetite	39%	4%
Insomnia	23%	3%
Abdominal Pain Upper	12%	6%
Irritability	10%	0%
Vomiting	9%	4%
Weight Decreased	9%	1%
Nausea	6%	3%
Dry Mouth	5%	0%
Dizziness	5%	0%
Affect lability	3%	0%
Rash	3%	0%
Pyrexia	2%	1%
Somnolence	2%	1%
Tic	2%	0%

Table 2 Adverse Reactions Reported by 2% or More of Adolescent (Ages 13 to 17 Years) Patients Taking Vyvanse and at least Twice the Incidence in Patients Taking Placebo in a 4-Week Clinical Trial

	Vyvanse (n=233)	Placebo (n=77)
Decreased Appetite	34%	3%
Insomnia	13%	4%
Weight Decreased	9%	0%
Dry Mouth	4%	1%

Table 3 Adverse Reactions Reported by 2% or More of Adult Patients Taking Vyvanse and at least Twice the Incidence in Patients Taking Placebo in a 4-Week Clinical Trial

	Vyvanse (n=358)	Placebo (n=62)
Decreased Appetite	27%	2%
Insomnia	27%	8%
Dry Mouth	26%	3%
Diarrhea	7%	0%
Nausea	7%	0%
Anxiety	6%	0%
Anorexia	5%	0%
Feeling Jittery	4%	0%
Agitation	3%	0%
Blood Pressure Increased	3%	0%
Hyperhidrosis	3%	0%
Restlessness	3%	0%
Weight Decreased	3%	0%
Dyspnea	2%	0%
Heart Rate Increased	2%	0%
Tremor	2%	0%

In addition, in the adult population erectile dysfunction was observed in 2.6% of males on Vyvanse and 0% on placebo; decreased libido was observed in 1.4% of subjects on Vyvanse and 0% on placebo.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of Vyvanse. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events are as follows: palpitations, cardiomyopathy, mydriasis, diplopia, difficulties with visual accommodation, blurred vision, eosinophilic hepatitis, anaphylactic reaction, hypersensitivity, dyskinesia, tics, depression, dermatillomania, aggression, Stevens-Johnson Syndrome, angioedema, urticaria, and seizures.

DRUG INTERACTIONS

Acidifying and Alkalinizing Agents

Ascorbic acid and other agents that acidify urine increase urinary excretion and decrease the half-life of amphetamine. Sodium bicarbonate and other agents that alkalinize urine decrease urinary excretion and extend the half-life of amphetamine. Adjust the dosage accordingly.

Monoamine Oxidase Inhibitors

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

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C.: Risk Summary

There are no adequate and well-controlled studies with Vyvanse in pregnant women. Vyvanse should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Amphetamines are excreted into human milk. Long-term neurodevelopmental effects on infants from amphetamine exposure are unknown. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness have been established in pediatric patients with ADHD ages 6 to 17 years. Safety and efficacy in pediatric patients below the age of 6 years have not been established.

Geriatric Use

Clinical studies of Vyvanse did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

DRUG ABUSE AND DEPENDENCE

Vyvanse contains lisdexamfetamine, a prodrug of amphetamine, a Schedule II controlled substance.

OVERDOSAGE

Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice for treatment of overdosage. Individual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses.

Manifestations of amphetamine overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia, and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Other reactions include arrhythmias, hypertension or hypotension, circulatory collapse, nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

Manufactured for: Shire US Inc., Wayne, PA 19087
Made in USA
For more information call 1-800-828-2088

US Pat No. 7,105,486 and US Pat No. 7,223,735
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Shire

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Pediatrics

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WHAT'S TRENDING

The conversation continues all month long online.

1. Apophysitis of the lower extremities
2. A strategy to treat pollakiuria
3. Managing chronic daily headaches
4. Evaluating fontanels in the newborn skull
5. Oral health prevention and treatment

KANGAROO CARE BEYOND THE NICU

ContemporaryPediatrics.com/kangaroo

We caught up with Jae H. Kim, MD, PhD, associate clinical professor of pediatrics, University of California, San Diego, via a Google Hangout, for key takeaways from his neonatal presentation at AAP 2013 in Orlando. He discussed the clinical benefits of Mom and infant's first skin-to-skin contact during the "golden hour" following birth and keeping stable newborns with their mothers—plus the role that community-based pediatricians can play in promoting these practices that have been christened by the World Health Organization as Kangaroo Mother Care.

on facebook

We're tracking clinical news in the pediatric discipline and providing linkable tools for the pediatric practitioner. Friend us, like us, and see what your colleagues are posting!

Pamela Dietz
Enjoy the contents each month!

neurocore
It's nice to see all of the national media coverage on brain wave testing for ADHD, including your recent article...It would be interesting to see a comparison of the businesses providing brain wave testing for ADHD.

Luis Vasquez
BRAVO... great for healthcare providers in the rural areas of the world. Spanish Edition NEXT please...

feedback

We've heard from readers via our website on everything from vaccinations to ADHD. Now it's your turn to hit the comment link and share your thoughts.

Login or register to post comments

First, a dissent relating to our recent article on data showing that pediatricians obtain more assent from parents when they sound as if they "mean business" when discussing vaccinations:

Anonymous The assumption of parental cooperation is paternalism under the radar screen. Doctors need to educate parents in the shared decision-making model, if informed consent means anything.

digital app

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Contemp. Pediatrics
@ContemPeds
New AAP policy statement Peds should report parents to CPS for abuse & neglect if care declined for religious beliefs bit.ly/1byedKA

Fernando Bula
@ferbuleh
@ContemPeds it was about time, nonsense needs to be stopped. Lack of vaccines should be considered neglect as well at some point.

Contemp. Pediatrics
@ContemPeds
Profoundly disturbing piece on pediatricians & child porn. Dante has a special rung... bit.ly/1fpaMJg #childpornography #pediatrics

Sallie Porter
@DrSalliePNP
@ContemPeds Upsetting for sure.

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Continuous Refrigeration Sustained potency requires refrigeration. Probiotics are living organisms. If they are on the store shelf at room temperature, the cells are being damaged and are slowly dying.

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This product is not medicinal and is not intended to diagnose, treat, cure or prevent any disease.

BY KATHRYN FOXHALL

Clinical trial for infants did not disclose study risks

Criticisms from a federal agency about the informed consent provisions of a study of oxygenation levels for low-birth-weight infants has stirred one of the most prominent medical ethics discussions in recent years. The conversation has gone beyond informed consent in research to look at knowledge and consent in medical practice itself.

In March of this year, the Office of Human Research Protections (OHRP) within the Department of Health and Human Services determined that "The Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT)," which was done on about 1,300 infants at 22 sites from 2004 to 2009, "was in violation of the regulatory requirements for informed consent, stemming from the failure to describe the reasonably foreseeable risks of blindness, neurological damage, and death."

One of the study's goals was to "learn the appropriate levels of oxygen saturation in extremely low-birth-weight infants by comparing a lower versus a higher range of levels of oxygen saturation."

The OHRP said, among other things, that the template for the study's consent form section on risks versus benefits did not mention any risks relating to randomizing the babies to higher and lower levels of oxygen, but the form suggested that it was a low-risk study.

Although it would have been unwarranted to predict which babies would have which outcomes, the OHRP said, there was sufficient information to know "that participation might lead to differences in whether an infant survived or developed blindness" compared with what might have happened if the child were not in the study.

The OHRP statement stirred significant argument, including a letter in the *New England Journal of Medicine* in which almost 4 dozen experts in ethics and regulatory issues said they disagreed that random assignment of infants carried additional undisclosed risks as compared with standard of care.

The arguments continued in an August meeting called by OHRP in Washington.

Nancy Kass, ScD, of the Johns Hopkins Bloomberg School of Public Health, told the meeting there is a premise in clinical care that because professionals apply the "best knowledge to individual patients' medical problems," whatever risks are involved are reasonable trade-offs for the clinical benefits.

"Ethically, it cannot be defended that we have such different standards for when patients deserve to be given information by trusted health care providers about whether their recommended treatments are risky," she said.

Jeffrey Drazen, MD, editor-in-chief of the *New England Journal of Medicine*, said that recently when he was working in an intensive care unit, he counted over 50 questions a day that could have been decided with a flip of a coin. "We need to do better than that if we are going to improve our health care system," he said.

Jon Tyson, MD, MPH, of the University of Texas Medical School at Houston, noted the *Institutional Review Board (IRB) Guidebook* calls experimentation "the use of unproven therapies whether or not research is being performed."

"So, babies, whether they were in this trial or not, whichever oxygen saturation goal their physician selected, were experimental subjects whether or not they were research subjects," he said.

J. Michael McGinnis, MD, MPP, senior scholar at the Institute of Medicine (IOM), who stressed his statement was not an IOM position, said that research and practice should now be viewed as part of a "continuous cycle of knowledge generation," and the IOM has called for attention to any regulatory impediments.

The OHRP referred questions on the issue to a public affairs office that said there would be updated guidance, but there is no timetable for its release. cp

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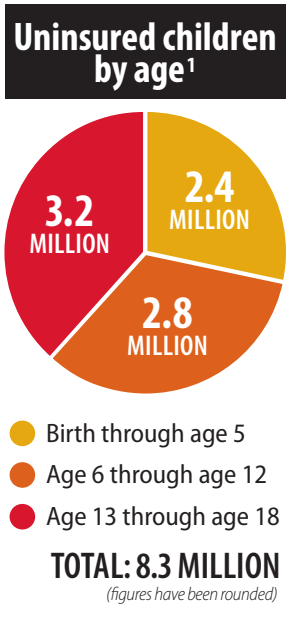
OBAMACARE: WHAT'S IN IT FOR KIDS?

GRETCHEN L SCHWENKER AND ROSE SCHNEIDER

Preventive health care services, including dental and vision benefits, will now be available under the ACA to millions of previously uninsured children.

The Patient Protection and Affordable Care Act (ACA), popularly known as Obamacare, will dramatically improve access to health insurance for children. In 2010, it was estimated that there were more than 8 million uninsured kids in the United States.[1] Older children aged 13 to 18 years comprised a greater percentage of the uninsured when defined by age, and other factors of race/ethnicity and income level also played a role. The ACA provides the opportunity to reach many more children from all backgrounds. More importantly, under ACA mandates, preventive health services are set to become available to millions of children.

Children aged younger than 19 years also can no longer be denied health insurance coverage because of a preexisting condition.[2] Families can choose a pediatrician as their child's primary care physician. The American Academy of Pediatrics (AAP) offers online resources at www.aap.org that are specific to each state to give information and support to both parents and pediatricians in search of a health insurance plan that appropriately covers the needs of families and their children.[3] Education on working with the new ACA marketplace and answers to questions on how parents can best evaluate insurance plan options are provided on the AAP website, www.healthychildren.org.



The new private health plans that have emerged because of the ACA must cover the cost of preventive care for pediatric patients.[2] These preventive services have been written into the essential health benefit (EHB) provisions in force under the ACA. Defined as services for those younger than the age of 19 years, such preventive health services will be part of all marketplace health plans and many others without the requirement of a copayment or coinsurance, or the need to meet a yearly deductible.[4] The list of pediatric preventive health services is extensive and includes screenings for blood pressure, depression, and obesity, and well-child checkups and immunizations. Perhaps the greatest impact will be felt through the inclusion of dental and vision services for children.

Pediatric dental services

Dental coverage is required by the ACA for children but not for adults. According to the American Dental Association (ADA), it is expected

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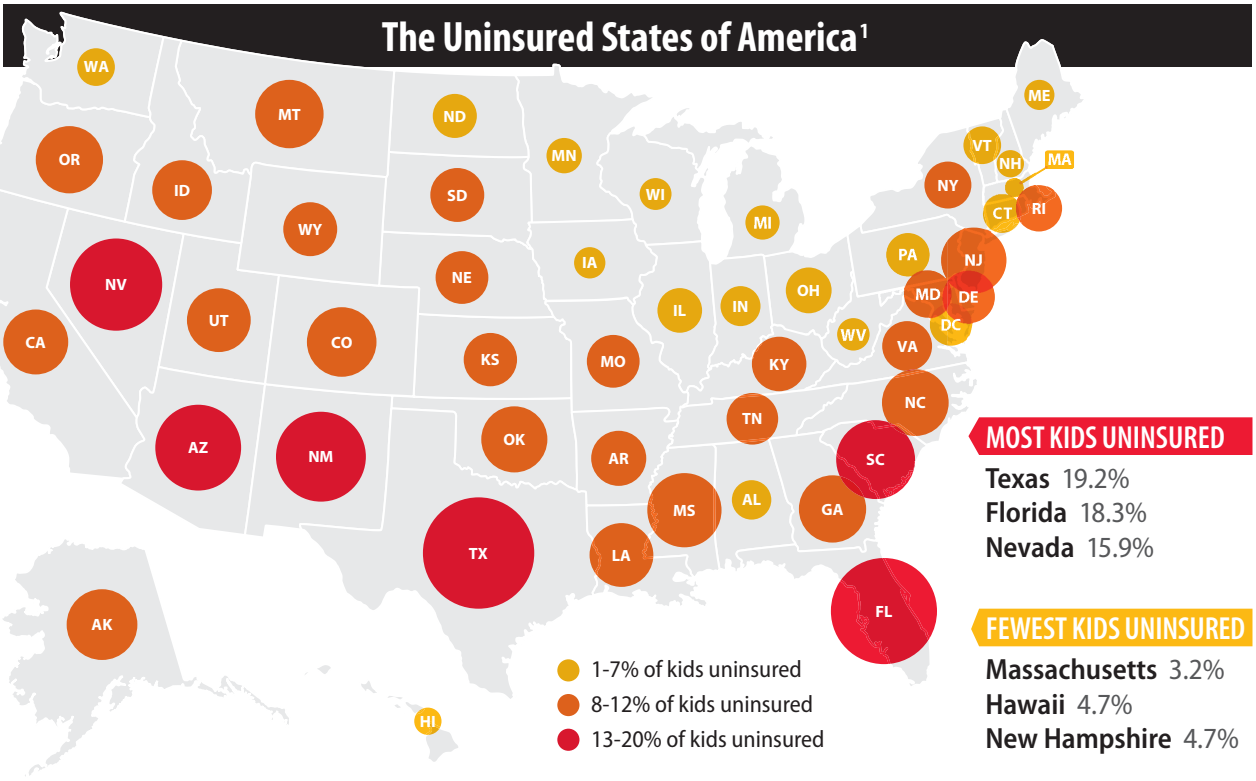

that approximately 8.7 million children will receive dental benefits by 2018.[5] This expansion of services will come through employer-sponsored insurance (2.5 million), health insurance exchanges or marketplaces (3 million), and Medicaid (3.2 million). Consequently, the number of children without dental benefits could be reduced by 55% over 2010.

All individual and small group market plans, both inside and outside the federal health insurance exchange, must be certified as qualified health plans (QHPs) after January 1, 2014. The QHPs must offer pediatric oral health services as part of the 10-category EHB package. Children can receive coverage through a QHP that also provides dental coverage, through a stand-alone dental plan purchased concurrently with a QHP, and through a bundled plan for which one premium is paid for individual medical and dental policies.[6]

This dental benefit must be offered within the health insurance exchanges overseen by the federal government, but it does not have to be purchased.[5] However, it must be offered and purchased in the individual and small-group markets outside the exchange. Families who are earning up to 400% of the federal poverty level (for a family of 4, an annual income of $94,200) qualify for a tax credit, thus lowering their monthly premiums.[6]

Covered preventive services will include teeth cleaning, x-rays, fillings, and orthodontics considered medically necessary.[7] Websites with information on these new pediatric dental services include the ADA, www.ada.org, and the Children's Dental Health Project, www.cdhp.org.

Pediatric vision services

Pediatric vision services will also be part of the medical plans that must be purchased under the ACA, including annual, fully dilated, routine comprehensive eye exams; follow-up visits; and correction of refractive error with eyeglasses and contact lenses.[8] Insurance plans generally have not included vision care before, but vision services have now been designated an EHB. Prior to ACA reforms, it had been estimated that over half of uninsured children had not had a well-child visit to a physician, which would have included vision screening.[9] These routine vision screenings are central to the early detection and treatment of vision problems.

For children from newborns aged up to 3 years, vision screening will include a red reflex test, corneal light reflection, ocular motility, pupil examination, external

examination, and vision assessment performed at all well-child visits.[8,10] For children aged 3 to 5 years, an annual vision screening with age-appropriate visual acuity testing will be required. Thereafter, vision screening should occur every 1 to 2 years. The change in care will be dramatic, considering that in the past approximately 1.43 million uninsured kids have had an unmet vision care need.[9]

The AAP also explains that vision screening should occur in the context of a medical home.[8] This approach to comprehensive care, which is not a specific physical location but rather a concept, allows a pediatric care team to work together with a child's family regarding the appropriate delivery of a child's medical and nonmedical needs. The new insurance plans will allow for a family-centered medical home that provides access to care and assists with specialty care, out-of-home care, education, family support, and community services. The AAP website, www.healthychildren.org, and the American Academy of Ophthalmology, www.aao.org, provide information on children's vision services under the ACA.

As pediatricians continue to help families navigate through their policy choices during the 6-month ACA open-enrollment period that began October 1, 2013, they can also help themselves learn about the Small Business Health Options Program (SHOP), the health insurance exchange/marketplace for small businesses comprised of 50 or fewer employees. Although pediatric practices do not have to provide their staffs with health insurance, those that do offer coverage through SHOP may qualify for tax credits. For information about the small business marketplace, go to www.healthcare.gov/small-businesses/. Information explaining how to find out if your practice qualifies for this tax credit can also be found at www.irs.gov/uac/Small-Business-Health-Care-Tax-Credit-for-Small-Employers. CP

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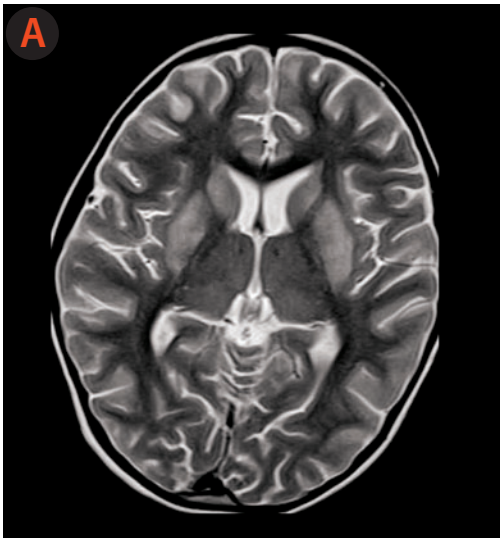

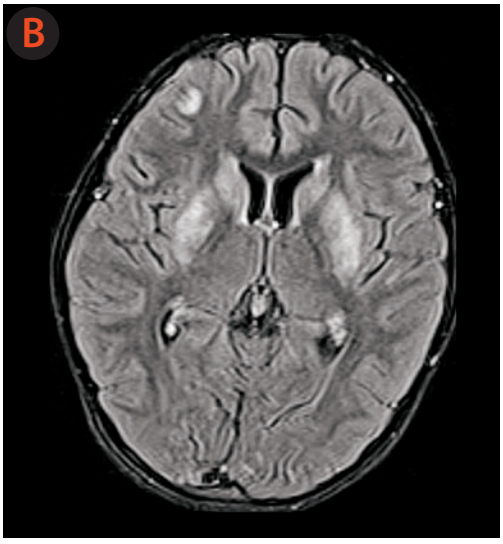

FIGURE

A: *Signal abnormalities in the caudal head and putamina as well as in the subcortical white matter of the frontal lobe.*

B: *Corresponding FLAIR image for section shown in A.*

Persistent tremors and agitation in a 6-year-old girl

PRERNA KUMAR, MD

THE CASE

A 6-year-old, previously healthy girl presents from an outside hospital for poor oral intake and new onset tremors. One week ago, symptoms began with fever, fatigue, and weakness that lasted for 4 days. She then complained of abdominal pain and developed 3 episodes of nonbilious, nonbloody emesis, which have since resolved. Her mother reports that the outside hospital course was pertinent for intravenous (IV) fluid rehydration along with an abdominal x-ray that demonstrated an ileus, for which the child received total parenteral nutrition for 2 days. The family is coming to you now because the child continues to be unable to take oral nutrition and has developed new troublesome symptoms.

CONTINUED ON **PAGE 44**

DR KUMAR is a third-year pediatric resident at Children's Hospital Colorado, Aurora. The author has nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.

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TREATING EOSINOPHILIC ESOPHAGITIS IN CHILDREN

SUSAN SCHUVAL, MD, AND DAVID GOLD, MD

Eosinophilic esophagitis is an increasingly recognized condition in children and adults that may mimic gastroesophageal reflux but that does not respond to acid suppression. Current treatment focuses on dietary modification and topical corticosteroids. However, future studies are needed to better define this disease's natural history and to identify effective therapies for children and adults.

Eosinophilic esophagitis (EE) is an emerging disease in children and adults. Despite the publication of consensus guidelines, EE is often misdiagnosed as gastroesophageal reflux, diagnosed late, or may go undiagnosed altogether. The objective of this review is to familiarize pediatricians with the presenting signs and symptoms of EE and to review current management strategies.

Background

Eosinophilic esophagitis was first described in 1995 in a group of 10 children presenting with long-term gastrointestinal (GI) symptoms that failed to improve with antireflux therapies but that ultimately responded to an elemental diet.[1] In 2007, the first set of consensus guidelines for the diagnosis and treatment of EE was published by a multidisciplinary task force.[2] The consensus recommendations were updated in 2011 to reflect advances in the understanding of disease epidemiology, pathophysiology, and treatment. The definition of EE was altered to include the concept of "a chronic, immune/antigen-mediated" condition.[3]

According to current consensus guidelines, EE is a clinicopathologic diagnosis defined by upper GI symptoms suggestive of esophageal dysfunction; defined histopathology with eosinophil-predominant inflammation; lack of response to acid suppression with high-dose proton-pump inhibitor (PPI) therapy for 6 to 8 weeks; and exclusion of other causes of esophageal eosinophilia. Esophageal biopsy must demonstrate at least 15 eosinophils/high-power

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field (eos/hpf [x400]) in at least 1 area and normal mucosa in the stomach and duodenum (Table 1).[3]

Pathophysiology

Eosinophilic esophagitis is hypothesized to result from a T-helper (Th)2-mediated inflammatory response to food and/or environmental allergens.[4] The Th2 cytokines interleukin-4, interleukin-5, and interleukin-13 have been implicated in disease pathogenesis as has eotaxin-3, a chemokine that attracts eosinophils to sites of inflammation. Chronic esophageal inflammation results in fibrotic changes referred to as esophageal remodeling.[5]

Epidemiology

Eosinophilic esophagitis has been described in patients ranging in age from 1 year to 98 years.[6] Three-quarters of all cases are seen in men.[2] Although more common in Caucasians, EE has also been described in all ethnicities and on 6 continents.[6] Familial cases of EE have been described with 7% of patients reporting a positive family history. Most likely, there is a genetic susceptibility predisposing individuals to EE.[2] Current incidence rates of pediatric EE are 10 per 100,000 children per year, with a prevalence rate of 43 per 100,000. Increasing prevalence rates have been reported in the past 2 decades.[7] In the past, EE was probably misdiagnosed as gastroesophageal reflux disease (GERD). Recent heightened awareness of this disorder may also account for observed increased prevalence rates.[6]

Clinical presentation

Young children often present with feeding refusal or failure to thrive. Recurrent vomiting and abdominal pain may occur in school-aged children. Older children and adolescents often present with dysphagia, choking, and food impaction. A detailed dietary history may reveal chewing and swallowing abnormalities, including prolonged mealtimes, compensatory mechanisms (cutting food in small pieces or requiring liquids to swallow solid foods), or avoidance of specific foods such as meat.[3] Seasonal variation of symptoms may correlate with aeroallergen exposure. Many patients lack findings on physical examination and have normal growth parameters, which may lead to a delay in diagnosis.[6]

TABLE 1 Criteria for diagnosis of eosinophilic esophagitis

Clinical	Must have symptoms related to esophageal dysfunction.
Histopathologic	One or more biopsies must show eosinophilic-predominant inflammation with >15 eos/hpf. Inflammation must be confined to esophagus. Other causes of esophageal eosinophilia must be excluded.
Treatment response	Eosinophilia does not resolve with acid-suppression therapy. Inflammation should remit with dietary exclusion and/or topical corticosteroids.

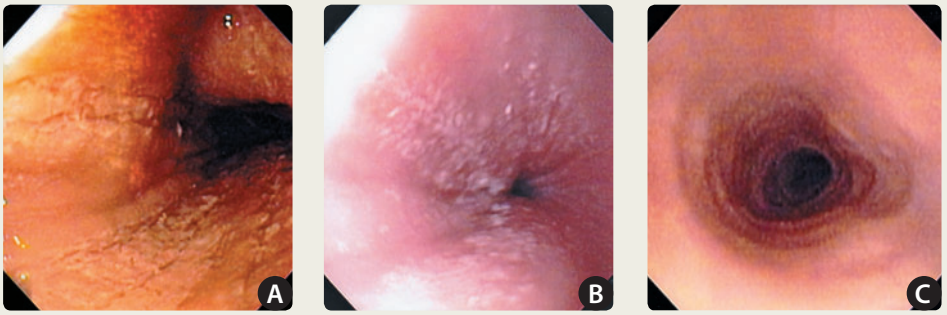
Abbreviation: eos/hpf, eosinophils per high-power field.
From Liacouras CA, et al.[3]

Allergic disorders are seen in 50% to 80% of patients with EE.[2] Asthma occurs in 14% to 70%, allergic rhinitis in 40% to 75%, and immunoglobulin E (IgE)-mediated food allergies are reported in 15% to 43% of children.[3]

Differential diagnosis

Other disorders that must be excluded from EE include GERD, infection, autoimmune disease, inflammatory bowel disease, and other systemic/GI processes. Differentiating EE from GERD may be difficult because both entities may present with similar symptoms (dysphagia, odynophagia, heartburn, chest pain, feeding disturbances), as well as esophageal eosinophilia. The degree of esophageal eosinophilia, however, is generally milder in GERD[7] because GERD more typically involves the distal esophagus, whereas EE occurs more diffusely throughout the esophagus. In addition, GERD may be excluded by lack of response to acid suppression (6-8 week course high-dose PPI), or by demonstration of normal pH monitoring study of the distal esophagus.[2] It is possible that EE and GERD may coexist. Esophageal inflammation in EE may enhance esophageal sensitivity to physiologic acid exposure, causing secondary GERD, or alternatively, GERD may develop secondary

FIGURE **Endoscopic findings for eosinophilic esophagitis**



A: Linear furrows

B: Exudate

C: Small caliber esophagus

to esophageal dysmotility caused by EE. Other causes of esophageal eosinophilia include eosinophilic gastroenteritis, hypereosinophilic syndrome, infection, achalasia, drug hypersensitivity, Crohn disease, celiac disease, autoimmune disease, and PPI-responsive esophageal eosinophilia (PPI-REE),[4] in which patients present with symptoms similar to those of EE and display moderate esophageal eosinophilia, but respond to PPI therapy.[8]

Endoscopic findings

Esophageal biopsy is required for diagnosis of EE. Esophageal abnormalities are frequently visualized on endoscopy, although the esophageal mucosa may appear normal in up to a third of patients.[3] Many of the endoscopic findings are nonspecific and include a granular or corrugated appearance of the mucosa, or loss of vascular markings.[2] More highly suggestive findings include a ring-like appearance of the esophagus, vertical linear furrows, or scattered areas of white papular exudate that contain numerous eosinophils (Figure). This exudate may be mistaken for *Candida* esophagitis and can occur anywhere within the esophagus. Strictures may be present as can a diffuse narrowing of the esophagus known as small-caliber esophagus.

Histopathology

Diagnosis of EE requires the documentation of esophageal eosinophilia. The peak eosinophil count/hpf is recorded from histologic examination of hematoxylin-eosin-stained esophageal tissue sections at 400x magnification. Multiple biopsy specimens from the proximal and distal esophagus should be obtained even if the mucosa appears normal, as eosinophilic inflammation may be patchy.[2] Ongoing inflammation may result in lamina propria fibrosis.[3] In children, biopsy of the gastric antrum and duodenum is necessary to exclude other GI disorders.

Laboratory evaluation

An estimated 50% to 80% of children with EE are atopic, and have concurrent atopic dermatitis, asthma, and/or allergic rhinitis.[2] Allergy evaluation should be undertaken in all patients with EE to determine relevant aeroallergens and food allergens. Laboratory evaluation may consist of complete blood count with differential to determine the presence of peripheral blood eosinophilia (absolute eosinophil count >300-350/mm^3), which is seen in 40% to 50% of patients. Serum IgE may be elevated (>114 kU/L) but may reflect the presence of other allergic diatheses such as atopic dermatitis.[6] Prick puncture skin tests (PST) or serum IgE tests may be helpful in determining the presence of specific IgE antibodies to environmental or food allergens.[2] Many patients will have positive PST to more than 1 food. The most common PST-positive foods in EE include milk, egg, soy, peanut, chicken, wheat, beef, peas, corn, potato, and rice.[9] Milk is the most common food allergen associated with EE, followed by wheat and egg, but there is a high incidence of false-negative PST to milk.[6] Atopy patch tests (APTs) to foods have also been used to evaluate delayed non-IgE-mediated food reactions in EE, but these tests are

IMAGE CREDIT / AUTHOR SUPPLIED

not standardized.[10] The most common APT-positive foods in EE include corn, soy, wheat, milk, rice, chicken, beef, potato, egg, and peas.[9]

Radiograph studies such as a barium swallow should be considered prior to endoscopy in patients with EE presenting with dysphagia, to alert the endoscopist to potential structural abnormalities such as strictures or small-caliber esophagus.[2] Esophageal manometry may be required to examine dysmotility if suspected clinically.

Treatment

Objectives of EE therapy include improvement in histology and quality of life, reduction in clinical symptoms, and prevention of complications such as food impaction or long-term sequelae such as strictures or small-caliber esophagus. Current treatment modalities include dietary modification and pharmacotherapy.

Dietary management. According to consensus guidelines, dietary modification should be considered for all children and some adults with EE because food allergens are implicated in disease pathogenesis.[3] The 3 dietary strategies used include elemental diet administration, empiric dietary elimination, and targeted food elimination (Table 2).[2]

Use of an elemental diet consisting of an amino acid-based formula remains the most-effective and accepted dietary intervention for EE.[1,9] These formulations are unpalatable, however, and compliance may be poor in children and adults. Formula administration may require nasogastric or gastrostomy feedings that may negatively impact quality of life.

A second dietary strategy used is empiric dietary elimination of allergenic foods.[11] A 2006 study retrospectively compared the efficacy of empiric dietary elimination versus elemental formula administration in children with EE.[12] Six allergenic foods (milk, soy, egg, wheat, peanut/tree nuts, fish/shellfish) were removed from the diet of these children for 6 weeks. Histopathologic improvement occurred in 74% of those receiving the 6-food elimination diet (SFED), compared with 88% of those receiving the elemental diet. Currently, many clinicians will recommend initiation of the SFED, followed by stepwise reintroduction of single foods into the diet, to identify specific food triggers of EE. Strict food avoidance may be difficult, however, and consultation with a dietitian may be needed to ensure that a nutritious diet is provided. There is also a potential risk of IgE-mediated reactions on food reintroduction.[8]

TABLE 2 Dietary management of eosinophilic esophagitis

Elemental diet (amino acid-based formula)	Neocate or Neocate Junior (Nutricia) EleCare or EleCare Junior (Abbott) PurAmino (Mead Johnson)
Six-food elimination diet	Completely remove these foods from diet for 6 wk: milk, soy, egg, wheat, peanut/tree nuts, fish/shellfish. Cautious reintroduction of single foods under medical supervision to identify specific food triggers.
Targeted diet	Prick skin tests and/or atopy patch tests to identify possible food triggers, which are eliminated from diet for >6 wk. Eventual reintroduction of single foods under medical supervision to identify specific food triggers.

From Furuta GT, et al.[2]

The third dietary treatment strategy is targeted food elimination, based on allergy testing. Patients undergo PST and/or APT to identify food triggers and eliminate them from the diet. Eventual food reintroduction is then utilized to identify causative foods. Investigators reported histologic resolution of EE in more than 75% of children after removal of food antigens identified by PST and APT.[9]

Other researchers retrospectively compared use of an elemental diet, the SFED, and targeted food elimination, based on PST and APT, in pediatric EE treatment.[10] Histologic remission was observed in 96% of patients receiving an elemental diet, compared with 81% remission in SFED recipients and 65% in targeted diet recipients. The researchers concluded that low negative predictive values of PST did not support their use in EE dietary planning.

Pharmacotherapy. Pharmacotherapy of EE usually consists of PPIs and topical swallowed corticosteroids (Table 3).[2,3] Proton-pump inhibitors are used for acid suppression, although EE is resistant

TABLE 3 Pharmacotherapy of eosinophilic esophagitis

PPIs[a]	Young children: • Omeprazole 1 mg/kg twice daily Adolescents and adults: • Omeprazole 20 mg twice daily • Lansoprazole 30 mg twice daily • Esomeprazole 40 mg twice daily • Pantoprazole 40 mg twice daily • Rabeprazole 20 mg twice daily
Topical swallowed corticosteroids[b]	Fluticasone (puffed and swallowed via MDI): • Children: 88-440 µg 2-4 times daily (to maximum adult dose) • Adults: 440-880 µg twice daily Oral viscous budesonide[c]: • Children <10 years: 1 mg daily • Older children and adults: 2 mg daily
Systemic corticosteroids	Prednisone: 1-2 mg/kg/d

[a]Failure to respond to 6-8 week course of PPI therapy is a diagnostic criterion for EE. PPI monotherapy is not recommended for patients with EE.
[b]Do not eat or drink for 30 min afterward; do not rinse mouth.
[c]Mix budesonide inhalation suspension (Pulmicort Respules) 0.5 mg/2 mL with 5 packets sucralose (Splenda).
Abbreviations: EE, eosinophilic esophagitis; MDI, metered-dose inhaler; PPI, proton-pump inhibitor.
From Furuta GT, et al[2]; Liacouras CA, et al.[3]

to PPI therapy. Oral corticosteroids are effective, but prolonged use is associated with systemic adverse effects. Systemic corticosteroids are reserved for severe cases of EE in which patients require hospital admission for severe dysphagia or weight loss.[3]

Topical delivery of corticosteroids directly to the esophageal mucosa was first proposed by researchers in 1998.[13] This involved swallowing, rather than inhaling, aerosolized corticosteroid preparations used for asthma treatment. Patients were advised to spray the medication directly into the mouth, swallow without rinsing, and to avoid intake of food or drink for at least 30 minutes afterward. Topical swallowed corticosteroids are now considered first-line agents for EE, although these drugs are not FDA approved for this use and there are few randomized, controlled trials of their efficacy.

Use of topical swallowed corticosteroids is preferred over oral corticosteroids because adverse effects are lessened and medications are delivered directly to the inflamed esophageal mucosa. Reduction in clinical symptoms and decreases in esophageal eosinophilia are seen. Topical corticosteroids are safe and effective, but only for as long as the duration of treatment, which is generally 6 to 8 weeks. Few adverse effects are seen but treatment may be complicated by dysphonia, oral thrush (in 20% of children), herpes, and *Candida* esophagitis. Other adverse effects of long-term topical corticosteroid use include reduction in growth velocity, cataracts, and adrenal suppression.[2,3] There are no studies of maintenance therapy in pediatric EE.

Three corticosteroid preparations have been studied in EE therapy: fluticasone propionate, budesonide, and ciclesonide. In 2002, investigators treated a small group of children with swallowed fluticasone propionate and found a significant reduction in esophageal eosinophilia and clinical symptoms after a 2-month course of treatment.[14] Topical corticosteroid therapy was more effective than dietary restriction of food allergens identified by PST or radioallergosorbent test.[2] A subsequent double-blind, placebo-controlled trial of swallowed fluticasone propionate for pediatric EE found that half of children treated with swallowed fluticasone achieved histologic remission compared with 9% of placebo recipients.[15]

To increase palatability, improve coating of the esophagus, and overcome swallowing difficulties that may occur in young or developmentally delayed children, researchers formulated a slurry of oral viscous budesonide.[16] Budesonide, another asthma medication usually administered via nebulizer, was mixed with sucralose to form a viscous liquid to be administered once daily. In 2010, a randomized, double-blind, placebo-controlled trial of oral viscous budesonide demonstrated histologic remission and clinical improvement in the majority of pediatric EE patients studied.[7]

A third topical corticosteroid, ciclesonide, was used successfully for treatment in a group of children with EE that had proved refractory to topical fluticasone propionate and dietary modification.[17]

Medications that have no proven utility in the treating EE include leukotriene receptor antagonists,

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mast cell stabilizers, and immunosuppressive medications.[3,6] Biologic agents such as anti-interleukin-5 (mepolizumab and reslizumab) have been studied but clinical improvement did not accompany histologic improvement.[6] Omalizumab and anti-tumor necrosis factor (TNF) agents have no efficacy in EE treatment.[3] Therapies in development for EE include antagonists to interleukin-13, eotaxin-3, and CRTH2, a prostaglandin D2 receptor.[18]

Other treatment. Esophageal dilation has been recommended in cases of dysphagia caused by esophageal narrowing or strictures. This may be complicated, however, by chest pain, esophageal tears, and perforation.[3,6,8]

Natural history

Although there are few longitudinal studies reporting outcomes, EE appears to be a chronic disease with long-term persistence of esophageal inflammation from childhood into adulthood.[10,19] Disease evolution is related to esophageal remodeling.[6]

Children with EE should be followed regularly by a pediatric gastroenterologist and/or allergist. Periodic endoscopy is usually recommended to monitor disease status because noninvasive biomarkers have not been identified. Clinical and histologic response to therapy and growth parameters should be closely followed.

Conclusion

Eosinophilic esophagitis is an increasingly recognized condition in children and adults that may present with symptoms suggestive of GERD that do not respond to acid suppression. Isolated esophageal eosinophilia is seen on biopsy. Treatment focuses on dietary modification and topical corticosteroids. Complications include strictures and small-caliber esophagus, leading to dysphagia and/or food impaction. Future studies are needed to better define the natural history of EE and to identify effective therapies for children and adults alike.

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BY MARIAN FREEDMAN; COMMENTARY BY MICHAEL G BURKE, MD

Driving distractions especially risky for teens with ADHD

An investigation of the combined risks of adolescence, attention-deficit/hyperactivity disorder (ADHD), and driving while engaged in texting or cell phone conversation found that while distractions significantly impair the driving performance of all adolescents, the negative effects of texting are especially prominent in those youngsters with ADHD.

The study was conducted in 61 adolescents aged 16 and 17 years—28 with ADHD and 33 controls. Each participant engaged in a 40-minute simulated drive. During the first 10 minutes, participants familiarized themselves with the simulator. The remaining 30 minutes were divided into 3 separate, 10-minute periods. During 1 of these periods the participant was not subject to any distraction while in the other 2, he or she received a phone call or text message that necessitated a response. During the course of each period, a car suddenly merged into the driver's lane or a pedestrian unexpectedly crossed the street in front of the participant's vehicle. Investigators examined participants' braking, swerving, and related responses to these unanticipated events and sampled their driving speed and position in relation to adjacent road lanes and traffic (lateral position) during the entire drive.

Compared with controls, teenagers with ADHD showed more variability overall in speed and lateral position. Average speed or braking response time did not vary between the 2 groups, however. Cell phone distraction had large effects in both groups on average speed, speed variability, and variability in lateral position, although all participants showed less variability in lateral position during conversation than when they were not subject to distractions.

During texting—the most impairing distraction—both groups drove more slowly and evidenced more speed and lateral position variability than when they were not distracted. Lateral position variability was more pronounced in participants with ADHD. They were outside their lanes for 3.3% of the drive during texting compared with 2.0% of the time for controls. Investigators therefore concluded that texting incrementally increases driving risk for adolescents with ADHD, adding to their existing ADHD-related driving impairments (Narad M, et al. *JAMA Pediatr.* 2013;167[10]:933-938).

COMMENTARY

In an accompanying editorial, F. K. Winston and colleagues endorse the practice of graduated driver licensing, a program adopted by many states that restricts new drivers to low-risk driving situations, progressively allowing them exposure to higher-risk situations with increased driving experience (*JAMA Pediatr.* 2013;167[10]:892-894). There is some evidence that this approach decreases teenaged fatalities in the first 6 months of driving. If becoming a safe driver is a developmental milestone, we must recognize that not every adolescent will meet that milestone at the same age. Parents of drivers in this study may recognize this, given that the drivers with ADHD had about 4 fewer months of driving experience than the controls. Maybe the parents of teenagers with ADHD dragged their feet in getting to the Department of Motor Vehicles, a delay that recognizes that not every child is ready to drive on his or her 16th birthday. **—Michael Burke, MD**

PASSIVE SMOKING INCREASES CHILDREN'S PAIN DURING MEDICAL PROCEDURES

A new study demonstrates that passive exposure to cigarette smoke increases how much pain children

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perceive during an invasive medical procedure. Investigators conducted the study in 100 children who underwent venous catheterization at a clinic in Turkey. Fifty of the children (mean age, 7.3 years) had been exposed to passive smoking and 50 (mean age, 7.7 years) had not. The fathers of the passive-smoking group all smoked in the child's house, as did 2 of the mothers.

During peripheral venous catheterization, the children's facial expressions were photographed as the needle was inserted. Investigators then evaluated these photographs using the Wong-Baker faces pain rating scale. The evaluation showed that children who were passively exposed to smoke perceived significantly more pain during the procedure than those who had not been exposed. Neither age nor gender significantly affected pain perception (Topaloglu N, et al. *Acta Paediatr.* 2013;102[11]:e493-e496).

COMMENTARY

If this is a cause-and-effect relationship, I wonder what the cause is and what made these researchers and others think of this idea. Perhaps nicotine, as a stimulant, acts to promote anxiety and a more acute response to the painful stimulus. In any case, here's one more reason for parents and guardians to protect their children from smoke. **—Michael Burke, MD**

ENCOURAGING TREND SEEN IN ADOLESCENTS' OBESITY-RELATED BEHAVIORS

Efforts to increase the time adolescents spend in physical activity and reduce the time they spend watching television seem to be paying off, according to analysis of data from 3 quadrennial surveys of students in grades 6 to 10. Using results of Health Behavior in School-aged Children surveys, investigators collected self-reported information on time spent in physical activity, watching television, playing video games, computer use, dietary intake, and weight status during 2001 to 2002 (14,818 students), 2005 to 2006 (9,227 students), and 2009 to 2010 (10,993 students).

Investigators identified significant increases overall in the number of days on which teenagers engaged in at least 60 minutes of physical activity and consumed fruits and vegetables. They also identified decreases in television viewing and consumption of sweets and sweetened beverages over the time period. Yet the average body mass index (BMI) percentile of the adolescents increased over time, particularly from 2001 to 2002 and from 2005 to 2006. The same patterns were observed in all racial and ethnic groups.

Overall, compared with younger adolescents, older teenagers engaged in more obesity-related behaviors, which included less physical activity; more computer use; eating fruits, vegetables, and weekday breakfasts less often; and consuming sweets and sweetened soft drinks more frequently. So investigators were not surprised to find that BMI percentiles were higher in older than in younger teenagers (Iannotti RJ, et al. *Pediatrics.* 2013;132[4]:606-614).

COMMENTARY

This report provides some good news! We still have a long way to go, but the huge cruise ship of the obesity epidemic might be beginning to turn. Perhaps the efforts of pediatricians, public health officials, nutritionists, educators, and parents are paying off. Take a minute to pat yourself on the back, and then get back to your continued efforts to change this threat to our patients' health. **—Michael Burke, MD**

Also of Note

Does vitamin D reduce acute otitis episodes in children who are prone to them? A study in 116 children with a history of recurrent acute otitis media (AOM) found that receiving oral vitamin D (1,000 IU/d) for 4 months did indeed significantly reduce the risk of developing uncomplicated AOM during this period compared with receiving placebo. However, the supplementation did not reduce the likelihood of spontaneous otorrhea (Marchisio P, et al. *Pediatr Infect Dis J.* 2013;32[10]:1055-1060).

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‡ Less than 2 years old.
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References: 1. Kelley MT, Walson PD, Edge JH, Cox S, Mortensen ME. Pharmacokinetics and pharmacodynamics of ibuprofen isomers and acetaminophen in febrile children. *Clin Pharmacol Ther.* 1992;52(2):181-189. **2.** Ashraf E, Ford L, Geetha R, Cooper S. Safety profile of ibuprofen suspension in young children. *Inflammopharmacology.* 1999;7(3):219-225.

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OUR 1ST ISSUES & ATTITUDES SURVEY

5 WAYS YOUR PRACTICE WILL CHANGE

& THE ONE WAY IT WON'T

TERESA A MCNULTY

Buffeted by a perfect storm of regulatory, fiscal, and technology factors, many pediatricians are voting with their feet.

In *Contemporary Pediatrics*' first annual Issues and Attitudes Survey, we asked you to candidly speak your mind—and you did so in spades. From the tighter pinch of reimbursement, to the sustained stressor of the unknowns surrounding the rollout of the Affordable Care Act (ACA), what emerged is a picture of dedicated practitioners stretched thin—and making some changes as a result.

What we did

The nearly 50-question confidential survey was fielded from November 7 through November 19, 2013, to a population of over 32,000 US-based pediatricians.

Who responded

Over 68% of the respondents were office-based pediatricians in private practice. The remaining approximately 30% were divided fairly evenly among pediatricians in hospital, academia, and "other" work settings. Slightly over half serve suburban communities,

63%

OF YOU SAY STRESS HAS INCREASED IN THE PAST YEAR

with 33% and 16% serving urban and rural communities, respectively. Participants were skewed slightly female by 9%, and had an average age of 52 years with an average of 17 years in practice. Eighty-eight percent indicated general pediatrics as their specialty, with adolescent medicine, neonatal-perinatal, family practice, pediatric allergy and immunology, and other specialties rounding out the remainder.

What we found

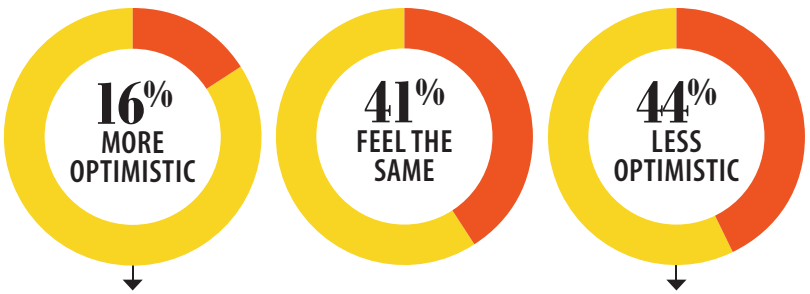
The very factors that caused you to pick pediatrics in the first place are being eroded by a perfect storm of regulatory, fiscal, and technology factors.

While "average salary earned by attending physicians in the specialty" ranked only an average of 2.3 on a scale of 1 to 5 in importance among the factors that survey respondents considered in selecting pediatrics as a specialty, survey comments reflect that pediatricians' even modest payment expectations are being challenged by a chaotic "new normal."

"Compensation has not increased for over 10 years," noted one commenter. Another concurs: "My income has consistently gone down, although my work load has gone up." Yet another elaborates that the problem is not the stagnant or shrinking compensation alone, but that factor in combination with burgeoning service expectations: "Pediatrics remains one of the lowest compensated specialties despite increasing demands to handle increasingly complex patients."

Many participants voiced the particular plight of the private practitioner caught between bureaucracies: "We need better reimbursement and less red tape from insurance companies and the government." Another lamented: "I have become disillusioned with medicine. Our leaders have compromised themselves to the politics of medicine instead of fighting for what is right for the patients and their families." Overall, 42%

Are you feeling more or less optimistic about your ability to adequately provide care for your patients in 2014 than last year?

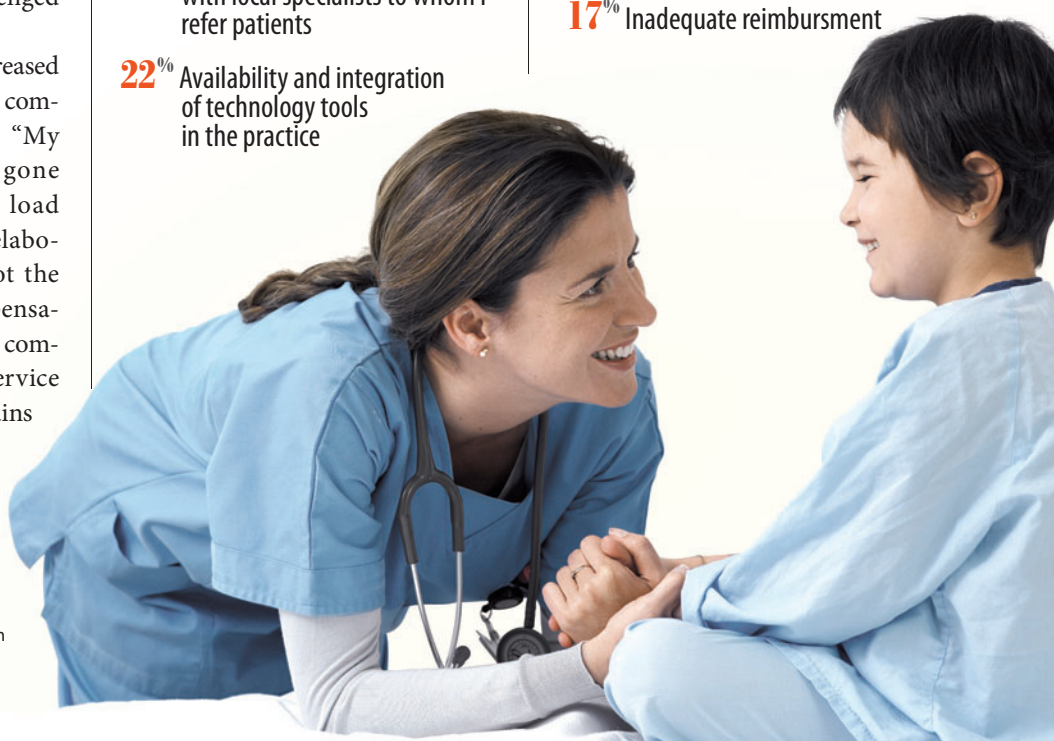


TOP 3 REASONS YOU ARE MORE OPTIMISTIC

- 37% Health care reform
- 23% I have good working relationships with local specialists to whom I refer patients
- 22% Availability and integration of technology tools in the practice

TOP 3 REASONS YOU ARE LESS OPTIMISTIC

- 39% Health care reform
- 24% Not enough time with patients
- 17% Inadequate reimbursment



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of those responding characterized their current satisfaction with their job situation as either "very" or "somewhat dissatisfied." Only 14% expressed extreme satisfaction.

the lowest ranked, lowest paid, and have the least respect of any of the medical specialties," one commenter summarized.

Yet others think that the

YOUR THOUGHTS

> *"Medicine undervalues what pediatricians do."*

The whimper of our discontent

The hydra of unhappiness has many heads. One oft-repeated sentiment expresses a generalized feeling of powerlessness against the forces most impacting pediatricians' daily lives. "Over the last 20 years, physicians have given up more and more control," wrote one pediatrician. "Quality care is falling tremendously due to all the extrinsic factors; I see nobody really pushing to support care of children by giving real value to pediatrics," stated another. Still another put it this way: "I feel care [is being] dictated without practical considerations in mind." Others voiced frustration at their sense that pediatrics is becoming the Rodney Dangerfield of medical disciplines: "Pediatricians are

27%

OF YOU ARE CONSIDERING A JOB CHANGE IN 2014

encroachment of physician extenders is one element of the "dissing" of the discipline: "More needs to be done to protect the work that pediatricians do. It seems everyone feels [nurse practitioners] can do our job." Still others worry not just about the pediatrician's lot, but, characteristically, about how their young patients will fare in the hands of others: "We continue to see increases in unqualified Minute Clinics attempting to care for children and leaving the mess for us to clear up. Little [has been done] to lobby for quality of care for pediatric patients."

1 You'll consider going part time or becoming an employee

A REACTION FOR EVERY ACTION ISN'T MERE PHYSICS

Perhaps the most dramatic response to the increased pressure has been the number of pediatricians who have elected to reduce hours to counter the stress—or who are considering doing so.

In this year alone, 13% of survey respondents elected to go from working full time (defined as 40 or more hours per week) to part-time status; another 14% say they are considering that move in 2014. The most often-cited reason for the move to part time was an effort to seek a "better life-work balance" (47%). This squares with the ranking in importance that participants gave to the 21 factors that they considered when choosing pediatrics as a specialty in the first place: "Having a balance between work life and personal life" clocked in as the fourth highest factor cited of the 21, behind only job satisfaction, having an enjoyable workday, and the collegiality of coworkers.

13%

OF YOU WENT PART TIME IN 2013

AND

14%

OF YOU MAY IN 2014

Interestingly, despite some expressions of an insufficient appreciation of the profession by the world at large ("[There is] not enough being done to educate the public about the value of pediatricians"), "perceived prestige of the field" was still held as a minor

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1. Savino F et al. *Pediatrics*. 2010;126:e526-e533.
2. Savino F et al. *Pediatrics*. 2007;119:e124-e130.
3. Szajewska H et al. *J Pediatr*. 2013;162:257-262.

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value overall, coming in as the third-lowest-ranked of the 21 factors that drove the election of pediatrics as a calling.

A different but related reaction to the heaving health care landscape is to depart the entrepreneurial arena—and you and your colleagues are mulling it over. When asked if they were considering leaving their own private practice to become an employee of a hospital or other organization in the next 12 months, 11% of those surveyed responded in the affirmative. Forty-eight percent of those answering yes specifically selected "current health care environment not conducive to entrepreneurs" as their reason. The recurring theme of "better work-life balance" was cited as the basis for 22%, and for 8% of respondents, the departure was being considered in a bid to reduce workweek hours to part time. Only 6% stated that the consideration was being made in order to seek a "better professional opportunity."

Even for the minority of those who responded that they felt more optimistic about their ability to adequately provide care for their patients in 2014 than in the current year, only 22% attributed that optimism to the "availability and integration of technology tools in the practice." Even fewer (8%) specifically credited their glass-half-full spirit to the implementation of an electronic health record (EHR) in the practice. In fact, 43% called out "ineffective or burdensome technology" as a key reason why their stress level at work had *increased* within the past 12 months. Only 18% said that the

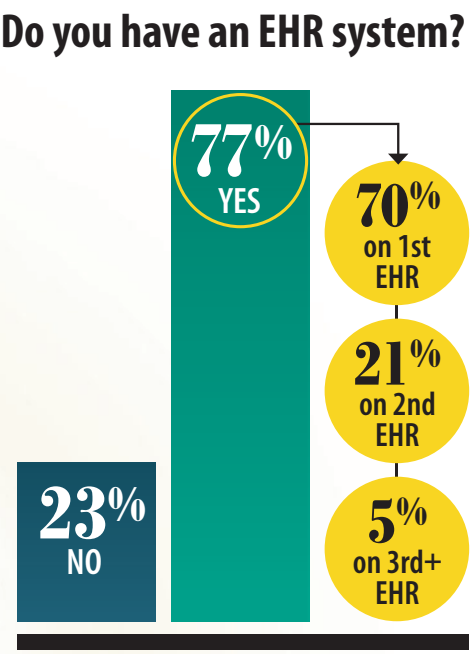
YOUR THOUGHTS

> *"EHRs are the work of the devil. Make them communicate with each other & make them efficient!"*

2 You're likely getting an EHR—or replacing one

THE DOUBLE-EDGED TECH SWORD

Repeatedly, the survey revealed technology to be both a boon and a bogeyman. Its value corresponded to the degree to which it had been effectively and efficiently integrated into the daily workflow and the perceived efficiency it brought to practice processes.



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addition of technology support had improved their lot by diminishing their stress level in their workplace.

THE EHR DO-OVER

Some of the disgruntlement may be in reaction to the *Groundhog Day*-like experience many practices are reliving in the implementation of version 2.0 of their EHR systems—having to repeat the downtime and staff training investments necessary to migrate to a new system when the first was found wanting either in functionality, realized workflow efficiencies, or both.

59%

OF YOU THINK 2014'S BIGGEST CHALLENGE WILL BE HEALTH CARE REFORM MANDATES

"No voice can be heard about the problems with EHRs," stated one respondent. Lack of systems' seamless data exchange was the locus of this commenter's 3-exclamation-marked irritation: "EHRs are the work of the devil . . . . Make them communicate with each other and make them efficient. Mandate this!!!" Still another laid the dearth of discipline-specific EHRs directly at the feet of his professional pediatric society for "not having an EHR for all pediatricians."

Whether the responsibility for the technology glitches lies with the dark deity or one of the pediatric fraternities, the impact—and often the churning—of EHR systems was evident in our survey findings. Of the 77% of practices that currently have an EHR system in place, 21% are on their second system, with 5% on their third or more. For some, the EHR challenge is in future tense; as late as the Q4 2013 fielding of the survey, nearly a quarter of respondents stated that their practice still had no EHR system in place at all, despite dangled federal carrots and impending sticks.

3 Your administrative paperwork burden will (continue to) burgeon—despite #2

THE PAPERLESS PRACTICE MYTH

The contradiction of the growing demands of administrative tasks on their workday despite technology's ubiquity was not lost on those responding to the survey. "Bureaucracy and paperwork are increasing," states one commenter flatly. Another added to the paper-chased chorus: "Little has been done to help the average office-based pediatrician to survive and prosper in this era of lower reimbursement, increasing administrative work, and third-party oversight."

THE 6 STRUGGLES

1. Dealing with insurance companies
2. EHR implementation
3. Maintaining work/life balance
4. Not enough time with patients
5. Compensation
6. Maintenance of Certification requirements

In fact, increased administrative work outstripped any other single factor as adding to pediatricians' stress levels, cited as the penultimate pain point by 61% of survey respondents. The related nettle of "inefficient workflow processes" also ranked a formidable 38% as a workplace-stress contributor.

Exacerbating the problem is the sense that the administrative onslaught is coming from all sides. As one survey respondent put it: "I can't write how I feel about the red tape nonsense . . . red tape from insurance companies, red tape from my academy, red tape from admin, etc. . . . Who is fighting for us while we are swamped in the trenches?"

YOUR THOUGHTS

"Even family practice doctors are getting paid more."

Another echoed: "We need less red tape and better reimbursement from insurance companies and the government!"

4 You'll wrestle with MOC

WHOSE SIDE ARE YOU ON ANYWAY?

One development that doesn't appear to be sitting well with those already chafing at mounting paperwork and administrative demands on their time is the Maintenance of Certification (MOC) requirement being implemented by the American Board of Pediatrics (ABP). Twenty-one percent of survey respondents chose MOC requirements as one of the top challenges to their effective practice as a pediatrician in 2013.

As one pediatrician summarized: "The requirements are becoming more stringent for obtaining MOC credit, especially for Part 4, and for many pediatricians, the current options for Part 4 MOC credit are: 1) expensive; 2) time consuming—need to be performed outside patient care hours; and 3) not easily applicable to practice, or at least it is hard for them to discern the benefit to their practice."

61%

OF YOU SAY YOUR WORKLOAD HAS INCREASED IN THE PAST YEAR

It seems clear that, for some, the MOC requirements hit at a cherished value that initially spurred their selection of pediatrics as a vocation as mentioned earlier: the elusive work-life balance. "Further, adding MOC requirements only increases our stress and makes finding a work-life balance that much harder," wrote one respondent. "I want less administrative nonsense, not more busy work!" exclaimed another. Others were more blunt: "MOC is a complete waste of time"; "the MOC is overwhelming and impractical"; and "don't even get me started on how ridiculous that all is!"

Also evident in the survey comments was a sense of disconnect between the programs' requisite time investment and the perception of its direct benefit to patient outcomes. "[There is] no proof these policies improve care for patients and make me a better physician," one pediatrician held. Another commenter believes that a second look should be taken at the MOC program entirely in light of pediatricians' day-to-day press: "Continued recertification, MOC requirements, and exam-taking, when there is limited time given patient loads, should be reassessed."

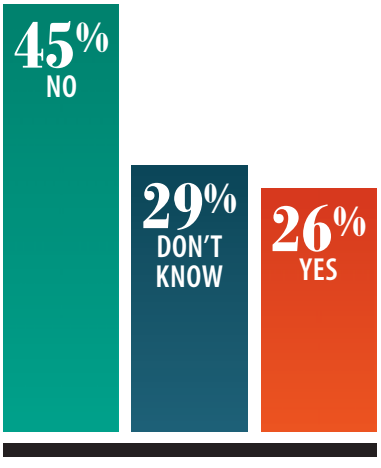
5 You fear you won't be able to provide the same level of care you did in 2013

WHO'LL LOOK OUT FOR THE KIDS?

When asked, 44% of those surveyed admit to being less optimistic about their ability to adequately provide care for their patients in 2014 than this year. Whereas health care reform was given as the primary reason for their darker view (39%), insufficient time with patients (24%) and inadequate reimbursement (17%) were also top mentions.

Still others point to more

Is your practice officially credentialed as a "patient-centered medical home"?



YOUR THOUGHTS ON MOC

"I want to be educated, not mummified in red tape."

YOUR THOUGHTS

> *"ACA shifts more care from pediatricians to midlevels, minute clinics, and rewards 'quick, impersonal care.'"*

subtle corrosions to their ability to sustain care at this year's levels, such as "inadequate community support systems" for their patients and their families (6%), their observation that they are "seeing more children at risk than previously" (5%), and that they believe they are "losing my patients to the popular culture" and "it is increasingly difficult to communicate with the parents of my patients"—both cited by 3% of respondents, respectively.

Success in any language

Despite the gloom, there were some positive signs that emerged from the survey. For example, when asked to characterize the degree to which language and medical literacy stood as barriers to effective patient care, only 14% of respondents perceived these as major impediments growing in severity. Fully 55% saw them as difficult barriers, but ones that were being actively addressed with some success. Others fully scored this in the "win" column, with over 30% of responding practices having "put training and resources in place so that this is no longer a barrier to care."

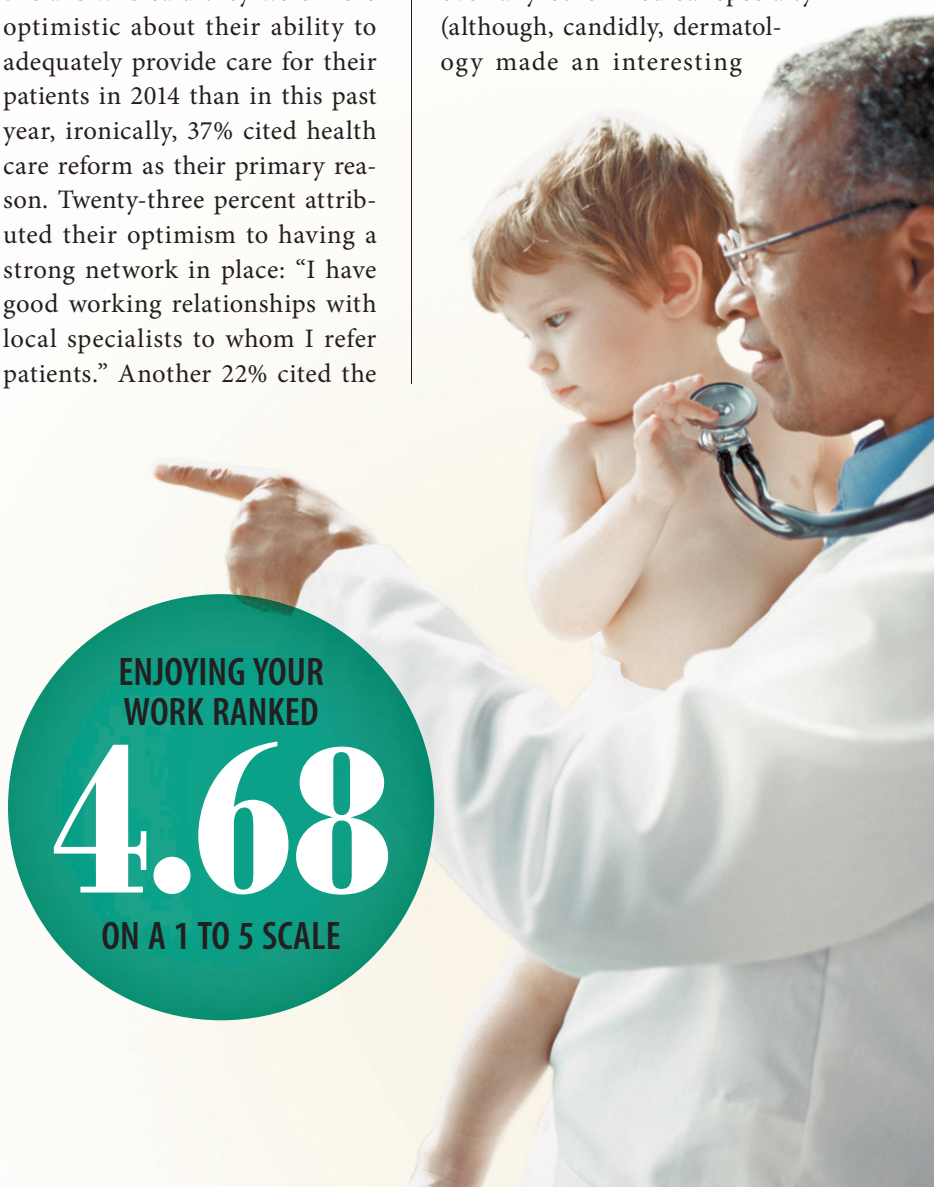
Glass half full

There were additional factors that mitigated some respondents' concerns about the future. Of pediatricians who said they were more optimistic about their ability to adequately provide care for their patients in 2014 than in this past year, ironically, 37% cited health care reform as their primary reason. Twenty-three percent attributed their optimism to having a strong network in place: "I have good working relationships with local specialists to whom I refer patients." Another 22% cited the availability and integration of technology tools in their practices as a basis for their positive view of the year ahead.

And the 1 way it won't!

EXCUSE ME, BUT YOUR LOVE OF KIDS IS SHOWING

The apparent constant in the equation of the year to come is that you'll still want to be caring for kids. Overwhelmingly, the survey shows, despite the year's travails, if you had it to do over again, over 60% of you would still choose to go into pediatrics over any other medical specialty (although, candidly, dermatology made an interesting



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YOUR THOUGHTS

> ***"I see nobody really pushing to support care of children by giving real value to pediatrics."***

showing at 14%!).

In fact, the instances in the survey in which organizations are cited with admiration are invariably mentioned in the context of their efforts or progress toward better care for children. Three percent of respondents point to effective health care education programs in local school districts as a reason to be optimistic about the year ahead, for example. "More local organizations are working hard at . . . improving patient care," commented one respondent. Another gives kudos to his professional society for being "out front on health policy and social issues that affect children." Props go to societies, too, from one commenter who "appreciates political activity for the benefit of children"; from another for recognizing societies for being "good advocates for children, not just the MD"; and from a third who thinks his association is "working hard to ensure the best care for children." Yet one more praises his state medical society for being "exactly what I need for advocacy."

Even the points of dissatisfaction expressed correlate to the degree to which your treasured doctor-patient interactions are being impeded. Twenty-four percent cited "not enough time with my patients" as a primary concern that informed their pessimism about their future ability to serve their young patients as well as they have in the past. Indeed, a full 30% cited this lack of patient face time as among the top challenges they confronted in 2013. Still, in the end, even in the face of the finding that 61% of you who responded to the survey stated that your workload has increased in the past year, on a 1-to-5 scale of the factors upon which you chose the pediatric specialty, "Having a low-stress work day," after all, ranked a paltry 2.

In a recent conversation about the convulsions of health care reform and its particular impact on Medicaid, one 30-year general surgeon acquaintance remarked that, "Pediatricians are the single-most altruistic of any of the medical specialties, bar none." Without a doubt. But, especially given the turmoil of the passing year, it's hard not to *also* think of Winston Churchill's assertion: "We have not journeyed all this way because we are made of sugar candy." CP

60%

OF YOU WOULD STILL CHOOSE PEDIATRICS IF YOU HAD IT TO DO ALL OVER AGAIN

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To add your thoughts about the 2013 Issues and Attitudes Survey, go to ContemporaryPediatrics.com/2013survey

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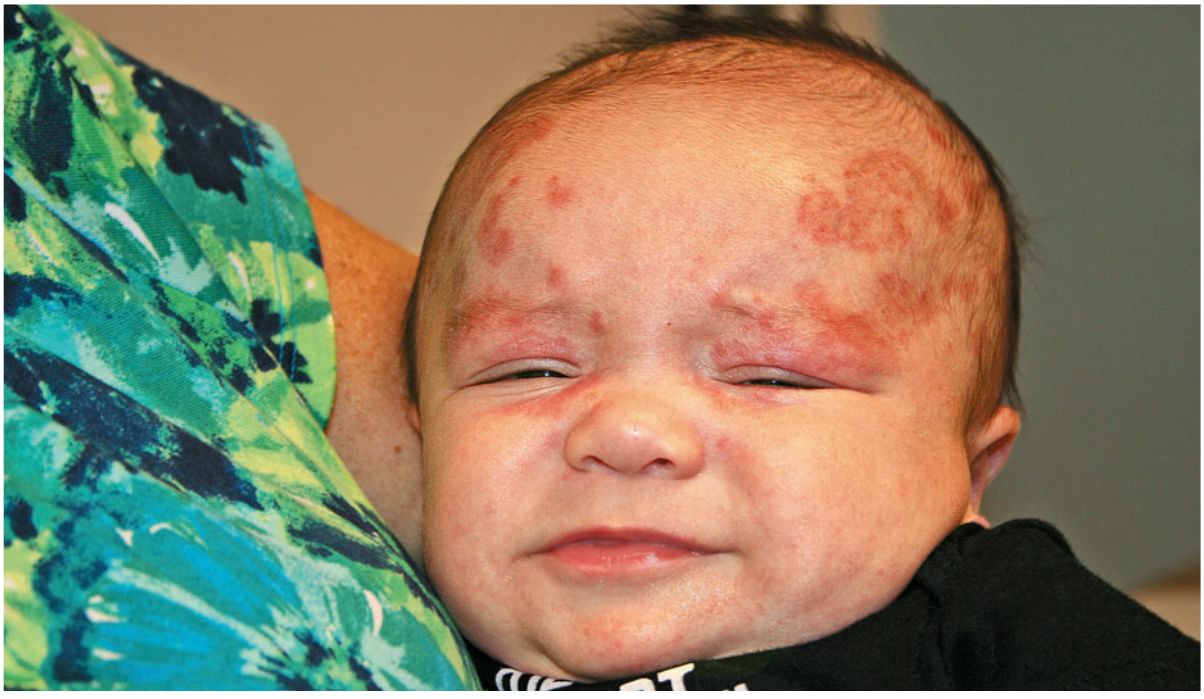

Neonatal rash is much more than skin deep

VANESSA PASCOE, BA, MS4

THE CASE

The frightened mother of a vigorous, healthy 14-day-old girl brings her daughter to you for an urgent consultation regarding a facial rash that has blossomed since a few subtle spots were noted at birth. What's your diagnosis?

FOR DISCUSSION SEE PAGE 36

TELL US ON FACEBOOK

Have you seen a puzzling skin condition in a pediatric patient? How did you arrive at your diagnosis? Share your story with us on Facebook. facebook.com/ContemporaryPediatrics

IMAGE CREDIT / AUTHOR SUPPLIED

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DIAGNOSIS:

Neonatal lupus erythematosus

EPIDEMIOLOGY AND PATHOGENESIS

Neonatal lupus erythematosus (NLE) is an uncommon autoimmune process caused by transplacental passage of maternal antibodies. It occurs in 1 of every 20,000 live births in the United States, with female neonates more affected than males (3:1 ratio).[1] It occurs in 1% to 2% of babies born to mothers with autoimmune disease[2] who possess anti-SSA/Ro, anti-SS/La, and/or anti-U1-ribonucleoprotein (U1-RNP) antibodies. Anti-SSA/Ro is positive in more than 90% of cases.[3]

CLINICAL PRESENTATION

Clinical NLE typically presents with dermatologic and/or cardiac symptoms.

Two-thirds of children with dermatologic manifestations have lesions present at birth, and the remainder develop lesions within 2 to 3 months postnatally.[4] The cutaneous eruption develops as annular erythematous plaques or arcuate macules with a slight scale and raised red borders. Atrophy, dyspigmentation, and/or telangiectasias may be present. The rash is photosensitive, may spread dramatically after sun exposure, and is most often located on the face and scalp.[5]

The most common and serious manifestation of NLE is congenital heart block. First detected by fetal ultrasound between 20 and 24 weeks' gestation, NLE is responsible for 85% of all cases of congenital heart block.[3] The incidence of this complication is 1% in mothers positive for anti-SSA/Ro antibodies, but rises to 25% in mothers with these antibodies who have had a previous child with congenital heart block.

Neonatal lupus often leads to transient asymptomatically elevated liver enzymes, which can rarely lead to hepatitis and liver failure. Its most common hematologic manifestation is thrombocytopenia, which may result in clinically apparent petechiae.[6]

DIFFERENTIAL DIAGNOSIS

The differential diagnosis of isolated polycyclic skin lesions in a neonate includes seborrheic dermatitis, tinea corporis, urticaria, and erythema marginatum. The differential diagnosis of isolated annular erythematous lesions includes erythema multiforme, erythema annulare centrifugum, and *Pityrosporum* dermal infection. However, NLE should be considered in any newborn with an annular skin eruption.

PREVENTION AND TREATMENT

Some investigators recommend hydroxychloroquine prophylactically beginning at 6 to 10 weeks' gestation in women who have previously given birth to a child with NLE and cardiac block.[7] However, data is preliminary, and further studies are needed.

The cutaneous rash is self-resolving as maternal antibodies leave the neonatal circulation, with a mean time to resolution of 4 months.[8] It is important to encourage sun protection because the lesions are photosensitive. Some investigators recommend low-potency topical steroids for 2 to 4 weeks.[9] Most cases are nonscarring, although dyspigmentation may persist in darkly pigmented infants for months to years, and telangiectasias may persist indefinitely.[9,10] Fetuses with second-degree heart block may be treated in utero by maternal administration of glucocorticoids, while children with third-degree heart block will likely need pacemaker implantation.[6,11]

PROGNOSIS

Neonatal lupus erythematosus with cardiac involvement is associated with a 20% to 30% mortality in the neonatal period, with children with congenital heart block and concurrent cardiomyopathy experiencing the highest mortality.[6] Fortunately, NLE's dermatologic, hepatic, and hematologic manifestations are rarely associated with permanent sequelae.[6]

Although 50% of mothers are asymptomatic at delivery, they are at risk for developing autoimmune disorders during the subsequent decade, including systemic lupus erythematosus and Sjögren syndrome.[12] CP

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For references, go to ContemporaryPediatrics.com/NLE

Best new tech of 2013

With all the new technology finding its way into the pediatric office this year, what tools most improve the quality of care you provide? *Contemporary Pediatrics'* tech guru presents the best of the best new tech from 2013.

J-Tip Needle-Free Injector: Delivers less painful, subcutaneous injection of lidocaine for intravenous starts.

Another interesting year for pediatric practice has flown by. As of this writing, patients are unable to enroll in the new health care exchanges due to flaws in the web-based registration system. As a consequence, the deadline for implementation of the "individual mandate" has been pushed back to 2014. In the months to come, Congress is expected to negotiate changes to the Affordable Care Act (ACA) or perhaps postpone its implementation. In other words, it's "business as usual" for those that regulate health care.

Meanwhile, pediatricians in the trenches are still providing the best care for children in an increasingly complicated world. Version 2.0 pediatricians will always consider improving their practices by integrating technologies that can facilitate a diagnosis, expedite therapy, or enhance the quality of care provided. This year, I have a bounty of "best" new tech products for your consideration, so let's get started.

Improving anesthesia for IV starts, and a new "Buzzy" device

According to 1 study, 63% of over 1,000 children surveyed said that they fear the needlestick associated with immunizations.[1] Eventually, we all will be immunizing our patients with needle-free, less-pain-producing syringe devices (see "The high-tech practice of the [near] future." *Contemp Pediatr.* 2013;30[8]:46-49). Pediatricians can now use a needle-free syringe system called the **J-Tip Needle-Free Injector** (National Medical Products; Irvine, California) to deliver buffered 1% lidocaine subcutaneously for intravenous (IV) starts.

Buffering lidocaine with sodium bicarbonate (1 ml of 8.4% sodium bicarbonate for every 10 ml of lidocaine) changes the pH of the final solution to 8.0, reducing the sting associated with lidocaine injection.[2,3] Both lidocaine and bicarbonate are inexpensive; a 50-ml vial of either medication costs as little as $5. The J-Tip Needle-Free Injector uses a small, compressed gas cylinder integrated into each disposable syringe. The J-Tip syringe is filled with buffered lidocaine via a standard 3 ml syringe with a Luer adapter. Once the area is prepped, the syringe is pressed against the skin and the device activates. An audible hiss is heard as the buffered saline is injected at high velocity into the subcutaneous tissue, creating a

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dime-sized, pain-free zone through which a needle may be inserted. Although the needle-free injection of lidocaine is not completely painless, it is less painful than lidocaine delivered with a traditional syringe fitted with a small gauge needle.[4]

Children who have sites prepped with EMLA anesthetic cream (lidocaine/prilocaine) must wait a full hour for optimal anesthesia effect, while those using a liposomal lidocaine anesthetic cream (ELA-MAX) must wait a half hour until full anesthesia is achieved. Using the J-Tip Needle-Free Injector, anesthesia is achieved in less than 2 to 3 minutes. The device has also been studied for lumbar punctures in infants and has been shown to be associated with less pain compared with traditional methods of injecting lidocaine prior to the procedure.[5] I can envision that the injection of lidocaine into the subcutaneous tissue surrounding a wart prior to cryotherapy is another potential use. It might also provide a reasonable substitute for children who are needle phobic and insist on the application of EMLA patches before subcutaneous or intramuscular injection of vaccines, although it is not intended for this purpose. The J-Tip injector comes in boxes of 25 that sell for $100.

While we are on the topic of reducing the pain associated with injections, there is now a smaller version of the very popular Buzzy device, the **Mini Buzzy** (MMJ Labs; Atlanta, Georgia), that reduces the pain associated with needlesticks. The Buzzy is a small vibrating plastic device fitted with a cold pack that is positioned "between the brain and the pain"; eg, above the needlestick on the arm. The device saturates sensory nerve endings with cold and vibration, interfering with the transmission of pain. Many patients in my practice request that the Buzzy be used for their immunizations. The Mini-Buzzy costs $39 and is intended for home use by children who receive injections of insulin, growth hormone, or other medications.

Mini Buzzy: Uses vibration and cold to block transmission of pain associated with needlesticks.

Update on needle-free injection for immunizations

I also wanted to make readers of *Contemporary Pediatrics* aware that the US Food and Drug Administration (FDA) has recently issued new guidelines regarding needle-free jet injection systems that will likely delay the widespread adoption of these devices by pediatricians in the United States.[6] Both the **Stratis** system (PharmaJet; Golden, Colorado) and the **ZetaJet** system (Bioject; Lake Forest, California) use spring mechanisms to deliver medication both subcutaneously and intramuscularly. Both companies have successfully marketed their systems overseas and are conducting efficacy studies with vaccines that will hopefully show that comparable antibody levels are achieved by jet injection systems versus traditional needle injections. We will need to wait until these systems have been scrutinized by the FDA before they will be discussed in detail here.

Stratis: Jet injection system delivers medication without a needle.

ZetaJet: Spring mechanism injects medication subcutaneously or intramuscularly.

Obtaining nasal aspirates

If you use traditional rapid immunoassay systems for testing patients for influenza or respiratory syncytial virus (RSV), you are aware that the best samples for testing are nasopharyngeal aspirates, which generally produce more accurate results compared with nasal swabs.[7] To obtain nasopharyngeal specimens, the patient is positioned supine with the neck extended. The provider or nurse squirts 1 to 2 ml of saline into the nasopharynx using a syringe or bulb attached to a lubricated catheter (usually an 8 French feeding tube), and aspirates the irrigation fluid. The fluid is then tested with the rapid test kit for RSV or influenza viruses.

Now we have 2 new ways to obtain nasal aspirate specimens. The **N-Pak Nasopharyngeal Aspiration Kit** (N-Pak; Baxter, Minnesota) offers 2 self-contained, inexpensive nasal aspirate "kits." The $8 bulb aspiration kit consists of a sealed bulb filled with 2 ml of saline. The bulb is attached to the included catheter, lubricated with the provided lubricating gel, and inserted into the nasal passage so a nasal aspirate can be obtained. The $13 kit has an irrigation syringe instead of a bulb. The N-Pak website has explanatory videos demonstrating how to use the kits to obtain optimal specimens.

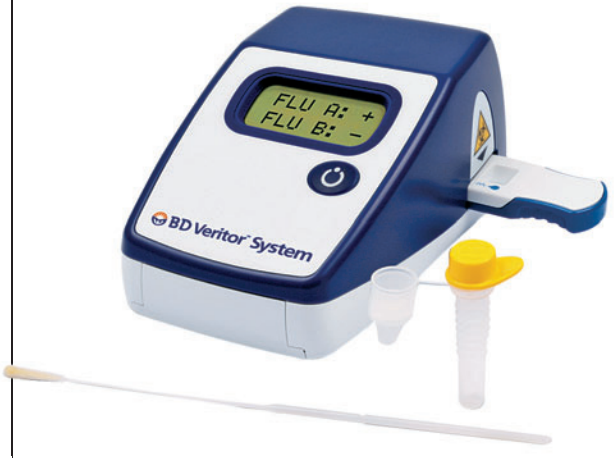
N-Pak Nasopharyngeal Aspiration Kit: Self-contained unit draws samples of nasal aspirate to test for influenza or RSV viruses.

Another device that can simplify the process of obtaining nasopharyngeal aspirates is the **CleaRinse Pro Nasal Irrigation and Aspiration** system (Bionix Medical Technologies; Toledo, Ohio). A disposable wash head is inserted into the device and filled with a supplied ampule of saline. The clinician inserts the device into a nostril, presses the irrigation button, and squirts the fluid into 1 nostril. The device is then placed in the opposite nostril and fluid is aspirated from the nasopharynx. Fluid is extracted from the collection chamber with a pipette and tested. The device is quite affordable at $230, and replacement wash heads sell for $120 for a box of 20 wash heads and saline ampules.

CleaRinse Pro: Uses disposable wash heads with saline to extract nasopharyngeal fluid for testing.

Expanding the high-tech rapid test repertoire

In previous "best tech" articles, I reported on new rapid influenza test systems, the **BD Veritor System**



BD Veritor System: Rapid influenza test system detects viral flu antigens and displays results.

(BD Diagnostics; Franklin Lakes, New Jersey) and the **Sofia Influenza A+B FIA** system (Quidel Corporation; San Diego, California). Both systems use sophisticated technologies to detect viral antigens and feature cartridge readers that visually display results on a liquid crystal display (LCD). Previously, these manufacturers introduced tests for influenza A and B for use with their respective devices. Both tests reported sensitivities for detecting influenza virus exceeding 90%—much higher than the 70% (or less) sensitivity of traditional rapid influenza kits. Both systems achieve improved accuracy over previous methods by improving the technology of antigen detection and automating the test procedure and interpretation.

Here is the exciting news! Both companies have been marketing rapid strep and RSV tests overseas for some time, and now are seeking regulatory approval to release these test kits in the United States. Both companies are supplying data to the FDA so they can sell these tests as CLIA waived. Quidel is also applying for CLIA-waived status for a Sofia hCG test. Both devices bring office diagnostics to a new level of accuracy. I would not be surprised if these new high-tech strep tests will yield results comparable to culture or polymerase chain reaction (PCR) tests. These assays may prove useful when a provider attempts to obtain a throat swab in an uncooperative child and the quantity of antigen on the swab may not be optimal. They may also be helpful when a child with an early strep infection has only a limited quantity of strep bacteria in the pharynx that can be captured on a swab. In these situations, rapid tests when performed by traditional methods may be negative. Watch this space for future updates.

Faster nebulizers for patients with cystic fibrosis and asthma

Pediatricians have long been familiar with the nebulizers and compressors manufactured and distributed by PARI Respiratory Equipment Inc (Midlothian, Virginia). The company is famous for its Bubble the Fish II Pediatric Aerosol Mask that improves medication compliance among our young asthmatic patients. This year, PARI has introduced its new **eRapid Nebulizer System** for treating patients with cystic fibrosis. The system is noiseless and delivers medications 50% faster than most traditional jet nebulizer systems. It uses a vibrating mesh to achieve drug delivery, and it can be powered either via batteries or AC wall power. It is expensive ($860) compared with standard jet nebulizer systems that usually sell for less than $100.

eRapid Nebulizer System: Vibrating mesh delivers medication 50% faster to cystic fibrosis patients.

Pediatricians should remember that PARI also sells a **Sprint Reusable Nebulizer** (approximately $20) for use with its **Vios Pediatric Aerosol Delivery System** (approximately $60). The Sprint Nebulizer reduces drug wastage and speeds treatment of asthmatic patients so that treatment can be completed in just 5 to 6 minutes. Because of these features, the Sprint Nebulizer improves parent and patient compliance. When used in the office to treat patients with asthmatic exacerbations, it improves symptoms faster and enhances workflow.

Sprint Reusable Nebulizer with Vios Pediatric Aerosol Delivery System: Speeds treatment for pediatric patients with asthma to just 5 to 6 minutes.

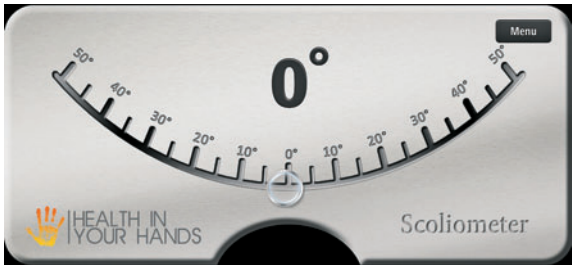
An upgraded point-of-care lipid analyzer

In the Pediatrics V2.0 article "Making a difference: point-of-care screening for hyperlipidemia" (*Contemp Pediatr.* 2013;30[4]:38-41), I described how pediatricians can test children routinely for hyperlipidemia using point-of-care analyzers. There is now an upgrade to one of the systems I described, the CardioChek PA System (Polymer Technology Systems; Indianapolis, Indiana). The new device is the **CardioChek Plus Analyzer,** which features a larger LCD screen, wireless communication, and the capability to perform a simultaneous lipid profile and a glucose electrochemical assay in 2 minutes. The device thus enables total cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides, calculated low-density lipoprotein (LDL) cholesterol, total cholesterol/HDL ratio, LDL/HDL ratio, non-HDL, and glucose results to be delivered simultaneously. The new device sells for $960. The lipid panel and glucose test strips cost about $10 each and need no refrigeration.

More medical apps for this and that

Over the past year, 2 articles in the Pediatrics V2.0 series have discussed smartphone-linked devices and mobile clinical knowledge support systems. Clinicians continue to be innovators and are improving pediatric medicine by providing creative and exciting applications for use with tablet computers and smartphones. Keep in mind that the majority of medical applications are available for iOS devices, with several available for both iOS and Android tablets and smartphones. Very few are available for Windows tablets and Windows smartphones.

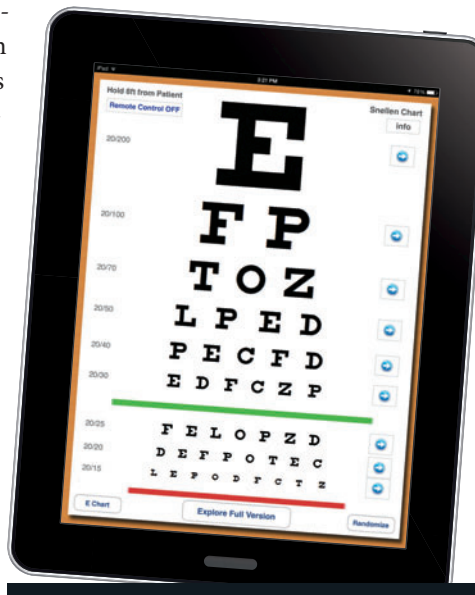
Some of the least expensive and most useful medical applications are the **Scoligauge** ($0.99, iPhone only), the **Scoliometer** ($1.99, iPhone; free, Android), and **Scoliometer HD** ($2.99, iPad) applications. These apps use the accelerometer built into smartphones and tablets to provide a fully functional (and fun to use) smart device scoliometer to screen adolescent patients for significant scoliosis. One simply runs the application and holds the smart device as instructed to measure the scoliometer angle. A scoliometer angle of 5° corresponds to a Cobb angle of 11°, and patients with angles of this magnitude or higher should be referred to an orthopedist for further evaluation. By the way, a recent clinical study demonstrated that the Scoligauge application performed as well as a standard scoliometer in detecting scoliosis in patients.[8]



Scoliometer: Uses smartphone or tablet to screen adolescent patients for scoliosis.

Eye Chart Pro ($19.99, iPad) is another application that many pediatricians would find useful. The application is launched and the iPad held at a distance of 8 feet from the patient. The app is used as a substitute for a standard eye chart to determine a child's visual acuity. A tumbling E chart is included that can be used for screening younger patients. A really neat feature of Eye Chart Pro is that an iPhone can be used as a remote control for changing charts or highlighting lines on the eye chart.

Pediatric hospitalists may find the **Peds PALS Dosage Scanner** ($0.99, iPhone and iPad) extremely helpful in pediatric resuscitations. The application provides the child's weight, pediatric resuscitation doses, defibrillation, and equipment sizes, even if the weight of the child is unknown. One can quickly measure the child using the length of the smartphone or tablet, and then read the resuscitation guidelines from the application. The latest edition even has initial ventilator settings in addition to all current PALS algorithms.



Eye Chart Pro: The iPad app substitutes for the standard eye chart to screen a child's visual acuity.

Skyscape Medical Resources: App for iPhone or iPad puts medical resources on a smartphone or tablet.

Lastly, Skyscape Inc has 2 free iOS applications that will appeal to most pediatricians who want to keep a number of medical resources in hand on their smartphones or tablets. The **Skyscape Medical Resources** app is available for both the iPhone and iPad and provides a free drug database, a comprehensive medical calculator, and a general medical resource, as well as a medical news database. Pediatricians can purchase additional resources such as the *Harriet Lane Handbook*, the American Academy of Pediatrics' *Report of the Committee on Infectious Diseases* (aka the *Redbook*), *Nelson's Pocket Book of Pediatric Antimicrobial Therapy*, *The 5-minute Pediatric Consult*, and dozens of others.

Skyscape has recently released its free, iPad-only medical reference suite, called **Omnio.** The application presents users with an attractive interface to organize and access free and purchased e-books, medical news, clinical trials, drug interactions, and web-based information. I find the interface easy to navigate and the sidebar search feature works very well.

Pediatrics V2.0 continues

I really have enjoyed writing these monthly Pediatric V2.0 articles. A year ago, I set out to make pediatricians aware of ways to improve our practices and integrate new and exciting technologies into our daily routines. There is much more to write about, and I look forward to continuing the series in 2014. See you next year! CP

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NEW PRODUCT CONTACT INFORMATION

J-Tip Needle-Free Injector
National Medical Products
57 Parker
Irvine, CA 92618-1147
Phone: 949.768.1147
www.jtip.com

Mini Buzzy
MMJ Labs LLC
322 Sutherland Place NE
Atlanta, GA 30307
Phone: 877.805.BUZZ
www.buzzy4shots.com

Stratis Needle-Free Injector System
PharmaJet
400 Corporate Circle, Suite N
Golden, CO 80401
Phone: 888.901.0009
www.pharmajet.com

ZetaJet
Bioject Medical Technologies Inc
26212 Dimension Drive,
Suite 260
Lake Forest, CA 92630
Phone: 949.215.2755
www.bioject.com

N-Pak Nasopharyngeal Aspiration Kit
N-Pak, Division of M-Pro LLC
7081 River Vista Ct
Baxter, MN 56425
Phone: 877.627.2554
www.n-pak.com

CleaRinse Pro Nasal Irrigation and Aspiration
Bionix Medical Technologies
5154 Enterprise Boulevard
Toledo, OH 43612
Phone: 800.551.7096
www.bionixmed.com

BD Veritor System
BD Diagnostics
1 Becton Drive
Franklin Lakes, NJ 07417
Phone: 201.847.6800
www.bd.com

Sofia Influenza A+B FIA
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121
Phone: 800.874.1517
www.quidel.com

eRapid Nebulizer System, Sprint Reusable Nebulizer, Vios Pediatric Aerosol Delivery System
PARI Respiratory Equipment Inc
2412 PARI Way
Midlothian, VA 23112
Phone: 800.327.8632
www.pari.com

CardioChek Plus Analyzer
Polymer Technology Systems Inc
7736 Zionsville Road
Indianapolis, IN 46268
Phone: 877.870-5610
www.cardiochek.com

PUZZLER CONTINUED FROM PAGE 12

The child's mother is very worried. She has noticed that the girl is anxious all the time, appears wobbly on her feet, and intermittently has involuntary and uncontrollable jerky movements of her arms. The mother says that her child is "just not herself," and she is most concerned because the child will neither talk nor eat as she did previously.

Review of systems is negative for sore throat, rhinorrhea, diarrhea, or rashes. There is no history of ingestion. There are no known sick contacts. There has been no recent travel, and no stressors or changes have occurred in the family's situation. The child has never before presented with these symptoms.

Physical exam

Physical examination reveals an afebrile, agitated child, with heart rate of 102 beats per minute; respiratory rate, 20 breaths per minute; blood pressure, 119/83 mm Hg; and oxygen saturation, 93% in room air. She moves rigidly and rotates her body only at the trunk, with no fluidity of her arms, legs, or head. She appears stiff in her posture and mechanical in all her movements. She is extremely restless, anxious, and fearful, with her eyes wide open and glossy. Her abdomen is soft, nontender, and nondistended. Her neurologic exam is grossly nonfocal, with 2+ reflexes throughout, intact sensation, and intact strength. Her pupils are equal, round, and reactive to light. Her gait is normal and not ataxic. She intermittently has tremors of her arms that do not subside with touch. She remains primarily mute, but when she does vocalize, she speaks rapidly in a high-pitched voice that is unintelligible.

Laboratory testing

Laboratory studies include a normal comprehensive metabolic panel, creatinine kinase, C-reactive protein, and erythrocyte sedimentation rate. Complete blood count reveals leukocytosis with a neutrophilic predominance and thrombocytosis (white blood cell count of 15.9 x 10^3/uL with 70% neutrophils and platelet count of 732 x 10^3/uL). She has a positive Monospot from the outside hospital. Because of her history of emesis, abdominal pain, and persistently poor oral intake with documented ileus on x-ray at the outside hospital, an abdominal computed tomography (CT) is obtained, which is unremarkable. Because of her tremors and behavioral symptoms, a head CT is obtained, which is also normal.

Connecting the dots

You wonder how to approach this mysteriously affected patient who is so startlingly incapacitated from her baseline. One approach is to methodically evaluate her for each symptom individually, as was done briefly with the abdominal pain and poor oral intake. However, this does not seem to fully capture the child's presentation. Thus, you try to identify the aspects of the child's behavior that are most abnormal and central to her illness, in an attempt to see whether they may be the hallmark of a single diagnosis. You realize that the patient's most concerning findings are actually her behavioral symptoms, so you admit her for further evaluation and management.

You monitor the patient closely during the first day of her admission and note that she remains persistently restless, disoriented, anxious, and paranoid. She absolutely refuses to feed herself. She is unable to sleep for more than an hour at a time without waking in sudden distress. She becomes completely mute. She is noted to be catatonic with a flat affect that lacks any emotional expression. Further history reveals that she also bit her mother early on in the course of her illness, which was extremely atypical and uncharacteristic for her.

The girl's acute onset behavioral changes, restlessness, disorientation, symptoms of catatonia, extreme anxiety, and tremors, with an otherwise nonfocal neurologic exam, preceded by a likely viral illness with fever for 4 days, suggest an encephalitis and lead your team to strongly consider a viral, postinfectious, or autoimmune etiology.

Differential diagnosis

Etiologies to consider (Table) include postinfectious encephalitis, viral encephalitis, and acute disseminated encephalomyelitis (ADEM). Coronavirus, coxsackievirus, cytomegalovirus, Epstein-Barr virus (EBV), herpes simplex virus (HSV), hepatitis A, HIV, influenza, measles, rubella, varicella zoster, West Nile virus, *Borrelia burgdorferi*, *Leptospira*, *Mycoplasma pneumoniae*, *Rickettsia*, and beta-hemolytic streptococci have all been associated with ADEM in the literature.[1-3] Bacterial meningitis seems less likely given that the child does not appear septic and that she is numerous days out from the initial onset of symptoms. Viral meningitis

TABLE Differential diagnosis for encephalitis

Infectious causes of encephalitis/myelitis
Bacterial:
• *Borrelia burgdorferi*
• *Leptospira*
• *Mycoplasma pneumoniae*
• *Rickettsia*
• Beta-hemolytic streptococci
Viral:
• Coronavirus
• Coxsackievirus
• Cytomegalovirus
• Epstein-Barr virus
• Herpes simplex virus
• Hepatitis A
• HIV
• Influenza
• Measles
• Rubella
• Varicella
• West Nile virus
Neurologic
• Transverse myelitis
• Acute disseminated encephalomyelitis (ADEM)
• Postinfectious encephalitis
• Seizures
• Postictal state
Metabolic
Inborn errors of metabolism:
• Amino acidemias
• Organic acidemias
• Mitochondrial pathology
Exogenous
• Ingestion
• Carbon monoxide poisoning
• Cyanide poisoning
• Heavy-metal poisoning
Endocrine
• Hyperthyroidism
• Thyroiditis-associated encephalitis
• Thyrotoxicosis
Autoimmune
• Lupus cerebritis
• Anti-N-methyl-D-aspartate receptor encephalitis
• Antiphospholipid antibody syndrome
• Sjögren syndrome
Major mental illness
• Psychosis

Abbreviation: HIV, human immunodeficiency virus.
From: Bennetto L, et al[1]; Tenembaum S, et al[2]; Kennedy PG[3]; Avner J[4]; Chapman MR, et al.[5]

and transverse myelitis should be considered, although these also seem less likely given that she does not have headache, meningismus, or any sensory or motor loss.

Although the patient's symptoms are persistent and rather atypical for even partial seizures as the primary etiology, seizures or a postictal state are certainly possible as potentially secondary processes.

Metabolic causes must be ruled out, including amino or organic acid disorders and mitochondrial pathology. However, in this patient's case, her age and presentation do suggest another etiology.

Toxic ingestions and exposures, including over-the-counter and prescription drugs as well as carbon monoxide or cyanide poisoning, should be excluded. These do not seem as likely in this patient's case, particularly given that no other family members are presenting with symptoms and there are no reported medications in the home.

Hyperthyroidism should be on the differential for restlessness and increased agitation. Thyroiditis also can be associated with an encephalopathy, although it does not fully explain this patient's paranoia, fear, and catatonic symptoms.

Major mental illness including acute psychosis should remain on the differential as well as autoimmune diseases, including systemic lupus erythematosus cerebritis, antiphospholipid antibody syndrome, Sjögren syndrome, and autoimmune encephalitis.[4,5]

Hospital course

Given the concern for encephalitis, either postinfectious or autoimmune, numerous services are consulted over the course of the patient's hospitalization, including Neurology, Psychiatry, Rheumatology, and Infectious Diseases. Because of the increased sensitivity of magnetic resonance imaging (MRI) and the severity of the patient's condition, a brain MRI is ordered by hospital day 2. It demonstrates nonenhancing T2 hyperintensity of the putamina, caudate, and, to a lesser extent, focal areas of the right hemispheric cortex with sparing of the thalami, brainstem, and limbic system structures. These findings seem consistent with postinfectious encephalitis. A lumbar puncture with sedation is performed on hospital day 3, allowing for more extensive cerebrospinal fluid (CSF) studies. Initial results are reassuring with normal glucose, low protein, and a negative gram stain. Given the low concern for bacterial meningitis, no antibiotics are started

and bacterial cultures return negative within 48 hours.

Intravenous acyclovir is started initially given the inability to rule out HSV encephalitis but is discontinued when the HSV polymerase chain reaction (PCR) returns negative. An electroencephalogram is ordered to evaluate the catatonic spells and rule out a postictal state. It demonstrates mild intermixed slowing consistent with mild global cerebral dysfunction. Further diagnostic workup includes CSF studies negative for EBV and West Nile virus and the absence of oligoclonal bands; negative *Mycoplasma pneumoniae* PCR; and negative serum EBV titers.

While the diagnosis is being worked up, supportive care includes improving sleep, decreasing agitation, ensuring patient safety, and providing adequate nutrition. A mental health counselor is requested to help guide the patient by using behavioral redirection and calming techniques. Physical therapy is involved to help improve the patient's strength and coordination and rehabilitate her back to her baseline function. Enteral feeds via nasogastric tube are initiated by hospital day 3 while occupational therapy continues to help the patient with oral feeds.

Therapeutic interventions for the girl's symptoms are initiated with the help of Psychiatry. Quetiapine and chlorpromazine are administered for her insomnia and catatonia with remarkable improvement. Her parents are happy that their daughter is now at least sleeping for more than a few hours at a time. Benztropine is started for her stiffness and rigidity as well as to limit extrapyramidal adverse effects, again with very good control of symptoms.

A medical conference is held with all consulting services and the primary team. Based on a review of the patient's psychiatric symptoms and behavioral changes, an autoimmune encephalitis, specifically anti-N-methyl-D-aspartate (anti-NMDA) receptor encephalitis, rises to the top of the diagnostic differential. Given this conclusion in the context of a currently negative infectious workup and no other more likely etiology, the decision is made to empirically treat the patient with intravenous immunoglobulin G (IVIG).

Epidemiology

Despite increasing physician awareness, the exact incidence of anti-NMDA receptor encephalitis is unknown. When first described in young women, anti-NMDA receptor encephalitis was thought to be primarily paraneoplastic, because more than half of the women were found to have ovarian teratomas and most women improved rapidly after tumor removal or immunotherapy. Now, it is increasingly diagnosed in children and males, and 40% to 50% of diagnoses have no associated tumor. Studies report a female predominance (at least 80%), with one-fifth of diagnoses made in patients aged younger than 19 years.[6] Nonetheless, case reports demonstrate a variable age range spanning from 20 months to 84 years. Lastly, there may be a higher incidence in Asian and Pacific Islander populations, although ovarian teratomas may be more commonly associated in black women.

Molecular pathogenesis

Anti-NMDA receptor encephalitis is associated with antibodies against the NR1 and NR2 subunits of the glycine and glutamate NMDA receptors and causes a characteristic neuropsychiatric syndrome.[5] Studies suggest that the process of antibody binding leads to depletion of receptors and the clinical features that are classic for anti-NMDA receptor encephalitis.[7,8] Additionally, the high prevalence of prodromal symptoms and often coexisting mycoplasma infection suggest the concomitant activation of an autoimmune cascade.

Anti-NMDA receptor encephalitis is primarily a clinical diagnosis. All patients present with psychiatric symptoms including mood dysregulation, paranoia, hallucinations, mutism, catatonia, and posturing.[8] Other symptoms include seizures, encephalopathy, dyskinesias, autonomic instability, and central hypoventilation. One study is cited for its results demonstrating 100% sensitivity and specificity for anti-NMDA receptor antibody testing.[9,10] However, another study shows that of 5 cases with typical clinical symptoms of anti-NMDA receptor encephalitis, only 3 were positive for anti-NMDA receptor antibody.[11] Furthermore, 3 patients with narcolepsy and severe psychosis were positive for the antibody and 4 patients with schizophrenia and schizoaffective disorders tested positive for anti-NMDA receptor antibody. In seronegative patients, the diagnosis thus may be based upon clinical presentation and response to treatment.

Treatment and management

Administering IVIG often dramatically improves the acute clinical course, allowing a gradual return

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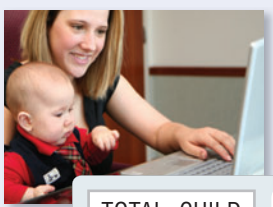

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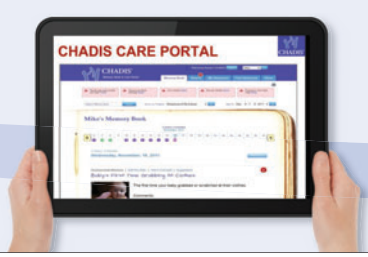

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to baseline function within a few days. Other first-line treatments include steroids or plasma exchange. For patients with minimal improvement using these modalities, immune modulating agents including cyclophosphamide and rituximab may have benefit. Adjunctive medications including antipsychotic agents, anticholinergics, and beta-blockers have been used to minimize the typical presenting symptoms. Supportive care is also critical because these patients tend to require prolonged and extensive hospitalizations for nutritional and respiratory support, as well as physical and mental rehabilitation.[5,7,12]

Back to our patient

Early in the patient's hospital course, nursing staff had noted that she continued to have sporadic episodes of extreme tachycardia and hypertension, initially thought to be secondary to agitation and anxiety. However, further review demonstrated that autonomic dysregulation could be commonly seen in anti-NMDA receptor encephalitis. Propranolol is initiated, with very good efficacy in controlling not only the patient's autonomic dysregulation but also her restlessness and akathisia.

IVIG (1g/kg/dose) is given twice over 2 days (on hospital days 4 and 5) with dramatic improvement in the patient's clinical course. The child still requires supportive medications including benztropine, chlorpromazine, quetiapine, and propranolol, but within 2 days of having completed IVIG therapy, she is already more interactive and responsive, with improved speech and increasing expressiveness. Although she is still easily agitated, overall she appears significantly more rested and calm. Her parents are extremely happy and relieved to see their daughter improving and they are glad to "have her back."

The patient's metabolic workup includes normal CSF amino acids, pyruvate, neopterin profile, folate, and neurotransmitter metabolites; normal serum amino acids, pyruvate, and acylcarnitine profile; and normal urine organic acids, homovanillic acid, and 5-hydroxyindoleacitic acid. Her respiratory viral PCR returns positive for parainfluenza 4, but given her lack of respiratory symptoms, the team believes this is unlikely to be an active contributing infection. She remains on droplet precautions during her hospital stay.

The patient continues to improve her oral intake, and nasogastric feeds are discontinued. She is discharged home on hospital day 8, with propranolol prescribed for akathisia. Pending studies at the time of discharge include a paraneoplastic panel and anti-NMDA antibodies.

Prognosis and follow-up

Most patients respond to immunotherapy and about 50% see clinical improvement within 4 weeks.[12]

Our patient is seen in the neurology clinic 1 month after discharge from the hospital. Her parents report that she has completely recovered, that her behavior is normal, and that she has not had any abnormal tremors, rigidity, or unusual movements. They also report no persistent symptoms of restlessness or rigidity and note that she has not required any propranolol since discharge. She experienced some leg pain after discharge, but this pain, too, completely resolved within 3 months. Of note, the patient's anti-NMDA antibodies and paraneoplastic autoantibody panel ultimately returned negative. CP

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