

CONTEMPORARY Pediatrics

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PUZZLER
CYANOSIS LEAVES
A GIRL TIRED AND BLUE

Expert Clinical Advice for Today's Pediatrician

ContemporaryPediatrics.com

PRACTICAL PEDIATRICS

BEATING KIDS' NO. 1 INFECTIOUS DISEASE

BREAK POINTS

Motivating Teen Smokers to Quit

OUTPATIENT CARE beyond the NICU

Vyvanse® (lisdexamfetamine dimesylate) capsules may be taken whole or opened and mixed in water¹

Vyvanse is a prodrug* that is converted into active *d*-amphetamine in the body¹

Exposure to active *d*-amphetamine is bioequivalent[†] when Vyvanse is taken as a whole capsule or mixed in water²



Recommended Dosing¹:

- 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.

How Vyvanse is converted¹

Administration¹

SWALLOW WHOLE



Capsule can be swallowed whole

MIX IN WATER

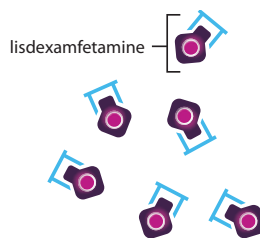
OR



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

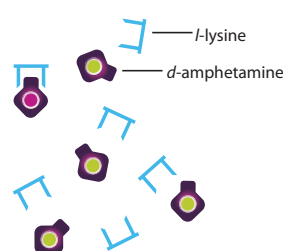
Metabolism^{1,2}

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)

- 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.
- 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 ($\geq 5\%$ 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.



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 overdose. 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

Vyvanse® is a trademark of Shire LLC

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

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S00452



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.

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Stimulant ADHD medications can suppress a child's appetite, leading to weight loss and delayed growth.¹⁻⁴

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Nutrition

PEDIATRICIANS ARE THE GATEKEEPERS OF CHILDREN'S ORAL HEALTH

If you haven't thought about the oral health of your patients, it's time.

At some point in the evolution of caring for people, care for our teeth and gums was separated from care for the rest of the body. As far back as the 5th century BC, both doctors and barbers served as the first early dental providers. As the practice of dentistry advanced with the development of technical devices (such as the bow drill and tooth extractor), the field gradually drifted away from medicine and into its own specialty.

As a consequence, for centuries medical doctors have taken care of people's physical health but have skipped over their teeth and headed straight to the back of the throat. That is largely how I practiced medicine until I learned about how important the teeth and gums are to our overall health. I then began to realize that if I examined the *entire* mouth, many of my patients had cavities more than any other problem—even more than obesity or asthma—and more of my youngest patients were receiving general anesthesia for dental restorations than for any other reason.

Caries is the most common chronic health condition of children—5 times more common than asthma¹—and is largely preventable. Given that all our patients have mouths (and most have teeth, too!), it only makes sense for medical providers to play a part in promoting oral health.

Physicians are now beginning to understand that having *good health* also includes having *good oral health*. The 2011 Institute of Medicine *Advancing Oral Health in America* report, written



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largely by our dental colleagues (but chaired by a pediatrician), asked for our help in promoting oral health.² The researchers emphasized the importance of preventive dental care as a strategy to reduce the incidence of dental conditions that patients, especially the underserved, can't easily get treated once developed—conditions such as cavities and periodontal disease. Even for well-served children, prevention is preferable to “drill and fill.” The report recognized the critical dental workforce shortage and the need to expand the provision of dental services outside the traditional dental office setting.

Pediatricians and other medical providers who care for children are well situated to optimize the oral health of their patients, thereby improving their overall health. Primary care providers are experts at screening for health problems and providing preventive services—that's what we do. We have the advantage of having many opportunities at well-child care and sick visits to get to know our patients and provide them with care. While it is rare for a child not to have ever seen a medical provider, 2008 data show that over 4 million US children have never received dental care, largely because they could not afford it.³

Our patients are best served if we incorporate oral health preventive strategies in our usual care. Patients should learn to expect this from us just as they expect us to provide them with immunizations and other preventive measures.



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Efficacy results at 15 to 18 months of age
after primary 2-dose regimen (n=3,486)^{a,b}

93%
protective efficacy^c
(95% CI, 57%–98%)

After additional follow-up of 2 years and 9 months^d

97%
protective efficacy^c
(95% CI, 72%–99.9%)
in children under 18 months

100%
protective efficacy^c
(95% CI, 24%–100%)
in children over 18 months

^aPedvaxHIB® was initially evaluated in a randomized, double-blind, placebo-controlled study of Native American (Navajo) infants (n=3,486). Each infant in this study received 2 doses of either placebo or lyophilized PedvaxHIB with the first dose administered at a mean of 8 weeks of age and the second administered approximately 2 months later; DTP and OPV were administered concomitantly; ^bProtective efficacy in such high-risk populations would be expected to be predictive of efficacy in other populations. A booster dose of PedvaxHIB is required in infants who complete the primary 2-dose regimen before 12 months of age. This booster dose will help maintain antibody levels during the first 2 years of life when children are at highest risk for invasive Hib disease; ^cEstimated from person-days at risk; ^dSubjects in this portion of the study received 1 to 3 doses of PedvaxHIB; ^eA lyophilized formulation was used in the study. A later study found the antibody response of Liquid PedvaxHIB to be comparable. The antibody responses induced by each formulation of PedvaxHIB were similar.

CI=confidence interval; DTP=diphtheria and tetanus toxoids and pertussis [vaccine]; OPV=oral polio vaccine; Hib=Haemophilus influenzae type b.

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Indication

PedvaxHIB is indicated for routine vaccination against invasive disease caused by *Haemophilus influenzae* type b in infants and children 2 to 71 months of age. PedvaxHIB should not be used in infants <6 weeks of age.

PedvaxHIB will not protect against disease caused by *Haemophilus influenzae* other than type b or against other microorganisms that cause invasive disease such as meningitis or sepsis.

PedvaxHIB IS NOT RECOMMENDED FOR USE IN INFANTS YOUNGER THAN 6 WEEKS OF AGE.

PedvaxHIB is administered in a 2-dose primary regimen before 14 months of age. Infants 2 to 14 months of age should receive a 0.5 mL dose of vaccine, ideally beginning at 2 months of age, followed by a 0.5 mL dose 2 months later (or as soon as possible thereafter). When the primary 2-dose regimen is completed before 12 months of age, a booster dose (0.5 mL) should be administered at 12 to 15 months, but not earlier than 2 months after the second dose.

Reference: 1. Centers for Disease Control and Prevention. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind—United States, 2013. <http://www.cdc.gov/vaccines/schedules/downloads/child/catchup-schedule-pr.pdf>. Accessed February 19, 2013.

Select Safety Information

PedvaxHIB is contraindicated in patients with hypersensitivity to any component of the vaccine. Persons who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine.

Use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions.

The most frequently reported (>1%) adverse reactions, without regard to causality, were fever (≥101°F), irritability, sleepiness, injection-site pain/soreness, injection-site erythema (≤2.5 cm diameter), injection-site swelling/induration (≤2.5 cm diameter), unusual high-pitched crying, prolonged crying (>4 hours), diarrhea, vomiting, crying, pain, otitis media, rash, and upper respiratory infection.

As with any vaccine, vaccination may not result in a protective antibody response in all individuals given the vaccine. As with other vaccines, PedvaxHIB may not induce protective antibody levels immediately following vaccination.

Please see the adjacent Brief Summary of the Prescribing Information.



Liquid PedvaxHIB® (Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate))

INDICATIONS AND USAGE

Liquid PedvaxHIB is indicated for routine vaccination against invasive disease caused by *Haemophilus influenzae* type b in infants and children 2 to 71 months of age.

Liquid PedvaxHIB will not protect against disease caused by *Haemophilus influenzae* other than type b or against other microorganisms that cause invasive disease such as meningitis or sepsis. As with any vaccine, vaccination with Liquid PedvaxHIB may not result in a protective antibody response in all individuals given the vaccine.

BECAUSE OF THE POTENTIAL FOR IMMUNE TOLERANCE, Liquid PedvaxHIB IS NOT RECOMMENDED FOR USE IN INFANTS YOUNGER THAN 6 WEEKS OF AGE. (See PRECAUTIONS in full Prescribing Information.)

Revaccination

Infants completing the primary two-dose regimen before 12 months of age should receive a booster dose (see DOSAGE AND ADMINISTRATION in full Prescribing Information).

CONTRAINDICATIONS

Hypersensitivity to any component of the vaccine or the diluent.

Persons who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine.

PRECAUTIONS

General

As for any vaccine, adequate treatment provisions, including epinephrine, should be available for immediate use should an anaphylactoid reaction occur.

Use caution when vaccinating latex-sensitive individuals since the vial stopper contains dry natural latex rubber that may cause allergic reactions.

Special care should be taken to ensure that the injection does not enter a blood vessel.

It is important to use a separate sterile syringe and needle for each patient to prevent transmission of hepatitis B or other infectious agents from one person to another.

As with other vaccines, Liquid PedvaxHIB may not induce protective antibody levels immediately following vaccination.

As reported with Haemophilus b Polysaccharide Vaccine and another Haemophilus b Conjugate Vaccine, cases of Hib disease may occur in the week after vaccination, prior to the onset of the protective effects of the vaccines.

There is insufficient evidence that Liquid PedvaxHIB given immediately after exposure to natural *Haemophilus influenzae* type b will prevent illness.

The decision to administer or delay vaccination because of current or recent febrile illness depends on the severity of symptoms and on the etiology of the disease. The Advisory Committee on Immunization Practices (ACIP) has recommended that vaccination should be delayed during the course of an acute febrile illness. All vaccines can be administered to persons with minor illnesses such as diarrhea, mild upper-respiratory infection with or without low-grade fever, or other low-grade febrile illness. Persons with moderate or severe febrile illness should be vaccinated as soon as they have recovered from the acute phase of the illness.

If PedvaxHIB is used in persons with malignancies or those receiving immunosuppressive therapy or who are otherwise immunocompromised, the expected immune response may not be obtained.

Instructions to Healthcare Provider

The healthcare provider should determine the current health status and previous vaccination history of the vaccinee.

The healthcare provider should question the patient, parent, or guardian about reactions to a previous dose of PedvaxHIB or other Haemophilus b Conjugate Vaccines.

Information for Patients

The healthcare provider should provide the vaccine information required to be given with each vaccination to the patient, parent, or guardian.

The healthcare provider should inform the patient, parent, or guardian of the benefits and risks associated with vaccination. For risks associated with vaccination, see ADVERSE REACTIONS in full Prescribing Information.

Patients, parents, and guardians should be instructed to report any serious adverse reactions to their healthcare provider who in turn should report such events to the U. S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.

Laboratory Test Interactions

Sensitive tests (e.g., Latex Agglutination Kits) may detect PRP derived from the vaccine in urine of some vaccinees for at least 30 days following vaccination with lyophilized PedvaxHIB; in clinical studies with lyophilized PedvaxHIB, such children demonstrated normal immune response to the vaccine.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Liquid PedvaxHIB has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with PedvaxHIB. Liquid PedvaxHIB is not recommended for use in individuals 6 years of age and older.

Pediatric Use

Safety and effectiveness in infants below the age of 2 months and in children 6 years of age and older have not been established. In addition, Liquid PedvaxHIB should not be used in infants younger than 6 weeks of age because this will lead to a reduced anti-PRP response and may lead to immune tolerance (impaired ability to respond to subsequent exposure to the PRP antigen). Liquid PedvaxHIB is not recommended for use in individuals 6 years of age and older because they are generally not at risk of Hib disease.

Geriatric Use

This vaccine is NOT recommended for use in adult populations.

ADVERSE REACTIONS

Liquid PedvaxHIB

In a multicenter clinical study (n=903) comparing the effects of Liquid PedvaxHIB® (Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)) with those of lyophilized PedvaxHIB, 1,699 doses of Liquid PedvaxHIB were administered to 678 healthy infants 2 to 6 months of age from the general U.S. population. DTP and OPV were administered concomitantly to most subjects. Both formulations of PedvaxHIB were generally well tolerated and no serious vaccine-related adverse reactions were reported.

During a three-day period following primary vaccination with Liquid PedvaxHIB in these infants, the most frequently reported (>1%) adverse reactions, without regard to causality, excluding those shown in the table, in decreasing order of frequency, were: irritability, sleepiness, injection site pain/soreness, injection site erythema (<2.5 cm diameter, see table), injection site swelling/induration (<2.5 cm diameter, see table), unusual high-pitched crying, prolonged crying (>4 hr), diarrhea, vomiting, crying, pain, otitis media, rash, and upper respiratory infection.

Selected objective observations reported by parents over a 48-hour period in these infants following primary vaccination with Liquid PedvaxHIB are summarized in the following table.

Fever or Local Reactions in Subjects First Vaccinated at 2 to 6 Months of Age with Liquid PedvaxHIB®

Reaction	No. of Subjects Evaluated	Post-Dose 1 (hr)			No. of Subjects Evaluated	Post-Dose 2 (hr)			
		6	24	48		6	24	48	
		Percentage					Percentage		
Fever ^b >38.3°C (≥101°F) Rectal	222	18.1	4.4	0.5	206	14.1	9.4	2.8	
Erythema >2.5 cm diameter	674	2.2	1.0	0.5	562	1.6	1.1	0.4	
Swelling >2.5 cm diameter	674	2.5	1.9	0.9	562	0.9	0.9	1.3	

^aDTP and OPV were administered concomitantly to most subjects.

^bFever was also measured by another method or reported as normal for an additional 345 infants after dose 1 and for an additional 249 infants after dose 2; however, these data are not included in this table.

Adverse reactions during a three-day period following administration of the booster dose were generally similar in type and frequency to those seen following primary vaccination.

Lyophilized PedvaxHIB

In The Protective Efficacy Study (see CLINICAL PHARMACOLOGY in full Prescribing Information), 4,459 healthy Navajo infants 6 to 12 weeks of age received lyophilized PedvaxHIB or placebo. Most of these infants received DTP/OPV concomitantly. No differences were seen in the type and frequency of serious health problems expected in this Navajo population or in serious adverse experiences reported among those who received lyophilized PedvaxHIB and those who received placebo, and none was reported to be related to lyophilized PedvaxHIB. Only one serious reaction (tracheitis) was reported as possibly related to lyophilized PedvaxHIB and only one (diarrhea) as possibly related to placebo. Seizures occurred infrequently in both groups (9 occurred in vaccine recipients, 8 of whom also received DTP; 8 occurred in placebo recipients, 7 of whom also received DTP) and were not reported to be related to lyophilized PedvaxHIB.

In early clinical studies involving the administration of 8,086 doses of lyophilized PedvaxHIB alone to 5,027 healthy infants and children 2 months to 71 months of age, lyophilized PedvaxHIB was generally well tolerated. No serious adverse reactions were reported. In a subset of these infants, urticaria was reported in two children, and thrombocytopenia was seen in one child. A cause and effect relationship between these side effects and the vaccination has not been established.

Potential Adverse Reactions

The use of Haemophilus b Polysaccharide Vaccines and another Haemophilus b Conjugate Vaccine has been associated with the following additional adverse effects: early onset Hib disease and Guillain-Barré syndrome. A cause and effect relationship between these side effects and the vaccination was not established.

Post-Marketing Adverse Reactions

The following additional adverse reactions have been reported with the use of the lyophilized and liquid formulations of PedvaxHIB:

Hemic and Lymphatic System

Lymphadenopathy

Hypersensitivity

Rarely, angioedema

Nervous System

Febrile seizures

Skin

Sterile injection site abscess

For more detailed information, please read the full Prescribing Information.

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Strategies could include the delivery of oral health anticipatory guidance and the application of fluoride varnish to high-risk children during a medical visit; co-location of dental hygienists into our practices; or the establishment of real, functional, and operational relationships with our communities' dental providers. Regardless of the strategies employed, primary care providers are perfectly positioned to teach our students, residents, and families that oral health is integral to overall health.


Pioneering oral health promotion programs, such as Into the Mouths of Babes in North Carolina, Access to Baby and Child Dentistry in Washington State, and the Cavity Free at Three program in Colorado, serve as examples of the benefits of oral health interventions. In these states, where efforts and resources have been dedicated to the oral health of their populations, children are benefiting and receiving more dental services from medical providers as well as dental providers.^{4,5} As a consequence, these children are having fewer teeth drilled and filled.⁶ Perhaps the increasing involvement of medical providers in reducing oral health disparities has begun to foster ongoing, collaborative relationships between physicians and our dental colleagues.

As a busy pediatrician myself, I understand the pressures that are placed upon us each day to see more patients and pack more into a visit. When my colleagues ask me how I have time to fit oral health into the spectrum of care I provide, I remind them that we have been providing oral health anticipatory guidance all along. We have long asked what children eat, if they sleep with a bottle, if they brush their teeth. Now, when I ask these questions, I not only provide parents with guidance on how best to provide optimal health for their children but I also include oral health in the discussion. This takes minimally more time.

Assessing a child's risk for dental problems isn't much different from how we assess risk for injuries (eg, Do you use a car seat?) or other preventable problems. I apply fluoride varnish to my patients' teeth depending on their risk for caries. Having streamlined our office processes and procedures and optimized what each member of my health care

team does, the time it takes to apply the fluoride is minimal. Now my patients have come to expect this care from me. They tell me that they don't want their kids to have dental disease and the pain associated with it. They tell me it scares them to have their child go to the operating room to have his or her dental disease repaired. They also tell me that they are embarrassed when their child has a smile filled with bad teeth. It's time we empower our families to expect us to provide them with the best care possible, and that includes attention to their oral health.

If you have already started to incorporate preventive oral health measures into the care you provide to your patients, kudos to you. If you haven't yet but are thinking about it, contact your American Academy of Pediatrics Chapter Oral Health Advocate (<http://www2.aap.org/oralhealth/COHA.html>) who can help you begin. If you haven't thought about the oral health of your patients, now is the time.

Harnessing the collective efforts of the various providers who treat young children is a strategy that has the potential not only to produce favorable oral health outcomes for the children we serve, but also to greatly improve our patients overall health and well-being. 

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Would dental therapists in school-based clinics improve kids' access to primary dental care?

Given the gaps in dental care in this country, particularly in children, some advocates are pushing for the introduction of a midlevel provider called a dental therapist who would do most of the basic work a dentist does.

Less than half of children on Medicaid received a preventive dental visit in 2008, according to a 2012 Mathematica Policy Research report.

Alaska and Minnesota already have dental therapists practicing. Although there are a variety of midlevel provider models that states are investigating, Oregon, Michigan, and Connecticut are considering or authorizing pilot projects; 8 states have pending legislation; and there are expressions of interest in other states, according to Shelly Gehshan, director of children's dental policy at Pew Charitable Trusts, which is a key advocate for the change.

In an extensive overview of the literature last year, the Kellogg Foundation said that dental therapists are now used in 54 countries, including the United Kingdom and Canada, and their use in New Zealand goes back to 1921. They work in school-based programs in most countries, the report said.

"We are right where the country was in the 1960s with the development of nurse practitioners. . . . In 10 or 20 years everybody will have them," states Gehshan. As with medical care in the 1960s, she said, dental care has too few providers, even as more people are getting insurance coverage.

Requirements for supervision of dental therapists by a dentist may vary from state to state, Gehshan says, although Pew does advocate for that supervision. On the other hand, she believes remote supervision has proved safe and effective in Alaska and Minnesota and with computers and phones it will happen elsewhere.

However, many people in dentistry don't agree with the effectiveness or cost-effectiveness of creating a dental therapist profession. Dueling reports have flown back and forth for some time. The American Dental Association said last year, "To the extent that workforce additions can help us break down some of the barriers . . . allowing nondentists to perform irreversible surgical procedures is not the way to go."

Paul Casamassimo, DDS, MS, of the American Academy of Pediatric Dentistry (AAPD), says his group's position is that "there is insufficient evidence to show that a dental therapist will improve access to care for children." If AAPD received compelling evidence that they do, "then we would reconsider our position," he said.

Many in the dental profession recognize that "under certain circumstances the therapists can provide care with adequate training," said Casamassimo, who is director of the AAPD Pediatric Oral Health Research and Policy Center. Yet there are studies indicating that dental therapists don't pay for themselves. He noted that a dentist must be involved in the care and a dental practice must be large enough to generate enough of the procedures that dental therapists do.

Many dentists are saying that Medicaid payments cover only a fraction of usual dental charges, so their question is why not adequately fund the current system rather than rebuilding it, said Casamassimo. With the nation training more dentists, he said, it's hard to tell how the economic model will work out.

On the other hand, a review in the September 2013 *American Journal of Public Health* argues that if the United States had publicly funded, school-based clinics staffed by dental therapists, primary dental care would be available to nearly all children and cost less.

MS FOXHALL is a freelance health writer in the Washington, DC, area. She has nothing to disclose in regard to affiliations with or financial interests in any organizations that may have an interest in any part of this article.



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The cost of capitalizing such a school-based system using dental therapists could be recovered rapidly by the savings, note the researchers, including Kavita Mathu-Muju, who is with the faculty of dentistry at the University of British Columbia. They also point out, “In the United States, no studies on the quality of care provided for children by dentists are available.”

Too few clinical trials for pediatric migraine

After a systematic search of the literature, the Minnesota Evidence-based Practice Center, commissioned by the federal Agency for Healthcare Research and Quality (AHRQ), found: “Evidence was low strength due to risk of bias and imprecision” in studies of preventive pharmacologic treatments for migraines in children.

The review noted there are no preventive drugs for this condition approved specifically for children.

The review found 24 publications of randomly controlled trials (RCTs) on 1,578 children and 16 nonrandomized studies. Among other things, it found 1 RCT for propranolol that indicated it prevented migraine more effectively than placebo, saying that the drug was estimated “to result in complete cessation of migraine attacks in 713 per 1,000 children treated.” It also found “no bothersome adverse effects that could lead to treatment discontinuation.”

The review did find 1 RCT for trazodone and 1 RCT for nimodipine that showed those drugs decreased migraine days more effectively than placebo. However, studies of topiramate, divalproex, and clonidine showed them to be no more effective than placebo.

The report also found, “Sodium valproate demonstrated no significant differences for migraine prevention or migraine-related disability compared with propranolol (2 RCTs) or topiramate (1 RCT).” Asked in an interview if that means that sodium valproate is as good as propranolol for this purpose, Tatyana A. Shamliyan, MD, MS, one of the study’s authors, said she and her colleagues did not make that conclusion because the trials were different in terms of elements

such as doses.

“But definitely physicians can use this information for individualized treatment decisions,” Shamliyan said. If, for example, propranolol doesn’t work, physicians might try other drugs while very carefully monitoring for adverse effects, she noted.

In studies comparing drugs with nonpharmaceutical interventions, 1 RCT found propranolol “had less effect than self-hypnosis on absolute number of migraine attacks.”

However, the report also noted that any long-term preventive benefits for drugs or other interventions are not known, nor have there been studies on quality of life or evidence for individualized treatment decisions. The report also said that no RCTs have looked at prevention of chronic, as opposed to episodic, migraines in children.


Shamliyan said that not much research has been done on the adverse effects of these drugs in children, making it difficult for physicians and parents to make decisions.

She said it has been 10 years since the last major review of this topic and, unfortunately, the lack of evidence has changed little. A Cochrane Review published in 2003 said, “There is a clear and urgent need for methodologically sound RCTs for the use of prophylactic drugs in pediatric migraine, starting with propranolol.”

Shamliyan does not know why more research has not been completed on treatment for pediatric migraine. She pointed out that she and Robert Kane, MD, published a study in 2012 in *Pediatrics* showing that of closed studies on all topics on children registered on ClinicalTrials.gov, only 70% were completed, and of that number only 29% were published.

Shamliyan and colleagues did a similar review for preventive drugs for migraine in adults and found different results, even though the methodology was the same. That report included the finding that, “For episodic migraine, approved drugs are effective but increase risk of adverse effects and treatment discontinuation due to adverse effects.”

The difference in the results reflects the paucity of trials conducted in the pediatric population, Shamliyan said.

The review was done under contract with the AHRQ, but the document says the conclusions do not necessarily represent AHRQ’s views. 

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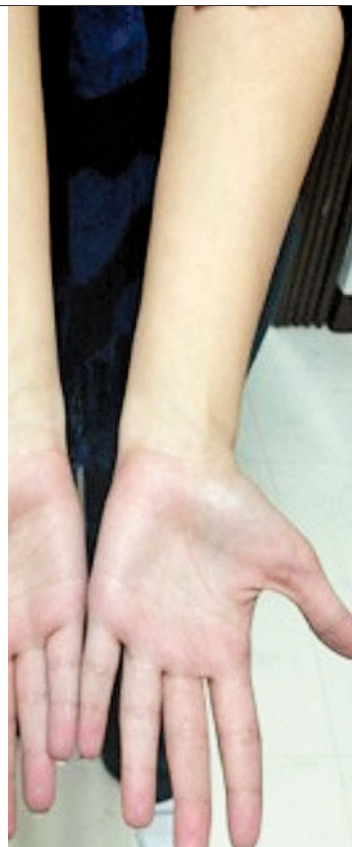
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Cyanosis leaves a girl tired and blue

ELIZABETH MEGAS, BS, MS3; AMIN J BARAKAT, MD;
AND AZIZA SHAD, MD



THE CASE

An 18-year-old girl presents at your office complaining of intermittent cyanosis of her hands and lower extremities. The first episode occurred 5 weeks ago and consisted of blue “streaks” that started at her ankles and progressed to her hips over the course of the day. She initially attributed the discoloration to her clothing, assuming that the dye from her new jeans had stained her skin. Interestingly, the onset of her symptoms also coincided with the beginning of her employment as a sales associate at a shoe store. The only other notable symptom associated with the first episode was excess fatigue, which the patient ascribed to long hours on her feet at work.

CONTINUED ON **PAGE 47**

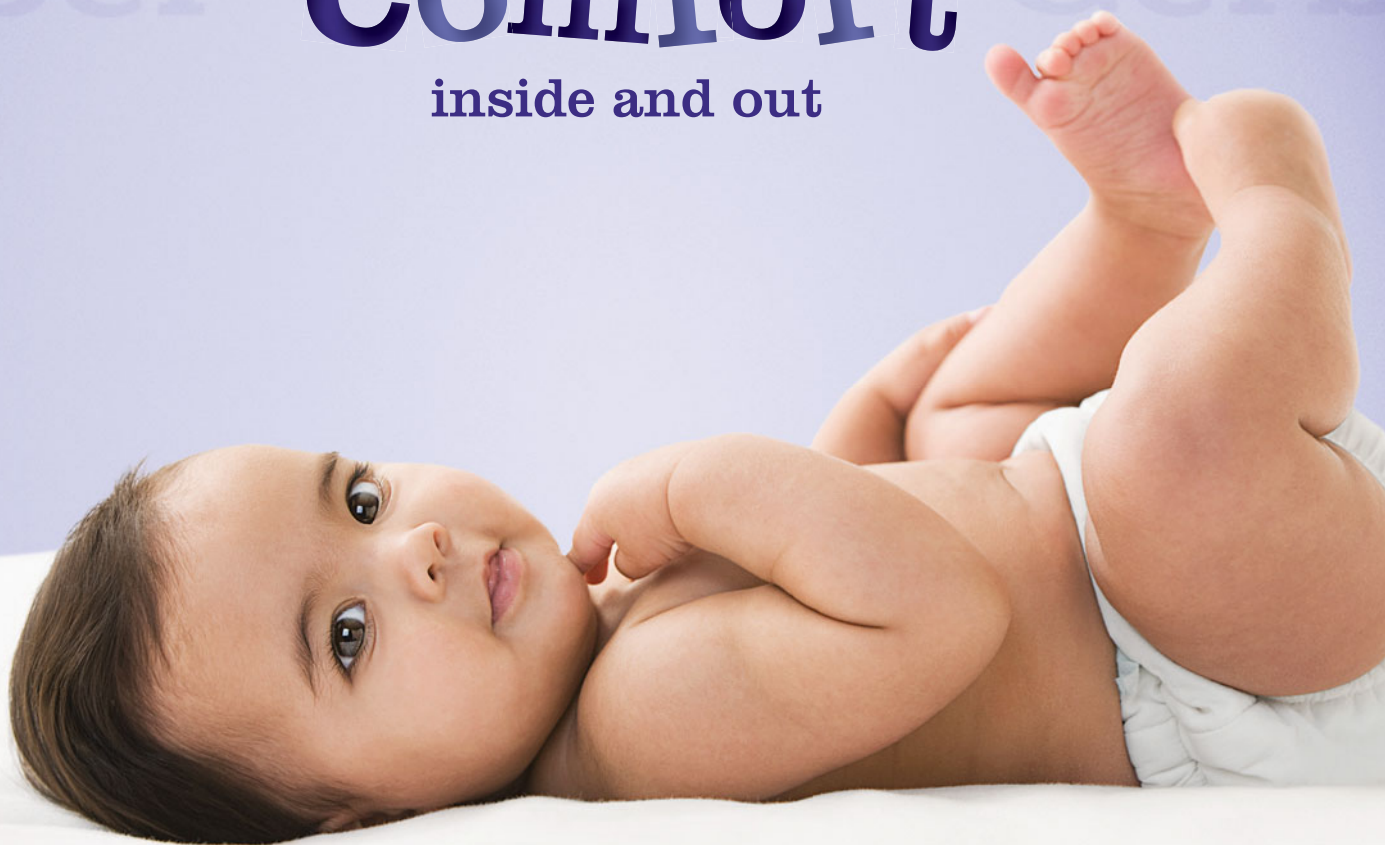
MS MEGAS is a third-year medical student at Georgetown University School of Medicine, Washington, DC. **DR BARAKAT** is clinical professor of pediatrics, Georgetown University Medical Center, Washington, and a pediatrician in Falls Church, Virginia. **DR SHAD** is chief of Pediatric Hematology/Oncology, Blood and Bone Marrow Transplantation, Georgetown Lombardi Comprehensive Cancer Center, Washington, DC, and Amey Distinguished Professor of Neuro-Oncology and Childhood Cancer. The authors have nothing to disclose in regard to affiliations with or financial interests in any organization that may have an interest in any part of this article.

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MOTIVATIONAL INTERVIEWING: HELPING TEENAGED SMOKERS TO QUIT

KATHRYN E MYHRE, MD, AND WILLIAM ADELMAN, MD

Although tobacco use among adolescents and young adults has declined in recent years, data show that more than 3 million high school students and 600,000 middle school students still smoke cigarettes regularly. Motivational interviewing is one intervention that pediatricians can use to help their teenaged patients quit smoking before the onset of nicotine addiction and its accompanying comorbidities.

Tobacco use is a leading cause of morbidity and mortality for adults in the United States, but it is a disease of adolescence. Fifty-nine percent of new smokers in 2010 had their first cigarette before age 18 years.¹ Among adult chronic smokers, 88% began by age 18 and 99% started before age 26.² Because use typically

begins during adolescence, consideration of this population is pivotal when developing and implementing intervention efforts.

Much progress has been made in reducing tobacco use among adolescents and young adults. The prevalence of daily cigarette smoking among US students in grades 9 through 12 decreased from



US Department of Health and Human Services.²

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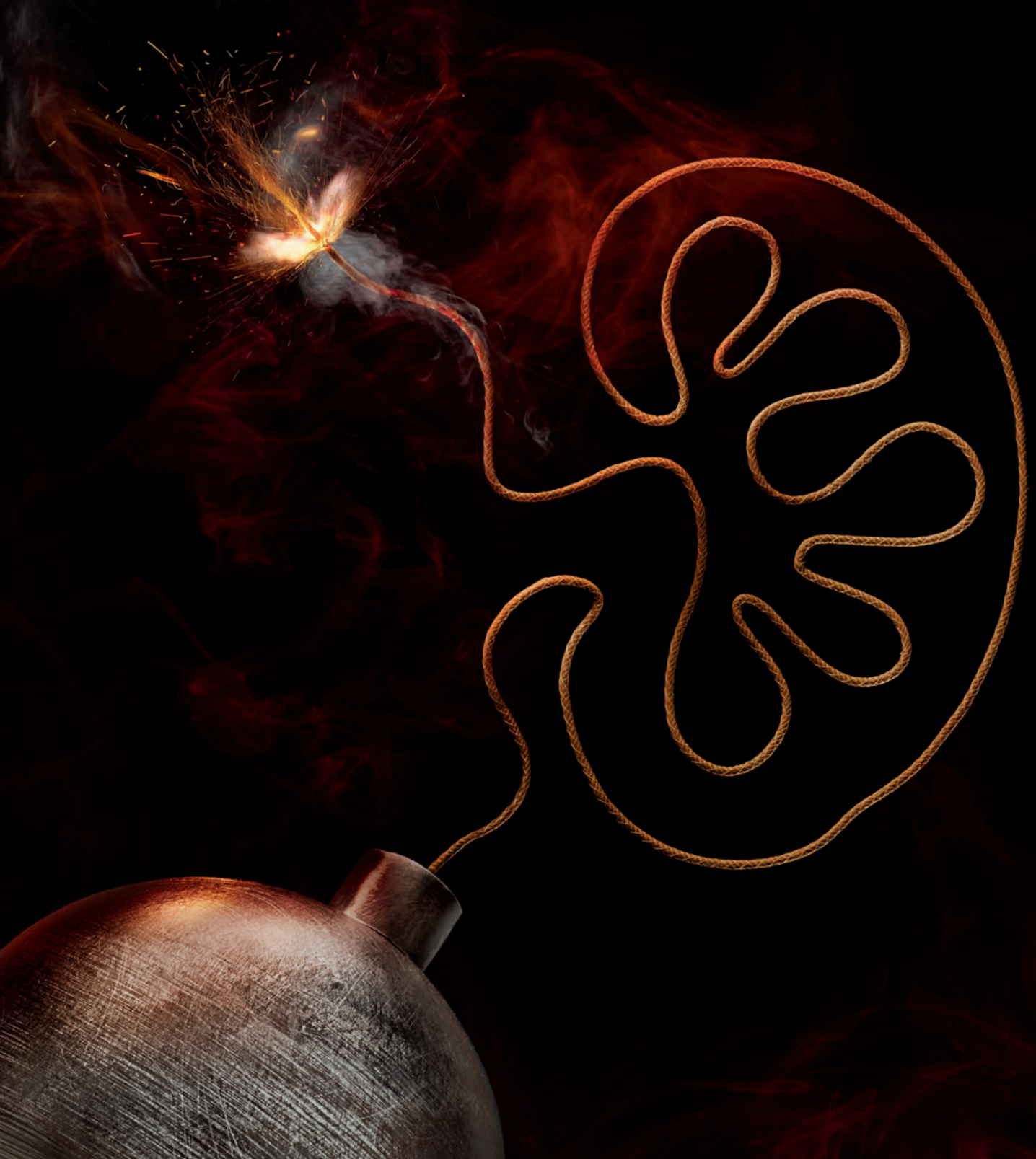
GETTY IMAGES/PHOTODISC/KUTAY TANIR

A close-up photograph of a lit fuse. The fuse is a thick, braided rope that enters from the bottom right and extends towards the center. At its tip, there is a bright, intense orange and yellow flame. From this point, a large number of fine, golden-yellow sparks are being ejected in all directions, creating a dense, starburst-like pattern. Above the flame, a plume of dark red and black smoke or ash is rising and drifting towards the top right corner. The entire scene is set against a solid black background, which makes the bright sparks and flame stand out prominently.

VUR can be a
short fuse with
long-term consequences

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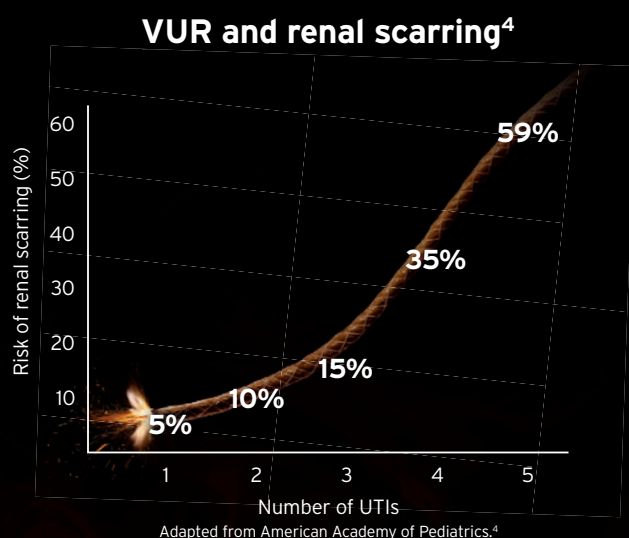
Because waiting to refer VUR patients
to a pediatric urologist can ignite
kidney damage



Febrile UTIs may cause renal scarring

Febrile urinary tract infections (UTIs), while a common diagnosis, may indicate the presence of vesicoureteral reflux (VUR). Patients who experience VUR arising from febrile UTIs are at high risk for renal scarring associated with infected urine coming into contact with the kidney.¹ Children experiencing a first UTI have a 70% risk of developing acute pyelonephritis, and 57% of these children will also develop renal scarring.²

The risk of renal scarring arising from VUR increases with each UTI and usually occurs during the first 3 to 5 years of life.^{3,4}



Although renal scarring may begin early in life, the consequences can last a lifetime and can include early-onset hypertension and end-stage renal disease.⁵

Spontaneous resolution may not take place in time to prevent renal damage

The longer the patient has had a diagnosis of VUR, the less likely it is that spontaneous resolution will occur,⁶ with or without antibiotics.¹ In patients aged 25 to 60 months with bilateral VUR grade III, only 30.5% of cases were resolved at 5 years.⁷

RBUS may not rule out VUR after a first UTI

According to the American Academy of Pediatrics (AAP) 2011 UTI Guidelines, a voiding cystourethrogram (VCUG) should not be performed routinely after a first febrile UTI, and is only indicated if a renal-bladder ultrasound (RBUS) reveals a need for further testing.⁸

However, RBUS may not detect VUR after a first UTI.⁹ In a group of patients undergoing RBUS following a first UTI, 24% of those with a normal RBUS were found to have VUR grades III and IV; adding VUR grade II to the analysis revealed that 40% of these patients had VUR following a normal RBUS.⁹ A reliance on RBUS could therefore result in delayed treatment and may increase the risk for permanent kidney damage.

Management of VUR often requires a specialized strategy

The pediatric urologist considers many factors beyond VUR grade when deciding upon a treatment plan, including increased reflux severity upon voiding, ureter anatomy and size, presence of duplication, bladder/bowel dysfunction, and other issues.^{10,11}

In addition to or in place of antibiotics, the pediatric urologist may suggest an outpatient procedure or surgical inpatient ureteral reimplantation.

Early referral to a pediatric urologist can help ensure that patients receive the VUR management they need—regardless of grade

Consider earlier referral to a pediatric urologist for patients with VUR

VUR is associated with renal damage that can severely impact patients throughout their lives. The successful management of VUR often requires the expertise of a specialist versed in the intricacies of the condition and its diagnosis as well as the outpatient procedure to treat it.

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20% to 10.2% between 2001 and 2011.³ However, despite this decline, more than 600,000 middle school students and 3 million high school students regularly smoke cigarettes.²

Furthermore, adolescents frequently are not able to quit cigarette smoking once adopting the behavior. For every 3 young smokers, only 1 will quit during his or her lifetime.² Older adolescents better understand the gravity of smoking than younger adolescents.⁴ However, the tragic ramification of this timing of understanding is that teenagers may already be addicted to nicotine before they internalize the risks.^{4,5} Therefore, we must motivate adolescents to quit smoking before the onset of addiction and its accompanying comorbidities.

Smoking-cessation interventions for adolescents

A 2006 Cochrane Review of smoking-cessation programs for young people reviewed many types of interventions, including cognitive behavioral therapy (CBT), use of pharmacologic agents, stages of change with the transtheoretical model (TTM), and motivational interviewing (MI).⁶ Both TTM and MI were effective, whereas CBT and pharmacologic agents for adolescents did not have a statistically significant effect.

Motivational interviewing is defined as “a collaborative, goal-oriented style of communication with particular attention to the language of change . . . designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring the person’s own reasons for change within an atmosphere of acceptance and compassion.”⁷ This technique improves tobacco-use cessation when compared with brief advice or usual care.⁸

The efficacy of MI for smoking cessation in the adolescent population is an area of ongoing research. Individual prospective trials on the subject include the 2005 study by Hollis and colleagues, in which more than 2,500 adolescents were randomized to motivational tobacco-cessation intervention versus brief dietary advice.⁹ This study revealed significantly higher abstinence rates after 2 years in the MI group (odds ratio [OR], 1.23; 95% confidence interval [CI], 1.03-1.47). Similarly,

TABLE 1 Core constructs of the transtheoretical model

Construct	Definition
Stages of change	Behavioral change occurs by progression through 6 stages (see Table 2), although not necessarily linearly.
Processes of change	“... Covert and overt activities people use to progress through stages. . . . [They] provide important guides for intervention programs, as processes are like independent variables that people need to apply to move from stage to stage.”
Decisional balance	“... Reflects an individual’s relative weighing of the pros and cons of changing.”
Self-efficacy	“... The situation-specific confidence that people can cope with high-risk situations without relapsing to their former behaviors.”

Prochaska JO, et al.¹²

a 2006 study by Kelly and Lapworth highlighted short-term reductions in the quantity and frequency of smoking after an adolescent MI intervention for smoking cessation as compared with standard care.¹⁰ A 2010 systematic review of the efficacy of MI in adolescent and adult populations examined 31 smoking-cessation trials and showed a higher likelihood of smoking abstinence in the MI group than in the control group (OR, 1.45; 95% CI, 1.14-1.83).¹¹

Practical application of motivational interviewing

How can pediatricians apply this promising technique of MI in clinical practice? Any intervention in a busy office must be practical, applicable, and efficient in today’s time-conscious practice environment. Pediatricians can use TTM simply to help

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implement programs of behavior change. The 4 core constructs of TTM are stages of change, processes of change, decisional balance, and self-efficacy (Table 1).¹² Using these constructs, the health care provider can assist the adolescent on his or her path from tobacco use to smoking cessation. The goal is simply to assist the adolescent in moving forward from one stage of change to the next; for example, from precontemplation to contemplation or from preparation to action (Table 2).¹²

Effective use of MI helps move people forward through these stages of change. There are 5 main principles of MI: (1) expressing empathy through reflective listening; (2) developing a discrepancy between patients' goals or values and their current behaviors; (3) avoiding argument and direct confrontation; (4) adjusting to patients' resistance rather than opposing it directly; and (5) supporting self-efficacy and optimism (Table 3).¹³

This approach to smoking cessation is effective for adolescents because it focuses on avoiding confrontation and instead allows the individual to reach his or her own conclusions regarding the best way to approach behavior change. Teenagers often come to the clinic expecting a lecture about the harms and consequences of smoking, rather than a self-directed exploration of choices. They may give more credence to a provider's encouragement about smoking cessation when they discover that the message is rooted in self-efficacy and in reconciling future goals with current behavior.

How might this process work in a clinical encounter? The following case-based example offers a scenario.

A case-based example

Part I: A 16-year-old male comes to the clinic for a routine basketball sports physical. Upon review of his psychosocial history, the boy reveals that he has smoked 5 cigarettes per day for the last year. He does not feel smoking is a problem for him and indicates that he does not want "another lecture about this." He is not currently interested in cutting back.

According to the "stages of change" nomenclature, this young man is precontemplative; he has not even thought about cutting down or quitting his tobacco use. He has no intention to change his

TABLE 2 Stages of change in the transtheoretical model

Stage	Definition
Precontemplation	No intention to take action within the next 6 months.
Contemplation	Intends to take action within the next 6 months.
Preparation	Intends to take action within the next 30 days and has taken some behavioral steps in this direction.
Action	Changed overt behavior for less than 6 months.
Maintenance	Changed overt behavior for more than 6 months.
Termination	No temptation to relapse and 100% confidence.

Prochaska JO, et al.¹²

smoking behavior in the near future. Using MI techniques, his pediatrician could take this opportunity to build rapport by expressing empathy through reflective listening. The practitioner aims to communicate to the patient that his view is valid and that he will not be judged for this. An example of effective reflective listening at this point could be, "So what I hear you saying is that you are tired of being lectured about your smoking. Tell me more about this." The statement shows the teenager that his provider is listening to him and that the provider seeks to understand how he feels; this information may catch the teenager off guard because he is expecting a lecture.

This provides an opportunity to guide the teenager to "develop discrepancy," which means helping the teenager discover the innate contradiction between his current behavior and his future goals. Sports-minded adolescents are unique because smoking may affect their athletic performance more noticeably than if they were sedentary. It is crucial to allow the teenager to develop his own reason for why smoking may interfere with his interests, rather than impose the concept on him. The pediatrician could go on to inquire, "What are your future basketball goals? How do you see smoking fitting in with these ambitions?" In the case of this patient, it is very

likely that these first 2 principles are the only ones that his pediatrician would address during the first office visit.

The entire motivational interview would take less than 5 minutes. The sports physical would conclude with a reiteration of the possible discrepancy offered by the patient, a simple statement from the pediatrician such as “*The single best thing you can do for your health is to quit smoking and I am here to help,*” and an invitation or suggestion to return for follow-up in a few weeks to revisit the topic after the young man has had some time to reflect.

Part II: *The young man returns to your office 6 weeks later. He presents after a week of coughing and nasal congestion, which has been interfering with his current basketball performance. In the middle of the visit, he mentions that he has been thinking about maybe cutting down on his cigarette smoking, but he starts identifying many reasons why this likely will not be successful.*

The young man is now in the contemplative

phase; he is both considering a healthful lifestyle change and simultaneously rejecting it. This is a great step forward along the stages of change and suggests that the previous MI visit was successful.

The next aspect of MI, “avoiding argumentation,” is especially important with the adolescent at this juncture.

Arguments escalate the tension of the interaction, and once an argument begins, the content of the discussion is lost.

Many teenagers

are master arguers who enjoy the gamesmanship of the encounter, and the typical pediatrician, whose goal is to effect change, does not stand a chance of achieving this goal when going head to head against a teenager in a disagreement. For this reason, argument is incompatible with MI.

VIDEO

Is there a place for electronic cigarettes in teen smoking-cessation programs? The safety and efficacy of these devices have not been fully studied, but what do the experts say? See our discussion at ContemporaryPediatrics.com/e-cigarettes

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¹Study completed among 500 women with children in May 2012 / ²Effectiveness of Oral vs Rectal acetaminophen, A Meta Analysis; Lee Hilary Goldstein MD, ArchPediatrics Adolesc Med/Vol 162 (No. 11), November 2008

TABLE 3 Principles of motivational interviewing

Principle	Key points	Example in practice
Express empathy	<ul style="list-style-type: none"> • Acceptance facilitates change. • Skillful reflective listening is fundamental. • Ambivalence is normal. 	<i>"So what I hear you saying is that you are tired of being lectured about your smoking. Tell me more about this."</i>
Develop discrepancy	<ul style="list-style-type: none"> • Awareness of consequences is important. • A discrepancy between present behavior and important goals will motivate change. • The patient should present the arguments for change. 	<i>"What are your future basketball goals? How do you see smoking fitting in with these ambitions?"</i>
Avoid argumentation	<ul style="list-style-type: none"> • Arguments are counterproductive. • Defending breeds defensiveness. • Resistance is a signal to change strategies. • Labeling is unnecessary. 	<i>"The single best thing you can do for your health is to quit smoking, and I am here to assist you when you are ready."</i>
Roll with resistance	<ul style="list-style-type: none"> • Momentum can be used to good advantage. • Perceptions can be shifted. • New perspectives are invited but not imposed. • The patient is a valuable resource in finding solutions to problems. 	<i>"It sounds like you have thought of a lot of possible stumbling blocks to cutting back. What could possibly be some solutions?"</i>
Support self-efficacy	<ul style="list-style-type: none"> • Belief in the possibility to change is an important motivator. • The patient is responsible for choosing and carrying out personal change. • There is hope in the range of alternative approaches available. 	<i>"I am really impressed with your consideration of cutting back on your cigarette use. I want you to know that I believe you can do it. Let's plan to meet back in a month to see how things are going."</i>

From Miller WR, et al.¹³

The main principle is less about what to say and more about the overall attitude behind the conversation. The goal is to use gentle persuasion instead of putting the patient on the defensive. If the conversation becomes argumentative, the pediatrician should attempt to terminate the argument and reassure the teenager that the provider cares for him, perhaps with a simple statement reiterating that the single best thing the teenager can do for his health is to quit smoking and that the provider is available to assist when the teenager is ready.

The fourth main principle of MI, "rolling with resistance," is not to be confused with condoning adolescent tobacco use or assuming an overall stance of passivity. Rather, the physician helps the teenager to generate his own solutions. For instance, this young man may explain that he will feel pressured to smoke when he is around his friends, or that he has tried to quit in the past but failed, so why would this time be any different? Using the techniques of MI, the practitioner

can reframe the question and put it back on the patient, allowing him to come up with his own solutions. For instance, one could say, *"It sounds like you have thought of a lot of possible stumbling blocks to cutting back. What could possibly be some solutions?"* This statement allows the teenager to feel empowered to identify workarounds for his dilemmas. In so doing, the teenager begins working through the preparation stage of change. If the teenager has no solutions to propose, the provider may offer suggestions for the patient to consider. If none seem to resonate with the patient, the provider may suggest they revisit the topic at a later time.

Finally, the fifth principle, "supporting self-efficacy," comes into play. The pediatrician has an excellent opportunity to reinforce the young man's confidence in his own ability to change. This sense of confidence is a strong predictor of successful behavior change. Teenagers show an increase in self-efficacy when they have both support and

effective strategies to assist in quitting smoking, such as concrete plans for changing behavior, avoiding triggers, and setting a quit date. The pediatrician may say, “I am really impressed with your consideration of cutting back on your cigarette use and your plan to avoid your smoking friends after practice to eliminate those 2 cigarettes in your day, and I want you to know that I believe you can do it. Let’s plan to meet back in a month to see how things are going.” This brief message of belief in the patient’s ability to succeed, along with reinforcement of a specific strategy to assist the teenager with cutting down use, does not take long to provide, but may pay dividends in supporting the patient’s self-esteem on the difficult path ahead.

Part III: *The patient returns to the clinic 1 month later. He informs you proudly that he has managed to cut down to only 1 to 2 cigarettes per day and he is now ready to quit completely.*

At this point, it is important to guide the patient to choose a concrete quit date. He has taken action to cut down on his tobacco use during the past month and is preparing to quit entirely. It is essential to commend the young man on the huge strides he has already taken and to counsel him about the potential challenges that lie ahead. Stumbling blocks may include peers who continue to smoke, brief relapses, and chemical cravings. Anticipating these challenges, and identifying plans of action for these obstacles in advance, will allow a smoother transition to the action stage as well as progression to the maintenance stage. The pediatrician should encourage the teenager to schedule a follow-up clinic appointment at the time of the quit date to encourage ongoing progress and facilitate brainstorming of the best way to deal with obstacles.

Conclusion

Motivational interviewing is a promising area of focus for primary care practitioners who treat adolescent smokers. Through gradual, brief incorporation of these 5 main principles—expressing empathy, developing discrepancy, avoiding argumentation, rolling with resistance, and supporting self-efficacy—into daily clinical practice, we assist adolescents’ movement along the stages of change

on the path toward smoking cessation. Our nation is moving in the right direction regarding adolescent tobacco use, and we, as pediatricians, can keep the momentum going. **99**

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Kids consume sugary drinks because they're available, affordable

Although overweight/obese Latino adolescents and their parents generally recognize that sugar-sweetened beverages are not healthy, the teenagers still consume these drinks for a variety of reasons, mostly because they are available at home, a new study shows.

Investigators interviewed 55 Latino parents and their overweight or obese children (aged from 10 to 18 years) about what beverages the children regularly drink, what they thought about the healthy versus unhealthy nature of the drinks, and why the teenagers made the choices they did. The children consumed sugar-sweetened beverages regularly—soda; sports, energy, and juice drinks; and culturally specific drinks—and lived in homes where such drinks were available. They also regularly consumed water.

Almost all parents and children considered soda unhealthy, with parents believing diet soda was at least as unhealthy as regular soda, citing the additives or chemicals it contains. About half of parents and youngsters thought that juice drinks were unhealthy because of too much sugar. The few adult and teenaged participants who thought that sports drinks were unhealthy and the half of parents and some youngsters who cited energy drinks as unhealthy also indicated that “too much sugar” was the reason. Nonetheless, half of parents prepared sugar-containing drinks associated with their Latino culture at home and considered these beverages healthy because of their high fruit content.

Both parents and youngsters recognized the health value of drinking water, but most parents and about half the children thought that tap water was unclear or unhealthy. (The study was conducted in the Los Angeles area, where tap water is considered safe.) Most parents, therefore, bought filtered or bottled water for home use. When asked why their children chose to drink water, a few mentioned that a nutritionist or doctor had advised it.

In addition to sugar-sweetened beverages at home or parents acceding to children's requests to buy them, the afford-

ability of these drinks facilitated their consumption, the interviews showed. A lack of rules about drinking sugar-sweetened beverages or a failure to understand rules or the consequences of breaking them appeared to be barriers to reducing consumption of these drinks (Bogart LM, et al. *Acad Pediatr*. 2013;13[4]:348-355).

COMMENTARY

You never know what parents don't know until you ask. In a 2007 study, investigators in Salt Lake City, Utah, found that 42% of Latino parents believed that the city tap water was unsafe to drink and never gave tap water to their children (Hobson WL, et al. *Arch Pediatr Adolesc Med*. 2007;161[5]:457-461). These researchers found similar results in this group of parents of obese and overweight Latino children and adolescents. I wonder if parents would be less likely to spend money on less healthy options such as soda and other sugar-sweetened beverages if they believed that tap water was safe. Ask a few parents, especially Latino parents, in your practice what they think of the safety of tap water in your community. You may be surprised by what you hear.

—Michael Burke, MD

PARENTS WANT TO KNOW RISKS OF HEAD CT IMAGING

Although about half of parents are aware of potential cancer risks arising from brain computed tomography (CT) scans, disclosure of current lifetime malignancy risks in an emergency department (ED) reduces by about 20% the proportion of parents who would be willing to proceed with a recommended head CT, and almost all parents prefer an informed discussion before going ahead. In addition, the vast majority of parents want to be informed of potential malignancy risks before proceeding with imaging.

These were the findings of a survey of parents of children in a tertiary care pediatric ED being evaluated for a head injury; the survey was administered before the child had been assessed by a physician. Participants

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were informed about the increased lifetime cancer risk and were given a handout about balancing the benefits and potential risks of head CT imaging.

Of almost 750 parents, 46.8% were aware of a possible increased lifetime malignancy risk from CT. However, 62.9% underestimated the current best risk estimate (about 1 in 10,000). At the start of the study, 90.4% of parents indicated they would be willing to proceed with a head CT if deemed necessary by the emergency physician, but this proportion fell to 69.7% after risk information was provided, and 41% would want further discussion with the physician before proceeding. A full 90.7% indicated that before having the testing they would prefer to know the potential malignancy risks of diagnostic tests that expose children to ionizing radiation (Boutis K, et al. *Pediatrics*. 2013;132[2]:305-311).

COMMENTARY

These researchers conclude their discussion by writing: "... We strongly recommend that physicians be well informed of the benefits and potential risks of CT imaging." We need to know this information not only to fulfill parents' wishes to be informed but also to help as we balance the risks and benefits of CT scans in making our recommendations to families. The most recent calculation that I've seen is that 4 million pediatric CT scans/year in the United States are projected to cause 4,870 future cancers (Miglioretti DL, et al. *JAMA Pediatr*. 2013;167[8]:700-707). —Michael Burke, MD

LENGTH OF HOSPITAL STAY VARIES WITH NATIVE LANGUAGE

Hospitalized children from Spanish-speaking families are likely to stay in the hospital for a longer time in association with a serious or sentinel event after admission than English speakers. Spanish-speaking children also may be more likely to experience such an event, according to an analysis of almost 34,000 admissions to a large children's hospital during a 2-year period. Serious and sentinel events were rare (only 87 in total), yet 14% of those who had them spoke Spanish, although Spanish-speaking patients represented only 8% of total patients.

Having an adverse event was independently associated with an almost 5-fold increase in length of stay. Among patients who had an adverse event, those whose families spoke Spanish had significantly longer hospital stays than children whose families spoke English (26 days vs 12.7 days, respectively). Finally, the length of stay for English-speaking children with a serious adverse event was 5 times longer than that of English-speaking children without such an event, whereas for Spanish-speaking children the mean length of stay was about 10 times longer in children with a serious adverse event compared with those without one (Lion KC, et al. *Hosp Pediatr*. 2013;3[3]:219-225).

COMMENTARY

The investigation found that children from Spanish-speaking families had increased likelihood of a serious or sentinel event, although the finding was not quite statistically significant. These researchers also report that use of qualified interpreters is "the rule" in their institution. Had the study been conducted in hospitals and practices where physicians and staff are less focused on using trained interpreters, their findings may have been even more convincing.

Language barriers are emerging as a significant and fixable cause of adverse outcomes in pediatrics. Only 55% of pediatricians surveyed say that they use formal interpreters to communicate to patients with limited English proficiency, a minimal increase from 50% in 2004 (Decamp LR, et al. *Pediatrics*. 2013;132[2]:e396-e406). —Michael Burke, MD

» Also of Note

Parents find both recommended and nonrecommended treatments for nasal congestion effective. A survey of 285 parents about what they use to relieve their infants' nasal congestion found that most parents used treatments recommended by their pediatricians, including nasal saline, humidifiers, and bulb syringes, but they also used Vicks and other over-the-counter (OTC) remedies their physicians do not recommend. White parents were more likely than minority parents to believe that OTC medications were effective. (Krugman SD, et al. *Clin Pediatr (Phila)*. 2013;52[8]:762-764).

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CONTINUITY OF CARE FOR NICU GRADUATES

RENEE D BOSS, MD, MHS, AND JANICE E HOBBS, MD, MPH

The discharge of a preterm infant from neonatal intensive care is a developmental milestone, yet it also marks the beginning of a challenging course of medical care from a complex system of outpatient providers. This article addresses the multiple strategies and resources that exist to help pediatricians coordinate health care and optimize quality of life for these children and their families.

Pretermaturity and congenital anomalies or syndromes are the most common reasons why newborns require hospitalization in a neonatal intensive care unit (NICU). Some infants are hospitalized for days to weeks, while some remain in the NICU or rehabilitation facilities for several months. At the completion of a lengthy hospitalization, clinicians must prepare parents to provide care at home, and to navigate outpatient follow-up in order to ensure a safe and successful discharge. Celebrating a NICU discharge for high-risk infants is a major milestone, yet optimizing outpatient continuity of care for medically complex infants is challenging. Many such infants require close monitoring of growth and nutrition, management of medications and durable medical equipment, and early recognition of respiratory illnesses and other infections. Many also require ongoing care from pediatric subspecialists, including neurodevelopmental care. Delivering high-quality continuity of

care for these infants is complicated by the lack of standardized guidelines for optimal follow-up.¹

In this discussion, we highlight common logistical barriers and ethical complexities encountered by the general pediatrician whose goal is comprehensive care for NICU graduates. Special emphasis is placed on preparing families for predictable short- and long-term outcomes for these infants.

Organizing medical care following NICU discharge

The medical home model is defined by the American Academy of Pediatrics (AAP) as accessible, continuous, comprehensive, family-centered, coordinated, compassionate, and culturally effective care delivered by a well-trained primary care physician.² Medical homes may particularly benefit high-risk infants and those families with additional risk factors for unmet health care needs. Families connected to a quality medical home are more likely

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to receive respite care, transportation, and rehabilitation services.³ In the National Survey of Children with Special Healthcare Needs, approximately half (49%) require assistive technologies; children most likely to get the necessary technologies are those with quality medical homes.^{4,5} Children with combinations of impairments, as is the case with many children with genetic syndromes, may particularly benefit from quality medical homes.^{6,7} The supportive services available in a medical home can assist families in navigating insurance issues, accessibility, and financial burdens.⁵

Although the medical home model is ideal for providing medical care to high-risk infants, most US pediatricians today do not yet have the resources in information technology, laboratory facilities, or quality-of-care reporting needed to qualify as a medical home.⁸ Some pediatricians may feel unable to care for medically complex infants because of limited funding and inadequate medical staff in their offices or because of perceived lack of training in developmental pediatrics and care coordination.^{9,10} In a survey of general pediatricians, over half believed that they did not adequately integrate medical care with the plans of other providers or agencies, or with families' needs for nonmedical services.⁹

Multiple strategies and resources exist for the general pediatrician who cares for infants with special health care needs. For instance, in 2012 the AAP published a clinical report to guide pediatricians with the hospital-to-home transition for children with dependence on technologies.¹¹ A 2008 AAP report can also assist primary care pediatricians with navigating the process for evaluating the need for and securing funding for assistive technologies.¹² A staff member dedicated to care coordination can increase access to services for families.¹³ In many settings, care coordination is most successful when it is done through partnership with families.

The AAP and the Institute of Medicine have addressed the importance of generalist-specialist communication in reference to chronic care for children with special health care needs.^{2,14} General pediatricians often face multiple communication barriers including delays in receiving consultants' notes, inability to speak directly with consultants, and difficulty coordinating communication among

multiple specialists.¹⁵ Parents find gaps in communication among their child's clinicians to be a burden.¹⁶ Often parents must serve as the messengers of information among specialists. Some parents are uneasy in this role, but other parents enjoy relaying information to physicians who do not depend on them as their only source for information. Integrated clinics that incorporate the medical home and tertiary care centers are one strategy for improving communication and decreasing family burden.¹⁷

Geographic location influences access to resources for pediatricians and families of NICU graduates, and is related to local poverty rates, budgets, insurance coverage, and program eligibility. One study found that children with special health care needs consistently received all preventive care within the past 12 months in only 1 of 4 regions of the United States.¹⁸ Access to follow-up clinics also varies by state and region. Most neonatal follow-up clinics are associated with academic institutions and large tertiary care centers. Discontinuous preventive care impacts the ability to monitor developmental progress and initiate appropriate services in a timely period. For areas with limited resources, the AAP recommends developing a partnership between NICUs and community physicians to perform developmental assessments of the infant at specific time points in the infant's growth.¹

Optimizing neurodevelopment

Promoting optimal neurodevelopment for NICU graduates is among the most important roles for the pediatrician. In 2002, the National Institute of Child Health and Human Development, National Institute of Neurological Disorders and Stroke, and the Centers for Disease Control and Prevention developed recommendations for developmental follow-up of high-risk infants at specific time intervals.¹ Infants merit follow-up based on their risk factors for adverse neurodevelopmental outcomes, including those infants born at <1,000 g birth weight and/or <28 weeks' gestation; infants with hypoxic ischemic encephalopathy or severe hyperbilirubinemia requiring exchange transfusion; and significant family demographic risk factors.¹ The American Heart Association has follow-up guidelines for infants with congenital heart disease,

with risk stratification based on likelihood for intellectual and developmental delays.¹⁹ Infants with concerning findings or family vulnerabilities should be referred for comprehensive follow-up programs. This allows for assessments of the home environment, early intervention referrals, and family support services.

At the time of NICU discharge, long-term neurodevelopmental outcomes are often uncertain. Families may not fully understand their infant's neurodevelopmental risk factors or how to access resources when there are concerns.¹³ Currently, there are no national data describing families' access to neurodevelopmental care or early intervention services. A study of Midwestern metropolitan NICU graduates suggested that families were more likely to use early intervention services if their infant experienced limitations on activities of daily living, if they perceived their infant to have significant medical problems, if services were arranged during the transition to outpatient care, or if their services were coordinated through a NICU follow-up clinic.¹³ Low family income and inadequate health insurance are consistent barriers to neurodevelopmental follow-up.^{5,13} Most NICU follow-up programs depend on several sources of funding for development and sustainability, with 81% relying on patient insurance as the primary source. NICU follow-up programs may be considered unprofitable by hospitals due to poor insurance reimbursements and greater long-term versus short-term financial benefits.¹⁰

All NICU graduates benefit from periodic developmental assessments by their primary care physician¹ (Table). Developmental domains for recommended follow-up include growth, neurologic status, and developmental status at each visit. Growth assessments should account for gestational age. Infant neurologic assessment should include gross motor function, tone, reflexes, cognitive skills,

cerebellar function, cranial nerves, and language. The findings of these assessments can guide the primary care physician in activating resources such as early intervention.

Supporting families

The general pediatrician is in a unique position to assess and support families whose children have special health care needs. A NICU hospitalization in most cases requires families to reset their expectations of their first experiences with their infant. Families climb a steep learning curve, adjusting to technical and detailed medical care. On NICU discharge, parents may spend many hours per week providing, coordinating, or managing care for their child. This can have a significant impact on the families' mental, physical, and financial health; families may feel isolated and experience diminished ability to function.^{1,20-25} Families of multiple births may struggle to manage the conflicting needs of a child with special health care needs with another child or

TABLE Primary care physicians' assessments for NICU graduates

	Special topics for review	Action items
First post-NICU visit	Hospital discharge summary Growth/nutrition history Medications Home equipment Subspecialty follow-up plans Vaccination status Family coping Advance care planning	Arrange needed labs/testing Prescriptions Growth/nutrition/development tracking to be corrected for gestational age Vaccination schedule
1-2 weeks later	Growth/nutrition Medications Home equipment Family coping	Adjust feeding and medication regimens for growth and corrected gestational age Confirm subspecialty follow-up
Well-child checks	Growth/ nutrition Neurodevelopment for corrected gestational age Medications Home equipment Family coping Advance care planning	Vaccines Adjust feeding and medication regimens for growth and corrected gestational age Confirm subspecialty follow-up Referrals if missing developmental milestones

Abbreviation: NICU, neonatal intensive care unit.

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more without such needs.²⁶

Some parents will have difficulty bonding with their infant, may be less responsive to infant cues, and may be less aware of their infant's development. A minority may experience depression or post-traumatic stress disorder. Without intervention, short-term infant growth and development may be suboptimal and long-term behavior problems and insecure attachment can occur.²⁷ Over time, the repeated family stressors that accompany recurrent infant illnesses, new medical complications, and developmental transitions can generate "chronic sorrow" or "chronic grief."^{20,28} Parents at greatest risk are those whose children have difficult-to-manage behavioral problems and those with intense daily care needs.^{29,30} Advocating for social supports and adequately trained caregivers to assist the family with ventilators, feeding pumps, and other technical devices can positively impact parents' social participation, sleep, and physical and mental health.^{31,32} It is also important to reassure families that they do not need to feel guilty or ashamed about their child's medical conditions.³³

Clinicians and families should also be aware that, within a NICU graduate's first year of life, there might be numerous unexpected costs, particularly immediately following discharge. One study found that direct medical costs for infants of very low birth weight was \$10,139 compared with \$1,179 for full-term infants within the first year after discharge, with an additional 7-fold increase in child care costs.³⁴ Families may take time off from work or resign indefinitely to meet their infant's needs, adding further expenses.²⁰ These out-of-pocket expenses may account for up to half a family's annual income; clinicians must be cognizant of financial burdens encountered by families when planning outpatient care.³⁴

After a NICU discharge, family dynamics and social factors play a significant role in a family's ability to remain positive in times of adversity.³⁵ A positive home environment has been shown to be protective against poor outcomes in children of extremely low and low birth weight. In the Kauai Longitudinal Study examining developmental resilience, protective factors for resilient subjects included positive temperament, favorable parental

attitudes, low levels of family conflict, less life stress, smaller family size, and counseling/remedial assistance.^{35,36} Other families speak of their great joy in watching their child overcome adversity and surpass their predicted limitations.³⁷ The experience of siblings also varies, and although some siblings may experience depression or behavioral problems, others may enjoy being a caretaker to their brother or sister with special health care needs.^{38,39} As health care providers we have the least control over a family's home environment, but we are in a position to learn about and engage relevant resources.


Long-term planning

Many parents of NICU graduates may have a good understanding of their infant's current health care needs, yet have little understanding of the long-term prognosis for health and developmental potential. For those infants who will go on to have long-term medical and neurodevelopmental complications, pediatricians are well positioned to engage families in periodic, longitudinal evaluations of evolving health care needs and the goals for future care. Many families find it beneficial to have written documentation of these goals.⁴⁰ Families may also benefit from ongoing attention to their access to community resources and social supports over time. As many as half of all children with intellectual and developmental disabilities will live with their parents for most, if not all, of their lives; this has ongoing impact on parental employment, finances, marital stability, and psychologic health.⁴¹ It is important to know what opportunities are present in the community for periods of respite for the family, times when they can attend to other needs and know that their child will be receiving high quality care.^{42,43}

When a NICU graduate has severe medical problems or profound neurodevelopmental disability, some families will choose treatment limitations, which may include decisions to decline surgeries, feeding tubes, or cardiopulmonary resuscitation. These families may benefit from the support of a palliative care provider, who can help to maximize quality of life for the child and family as the child's condition evolves. If the child will enter an education/day care program, clinicians should engage

caretakers/teachers in discussions of emergency care plans. The 2010 AAP policy can help pediatricians, families, and schools establish individualized plans for each child, although parents should be informed that school systems vary in their willingness to honor such requests.^{44,45}

Conclusion

Multiple resources exist to assist the general pediatrician in caring for NICU graduates with complex medical problems. Engaging these resources can help to optimize quality of life for these children and their families. Ongoing ethical complexities include adequate funding for medical homes and comprehensive NICU follow-up clinics, access to services across geographic areas, communication barriers to the delivery of high-quality care continuity, and longitudinal evaluations of goals of care for NICU graduates who go on to have significant medical and neurodevelopmental complications. 

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DIAGNOSIS:

Solitary mastocytoma

EPIDEMIOLOGY

Solitary mastocytomas are the second most common form of childhood-onset cutaneous mastocytosis, accounting for approximately 10% to 15% of cases.¹ They often develop before 1 year of age, with most presenting within the first 3 months of life. Adult involvement is rare, but has been reported in recent literature.²

MOLECULAR PATHOGENESIS

Mastocytomas, classified as myeloproliferative neoplasms, are believed to be caused by increased local concentrations of soluble mast cell growth factor, which stimulates local mast cell and melanocyte proliferation and increases local production of melanin pigment responsible for the hyperpigmented appearance of the cutaneous lesion.³ Several genetic mutations have been implicated in the pathogenesis, including impaired mast cell apoptosis as evidenced by up-regulation of the apoptosis-preventing protein BCL-2 and activating mutations of the proto-oncogene c-kit.^{4,5} Additionally, elevations in interleukin-6 levels have been observed and correlated with disease severity in cutaneous mastocytosis.⁶

DIAGNOSIS AND TREATMENT

Mastocytomas range in size from 1 cm to 4 cm and may present as single or several (referred to as urticarial pigmentosa) erythematous and golden-to-brown subtly elevated plaques, often with a leathery or peau d'orange texture. When a lesion is stroked, the release of histamine results in urticaria formation with the development of local erythema and edema. This change is referred to as the Darier sign, which is explainable on the basis of mast cell degranulation induced by physical stimulation.

Blistering may occur particularly in young infants when mastocytomas develop in areas subject to recurrent trauma, such as in the diaper area or around skin creases. Clinical examination is usually sufficient to make a diagnosis. However, a skin biopsy for histologic confirmation may be necessary in equivocal cases.

Most mastocytomas are not symptomatic. However, lesions causing intense pruritus may be treated with potent topical corticosteroids. Intralesional cortico-


steroids also may be helpful in reducing lesion size and associated symptoms. Surgical excision is usually reserved for intractable cases.

Although significant systemic disease is rare, mastocytomas may be associated with flares of asthma or extracutaneous symptoms, including pruritus, flushing, headaches, and gastrointestinal complaints. Symptoms usually respond to oral antihistamines and, when necessary, oral cromolyn sodium and/or phototherapy.

DIFFERENTIAL DIAGNOSIS

The characteristic skin lesions and Darier sign differentiate solitary mastocytomas from a broad differential diagnosis that includes pigmented nevi, xanthoma, juvenile xanthogranuloma, neurofibroma, hemangioma, granuloma annulare, Spitz nevus, pseudolymphomas, and arthropod bites.

PROGNOSIS

Mastocytomas are benign and generally involute spontaneously either completely or partially by adulthood. However, prognosis is related to age at presentation, with children manifesting skin lesions within the first 2 years of life most likely to undergo spontaneous resolution.⁷ Parents can be reassured that persistent symptoms or progression to systemic mastocytosis is rare. 

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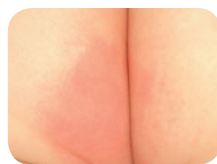
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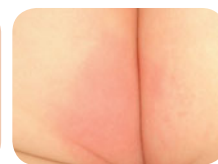
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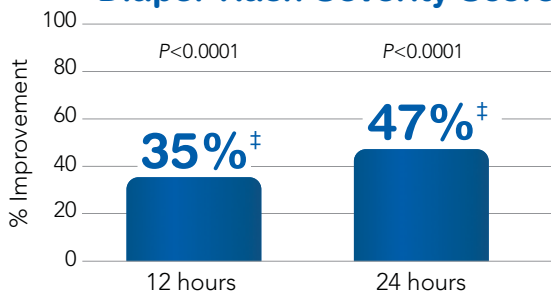
^{*}Trial assessing the efficacy of DESITIN® Maximum Strength Original Paste for 3±1 hours in children (N=31) 3-36 months of age, with mild to moderate diaper rash, wearing diapers for 24 hours a day.¹

[†]P=0.0001

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CHILDREN'S ORAL HEALTH

LISETTE HILTON

Alarming rates of pediatric dental caries and spotty access to dental professionals are driving basic dental care into the pediatrician's domain.¹

Basic oral health care is becoming a standard part of the well-child checkup. There's good reason. Today's most common chronic childhood disease is dental caries, which affects 42% of children aged 2 to 11 years and half of those aged 12 to 15 years.^{1,2} The problem is worse for children from low-income families and some racial and ethnic groups, according to the Centers for Disease Control and Prevention (CDC).²

According to the American Academy of Pediatrics (AAP), early childhood caries is 5 times more common than asthma and 7 times more common than hay fever.³

There are immediate quality of life and health impacts to poor oral health. One example: US children miss 51 million or more school hours a year because of dental disease.¹ The pain and chewing difficulty that can result affect weight, speech, and concentration—all of which can negatively affect learning.⁴ Long-term consequences of poor oral health include gum disease and tooth loss, as well as diabetes, stroke, heart disease, premature births, and more.²

Also among the newly discovered potential consequences of poor oral health is human papillomavirus (HPV).⁵ Oral health issues in children can even lead to death. It did in 2007 for Deamonte Driver, a 12-year-old boy in Maryland, who died after bacteria from an abscessed tooth spread to his brain.⁶

Opening prevention's door

One of the barriers to better oral health for children and families is access. This is exacerbated by a shortage of pediatric dentists in the United States—especially those who accept Medicaid. Only about 45% of 2- to 6-year olds in this country go to the dentist at least once

BUT ONLY
1.5%
SAW
DENTIST

Onikul R, et al.²⁰

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in a given year; yet, the AAP and American Academy of Pediatric Dentistry (AAPD) recommend that children have an established “dental home” by 1 year of age.⁷

Given that preventive health services are delivered on a much larger scale in pediatricians’ offices, many experts say pediatricians are ideal front-line providers who can detect oral health issues and begin the process of care and prevention. According to proceedings from the US Surgeon General’s Workshop and Conference on Children and Oral Health in 2001, “Oral health cannot be considered separate from the rest of children’s health and well-being, just as the mouth cannot be separated from the rest of the body.”⁸

One of the “whole health” messages being promoted by the “Watch Your Mouth” campaign in Washington State—a program to raise awareness about the importance of children’s oral health—is: Sealants and fluorides are as important in protecting against disease as immunizations.⁹

FAST FACT Only 2% of children have seen a dentist by their first birthdays.¹⁵

The knowledge gap

While pediatricians agree they should become more involved in oral health assessment and care and regularly express their willingness to do so in surveys, one of the key barriers remains insufficient preparation to do so.

Results from a national survey by AAP revealed that “90%

TOP 6 TIPS FOR PEDIATRICIANS TO ENSURE CHILDREN’S ORAL HEALTH

1. If not familiar, learn how to assess oral health in children. (See *Resources for Pediatricians* on page 40.)
2. Recognize risk factors that contribute to poor oral health with use of an oral health risk assessment tool. (See *Resources for Pediatricians* on page 40.)
3. Identify dental professionals in the community who will provide a dental home (including providers for children with developmental disabilities and those who may require sedation/anesthesia).
4. Develop collaborations with dental partners to coordinate care for children.
5. Include anticipatory guidance on appropriate oral hygiene and habits for all children, especially those at high risk due to special health care needs.
6. Advocate for oral care for children in your local area.

Adapted from Norwood KW Jr, et al.¹⁴

of pediatricians said they should examine the patient’s teeth for caries and educate families about preventive oral health. However in practice, only 54% reported examining the teeth of more than half of their 0- to 3-year-old patients and only 4% regularly applied fluoride varnish.²⁴

Fully 41% of survey respondents cited their lack of training on how to correctly perform screening dental examinations on young children and to educate families on preventive oral health as the most common barrier to their participation in oral health-related activities.¹⁰ Fewer than 25% reported having received oral health education in medical school, residency, or continuing education.

While researchers in one study suggested that risk-based prioritization of dental referrals during well-child visits might improve dental access for infants and toddlers, they found pediatricians’ referral rates to pediatric dentists when the children had disease, or were at elevated risk for caries, was low.¹¹

However, there are forces at

FAST FACT There were 49,258 visits by children to emergency rooms in 2009 for preventable dental problems.¹⁶

work that might result in more pediatricians including oral health in their well-child visits. Among those are increasing reimbursement and demand for oral health services, as well as studies indicating that what pediatricians do actually helps. When researchers studied the results of “Into the Mouths of Babes,” a medical office-based preventive oral health program, they found children who received 4 or more physician-conducted oral health exams by age 3 years were less likely to be hospitalized for dental caries by their sixth birthdays.¹² While the specifics of its delivery model remain unclear,

VIDEO

Go to ContemporaryPediatrics.com/krol to see our interview with David M. Krol, MD, MPH, FAAP, children’s oral health advocate, the Robert Wood Johnson Foundation.

RESOURCES FOR PEDIATRICIANS

Patient evaluation

Download the interactive iOS-format *Smiles for Life Oral Health Reference Guide* to your iPhone or iPod Touch. It summarizes key areas in oral health for primary care providers, including counseling at routine visits, tooth eruption charts, and prescribing guidelines.

► <http://tinyurl.com/OralHealthRefGuideApp>

Download AAP's *Oral Health Risk Assessment Tool* and guidance document.

► <http://tinyurl.com/AAPOralHealthRiskAssessTool>

Download the National Maternal and Child Oral Health Resource Center's *Oral Health Pocket Guide: Caries-Risk Assessment Tool (CAT)*.

► <http://tinyurl.com/NMCOralHealthRiskAssessmenTool>

Self-enrichment

AAP and the Society of Teachers of Family Medicine (STFM) offer online training modules for pediatric care providers on examining a baby's mouth for caries.

► AAP: <http://tinyurl.com/AAPOnlineCariesTraining>

► STFM: <http://tinyurl.com/STFMOnlineCariesTraining>

STFM provides this in-office fluoride varnish curriculum on the benefits, safety precautions, and dosing for fluoride, as well as how to apply fluoride varnish and provide follow-up care.

► <http://tinyurl.com/STFMFluorideVarnishTutorial>

A "lap-to-lap" technique for holding squirmy toddlers can help facilitate the mouth exam procedure. Leticia Mendoza-Sobel, DDS, and Ben Taylor, DDS, demonstrate in this "how-to" video.

► <http://tinyurl.com/ToddlerOralExamTechniqueVideo>

Reimbursement

Check Medicaid reimbursement for primary care-provided oral health services with this online table.

► <http://tinyurl.com/MedicaidReimbursementByState>

the Affordable Care Act promises to put increasing emphasis on the roles of pediatricians on children's oral health. According to a White House document, the Pediatric Benefit Package includes oral and vision coverage for all children.¹³

Nasreen Talib, MD, MPH, professor of pediatrics, University of Missouri Kansas City School of



Dr. Talib

Medicine, says pediatricians should conduct oral health risk assessments for all children after 6 months of age or at first tooth eruption.

Talib says it's important to ask parents or family caregivers about their oral health as well. Babies' bacteria that lead to dental decay are passed from the parent to the child, often by sharing utensils or food, she says.

Who is at high risk?

There are certain at-risk groups to which pediatricians should pay special attention, says Charlotte Lewis, MD, MPH, associate professor of pediatrics, University of Washington School of Medicine. According to Lewis, whose research for the last 15 years has focused on pediatric oral health issues, low-income children tend to experience more complications from dental disease, including toothaches and abscesses that can lead to more serious problems, and have the most difficulty accessing professional dental care.

FAST FACT More than 14 million low-income children did not see a dentist in 2011.¹⁸

"Children with special health care needs (CSHCN) also need more attention," Lewis says. These include kids whose conditions directly impact their susceptibility to caries or increase their risk for complications of oral, or dental, disease (eg, cleft lip and palate, congenital heart disease). CSHCN also includes those whose condition makes it difficult to practice regular oral hygiene or obtain professional dental care, such as those with autistic spectrum disorder with sensory or behavioral challenges and spastic cerebral palsy.

In some cases, the pediatrician will determine other children are at high risk during the history taking. One example, children

» PODCAST

Go to ContemporaryPediatrics.com/clewis to listen to more of our interview with Dr. Lewis.

FAST FACT US children miss at least 51 million school hours a year because of dental disease.¹⁷

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Reference: 1. Institute of Medicine Report Brief. Dietary reference intakes for calcium and vitamin D. <http://www.iom.edu/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D/DRI-Values.aspx>. Accessed March 28, 2013.

FAST FACT Currently, 40 states have Medicaid programs that reimburse medical providers for preventive dental care, including fluoride varnish application.¹⁹

who go to bed with their bottles are at higher risk for dental issues, Talib says. It's also good to ask new moms if they're breastfeeding throughout the night. "If so, there is exposure to the teeth from carbohydrates that can cause problems."

Other children at risk for dental issues include those who take medications that cause mouth dryness, according to Talib. "Saliva is a protective factor," she notes.

What to do to help high-risk kids

Children at high risk for oral health issues, according to Lewis, should begin an intensive caries primary prevention program during the first year of life. The program includes: 1) having parents begin brushing with fluoride toothpaste (rice-grain-size) twice daily at first tooth eruption; 2) twice-yearly fluoride varnish painted onto the teeth with application beginning at first tooth eruption; 3) an oral screening examination at every visit for detection of early signs of dental decay or other oral or dental problems; and 4) oral health anticipatory guidance provided at all well-child visits.

"Based on evidence-based recommendations, there is no longer a place for using fluoride drops in children who live in nonfluoridated communities," Lewis says, "[as] evidence about the effectiveness of fluoride toothpaste in preventing caries is so overwhelming."

Evidence is not as clear about optimal care for children not considered at high-risk for caries, according to Lewis.

"There is some evidence to support that all children should begin brushing with a rice-grain-size of fluoride toothpaste at first tooth eruption," Lewis says. "There is not a strong body of evidence to support fluoride varnish in low-caries-risk children."

Making the referral

Ideally, a child at high risk for caries also should see a dental professional during the first year of life, according to Lewis.

"A direct referral from the pediatrician or other primary medical care provider to a specific dental professional can be very helpful," she says. "Depending on where a child lives, it may be easy or hard for a low-income . . . infant, toddler, or child with special dental care needs to be able to see a dental professional beginning in the first year of life. In some situations, it can be hard to access dental care for any child under 3 years of age and, particularly so, for low-income children."

Children should be evaluated by a dental professional for placement of sealants onto their permanent

molars when they erupt at about 6 years of age for the first and at 12 years of age for the second permanent molars, Lewis says.

Making this seamless

Remembering to assess for oral health is made easier with an electronic medical record (EMR), according to Talib. She says she has incorporated reminders into her practice EMR, which offers prompts for oral health risk assessment questions.

"I think the most important thing for pediatricians and other primary care providers who care for children to know is that, if you incorporate [basic oral health care] into your well-child-care visit routine, it doesn't take that much extra time," Lewis says. "Adopting a new behavior such as incorporating oral health into your routine is challenging for everyone and it takes dedication, planning, and practice. And then, it becomes second nature." CP

CP CONTEMPORARYPEDIATRICS.COM »

For information about receiving Medicaid reimbursement for pediatric oral care, go to ContemporaryPediatrics.com/CDTs-oral care

For an extended version of this article, go to ContemporaryPediatrics.com/oralhealth

RESOURCES FOR PARENTS

Download these helpful PDFs for your patients' caregivers to take home:

A Healthy Mouth for your Baby (English):

► <http://tinyurl.com/HealthyMouthEnglish>

A Healthy Mouth for your Baby (Spanish):

► <http://tinyurl.com/HealthyMouthSpanish>





Avoiding technology 'growing pains'

This month's article discusses how to best investigate the benefits of new devices and testing products for your clinical practice and how to avoid the pitfalls of adopting new technologies.

Introducing new technology into a medical practice is not the same as buying a new 60-in television for a "man cave" or a crock pot for the kitchen. One must be cautious and consider the benefits and risks of being an early adopter of a new diagnostic device. Pediatricians must have confidence that their tests are accurate, and performed and interpreted correctly. In this edition of Pediatrics V2.0, we'll discuss how to best investigate the acquisition of a new device for your practice. Also, we will take a look at several commonly used office technologies and explain how to avoid pitfalls.

Be a wise consumer

All pediatricians should seek out a reputable, dependable medical supply salesperson. Fortunately, medical supply vendors have not been supplanted by Internet sales. McKesson (San Francisco, California) comes to mind as one of the large medical supply companies with a national sales force, and many smaller companies employ experienced salespersons

as well. Experienced sales representatives often can give you the best price on your equipment, resolve questions, expedite repairs, and let you know when something new and exciting becomes available. Best of all, they have affiliations with medical equipment manufacturers (such as Welch Allyn; Skaneateles Falls, New York), so if you want to learn about a particular device or test, they can make a phone call and facilitate a demonstration, and perhaps even arrange an in-office trial.

Experienced pediatricians always investigate competing products before writing a check. They also seek opinions from colleagues and contact manufacturers directly when gathering information. All this effort helps them avoid some very expensive mistakes. While it's always nice to be among the first to implement a brand new technology, sometimes patience proves to be a virtue. In some situations, it pays to wait until all the "bugs" are worked out by the manufacturer and purchase a more mature product a year or more after the inaugural release.

If you are among the first to buy a new product, get

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a written agreement that you will get a “free” upgrade or a guaranteed credit allowing you to trade the version 1.0 model for the next version when it becomes available. Finally, when you are close to purchase, make sure that you understand the warranty and that you have a clear understanding of what consumables need to be ordered on a regular basis. Keep in mind that some lab tests must be stored in a refrigerator and brought up to room temperature before they are performed (some lipid tests, for example). Also for CLIA-waived lab tests, understand how often controls need to be run (usually once a day for rapid tests and when you start a new box of tests). Negotiate for free on-site training for the product and on-site support if applicable.

Can you afford it?

When considering the purchase of a new technology for your practice, determine the return on investment and whether the procedure is reimbursed by insurance companies. It is always worthwhile to get the suggested billing codes from the manufacturer and contact insurance companies for reimbursement information. These days, there are few office procedures, other than wart treatments, that generate significant profit per procedure, so spend your money wisely. Some devices are worth an investment, not because they generate revenue for the office but because they will expedite office visits (otoacoustic emission hearing screeners, for example), allowing the practice to fit in a few more visits each day.

Remember that an expensive device or piece of equipment (a photoscreener, or a high-end multi-function scanner, printer, fax, and copier) often can be leased. With technologies that may be obsolete in a few short years, this may be the best way to ensure your technology stays current, and that your office is always equipped with the latest and greatest equipment to provide patients with the most cutting-edge care.

It is often helpful to contact colleagues who may have already purchased the high-end device you are investigating and seek their opinions regarding usefulness and ease of operation. I have been a member of the American Academy of Pediatrics (AAP) Section on Administration and Practice Management for many years, and its listserv is often busy with interesting discussions regarding office technologies. Another AAP section with a growing number of members is the

Section on Advances in Therapeutics and Technology. This section also has a busy listserv.

Finally, it may be helpful to review catalogs from companies such as Henry Schein Medical or Medical Arts Press, because often they highlight new products and they may provide you with a good idea whether your sales representative is actually giving you competitive pricing. Remember, it is not just the expensive, high-tech items that make practicing pediatrics exciting for providers and staff. Sometimes all it takes to make your patients happy are new patient-pleasing Band-Aids, or flavored tongue blades, or table paper with cartoon characters.

Train and practice

Depending on the device being implemented, make sure the staff is sufficiently trained to operate the device correctly. Take advantage of the training disk, the online tutorial, or the office in-service when available. Also, put a written procedure together to include in your practice’s “Procedures and Policies” binder so that new staff members can review this information before using the device. They should be supervised by experienced staff before they are allowed to go solo. And, lest we forget the obvious, always, always read the manual!

Tested, but not necessarily proven

The majority of new medical devices that come to market have been reviewed by the US Food and Drug Administration and found to be similar in function to a device that has previously been on the market (class 2 devices). A few mostly implantable devices undergo a more rigorous approval process, requiring clinical trials proving both safety and efficacy (class 3 devices). The end result is that when a new device comes to market, especially one that introduces a new technology, pediatricians must determine how accurate, reliable, and useful that device is in clinical practice. The Table provides some advice for comparing results from your devices to accepted “standards,” so you can determine their reliability and measurement bias that will provide insight as to when you need to repeat a test or seek an alternative test.

When rapid strep tests first became available, we obtained double swabs and ran office throat culture plates along with rapid strep tests to determine the

TABLE Comparing office tests to reference standards

Test	Office test	Reference “gold standard”	Comments
Streptococcal pharyngitis	Rapid antigen tests: OSOM Acon QuickVue	Throat culture	AAP’s <i>Red Book</i> recommends backing up all negative rapid strep assays. If this is not done in your practice, it is useful to periodically back up 25 to 50 negative rapid strep tests with throat cultures. This will determine your “real world” false negative rate of rapid tests and whether you need to reconsider backing up your rapid tests.
Hemoglobin	HemoCue Pronto-7 HemoPoint Stat-Site	Complete blood count (CBC)	Sometimes patients you screen for anemia will need full lab CBCs. Comparison of office hemoglobin values to those performed by the reference lab will help you determine bias of your office test and threshold for following up the screening test with full CBC.
Bilirubin	BiliChek Bili-Meter	Total serum bilirubin (TSB)	An elevated office transcutaneous bilirubin is always followed up by a TSB. Monitoring the office measurements and comparing them to serum measurements gives you an idea if your device tends to overestimate or underestimate values reported by your reference lab.
Temperature	Exergen temporal artery thermometer	Digital rectal thermometer	Comparison of values will help determine ability of the scanner in identifying febrile infants and children and when to use digital thermometers.
Glucose (finger-stick)	Accu-Chek OneTouch	Serum glucose (venous)	In the office setting, finger-stick glucose measurements are helpful in screening for hypoglycemic and hyperglycemic states. Comparison with venous measurements performed by your reference lab will help determine how closely your finger-stick assays compare with those of the reference lab.
Lipid panel	Cholestech LDX CardioChek	Lipid panel	Drawing several double specimens and sending 1 to the lab will allow you to see how measurements compare and help determine a threshold for sending specimens to your reference lab.

Abbreviations: AAP, American Academy of Pediatrics; CBC, complete blood count; TSB, total serum bilirubin.

limitations of the new technology. We discovered that when rapid strep tests were positive, most of the time our traditional throat cultures were positive as well. Unfortunately, a substantial number of negative rapid strep tests proved to be false negatives, and subsequently we backed up negative rapid strep tests with throat culture, as is still recommended by the *Report of the Committee on Infectious Diseases*, aka the *Red Book*.

Such office-based validation of new technology taught us a valuable lesson. Sensitivities and specificities as reported by manufacturers are performed under “ideal” lab conditions, and often do not reflect real-world practice. It is not an easy chore to obtain a throat swab from an uncooperative child. Each of us has developed our own methodology to obtain an optimum specimen (“say ah” just doesn’t cut it for

most). Some pediatricians won’t permit support staff to obtain swabs until they can consistently demonstrate an ability to obtain good specimens. Bottom line, if you don’t have enough streptococcal antigen on the swab, you are likely to get a negative rapid test. Most pediatricians also know they are more likely to get false negatives early in the course of a strep infection when the numbers of bacteria in the throat have not reached levels that are seen several days into the illness.

This healthy level of skepticism also proved valuable when ear thermometers were introduced to office practice. Before clinical studies were published that detailed the accuracy and limitations of what were initially called tympanic thermometers, pediatricians interested in purchasing devices from competing manufacturers would convince the vendor to let them trial

the device prior to purchase. Prudent pediatricians compared the measurements these devices produced to their standard glass or digital thermometers and came to 1 of 2 decisions: Either the device was not ready for “prime time,” or it was, in fact, worth integrating into practice because it would speed the taking of vital signs and could be used in children in whom detection of fever was not critical. Today, most pediatricians have confidence in the utility of forehead temperature scanning thermometers, so they are routinely used in most pediatric practices.

Fine-tune your technology

Most technologies improve over time (and get less expensive). These days, our strep tests are easier to perform and more accurate than they’ve ever been. Some pediatricians have discovered that when they compare rapid strep tests to throat culture, the false negative rate is so low that they choose not to back up rapid strep tests unless the patient has not been ill long or they have a strong clinical suspicion of a strep infection. It is always a good idea to run 25 to 50 rapid strep tests with backup culture periodically to determine what your practice’s false negative rate is and whether it is significant enough to warrant performing backup throat cultures regularly. This is a good example of how we should continue to keep an open mind regarding using technologies and examining ways to define and implement “best practices.”

Transcutaneous bilirubin testing

By now we have had extensive experience using transcutaneous bilirubinometers in the hospital setting in screening newborns prior to discharge for rising bilirubin levels, or for levels that warrant a more accurate serum bilirubin level to determine whether phototherapy is indicated or whether we can closely monitor a baby on an outpatient basis. When using these devices in the office, it would be wise to remember their limitations. These are screening devices whose measurements correlate well with total serum measurements. In my own experience, there is usually only a 1-mg/dL to

2-mg/dL difference between the 2 measurements. It has been well documented that the accuracy of transcutaneous bilirubin measurements diminishes with serum levels over 15 mg/dL. It is recommended that decisions regarding initiating phototherapy should be made based on serum levels only. Additionally, once phototherapy has been initiated, then serum levels should be followed rather than transcutaneous measurements.


Pulse oximetry

We have become dependent on pulse oximeter measurements to help make important clinical decisions, and it can be frustrating when it is difficult to obtain these important readings when we evaluate a child in respiratory distress. Oximeter measurements are reassuring when they are normal and worrisome when they are low, so it would be wise for practices to trial different brands prior to purchase and not

to err on the side of buying a less expensive device. Pulse oximeters are a good example of “you get what you pay for.” Some can acquire a signal more quickly than others, and provide information about pulse rate and quality of pulse/signal. As you are aware, there are many different sensor types

that can facilitate taking these measurements, so it is well worth your investment to trial a variety of finger clip as well as reusable and disposable wraparound sensors so your office staff have a variety from which to choose. It is important that staff have the opportunity to gain experience with all sensor types. Purchase from companies that are willing to provide “in-service” demonstrations following purchase and that will check back on their use from time to time.

Parting words

Remember, no test is perfect. In clinical practice, we may be dealing with false-positive as well as false-negative tests. Devices are only as good as the people performing the tests and interpreting results. As clinicians, we should always be prepared to retest or to use alternative methods to rule in or rule out a suspected diagnosis. When in doubt, clinical judgment always should prevail over technology. 

Devices are only as good as the people performing the tests and interpreting results.

PUZZLER CONTINUED FROM PAGE 16

As the episodes recurred in the coming weeks, however, she began to worry and decided to see you. She also complains of persistent fatigue (despite adequate sleep) and several headaches per week. She describes the headaches as dull, aching, and nonlocalized. She denies any chest pain or shortness of breath.

Her past medical history is significant for iron deficiency anemia that was previously treated with iron supplementation, although she has not taken iron for years. Her mother also had iron deficiency anemia that was treated with iron supplementation and her maternal grandmother and uncle had vitamin B₁₂ deficiency treated with B₁₂ injections. She denies any illicit drug use, recent travel, over-the-counter medications, or known chemical exposure. Her menstrual cycle is normal with no irregular bleeding.

On physical exam her vitals are normal and she

is not in any acute distress. Cardiac and respiratory exams are normal. Examination of her skin reveals cyanosis of the extremities, notably blue/green discoloration of the thigh in a splotchy distribution. Similar discoloration is present on her hands (Figure).

You order labs, and her complete blood cell count is normal with a white blood cell count of 7.2 k/ μ L; hemoglobin of 12.9 gm/dL; hematocrit of 38.3%; mean corpuscular volume of 88 fL; red cell distribution width of 14.1%; and platelet count of 271 k/ μ L. Iron studies also are normal with iron of 55 μ g/dL; total iron binding capacity of 390 μ g/dL; and ferritin of 72 ng/mL. Metabolic studies reveal normal electrolytes. You also perform allergy testing, which is negative.

Differentials

Due to the absence of cardiac or pulmonary findings, you decide that her cyanosis is likely due to a hematologic etiology. Suspecting methemoglobinemia, you develop a differential diagnosis including congenital cytochrome



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TABLE 1 Differential diagnosis for methemoglobinemia

Etiologies		
Toxic (acquired)	Dietary or environmental chemicals	Chlorates Chromates Copper sulfate Fungicides Naphthalene Nitrates Nitrites
	Industrial chemicals	Aniline dyes Herbicides Pesticides
	Drugs	Amyl nitrite Benzocaine Dapsone Lidocaine Metoclopramide Nitric oxide Nitroprusside Phenazopyridine Prilocaine
Enteritis-associated	Intestinal nitrate and nitric oxide	Promotes methemoglobin formation
	Acidemia	Inhibits enzymatic reduction systems
Congenital	Hemoglobin M disease Methemoglobinemia	

Adapted from Osterhoudt KC.¹

B5 reductase deficiency, environmental exposure to toxins, hemoglobin M disease, or an enteritis-associated phenomenon (Table 1).¹ Enteritis-associated methemoglobinemia is usually seen in infants aged younger than 6 months. However, because your patient does not have any enteritis-associated symptoms, this diagnosis can be ruled out.

Further workup

You order a methemoglobin reductase level that shows a result of 7.4 IU/g Hb (normal range is 8.2-19.2 IU/g Hb). This is considered to be a mild to moderately decreased level, suggestive of a methemoglobin reductase deficiency. You refer the patient to hematology for further evaluation.

Hemoglobin electrophoresis is performed to evaluate for hemoglobin M disease. Results are normal with 97.3% hemoglobin A (normal range is 95.8%-98.0%) and 2.7% hemoglobin A2 (normal range is 2.0%-3.3%), which rules out the possibility of hemoglobin M disease. The methemoglobin reductase level is repeated and is still mild to moderately decreased at 7.3 IU/g Hb. The methemoglobin level is 0.1%, falling within the normal range of 0.0% to 1.5%. Although the patient was not experiencing cyanosis at the time that these labs were drawn, the level would likely be elevated during an acute episode. Typically cyanosis appears when methemoglobin levels exceed 1.5 g/dL or 10% to 20%.²

Discussion

Methemoglobin is a derivative of hemoglobin that is generated by the oxidation of iron from the ferrous (Fe^{2+}) to the ferric (Fe^{3+}) state. Methemoglobin cannot transport oxygen and therefore its accumulation results in a functional anemia.³ Additionally, the presence of ferric heme groups shifts the oxygen dissociation curve to the left and impairs oxygen delivery, which contributes to the cyanotic presentation of methemoglobinemia.^{2,4}

Under physiologic conditions, a small amount of methemoglobin is formed spontaneously and is found in 1% to 2% of circulating blood.² It is normally maintained at this level by NADH-cytochrome B5 reductase (methemoglobin reductase).⁵ Methemoglobinemia results when there is an excess of methemoglobin, usually owing to a hereditary deficiency in the reductive pathway or excess oxidation of hemoglobin iron following exposure to certain toxic substances (Table 2).^{2,5,6}

Hereditary methemoglobinemia is a rare disorder that results from a deficiency of NADH-cytochrome B5 reductase. In Type I, the most common form, the deficiency is limited to red blood cells.⁷ The major symptom is cyanosis, but patients may experience fatigue, headache, and dyspnea on exertion when methemoglobin levels exceed 30%.¹ Patients that are heterozygous for the NADH-cytochrome B5 reductase deficiency usually have normal methemoglobin levels, but may develop acute, symptomatic methemoglobinemia after exposure to certain drugs or toxins.⁵

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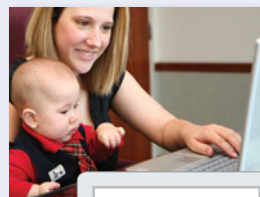
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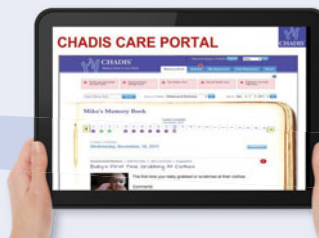


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TABLE 2 Methemoglobin-inducing agents

Amyl nitrite	Local anesthetics
Aniline dyes	Naphthalene
Benzocaine	Nitrates
Chlorates	Nitrites
Food additives	Phenols
Inks	Shoe dye or polish
Lidocaine	Sulfonamides

From Tanen DA.²

Treatment

Type I deficiency is associated with a normal life expectancy and no treatment is indicated. Most patients tolerate their condition well, even with methemoglobin levels as high as 40%.⁸ In cases that are exacerbated by toxic exposure, treatment is simply avoidance of the offending agent.⁶ In severe cases with methemoglobin levels between 40% to 60%, the treatment of choice is intravenous methylene blue. Methylene blue serves as a cofactor to a normally dormant NADH-dependent methemoglobin reductase, thus correcting the methemoglobinemia.⁴

Our patient

Based on our patient's presentation and enzyme levels, her diagnosis is Type I NADH-cytochrome

B5 reductase deficiency manifesting with episodes of cyanosis secondary to toxic exposure at her place of employment. One of the toxins that has been associated with methemoglobinemia is aniline dye, which is commonly used in the shoe industry. Our patient was advised to change her place of employment to avoid the chemical exposure that triggered her episodes. After she stopped working at the shoe store, her cyanosis resolved. 39

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
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Vitamin D, IU	160	160	0	0	0	0	0	80	4	0	0	0
Potassium, mg	310	390	195	184	466	n/a	73	300	23	44	68	67
 Fiber, g	1	3	4.5	1	1	0	1	0	0	<1	4	1
Calories	240	150	95	280	155	160	160	70	70	140	125	150
Protein, g	7	7	0.5	4	2	1	2	7	6	3	4	2
Total Carbs, g	33	21	25	35	15	36	24	13	1	20	21	18
Sugars, g	18	17	19	29	neg	18	14	13	0	1	<1	1
Total fat, g	9	5	0.3	14	10	1	7	<1	4.5	7	3	7
Sat fat, g	1	1	0	5	1	0	2	0	3	1.5	<1	1
Cholesterol, mg	10	<5	0	7	0	0	0	<5	15	1	0	0
Sodium, mg	90	90	2	136	136	130	156	100	170	276	140	174
Vitamin A, IU	500	500	98	92	0	0	neg	10	145	44	42	0
Iron, mg	2.7	2.7	neg	<1	neg	neg	3	neg	0	1.39	<1	<1
Vitamin E, IU	6	6	<1	1	3	0	1	0	<1	<1	2	0
Vitamin C, mg	24	24	8	neg	5	0	0	2	0	0	0	0
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Number of V&M at 10% or more	25	25	2	3	2	0	2	3	1	2	0	2

*Top 10 midday snack foods for kids 2-12. NPD Group's Snack Fact, year ending March 2011.

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